BROWNRUDNICK

ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

185 Asylum
Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

September 30, 2015

RECEIVED
SEP 30 2015
Office of
HEALTHCARE ACCESS

VIA HAND DELIVERY

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Certificate of Need Application to Establish and Operate a Primary and Elective Angioplasty Program at The William W. Backus Hospital in Norwich, Connecticut

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital ("Backus"), enclosed please find the original and four (4) copies of a Certificate of Need Application to establish and operate a Primary and Elective Angioplasty Program at Backus Hospital, along with a CD containing an electronic copy of the Application.

Also enclosed is a check in the amount of $500.00 representing the filing fee.

Please do not hesitate to contact me if you have any questions.

Very truly yours,

BROWN RUDNICK LLP

By: Robert J. Anthony

RJA:ct
Enclosure

62191042 v1-WorksiteUS-032836/0001

brownrudnick.com

2955

BROWN RUDNICK LLP
HARTFORD OPERATING ACCOUNT
1 FINANCIAL CTR., 18TH FLOOR
BOSTON, MA 02111

53-13/110 MA
47876

DATE September 28, 2015

PAY TO THE ORDER OF Treasurer, State of Connecticut $ 500 00/100

Five Hundred and No/100 DOLLARS

Security Features Details on Back.

Bank of America

ACH R/T 011000138

FOR CMM 32836/1

Claudia Teitelbaum MP

[redacted]

AFFIDAVITS

Affidavit

Applicant: Hartford Hospital

Project Title: Establishment of Primary and Elective Percutaneous Coronary Intervention at The William W. Backus Hospital

I, Stuart Markowitz, MD, President of Hartford Hospital being duly sworn, depose and state that the (Facility Name) said facility complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.

Stuart L Markowitz MD — 9-24-15

Signature — Date

Subscribed and sworn to before me on September 24, 2015

Martha Santilli

Notary Public/Commissioner of Superior Court

My commission expires: MARTHA SANTILLI NOTARY PUBLIC OF CONNECTICUT My Commission Expires 5/31/2019

Affidavit

Applicant: The William W. Backus Hospital

Project Title: Establishment of Primary and Elective Percutaneous Coronary Intervention at The William W. Backus Hospital

I, David A. Whitehead, President of The William W. Backus Hospital being duly sworn, depose and state that the (Facility Name) said facility complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.

Signature 09/23/15
Date

Subscribed and sworn to before me on 9/23/15

Notary Public/~~Commissioner of Superior Court~~

My commission expires: 4/30/16

PUBLISHER'S CERTIFICATE

9/7/15

LEGAL NOTICE
PUBLIC NOTICE

Under Connecticut General Statute 19a-638, Hartford Hospital and The William W. Backus Hospital propose to establish and operate a primary and elective angioplasty program at Backus Hospital located at 326 Washington Street, Norwich, Connecticut 06360. The anticipated capital expenditure associated with the proposed project is $4,982,053. Hartford Hospital and Backus Hospital will file a Certificate of Need application for this project with the Department of Public Health's Office of Health Care Access.

9/8/15

LEGAL NOTICE
PUBLIC NOTICE

Under Connecticut General Statute 19a-638, Hartford Hospital and The William W. Backus Hospital propose to establish and operate a primary and elective angioplasty program at Backus Hospital located at 326 Washington Street, Norwich, Connecticut 06360. The anticipated capital expenditure associated with the proposed project is $4,982,053. Hartford Hospital and Backus Hospital will file a Certificate of Need application for this project with the Department of Public Health's Office of Health Care Access.

9/9/15

LEGAL NOTICE
PUBLIC NOTICE

Under Connecticut General Statute 19a-638, Hartford Hospital and The William W. Backus Hospital propose to establish and operate a primary and elective angioplasty program at Backus Hospital located at 326 Washington Street, Norwich, Connecticut 06360. The anticipated capital expenditure associated with the proposed project is $4,982,053. Hartford Hospital and Backus Hospital will file a Certificate of Need application for this project with the Department of Public Health's Office of Health Care Access.

State of Connecticut,

ss. Norwich

County of New London,

On this **9TH** day of **SEPTEMBER 2015**

personally appeared before the undersigned, a Notary Public, within and for said County and State

Whitney Seidl, Proof of Publication

of the "THE BULLETIN" a daily newspaper published at Norwich, County of New London, State of Connecticut, who, being duly sworn, states on oath that

LEGAL NOTICE

PUBLIC NOTICE

HARTFORD HOSPITAL

CERTIFICATE OF NEED APPLICATION

a true copy of which is hereto annexed, was published in said newspaper in its issue of the

7TH, 8TH, & 9TH DAYS OF SEPTEMBER 2015

W Seidl

Subscribed and sworn to before me this 9th day of Sept. A.D. 2015

Catherine M. Holden

Notary Public

My Commission Expires 6/30/19

CATHERINE M. HOLDEN
NOTARY PUBLIC
MY COMMISSION EXPIRES JUNE 30, 2019

Checklist

Instructions:

1. Please check each box below, as appropriate; and
2. The completed checklist *must* be submitted as the first page of the CON application.

☒ Attached is a paginated hard copy of the CON application including a completed affidavit, signed and notarized by the appropriate individuals.

☒ *(*New*).* A completed supplemental application specific to the proposal type, available on OHCA's website under "OHCA Forms." A list of supplemental forms can be found on page 2.

☒ Attached is the CON application filing fee in the form of a certified, cashier or business check made out to the "Treasurer State of Connecticut" in the amount of $500.

☒ Attached is evidence demonstrating that public notice has been published in a suitable newspaper that relates to the location of the proposal, 3 days in a row, at least 20 days prior to the submission of the CON application to OHCA. (*OHCA requests that the Applicant fax a courtesy copy to OHCA (860) 418-7053, at the time of the publication)*

☒ Attached is a completed Financial Attachment

☒ Submission includes one (1) original and four (4) hard copies with each set placed in 3-ring binders.

☒ The following have been submitted on a CD

1. A scanned copy of each submission in its entirety, including all attachments in Adobe (.pdf) format.
2. An electronic copy of the applicant's responses in MS Word (the applications) and MS Excel (the financial attachment).

For OHCA Use Only:

Docket No.: 15-32031-Con **Check No.:** 2955
OHCA Verified by: [signature] **Date:** ~~10/1/15~~ 10/1/15

General Information

Name of Applicant:	Name of Co-Applicant:
The William W. Backus Hospital	*Hartford Hospital*

Connecticut Statute Reference:
19a-638(a)(9)

Main Site

MAIN SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	MAIN SITE NAME
The William W. Backus Hospital	*007228710 (inpatient)*	*Acute Care Hospital*	*The William W. Backus Hospital*
STREET & NUMBER			
326 Washington Street			
TOWN		ZIP CODE	
Norwich		*06360*	

Main Site

MAIN SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	MAIN SITE NAME
Hartford Hospital	*4041869 (Inpatient)*	*Acute Care Hospital*	*Hartford Hospital*
STREET & NUMBER			
80 Seymour Street			
TOWN		ZIP CODE	
Hartford		*06102*	

Project Site

PROJECT SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	PROJECT SITE NAME
The William W. Backus Hospital	*007228710 (inpatient)*	*Acute Care Hospital*	*The William W. Backus Hospital*
STREET & NUMBER			
326 Washington Street			
TOWN		Zip Code	
Norwich		*06360*	

Operator

OPERATING CERTIFICATE NUMBER	TYPE OF FACILITY	LEGAL ENTITY THAT WILL OPERATE OF THE FACILITY (or proposed operator)
	Acute Care Hospital	*The William W. Backus Hospital*
STREET & NUMBER		
326 Washington Street		
TOWN		ZIP CODE
Norwich		*06360*

Chief Executive	NAME		TITLE		
	David A. Whitehead		*SVP & President, The William W. Backus Hospital & Hartford HealthCare East Region*		
	STREET & NUMBER				
	326 Washington Street				
	TOWN			STATE	ZIP CODE
	Norwich			*CT*	*06360*
	TELEPHONE	FAX	E-MAIL ADDRESS		
	860-889-8331		*David.Whitehead@hhchealth.org*		

Chief Executive	NAME		TITLE		
	Stuart K. Markowitz		*SVP & President, Hartford Hospital & Hartford HealthCare Hartford Region*		
	STREET & NUMBER				
	80 Seymour Street				
	TOWN			STATE	ZIP CODE
	Hartford			*CT*	*06102*
	TELEPHONE	FAX	E-MAIL ADDRESS		
	860-545-2349		*Stuart.Markowitz@hhchealth.org*		

		Title of Attachment:
Is the applicant an existing facility? If yes, attach a copy of the resolution of partners, corporate directors, or LLC managers, as the case may be, authorizing the project.	YES ☒ NO ☐	*Under current HHC bylaws/governance, Board approval is not required in order to authorize a submission of a CON.*
Does the Applicant have non-profit status? If yes, attach documentation.	YES ☒ NO ☐	***Exhibit 27***
Identify the Applicant's ownership type.	PC ☐ LLC ☐ Corporation ☒	Other: _____
Applicant's Fiscal Year (mm/dd)	Start 10/1 End 9/30	

Contact:

Identify a single person that will act as the contact between OHCA and the Applicant.

Contact Information			
NAME		TITLE	
Janette Edwards		*Regional Director, Planning & Business Development* *The William W. Backus Hospital*	
STREET & NUMBER			
326 Washington Street			
TOWN	STATE	ZIP CODE	
Norwich	*CT*	*06360*	
TELEPHONE	FAX	E-MAIL ADDRESS	
860-425-3872	*860-889-2796*	*Janette.Edwards@hhchealth.org*	
RELATIONSHIP TO APPLICANT	*Employee*		

Identify the person primarily responsible for preparation of the application (optional):

Prepared by			
NAME		TITLE	
STREET & NUMBER			
TOWN	STATE	ZIP CODE	
TELEPHONE	FAX	E-MAIL ADDRESS	
RELATIONSHIP TO APPLICANT			

Executive Summary

The purpose of the Executive Summary is to give the reviewer a conceptual understanding of the proposal. In the space below, provide a succinct overview of your proposal (this may be done in bullet format). Summarize the key elements of the proposed project. Details should be provided in the appropriate sections of the application that follow.

The William W. Backus Hospital ("Backus") and Hartford Hospital ("Hartford" or "HH") (collectively, the "Applicants") propose the establishment of a Primary and Elective Percutaneous Coronary Intervention ("PCI") Program at Backus Hospital to improve patient access for eastern Connecticut residents suffering from a common form of heart attack known as a ST-Segment Elevation Myocardial Infarction ("STEMI"), new or presumed new onset Left Branch Bundle Blockage ("LBBB"), or Acute Coronary Syndrome (Non ST-Elevation Myocardial Infarction, "NSTEMI"). The Applicants will demonstrate that more than sufficient demand exists in this rural region of 231,419 people to support a PCI program at Backus Hospital. Residents of this part of the State currently must travel more than 30 minutes for PCI services due to lack of availability. There are also cultural, geographic, transportation and economic barriers that prevent these residents of this part of the State from appropriately accessing life-saving services in a timely manner, especially in emergencies. If this proposal is approved, Backus would be the closest PCI program in Connecticut for these 231,419 people.

Today, PCI is the standard of care for treating emergent heart conditions, and should be administered as soon as possible after the onset of symptoms. Patients suffering the symptoms of a heart attack seek medical attention at the nearest emergency facility, and as previously noted, all PCI-capable facilities are more than 30 minutes away in this area. The process of evaluating patients in a community hospital and then transporting them to another facility inevitably entails delays, and those delays result in damage to heart muscle that can be prevented. Studies show that time is one of the most important factors in saving heart muscle during a cardiac emergency. The less time elapsed from the onset of symptoms until the beginning of treatment, the greater the patient's chances of minimizing permanent damage to heart muscle. Connecticut's residents' access to PCI procedures should not be limited by where they live.

The Applicants will show that the vast majority of patients from the area that can be served by Backus currently travel to 4 Connecticut hospitals for PCI procedures (out of State hospitals not considered): Hartford Hospital, Yale New Haven Hospital, Lawrence and Memorial Hospital and Saint Francis Hospital. Again, it is important to point out that none of these hospitals - and thus no PCI services - are within a 30 minute drive time for these residents. Also, no individual hospital currently providing PCI procedures, including Lawrence and Memorial Hospital which serves a different market and only performed 22 PCI procedures in FY2014 on patients from this

area, will suffer inordinately from any shift of volume that would result from approval of this proposal. Each hospital will be able to maintain volume levels more than sufficient to meet American College of Cardiology/American Heart Association ("ACC/AHA") minimum standards. Patient benefits, however, that will accrue to this area served by Backus where a clear void currently exists, will be significant.

The area to be served by Backus includes 3 towns designated as 'Health Professional Shortage Areas' and 11 towns designated as 'Medically Underserved Areas.' It is also an area at high-risk for coronary artery disease due to the high level of risk factors in an older population. More than 45% of this population is over the age of 45, compared to 41% nationally. There is also a high rate of obesity, diabetes and smoking - all factors resulting in projected increases in the need for and utilization of cardiovascular services in this region. Social determinants of health, such as low socioeconomic status, high rates of underinsured and uninsured, and high a population-to-physician ratio, perpetuate the disease burden in this area. These factors and limited access to PCI services contribute to the current rates of emergency PCI and elective PCI interventions for residents in this rural part of the State being significantly below State and National levels. This, in turn, leads to higher than necessary (or acceptable) rates of morbidity and mortality.

Finally, under today's system of care, there are hidden costs that burden families of patients who are transported to, or seek treatment from, hospitals far from home. Duplicative out- of- pocket costs associated with a second hospital admission and duplicative procedures, lost work, childcare fees and travel expenses are an economic burden to the residents of this region. Less quantifiable but equally important is the effect of stress on the family separated by illness and geography, as well as the impact on future care coordination and management of the patient's heart condition..

A PCI program at Backus will fill a void that exists in the eastern region of Connecticut and will improve the quality and accessibility of health care for these residents, who now must travel significant, unreasonable and unsafe distances, or be transported by LIFE STAR or EMS, for PCI services. The Applicants urge the approval of this proposal so that residents of this region have convenient and timely access in their own community to these critical, life-saving procedures.

Pursuant to Section 19a-639 of the Connecticut General Statutes, the Office of Health Care Access is required to consider specific criteria and principles when reviewing a Certificate of Need application. Text marked with a "§" indicates it is actual text from the statute and may be helpful when responding to prompts.

Project Description

1. Provide a detailed narrative describing the proposal. Explain how the Applicant(s) determined the necessity for the proposal and discuss the benefits for each Applicant separately (if multiple Applicants). Include all key elements, including the parties involved, what the proposal will entail, the equipment/service location(s), the geographic area the proposal will serve, the implementation timeline and why the proposal is needed in the community.

Backus is a duly-licensed acute care general hospital located in Norwich, Connecticut. Backus is licensed for 233 beds/bassinets and offers a full range of inpatient and outpatient medical services to Eastern Connecticut. Backus is continually evaluating the need for new programs that will enhance timely access to life-saving services for eastern Connecticut residents.

With this mission in mind, Backus proposes to add Primary Percutaneous Coronary Intervention ("Primary PCI" or "Primary Angioplasty" or "Emergent Angioplasty") as well as Elective Percutaneous Coronary Intervention ("Elective PCI" or "Elective Angioplasty" or "Non-Emergent Angioplasty") to the suite of cardiovascular and other services already available at its Main Campus location, through its affiliation with Hartford HealthCare ("HHC"). Backus proposes to establish an interventional cardiac program through leveraging the existing expertise and experience at Backus in related fields and the expertise and experience of its tertiary/quaternary care partner, Hartford Hospital, also a member of HHC.

Hartford Hospital is the major teaching hospital affiliated with the University of Connecticut Medical School, serving the New England region. HH is an 867-bed regional referral center that provides high quality care in all clinical disciplines.

Major centers of clinical excellence include cardiology, oncology, emergency services and trauma, mental health, women's health, orthopedics, bloodless surgery and advanced organ transplantation. Hartford is at the forefront of robotic surgery with eight da Vinci surgical robots and a MAKO robot specializing in robotic orthopedic procedures. Hartford owns and operates LIFE STAR air ambulance system.[1] Hartford locates a LIFE STAR helicopter at Backus, the only air ambulance based East of the Connecticut River, to ensure residents of Eastern Connecticut have access to advanced clinical care as quickly and efficiently as possible when every second counts.

[1] *http://www.harthosp.org/AboutUs/HartfordHospitalToday/default.aspx*

Through its Henry Low Heart Center, Hartford is a national leader in the treatment of heart disease and has one of the busiest cardiac catheterization laboratories in the State of Connecticut, performing over 1,000 angioplasties on an annual basis.

Hartford Hospital and Backus have determined, and will demonstrate, that there is a clear public need for a Primary and Elective PCI program in Eastern Connecticut, specifically at the Backus main campus in the town of Norwich. Many residents of the greater Norwich area, particularly those residing to the north and east, are without timely access to this life-saving intervention, which has long been the nationally recognized standard of care for treating a common form of heart attack known as a ST-Segment Elevation Myocardial Infarction ("STEMI"), as well as new or presumed new onset Left Branch Bundle Blockage ("LBBB"). Elective PCI is the standard for treating Acute Coronary Syndrome (Non ST-Elevation Myocardial Infarction, "NSTEMI") in people with intermediate to high risk factors. Elective PCI is also the standard for treating patients with symptoms of recurrent myocardial ischemia ("Unstable Angina" or "UA") and/or high risk findings on a non-invasive stress test. Applicants will show how the proposed Primary and Elective Angioplasty program meets an identifiable need for these services in the Backus Angioplasty Region (as defined and discussed in response to question 6), and how operation of such a program will greatly improve access to and enhance the quality of cardiovascular care in the Backus community.

As stated in section 3.4.3 of the Statewide Health Care Facilities and Services Plan, Primary and Elective PCI is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a diagnosed blockage in the heart. Primary PCI is used to treat emergency situations and is the most effective way to treat most heart attacks. Elective PCI is often a scheduled procedure following extensive cardiac testing and/or a post-cardiac event (such as a NSTEMI AMI) to relieve chest pain and related symptoms and, in many patients, prevent more serious heart conditions. In both cases, an expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

PCI is often combined with the permanent placement of a small wire mesh tube called a stent to help prop the artery open and decrease the chance of it narrowing again. Some stents are coated with medication to help keep the artery open (drug-eluting stents), while others are not (bare-metal stents). [2]

Myocardial infarction is defined by pathology as myocardial cell death due to prolonged ischemia (an inadequate blood supply to the heart muscle).[3] *A STEMI occurs when an acute*

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[2] *Statewide Health Care Facilities and Services Plan, October 2012, Section 3.4.3, p. 39.*

[3] *Johanne Sn, Jean-Philippe Collet, Chandrasekaran Nagaswami, et al. (2011) Composition of Coronary Thrombus in Acute Myocardial Infarction J Am Coll Cardiol, March 22; 57(12): 1359–1367.*

coronary thrombosis totally occludes a coronary artery.[4] *In other words, a STEMI occurs when a vessel becomes blocked or closed, causing a decreased or interrupted blood flow to the heart. A STEMI requires immediate intervention to restore circulation to the vessel and to allow for reperfusion, or restoration of blood flow, of the cardiac muscle that became ischemic. Reperfusion therapy by primary percutaneous coronary intervention with stenting has proven the optimal approach to reduce morbidity and mortality in STEMIs.*[5]

During the 1990s, PCI for STEMIs and thrombolytic therapy coexisted, with PCI common at PCI-equipped hospitals and thrombolytic therapy common at non-PCI hospitals. Two European publications in 2003, however, shifted this dynamic by documenting that PCI is superior to thrombolytic therapy when performed quickly[6,7]. *Current American College of Cardiology/American Heart Association ("ACC/AHA") Guidelines call for reperfusion with PCI of STEMI patients within 90 minutes of first medical contact. U.S. hospitals have struggled to successfully implement the recommended course of treatment, particularly because only 25% of acute care hospitals in the nation provide PCI.*

Patients who undergo an Elective PCI have risk factors, or test results which show that if a PCI to correct the blockages causing the ischemia is not performed, the patient would be more likely to have a fatal myocardial infarction in the future. Unlike primary PCI, this procedure is scheduled, but ideally takes place within 24-48 hours of diagnosis to effectively reduce the risk of future cardiac events. Once these patients have their coronary intervention, their reoccurring symptoms are alleviated and they are able to return to their baseline health.

As discussed in greater detail throughout this application, Applicants are basing the clear public need for the proposed Primary and Elective Angioplasty program on factors including, but not limited to, the following:

1. *The establishment of a PCI program at Backus Hospital is in alignment with the State Health Plan, and will fill a health care void currently present in Eastern Connecticut. If this Application is approved, residents living in this geographically isolated and rural region will have access to life-saving procedures for treatment of the leading cause of death in Connecticut (and nationally).*

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[4] *Kristian Thygesen, Joseph S. Alpert, Harvey D. White (2007) Universal Definition of Myocardial Infarction Circulation;116:2634-2653*

[5] *Maarten A. Vink, Miranda C. Kramer, Xiaofei Li, et al. (2011) Clinical and Angiographic Predictors and Prognostic Value of Failed Thrombus Aspiration in Primary Percutaneous Coronary Intervention, J Am Coll Cardiol Intv, 4:634-642.*

[6] *Widimsky P, Budesínsky T, Vorác D et al. (2003) Long distance transport for primary angioplasty versus immediate thrombolysis in acute myocardial infarction European Heart Journal; 24:94–104*

[7] *Keeley EC, Boura JA, Grines CL. (2003) Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials. Lancet; 361:13–20*

2. *Lawrence and Memorial Hospital, currently the only PCI provider in Eastern Connecticut, primarily serves a different geographic market than Backus and is also not accessible within a 30 minute drive for residents in the Backus Angioplasty Region. For these reasons, Lawrence and Memorial is not treating the majority of these patients today.*

3. *PCI is the nationally recognized standard of care for treating STEMI, NSTEMI and new or presumed new onset LBBB; All residents in Eastern Connecticut, not just those in the greater New London area, deserve the same medical standard of care and access to the same level and quality of services.*

4. *Nationally, approximately half of all PCI's are performed on patients with UA or NSTEMI and approximately 35-40% of UA/NSTEMI patients will undergo Elective PCI.*[8]

5. *164,000 residents of the greater Backus Angioplasty Region, particularly those residing to the north and east of Norwich, do not have timely access to a Connecticut Primary or Elective PCI-equipped hospital within 30 minutes' drive time, as specified by Department of Public Health Office of Emergency Management Services Policy Guidance ("DPH OEMS Guidance"); overall, a PCI program at Backus would be the closest Primary and Elective PCI program for 231,419 residents of Eastern Connecticut.*

6. *Patients who present to Backus with STEMI/LBBB are being transferred or are seeking care, in most instances, more than 40-50 miles to hospitals with programs for intervention. Other patients are being diverted from the Backus emergency department (the emergency department closest to their homes), per DPH OEMS Guidance, because Backus does not offer a PCI program. The delays associated with transfer result in many patients not receiving Primary Angioplasty within 90 minutes of presentation at an emergency department, as recommended by the ACC/AHA and as the standard of care dictates. Delays associated with diversion and transport increase the total ischemic time (the amount of time from symptom onset to treatment), which also must be managed in order to ensure the highest quality clinical outcomes.*

7. *Patients requiring Elective Angioplasty must leave their home community to travel great distances to facilities offering this service, which is a burden on both the patient and their family. In some cases, patients who do not have the means to travel, may forego this potentially lifesaving procedure.*

8. *The establishment of a primary and elective PCI program at Backus Hospital will eliminate duplicative services, multiple procedures and patient interventions, and will result in better*

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[8] *Dehmer, Gregory J., Blankenship, James C., Cilingiroglu, Mehmet, et al. "SCAI/ASS/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention without On-Site Surgical Backup." Circulation. 2014; 129: 2610-2626.*

care and ultimately reduce the cost of care to the patient and the health care system in Connecticut.

9. *The community health needs of the Angioplasty Region demonstrate a high rate of obesity, diabetes, smoking and heart disease, as well as mortality from heart disease. Other demographic factors such as rural geography and an aging population support the need for a PCI program at Backus.*

10. *Residents of the Backus Angioplasty Region have a higher incidence of STEMI than the State and Nation, a higher incidence of NSTEMI than the Nation, and have more risk factors for cardiovascular disease in general than other Connecticut residents, yet the rates of Primary PCI and Elective PCI interventions for this populations are significantly below the State and National levels.*

11. *Backus has the necessary infrastructure in place to expand its cardiovascular services to include Primary and Elective Angioplasty. Plans exist to build an additional catheterization lab suite in order to provide service with two catheterization labs, as well as creating a back-up catheterization room in the current Backus interventional radiology suite, upon CON approval.*

12. *Hartford Hospital, one of the Region's leading providers of comprehensive cardiac services, will provide the necessary training, oversight, and tertiary backup to ensure a high quality, efficient, and seamless PCI services at Backus.*

13. *Backus has historically provided initial care to a significant number of patients who were ultimately transferred to other providers for Primary or Elective Angioplasty. Virtually all of these patients could be cared for at Backus if Backus offered PCI services. Over each of the last four years Backus transferred an average of 70 patients who, while receiving a diagnostic catheterization, were identified as requiring an Elective PCI. Additionally, 295 individuals who would meet the patient selection criteria and who reside within the Angioplasty Region, are projected to receive an Elective PCI procedure in FY 2016; these individuals could be served at Backus, keeping their care close to home and improving coordination of services among local providers if this proposal is implemented.*

14. *The volume for PCI at Backus is projected to be more than enough to sustain a quality and safe PCI program and to meet the institutional minimum number of 200 PCI cases per year as recommended in a 2014 Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions (SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup) (attached as* ***Exhibit 1****).*

Backus Locations & Services

The proposed Primary and Elective Angioplasty program will compliment a number of inpatient and outpatient services, and a full suite of cardiovascular services, already available at Backus. In addition to the provision of inpatient and outpatient services at its Main Campus, the Hospital operates various outpatient care centers at locations throughout eastern Connecticut, including Norwich, Colchester, Montville, Ledyard, Waterford, and North Stonington. The Backus Family Health Centers offer a broad array of services including, but not limited to, primary/urgent care, pediatrics, diagnostic imaging, laboratory, EKG, and physical and occupational therapy. Backus also operates a 24/7 Satellite Emergency Department in the town of Plainfield, and the Backus Outpatient Care Center in Norwich.

Quality Care at The William W. Backus Hospital

Backus Hospital has consistently provided the residents of eastern Connecticut high-quality care, as demonstrated by both public and internal quality metrics. High quality has been sustained through a commitment to transform the Hospital into a high-reliability organization ("HRO"). Since 2013, 100% of staff, management, and physicians have been trained in High Reliability principles. High Reliability is a healthcare performance improvement initiative created by Healthcare Performance Improvement ("HPI"), which is a company that "improves reliability in healthcare by helping organizations achieve and sustain high performance outcomes in safety, quality and satisfaction."[9] A highly-reliable organization has a sustained, system wide focus on safety principles, with techniques based on best practices in industries such as nuclear power and aviation. "While healthcare has focused on traditional process improvement as a means to better outcomes, high-reliability organizations recognize that optimizing outcomes requires a concurrent focus on human behavior accountability. The HPI method focuses on preventing human errors and detecting and correcting system weaknesses that can lead to events of harm and unwanted outcomes."[10]

The impact of the commitment to becoming an HRO is demonstrated by the Leapfrog Group Hospital Survey, which "assesses hospital safety, quality, and efficiency based on national performance measures"[11] and produces a comparative safety score for each participating hospital. Backus Hospital has received an "A" grade for the last three evaluation cycles (Spring 2015, Fall 2014, Spring 2014), the highest score possible.[12] This sustained "A" grade is an improvement over 2013 and 2012 scores. See ***Figure 1****, below:*

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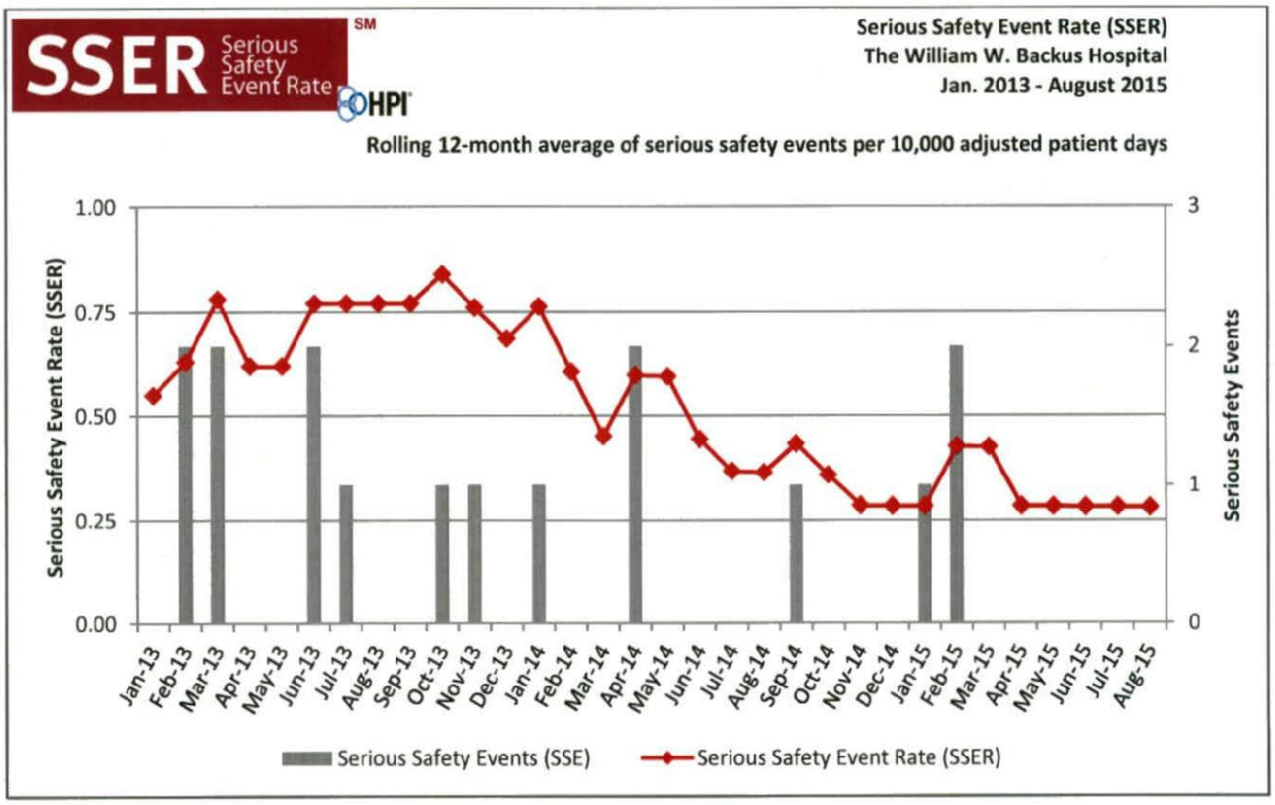
[9] *Healthcare Performance Improvement, "About our Company."*
[10] *Ibid.*
[11] *https://leapfroghospitalsurvey.org/*
[12] *http://www.hospitalsafetyscore.org/table-details/william-w-backus-hospital?findBy=state&state_prov=CT&agree=agree&rPos=0&rSort=distance*

Figure 1 – Backus Hospital LeapFrog Scores

2015		2014		2013		2012	
	A	A	A	B	C	C	C
Fall	Spring	Fall	Spring	Fall	Spring	Fall	Spring

The journey to becoming a HRO has also resulted in a decline in the Serious Safety Event Rate ("SSER") at Backus. A "Serious Safety Event" is an incident that reaches the patients and causes moderate to severe harm or death as a result of a deviation from a generally accepted performance standard of care. The SSER is a rolling 12-month average of Serious Safety Events, based on 10,000 adjusted days. Backus monitors its SSER on a monthly basis. The Hospital has made progress towards eliminating Serious Safety Events, and in Fiscal Year 2015 (August) have had 9 of 11 months without a Serious Safety Event. See ***Figure 2****, below, for a detailed chart:*

Figure 2 – Backus Hospital Serious Safety Event Rate, January 13, 2003-August 15, 2015



Sustained quality improvement has also impacted internal quality metrics tracked by the Critical Care Unit, and further demonstrate the Hospital's "A" grade. See ***Figure 3****, below for detailed information about ventilator associated pneumonias, ventilator infection rates, blood stream*

infection rates, and Catheter Associated Urinary Tract Infection ("CAUTI") rates. The addition of a Primary and Elective PCI program at Backus Hospital is expected to experience similarly high quality scores.

Figure 3 – Backus Hospital Critical Care Unit Infection Rate

Infection Rate	*FY 2015, July Result*
CCU-Ventilator Associated Pneumonia/1000 Days	*.79*
VAE Infection- IVAC Rate per 1000 Vent Days	*2.364*
VAE Infection - Possible VAP Rate per 1000 Vent Days	*2.364*
VAE Infection- Probable VAP Rate per 1000 Vent Days	*0*
VAE Infection- VAC Rate per 1000 Vent Days	*7.092*
CCU CLABSI Rate/1000 Days	*.85*
CCU CAUTI Rate/1000 Days	*1.684*
Primary Bloodstream Infections, CCU (total)	*1*
Urinary Tract Infections, CCU (total)	*3*
Ventilator-Associated Pneumonia, CCU (total)	*1*
Infection Related Ventilator Associated Complication, CCU (total)	*3*

Cardiovascular Care Continuum at The William W. Backus Hospital and Hartford Hospital

Backus Hospital is a regional leader in cardiac care, with programs and services that can appropriately support the proposed Angioplasty program. Backus continues to make the necessary investments to enhance cardiovascular services offered to the residents of eastern Connecticut. In September 2011, the Hospital upgraded its depreciated cardiac catheterization lab equipment with a new Philips FD10 X-Ray, Philips Xper Hemodynamic monitoring, and Philips Xcelera Cardiac Imaging System. This system is integrated into the Hospital-wide informatics system. In addition to the catheterization lab upgrades, the Cardiology Service Line started a Vascular Steering Committee, Chest Pain Observation Unit, Heart Failure Program, and is currently expanding the existing Peripheral Vascular program. The continued development and expansion of a Heart Failure Program is a specific strategic priority at Backus, with a focus on infusion services and education.

The following inpatient and outpatient cardiovascular services are currently available to patients at Backus:

Diagnostic and Treatment Programs:

- *Diagnostic Cardiac Catheterizations: Utilizing a radial or femoral approach cardiologists perform left and right heart catheterizations*
- *Pacemaker Insertions, Evaluations and Follow-up*
- *Implantable Cardiac Defibrillator ("ICD") Insertions, Evaluation and Follow-Up*

- *Stress Testing (Exercise and Pharmacologic)*
- *Nuclear Cardiac Imaging (Rest and Stress)*
- *Cardiac Imaging Services including a 126 Slice CT scanner and MRI*
- *Echocardiology (Transthoracic, Transesophageal, Resting, Exercise and Exercise Dobutamine): The Echocardiology lab was accredited by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) in 2004.*
- *24- Hour Holter Monitoring*
- *48- Hour Holter Monitoring*
- *30 Day Event Monitoring*
- *24- Hour Ambulatory Blood Pressure Monitoring*
- *EKG testing*
- *Electrical Cardioversions*
- *Intra-Aortic Balloon Pumping ("IABP")*
- *Vascular Surgical Services:*
    - *Several procedures, such as peripheral angioplasty and stenting, are performed in the interventional radiology suite. The radiology technical staff of interventional radiology is cross-trained to the cardiac catheterization lab. The radiology technicians' experience with peripheral angioplasty and stenting will complement a Primary and Elective PCI program.*
- *Heart Failure Program:*
    - *This program was initiated in April of 2012. This is a comprehensive program stretching the continuum of care for this patient population.*

In addition to the foregoing diagnostic and treatment programs available to the residents of eastern Connecticut, the following services are in place that will complement the proposed Primary and Elective PCI program.

Inpatient Services

Backus operates a 12 bed Critical Care Unit ("CCU"), a 6 bed Progressive Care Unit, two Telemetry Units, which are 28 beds and 19 beds respectively. In addition to the telemetry units, the Hospital is able to provide cardiac monitoring to an additional 16 patients on its medical-surgical floors. The CCU will be the primary unit for all post- PCI patients. The CCU was a recipient of the American Association of Critical Care Nurses (AACN) Beacon Award in 2010 which recognizes Critical Care Units exceptional care through improved outcomes and greater overall satisfaction. All of inpatient services have the ability to remotely review the patient's medical record, including test results and imaging.

The Critical Care Leadership Team consists of the following:

- *Full time Regional Director of Critical Care Services*
- *Full time Critical Care Manager*
- *Part Time Critical Care Medical Director*
- *Part Time Cardiology Medical Director*
- *Critical Care Educator*
- *Critical Care Clinical Nurse Leader*

The cardiac catheterization lab maintains Intra Aortic Balloon Pump ("IABP") competencies. There is an education plan in place for CCU staff to obtain competency in IABP (see ***Exhibit 2****). All registered nurses on the units listed above are advanced cardiac life support ("ACLS") trained. The Hospital has a rapid response team ("RRT") and a resuscitative team. All the above units have cardiac monitor technicians available 24/7.*

In addition to the clinical care provided in the Hospital inpatient units, the cardiovascular service line has implemented a Heart Failure Program. This program aims to provide a continuum of care beyond the inpatient setting, with the realization that patients must manage their condition after discharge from the Hospital. Any inpatient with a diagnosis of Primary Heart Failure is automatically enrolled in the Heart Failure Program upon admission. These patients are followed by a Heart Failure Program Coordinator. Participating patients are provided with structured education during their inpatient stay, followed by subsequent physician appointments and follow-up medication consultations with pharmacists on an outpatient basis. The use of telehealth through Hartford HealthCare at Home for qualified patients is initiated upon discharge from an inpatient stay to help the patient manage their symptoms outside of the Hospital.

The proposed PCI program at Backus is the next logical step in order to continue to invest in enhancing the comprehensive cardiovascular care needed by the residents in eastern Connecticut.

Outpatient Services: Cardiovascular Prevention Programs

In addition to the inpatient services discussed above, Backus offers the following outpatient/community services relevant to this proposal:

Cardiac Rehabilitation

Backus has a well-established Cardiac Rehabilitation program that provides services to residents throughout eastern Connecticut. The goal of the Cardiac Rehabilitation program is to provide a dynamic process that assists the known cardiac patient, and those who are at high risk of developing cardiac disease, to achieve and maintain an optimal level of health. The

physiological, emotional, economic, social, and vocational states of the patient are included in the program's definition of health. The program is adaptable to the individual patient and his/her changing needs over the course of his/her rehabilitation.

The program utilizes a multidisciplinary educational approach to health and wellness with a staff consisting of Registered Nurses and Exercise Physiologist/Exercise Specialists. The team actively involves the patient and family in setting realistic goals towards a return to a productive life.

The Backus Cardiac Rehabilitation program has three phases, following the treatment stages of a cardiac patient:

- *Phase I Cardiac Rehab for inpatients. The focus in this phase of the program is on education, with a timeline tailored to an inpatient stay.*
- *Phase II Cardiac Rehab for outpatients. The emphasis during this phase is on risk factor modification through exercise and education. This phase of the program lasts for 12 weeks, or up to 36 sessions.*
- *Phase III Cardiac Rehab is the maintenance program for outpatients. This phase is based on a self-pay rate and can last a lifetime.*

In fiscal years 2011-2015 (through August), the program had more than 21,856 cardiac rehabilitation visits, including 18,503 phase II visits, and approximately 3,353 Phase III visits.

Community Programs and Support

Backus' commitment to the health and wellbeing of the community goes beyond the walls of the Hospital. Backus has an active Community Health Education Department, which provides hundreds of low or no cost community programs and activities on an annual basis. Many of the programs sponsored by the Hospital relate to cardiovascular health and wellbeing.

In fiscal years 2011-2014, Backus supported and sponsored a number of community programs addressing obesity, diabetes, and cardiovascular diseases. Programs such as blood pressure clinics, cardiac rehab nutrition classes, community cholesterol screenings, diabetes support groups, Enjoy LIFE (a program focused on obesity and wellness), Life Happens (a holistic program aimed for high school students), Living with Diabetes: An Outpatient Self-Management Program, a diabetes and exercise program, smoking cessation classes and education, stroke support groups, a bariatric support group and exercise program, sponsorship and participation in the American Diabetes and Heart Association walks, and a multitude of healthy eating programs served over 2,429 individuals in eastern Connecticut, at a cost of $136,903 . Seventy-seven individuals completed the 14 to 18-week Medical Weight Loss Clinic classes from FY 2010-2015, with a total combined weight loss of 782 pounds.

Each of these programs contributes to the prevention and management of cardiovascular disease and related co-morbidities.

Hartford Hospital's Cardiac Services

Hartford Hospital also provides inpatient, outpatient, and community programs that will complement and support the proposed PCI program at Backus. The Hartford Hospital Henry Low Heart Center ("HLHC") offers an array of comprehensive services and sophisticated techniques in a setting of highly personalized care.

The HLHC is dedicated to the care of the heart in all its complexities. It offers outstanding multi-disciplinary cardiovascular programs designed to provide excellence in treatment, diagnosis and management through the entire spectrum of cardiovascular disease. The HLHC has an unwavering commitment to provide the very best care to cardiac patients who need clinical services, angioplasty, surgery or other procedures, as well as others who want to make their hearts healthier through preventive, pharmacological or rehabilitative therapy. Clinical research in cardiovascular disease is another major component of the program.

The HLHC is a full service cardiac provider, offering multidisciplinary cardiac care, including an A-Fib Center, Cardiac Catheterization and Angioplasty, Cardiac Electrophysiology, Cardiac Rehabilitation Programs, a Chest Pain Center, Congestive Heart Disease Center, Echocardiography, Extracorporeal Membrane Oxygenation, Heart Failure Infusion Program, Heart Failure Rescue Program, Heart Surgery and Transplant, LDL-Apheresis Center, Minimally Invasive Maze Surgery, Nuclear Cardiology, Preventive Cardiology, and a Transcatheter Aortic Valve Replacement Program.

The HLHC is committed to the community, providing education and patient resources. The HLHC provides the most comprehensive services for the prevention and management of cardiovascular disease in the region. Its programs and services are tailored to help people with known or suspected heart disease, or those recovering from a heart attack or cardiac surgery.[13]

The Department of Preventive Cardiology at Hartford Hospital offers a series of comprehensive programs focusing on the prevention, management and treatment of heart disease through patient care and education. These include an Athlete's Heart Program, Cardiac Rehabilitation Program, Cholesterol Management Program, Counseling and Stress Management, a Vascular Screening Program, and a Women's Heart Program.

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[13] *http://www.harthosp.org/heart/CardiacCatheterizationAngioplasty/default.aspx*

Incidence of Cardiovascular Disease in Eastern Connecticut

Eastern Connecticut is disproportionately affected by risk factors contributing to cardiovascular events. Recent studies[14], both commissioned by Backus and those published on a State or National level, illustrate the magnitude to which the region suffers from co-morbid conditions attributed to cardiovascular diseases and other conditions. The region is more obese, sedentary, and more dependent on tobacco products than the rest of the State or the Nation (see the 2015 Community Health Needs Assessment, Eastern Region, Connecticut, Prepared for Hartford Healthcare attached as ***Exhibit 3****). Further, social determinants of health, such as low socio-economic status, high rates of underinsured and uninsured and barriers to accessing care, and a high population-to-physician ratio perpetuate the disease burden in the region. Individuals in the New London and Windham Counties are dying at a younger age than others in different areas of the State (see the 2015 County Health Rankings, Connecticut – A Robert Wood Johnson Foundation Program – as well as excepts from the RWJF website attached as* ***Exhibit 4****).*

These factors indicate that access to life-saving cardiovascular services, specifically a Primary and Elective PCI program is necessary in the Backus Angioplasty Region. If developed at Backus, a PCI program will alleviate the additional burden placed upon patients and their families suffering from STEMI, LBBB, and NSTEMI who leave the region for emergency cardiac care.

2. Provide the history and timeline of the proposal (i.e., When did discussions begin internally or between Applicant(s)? What have the Applicant(s) accomplished so far?).

A discussion regarding the establishment of a PCI program at Backus has been ongoing since 2011. Backus recognized that a need for these services existed, through anecdotal and empirical evidence. Backus did not have the necessary physician resources to implement, support, and sustain a program at that time, however Backus' affiliation with Hartford HealthCare provides the necessary elements to establish and run an effective program. Backus and Hartford Hospital formally began discussions in December of 2014. A market assessment has been conducted, physician alignment requirements have been met, transfer agreements are approved, and physical plant requirements have been determined. The Applicants cannot go further to execute the program without CON approval from the Office of Health Care Access.

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[14] *Please refer to citation for the William W. Backus Hospital Community Health Needs Assessment (**Exhibit 3**), State Health Assessment, the Burden of Cardiovascular Diseases in Connecticut, the Robert Wood Johnson Foundation County Health Rankings and Roadmaps (**Exhibit 4**), the State Health Plan Supplement and the National Institute of Health's Obesity Evidence Report (**Exhibit 23**).*

3. Provide the following information:

    a. utilizing **OHCA Table 1**, list all services to be added, terminated or modified, their physical location (street address, town and zip code), the population to be served and the existing/proposed days/hours of operation;

See Table 1.

    b. identify in **OHCA Table 2** the Angioplasty Region towns and the reason for their inclusion (e.g., provider availability, increased/decreased patient demand for service, market share);

See Table 2.

4. List the health care facility license(s) that will be needed to implement the proposal;

No additional licenses will be sought as part of this proposal.

5. Submit the following information as attachments to the application:

    a. a copy of all State of Connecticut, Department of Public Health license(s) currently held by the Applicant(s);

*Attached as **Exhibit 5** are the Department of Public Health, General Hospital licenses for The William W. Backus Hospital and Hartford Hospital.*

    b. a list of all key professional, administrative, clinical and direct service personnel related to the proposal and attach a copy of their Curriculum Vitae;

*Attached as **Exhibit 6** are copies of the Curriculum Vitae for the following key personnel:*

- *Nader Bahadory, MD*
- *Mariane Carna*
- *Rebecca Durham*
- *John Foley, MD*
- *Dan Lohr*
- *Stuart Markowitz, MD*
- *Robert Sidman, MD*
- *Paul Thompson, MD*
- *Carolyn Trantalis*
- *David Whitehead*

*Attached as **Exhibit** 7 are copies of the Curriculum Vitae for the following supporting physicians involved with the project:*

- *John Michael Chua Chiaco, MD*
- *Francis Kiernan, MD*

c. copies of any scholarly articles, studies or reports that support the need to establish the proposed service, along with a brief explanation regarding the relevance of the selected articles;

*See the Percutaneous Coronary Intervention Assessment prepared by 3d Health, Inc. (attached as **Exhibit 8**), and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction and the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (attached as **Exhibit 9**).*

*The scholarly articles cited throughout this application are included in **Exhibit 10** and are listed below:*

- *CDC Heart Disease Facts*
- *Time Delay to Treatment and Mortality in Primary Angioplasty for Acute Myocardial Infarction: Every Minute of Delay Counts*
- *Widening of Socioeconomic Inequalities in U.S. Death Rates, 1993-2001*
- *Selecting a Reperfusion Strategy for Acute ST Elevation Myocardial Infarction*
- *Impact of Primary Coronary Angioplasty Delay on Myocardial Salvage, Infarct Size, and Microvascular Damage in Patients With ST-Segment Elevation Myocardial Infarction*
- *System Delay and Mortality Among Patients With STEMI Treated With Primary Percutaneous Coronary Intervention*
- *Effect of Door-to-Balloon Time on Mortality in Patients With ST-Segment Elevation Myocardial Infarction*
- *Association of Door-to-Balloon Time and Mortality in Patients Admitted to Hospital with ST Elevation Myocardial Infarction: National Cohort Study*
- *Association of Door-In to Door-Out Time With Reperfusion Delays and Outcomes Among Patients Transferred for Primary Percutaneous Coronary Intervention*
- *Composition of Coronary Thrombus in Acute Myocardial Infarction*
- *Universal Definition of Myocardial Infarction*
- *Clinical and Angiographic Predictors and Prognostic Value of Failed Thrombus Aspiration in Primary Percutaneous Coronary Intervention*
- *Long Distance Transport for Primary Angioplasty vs Immediate Thrombolysis in Acute Myocardial Infarction*
- *Primary Angioplasty Versus Intravenous Thrombolytic Therapy for Acute Myocardial Infarction: A Quantitative Review of 23 Randomised Trials*

Cited documents illustrate the identified need, provide guidance on the safe and effective establishment of the program, or support the need for program in the defined Angioplasty Region.

d. letters of support for the proposal;

There is tremendous support in the defined Angioplasty Region for Backus's proposal to develop a PCI program. Backus communicated its plans for the proposed program to the community through phone calls, emails, and face to face meetings with EMS, municipal leaders, physicians and patients. Fire department chiefs and assistant chiefs, ambulance personnel, physicians, and chief municipal leaders throughout the Angioplasty Region have been contacted. The response has been overwhelmingly positive and universally supportive. These stakeholders understand that there is a lack of adequate access to PCI services in the region and they can speak to the practical realities of this situation for area residents in need of care. Additionally, Day Kimball Hospital has provided a letter of support, citing barriers in its communities for needed access to PCI services. Residents of these communities cannot access a PCI capable facility in a timely fashion within the State of Connecticut. Letters of support from area fire departments, municipal leaders, physicians, patients and EMS personnel are attached as ***Exhibit 11****.*

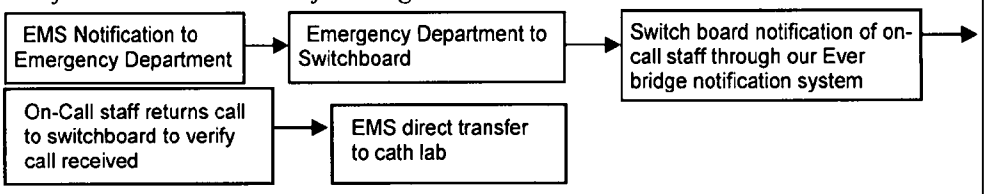
e. the protocols or the Standard of Practice Guidelines that will be utilized in relation to the proposal. Attach copies of relevant sections and briefly describe how the Applicant proposes to meet the protocols or guidelines.

Below is a chart that details how Backus will meet each of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention recommendations for PCI. These criteria are all consistent with national guidelines and best practice recommendations.

Figure 4 – Standards for Providing Primary and Elective PCI

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention	***How Backus Will Meet Standard***
4.1.1 Equipment	*The Cardiac Cath Lab has two defibrillators, one in the lab itself and one in the holding area outside the lab. Backus has POC testing for ACT and AVOX testing.* *The Digital Cine images are kept on file for 10 years. The X-ray equipment and staff lead is examined by a qualified physicist once a year. The X-Ray equipment also has yearly preventative maintenance preformed.*
4.1.2 Staffing	*There will be an Interventional Cardiologist performing all PCI cases. There will be one RN and two Radiologic Technologists in the room during each procedure. All the Catheterization Lab staff are BLS and ACLS certified. The Radiologic Technologists are credentialed by the American Society of Radiation Technologists.*

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention	***How Backus Will Meet Standard***
4.1.3 Time Out Procedures	*The Cardiac Catheterization Lab staff will follow the William W. Backus Hospital policy related to Universal Protocol.*
4.2.1 Informed Consent	*Informed consent will be obtained prior to each procedure. The Interventional Cardiologist will make every attempt to provide information regarding the risks and benefits of different strategies to the patient and family along with the benefits of rapid intervention for STEMI patients.*
4.3 Radiation Safety: Recommendations	*Total fluoro time is documented in the Backus electronic medical record and tracked quarterly in departmental QI. Low dose capability is now available on Phillips FD10. Radiation shielding for staff includes a full vest, thyroid, and skirt along with a radiation dose tracker.*
4.4 Contrast-Induced AKI (Acute Kidney Injury)	*A contrast questionnaire will be completed with all patients who will be having a cardiac cath to screen for potential contrast-induced AKI prior to the procedure. The RN will notify the physician for patients at risk for potential contrast induced AKI. Total contrast used intra-procedure is documented in the electronic medical record.*
4.7 Bleeding Risk	*The Lab utilizes many avenues to reduce the potential of bleeding. Each patient's treatment is individualized to minimize bleeding risk. Backus currently performs radial diagnostic catheterizations. Backus utilizes a variety of devices to obtain hemodynamic stability after the procedure.*
Procedural Considerations	
Personal and Facility Requirements for PCI Programs	• *See* ***Exhibit 2*** *for education plan.* • *The Lab will be staffed 24/7, 365 days per year with on-call personal available during off hours.* • *The Intensive Care Unit staff is competent in ventilator management, invasive hemodynamic monitoring, and operation of a temporary pacemaker. Training on the management of an IABP will take place to provide our ICU RN's the ability to care for an unstable patient coming from the Catheterization Lab.* • *Backus has Anesthesia available 24/7 in house to provide endotracheal intubation if necessary* • *LIFE STAR and Paramedics are available to handle endotracheal intubation and IABP during transport.* • *Backus has an agreement with Hartford Hospital for any patients who require cardiac surgery. See* ***Exhibit 13*** *for the Cardiac Surgery Transfer Agreement. Backus will test the transfer process to Hartford Hospital at least two times per year.* • *The Cardiac Cath Lab utilizes Philips FD10 X-Ray and Philips X-Per Monitoring Equipment. This equipment was installed in September 2011.* • *There will be two IABP's available. The Preventative Maintenance is completed on this equipment once a year. The IABP catheters are compatible with LIFE STAR transport.* • *There is currently real-time transfer of images with Hartford Hospital. This will be particularly important if Backus has patients who require surgical intervention. By 2017 Hartford HealthCare will be on one electronic medical record allowing for real time review of cases and documentation.*

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention	***How Backus Will Meet Standard***
Personal and Facility Requirements for PCI Programs Cont.	• *Backus has selected and will stock the appropriate inventory of interventional equipment. The inventory list is attached as* ***Exhibit 14****.* • *The hospital currently participates in the ACTION Registry with ACC NCDR and will participate in the ACC NCDR PCI registry*
Document Requirements for Off-Site Surgical Back-Up	• *Backus has written agreements for emergency transfer of patients to Hartford Hospital with Cardiac Surgery.* • *There have been transport protocols developed and approved. The transport protocols are attached as* ***Exhibit 15****. Backus will test transfer protocols at least two times each year.* • *Documentation of the transfers will take place along with areas for improvement in the transfer process. All patients transferred out after an intervention will be followed up and reviewed by the Catheterization Lab Medical Director, Catheterization Lab manager and the involved Interventional Cardiologist.*
Document Requirements for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals without On-site Cardiac Surgery	• *Detailed patient criteria for Primary PCI /Elective PCI interventions and patients requiring emergent transfer for coronary bypass surgery is discussed in response to question 5e.*
5.2.2.2 Primary PCI of the Infract Artery	*Backus has a system in place that will allow patients to have PCI performed within 90 minutes of the first medical contact.* *The systems in place are as follows:* *The on-call team is required to arrive at the hospital within 30 minutes of notification.* *Notification will occur in the following manner:*  *If there is no return call by the on-call staff to the switchboard within 5 minutes the switchboard operator will try the second number provided. If there still is no response after 5 minutes the operator will call the Cath Lab Medical Director and/or the manager of the Cath Lab notifying them of the delay.*

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention	***How Backus Will Meet Standard***
5.7 Interventional Pharmacotherapy	*All Registered Nurse staff is competent in the administration and monitoring of conscious sedation. The competency criteria are attaches as* ***Exhibit 16****. The physicians performing the procedure are also competent to administer conscious sedation*
6.4.3 Cardiac Rehabilitation	*Backus Hospital will offer enrollment to all patients post-PCI into its Cardiac Rehabilitation program.*
6.5 Secondary Prevention	*After the procedure, intensive education will take place while the patient is in the facility. As an outpatient the following services are available to our patients to utilize to their benefit: weight loss programs, smoking cessation, cardiac support group, diabetes management programs, blood pressure clinics, cholesterol screenings. See the response to question 1 for an overview of the services offered.*
7.1 Quality and Performance	*Monthly quality review will take place. Attached as* ***Exhibit 17*** *are the PCI Overall Outcome and Quality Measurements and the ACCF/AHA/SCAI/AMA-Convened Physician Consortium National Committee for Quality Assurance dated February 2013*

*Patient selection guidelines have been determined based upon the ACCF/SACI/STS/AATS /AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization, Focused Update (**Exhibit 12**) and the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.*

*Specifically, selection criteria are based on Tables 7 and 8 (page e596-e597, respectively) in the 2011 document (**Exhibit 9**), excerpts of which are included below - see **Figure 5** and **Figure 6**.*

Figure 5 – Primary PCI Patient Selection Guidelines

Table 7. SCAI Expert Consensus Document Requirements for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in patients with

- >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired
- Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography
- Lesions in other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms)
- Lesions with TIMI flow grade 3 that are not amenable to stenting in patients with left main or 3-vessel disease that will require coronary bypass surgery
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention

Transfer emergently for coronary bypass surgery patients with

- High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support
- Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer

IABP indicates intra-aortic balloon pump; LV, left ventricular; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis in Myocardial Infarction.

Adapted with permission from Dehmer et al.[352]

Figure 6 – Elective PCI Patient Selection Guidelines

Table 8. SCAI Expert Consensus Document Requirements for Patient and Lesion Selection and Backup Strategy for Nonemergency PCI by Experienced Operators at Hospitals Without On-Site Cardiac Surgery

Patient risk: expected clinical risk in case of occlusion caused by procedure

High patient risk: Patients with any of the following

- Decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders
- LVEF <25%
- Left main stenosis (≥50% diameter) or 3-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries)
- Single-target lesion that jeopardizes >50% of remaining viable myocardium

Lesion risk: probability that procedure will cause acute vessel occlusion

Increased lesion risk: lesions in open vessels with any of the following characteristics

- Diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments
- More than moderate calcification of a stenosis or proximal segment
- Location in an extremely angulated segment (>90%)
- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- Substantial thrombus in the vessel or at the lesion site
- Any other feature that may, in the operator's judgment, impede successful stent deployment

Aggressive measures to open CTOs are also discouraged because of an increased risk of perforation

Strategy for surgical backup based on lesion and patient risk

- High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.
- High-risk patients with non–high-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.
- Non–high-risk patients with high-risk lesions require no additional precautions.
- Non–high-risk patients with non–high-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.

CTO indicates chronic total occlusion; CVA, cerebrovascular accident; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

Adapted with permission from Dehmer et al.[352]

f. copies of agreements (e.g., memorandum of understanding, transfer agreement, operating agreement) related to the proposal. If a final signed version is not available, provide a draft with an estimated date by which the final agreement will be available.

Transfer agreements between Backus and Hartford Hospital are attached as ***Exhibit 13****.*

Public Need and Access to Care

§ *"Whether the proposed project is consistent with any applicable policies and standards adopted in regulations by the Department of Public Health;" (Conn.Gen.Stat. § 19a-639(a)(1))*

6. Describe how the proposed project is consistent with any applicable policies and standards in regulations adopted by the Connecticut Department of Public Health.

DPH EMS Guidelines Support the Need for a PCI Program at Backus

The need for rapid reperfusion for STEMI patients was acknowledged by DPH on January 23, 2012, when it published policy guidance regarding the transport of STEMI patients to Primary PCI-capable facilities (see ***Exhibit 18****, DPH Policy Guidance for STEMI Patients Memorandum, attached). The DPH Guidance requires the transport of patients identified in the field with a STEMI to a Primary PCI-capable hospital if the facility is within 30 minutes' drive time. If there is not a facility within 30 minutes, EMS personnel must make a transport decision with direct medical oversight. DPH asserts that this transport guidance will ensure that a Primary PCI is received within 90 minutes from initial medical contact, as the standard of care requires.*

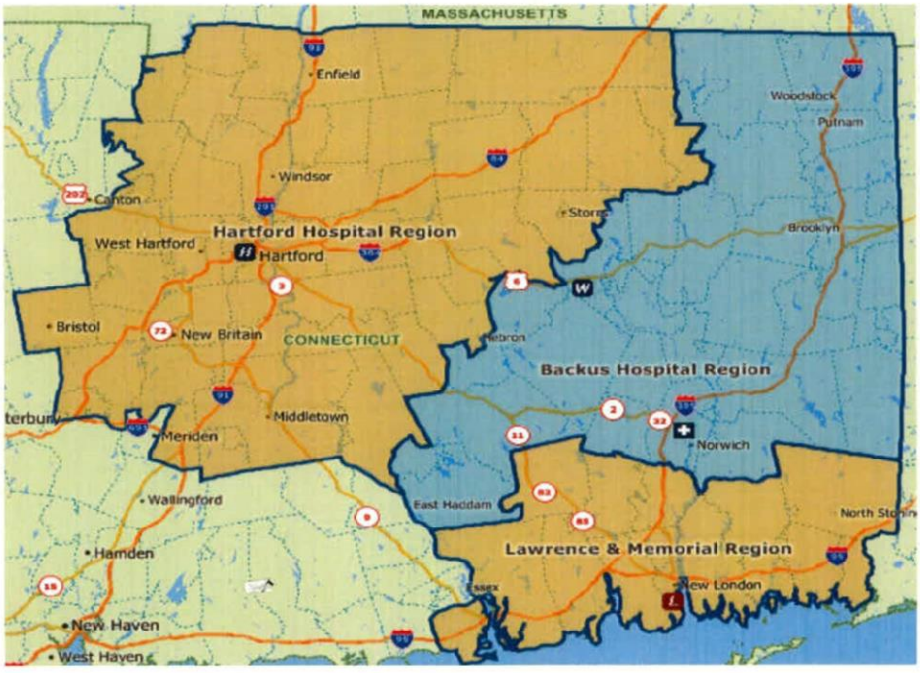
Under the DPH Regulations, STEMI patients are identified in the field via an EKG performed on the ambulance. This can only occur if a paramedic is on-board the ambulance, either at the time of patient pick up or through interception en route to the hospital, and the ambulance has the ability to conduct an EKG. In the defined Angioplasty Region only three ambulance services have this ability: American Ambulance, the Mohegan Tribal Ambulance, and the Windham Hospital Paramedic Program ("American," "Mohegan," and "Windham Paramedics"). In total, there are 50 Backus sponsored paramedics working at Mohegan or American, which covers all of New London and Windham Counties. There are only 15 Advance Life Support ("ALS") vehicles available in the region. On average, there are 10 available ALS staffed vehicles during the day, and 6 during the night. The ALS service in the northeast region is provided by Windham Paramedics, which covers 13 towns and 330 square miles. The remaining ambulance services are mainly volunteer-based and only Basic Life Support ("BLS") capable. These services are not qualified to determine if a patient is experiencing a STEMI when picked up in the field. Thus, patients with unidentified STEMIs continue to arrive at Backus Hospital in need of Primary PCI, as there is not always a paramedic available to intercept a BLS ambulance in the field to diagnose a STEMI patient. Currently these STEMI arrivals necessitate a second transport to a PCI-capable facility, but if this proposal is approved, they will be able to receive immediate Primary Angioplasty at Backus.

Backus commissioned 3d Health, Inc.("3d Health"), a healthcare consulting firm based in Chicago, to analyze the demand for and availability of Primary and Elective PCI in Eastern

Connecticut and whether residents are able to access these nationally recognized life-saving services in a timely fashion and in accordance with standard of practice and OEMS guidelines. 3d Health also looked at incidence/prevalence data, use rates, relative market share and outmigration and used this data to project volume for the proposed Primary and Elective Angioplasty program. 3d Health came to the conclusion that there is an unmet need for timely Primary and Elective PCI,, and that 231,419 people will benefit from more readily available interventional cardiac care if this proposal is approved.

In conducting its needs assessment and market share analysis (see the Percutaneous Coronary Intervention Assessment by 3d Health, Inc. "3d Health" attached as ***Exhibit 8****), 3d Health defined a Backus Hospital Angioplasty Region, ("PCI Region," or "Angioplasty Region") (3d Health Assessment, p. 4). This Angioplasty Region was determined through analyzing eastern Connecticut zip codes, and assigning zip codes to regions based on the closest potential Connecticut PCI facility. See* ***Figure*** *7, below, for a map of the Backus Angioplasty Region. This reflects the geography where Backus would be the closest PCI provider in the State for each zip code included in the shaded region.*

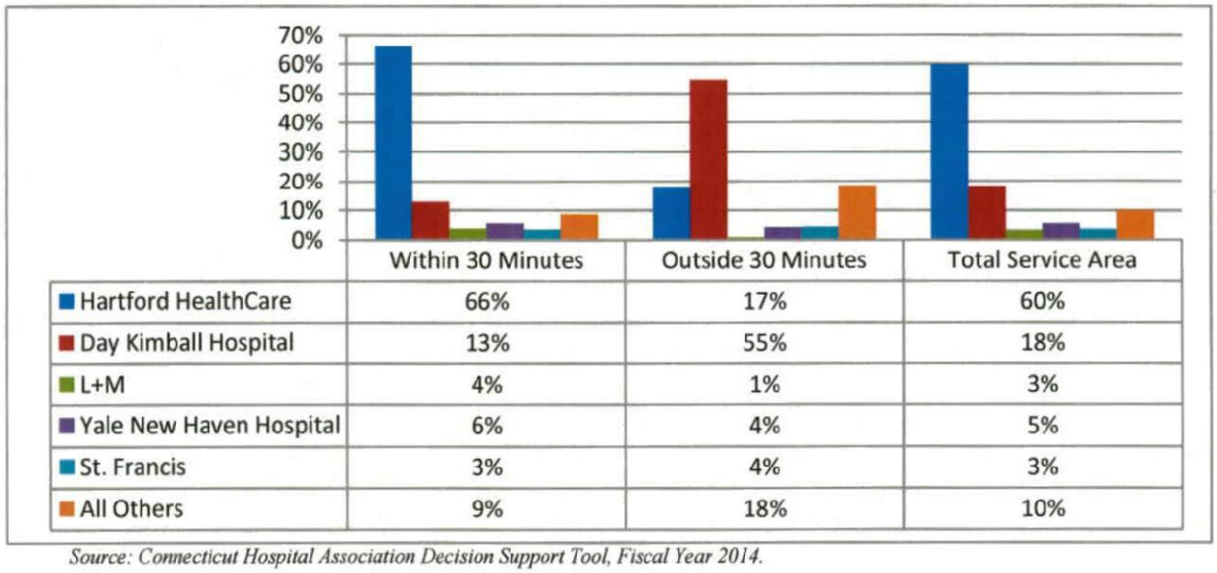
Figure 7 – Backus Hospital Angioplasty Region



The Angioplasty Region does not differ significantly from the traditionally defined Backus and Windham Hospital service area, with the exception of the inclusion of towns in the very far north east corner of the State (Thompson, Woodstock, Pomfret, and Putnam), and East Haddam. Additionally, it was determined that Hartford HealthCare providers (Backus, Windham and Hartford Hospital) hold dominate inpatient market share within the Angioplasty Region. When

analyzing the geography identified by 3d Health by proximity to Backus (within a 30 minute drive time or outside a 30 minute drive time) it was determined that Hartford HealthCare providers hold 60% of the total market, followed by Day Kimball with 18% of the market. Other regional providers, such as L+M only hold approximately 3% of the market; Yale and St. Francis hold 5% and 3%, respectively. The remaining 10% of the Backus Angioplasty market is split between all other acute care facilities in Connecticut. See ***Figure 8****, below:*

Figure 8 – Angioplasty Region Inpatient Market Share



	Within 30 Minutes	Outside 30 Minutes	Total Service Area
Hartford HealthCare	66%	17%	60%
Day Kimball Hospital	13%	55%	18%
L+M	4%	1%	3%
Yale New Haven Hospital	6%	4%	5%
St. Francis	3%	4%	3%
All Others	9%	18%	10%

Source: Connecticut Hospital Association Decision Support Tool, Fiscal Year 2014.
Hartford HealthCare defined as Backus, Hartford, and Windham Hospitals

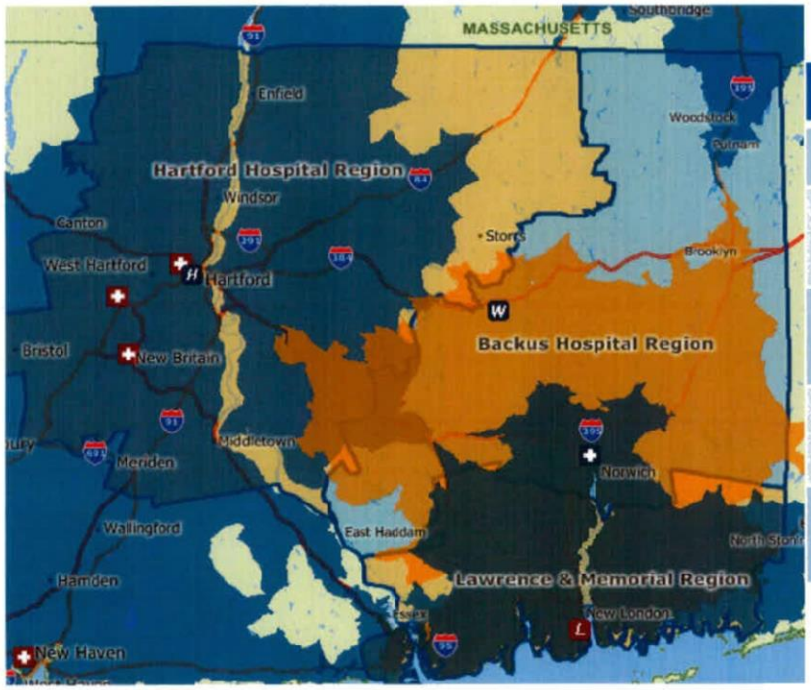
A list of the towns included in the Backus Angioplasty Region (defined as the geography where Backus would be the closest Connecticut PCI provider) is included in ***Figure 9****, below:*

Figure 9 - Towns within the Backus Angioplasty Region

Towns Within 30 Minutes Drivetime to Backus Hospital	*Norwich* *Amston* *Bozrah* *Brooklyn* *Canterbury* *Chaplin* *Colchester* *Columbia* *Franklin* *Griswold-Lisbon*	*Killingly* *Lebanon* *Mansfield Center* *Plainfield* *Preston* *Scotland* *Sprague* *Sterling* *Voluntown* *Windham*
Towns outside of 30 minutes to Backus Hospital, but where Backus Hospital would be the closest Connecticut provider of Primary and Elective PCI services.	*East Haddam* *Hampton* *Pomfret* *Putnam* *Thompson* *Woodstock*	

Although there are numerous hospitals in Connecticut that provide PCI services, only one is located in eastern Connecticut, and none are within 30-minutes' drive time for thousands of residents of the defined Angioplasty Region. As can be seen from the map on pages 34 of the 3d Health Assessment, towns surrounding, and to the north of, Norwich, do not have access to a PCI-capable Connecticut hospital within 30 minutes. If Backus Hospital establishes a PCI program, 51% of the Angioplasty Region, or 118,000 residents, would gain access to a facility that offers Angioplasty within 30 minutes, and an additional 67,000 residents would have improved access within 10 minutes. Backus would also be the closest PCI facility for an additional 28,000 residents in the Northeast portion of the state, and would become the closest Connecticut provider to 18,000 residents. Thus, the potential for a program at Backus would vastly improve regional access to cardiac care (3d Health Assessment, p. 33-34). See ***Figure 10****, below.*

Figure 10 – Backus Hospital Angioplasty Region by Segment



Angioplasty Region Segment	*Population*
No access within 30 minutes	*146,000*
Access within 30 minutes if Backus offered	*118,000*
Access within 40-50 minutes if Backus offered	*28,000*
No access to a CT hospital within 30 minutes	*18,000*
Access today; within 10 minutes of Backus	*67,000*

30 Minute Drive Time, Existing PCI Providers

30 Minute Drive Time, Potential Backus Program

De Luca, et al. studied the effect of time delay to treatment and mortality in primary angioplasty for STEMI. De Luca's 2004 study, published in "Circulation," reiterates the necessity of timely reperfusion, stating that "the major finding of the present study is that every minute of delay in

treatment of patients with STEMI does affect 1-year mortality, not only in thrombolytic therapy but also in primary angioplasty. In fact, the risk of 1-year mortality is increased by 7.5% for each 30 minute delay... Although primary angioplasty, in comparison with thrombolysis, may guarantee a higher rate of reperfusion in patients presenting late, it cannot prevent myocardial necrosis, which is related to the duration of occlusion, particularly in high-risk patients."[15] *Establishing a Primary and Elective Angioplasty program at Backus Hospital in partnership with Hartford Hospital will improve timely access to Primary PCI for 231,000 individuals, lessening mortality in this population, as well as increased necrosis, and vastly improving access to life saving care.*

See also the response to question 7, below.

§ *"The relationship of the proposed project to the statewide health care facilities and services plan;" (Conn.Gen.Stat. § 19a-639(a)(2))*

7. Describe how the proposed project aligns with the Connecticut Department of Public Health Statewide Health Care Facilities and Services Plan, available on OHCA's website.

The project aligns well with the Connecticut Department of Public Health Statewide Health Care Facilities and Services Plan[16]*, as well as the 2014 Supplement to the Plan*[17] *("State Health Plan," and "Supplement"). Specifically, section 3.4 of the State Health Plan addresses the need and standards for cardiac services. Section 3.4.3 addresses PCI and PCI without surgical backup.*

The State Health Plan recognizes that over the last several years the standards for a PCI program without cardiac surgical backup have changed. If a clear public need can be demonstrated, the program fills a healthcare void, and the guidelines as discussed below are met, a PCI program without on-site cardiac surgery backup can safely be implemented. Specifically, the State Health Plan provides that "increasing operator experience, improvements in surgical techniques and major advances in technology and pharmacology have contributed to a progressive trend to allow PCI without on-site surgical backup. (State Health Plan, § 3.4.3.1). New evidence gives support to the positive effects that these medical advances contributed to the significant reduction in emergency surgery following PCI." The State Health Plan also provides that those hospitals seeking authorization to initiate an elective PCI program without on-site cardiac surgery backup must: (1) meet the conditions required in the American College of Cardiology Foundation/American Health Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) practice guidelines for percutaneous coronary intervention without on-site surgical backup; and (2) demonstrate a clear public need for the program. Specifically, the guidelines indicate that it is only appropriate to consider the

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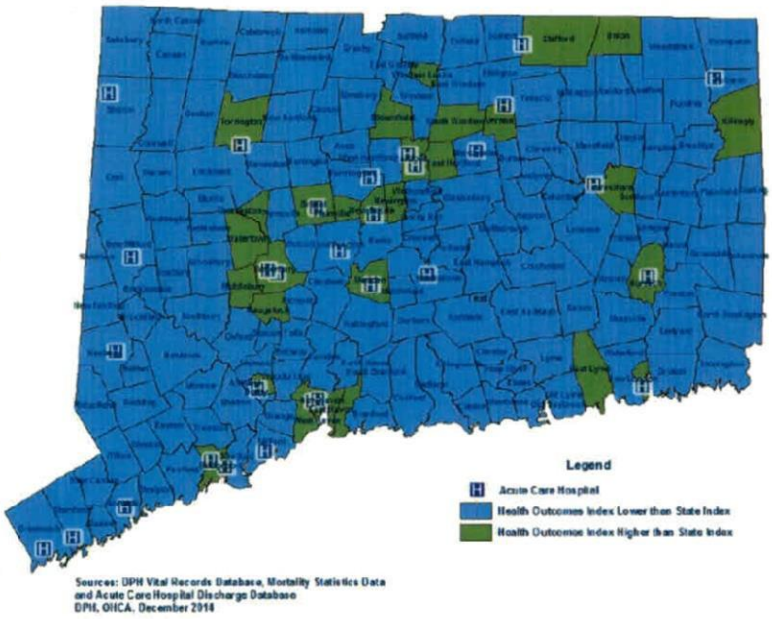
[15] *De Luca, et al. "Ischemic Time and Mortality in Primary Angioplasty." Circulation. 2004; 109: 1223-1225.*
[16] *http://www.ct.gov/dph/lib/dph/ohca/publications/2012/ohcastatewide_facilities_and_services.pdf*
[17] *http://www.ct.gov/dph/lib/dph/ohca/publications/2014/final_2014__facilities_plan_-_2_24_15.pdf*

initiation of the PCI program without on-site cardiac surgical backup if this program "will clearly fill a void in the healthcare needs of the community." They further note that "competition with another PCI program in the same geographic area ... may not be in the best interests of the community (emphasis added)." As discussed, Backus' proposed PCI program would not be in competition with Lawrence and Memorial Hospital's program or other Connecticut programs given the different geographic area served by Backus.

The 2014 Supplement to the State Health Plan specifically Section 3 references areas of "unmet healthcare need." The 2014 Supplement highlights, unmet healthcare needs are "disproportionately experienced..." throughout Connecticut. The Backus Angioplasty Region fits squarely within an area of unmet need. Unmet healthcare need is defined as the "inadequate availability of healthcare services deemed necessary to address a particular health problem." Among the barriers to accessing healthcare may be the physical unavailability of the service. Multiple towns within the defined Backus Angioplasty Region, specifically the towns of Norwich, Windham, and Putnam, all fall into areas of unmet need, and experience worse health outcomes than the State, see ***Figure 11****, below.*

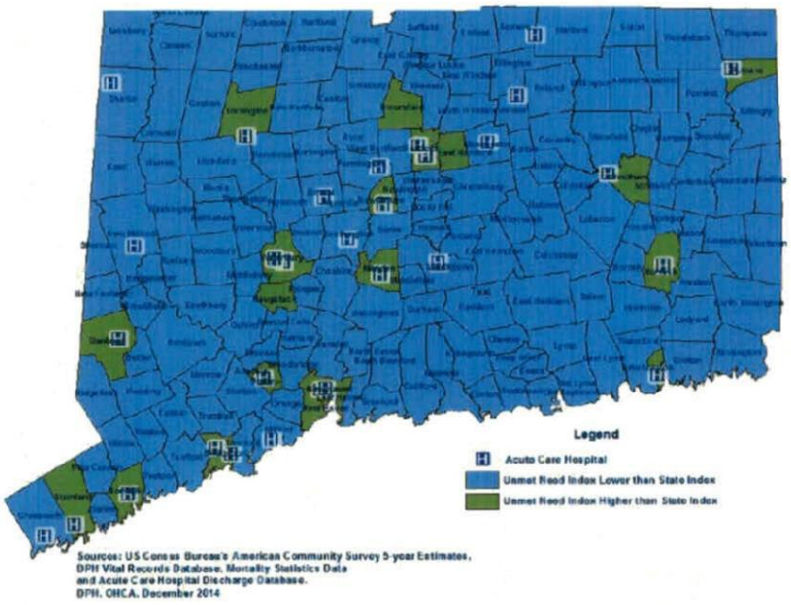
Figure 11 – Health Outcomes by Town



The Supplement also describes a Health Outcomes Index Score which was calculated for all towns in Connecticut. According to the Plan, "the health outcomes index score examines five indicators that serve as proxies to the health of a community, due to differential access and outcomes...the State Health Outcome Index is 5; a score lower than 5 implies an individual town has better health outcomes compared to the State...[a score] higher than the Connecticut index

indicate[s] poorer health outcomes" (State Health Plan Supplement, p. 73). Norwich, Windham, and Killingly all have a Health Outcomes Index higher than the State, indicating worse health outcomes, see ***Figure 12****, below.*

Figure 12 – Unmet Need Composite Index, by Town



Socioeconomic factors also impact the health status of a community. The Supplement describes the Health Impact Pyramid and the Social Determinants of Health, and indicates that socioeconomic factors have the largest impact on the health of a community (State Health Plan Supplement, p. 78).

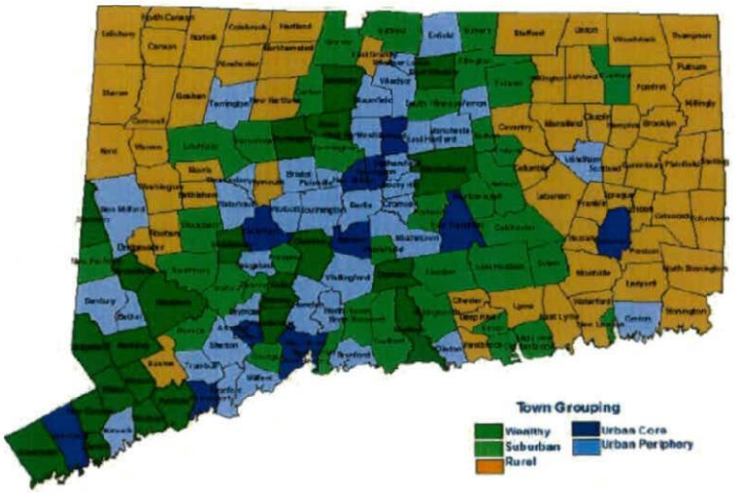
Figure 13 – Health Impact Pyramid

Source: Frieden, Thomas R. A Framework for Public Health Action: The Health Impact Pyramid. *American Journal of Public Health*. April 2010, 100(4), 590-595.

The Supplement states that "in 2009, the Connecticut State Data Center analyzed socioeconomic data for Connecticut's 169 towns and organized them into five distinct groups based on three characteristics: population density, median family income, and percent of population living below the federal poverty level" (Supplement, p. 52). The resulting distribution is the concept of "Five Connecticuts." The Five Connecticuts creates classifications or categories, which "range from 'Wealthy' (exceptionally high income, low poverty, and moderate population density) to 'Urban Core' (lowest income, highest poverty, and highest population density)" (Supplement, p. 52). The majority of the Backus Angioplasty Region is classified as "rural," with the exception of the town of Windham which is classified as "urban periphery" and Norwich which is classified as "urban core" (Supplement, p. 53). The report, "The Changing Demographics of Connecticut – 1990 to 2000, Part 2: The Five Connecticuts" (attached as ***Exhibit 19****) details the characteristics of each classification. Rural is defined as having "average income, below average poverty, and the lowest population density." The Urban Periphery has "below average income, average poverty, and high population density." The Urban Core has "the lowest income, highest poverty, and highest population density" (Five Connecticuts, p. 1). These socioeconomic classifications present different health challenges. As stated in the State Health Assessment, "health is greatly influenced by socioeconomic status; persons of lower income or lower educational attainment generally have less favorable health profiles compared to their counterparts with higher income or greater educational attainment. There are several mechanisms by which socioeconomic status may influence health, including the physical, social, and economic context in which people live and work. This context may influence access to health promoting resources such as affordable healthy food and safe places for recreation; exposures to adverse physical environments (toxic substances or unsafe occupational conditions); and the concentration of stressors such as exposure to violence, social, political, and economic exclusion, and discrimination" (State Health Assessment, p. 24).*

Figure 14 – Town Socioeconomic Grouping: The "Five Connecticuts," 2009

Figure 9. Town Socioeconomic Grouping: the "Five Connecticuts," 2009



Source: Connecticut State Data Center. The Changing Demographics of Connecticut: the Five Connecticuts. Recreated graph from updated 2009 data provided through personal communication.

*The result of high unmet needs and health outcomes and lower socioeconomic status is illustrated by the Supplement when analyzing the Age Adjusted Mortality due to Heart Disease by Town (**Figure 15**). Three towns within the Backus Angioplasty Region, Windham, Brooklyn, and Plainfield, have higher mortality due to heart disease than the State (Supplement p. 67). In totality, these towns are home to approximately 50,000 residents of Eastern Connecticut. They are currently not able to access Elective or Primary PCI without traveling long distances from their homes. In all three cases, Backus would be the closest Primary and Elective PCI provider for these residents. Hartford Hospital and L+M currently the closest Connecticut providers in the region, are well outside of the 30 minute drive time. See **Figure 16**, below, for a drive time chart. Additionally, the majority of patients originating from these towns are not receiving care at L+M. In Fiscal Year 2015 (annualized) 3 residents from these towns received care at L+M, 2 residents received care at L+M in 2014, and 0 received care in 2013 (see selected L+M OHCA filings in Docket No. 12-31768-CON, attached as **Exhibit 20**).*

Figure 15- Age Adjusted Mortality due to Heart Disease, by Town, Connecticut 2006-2010

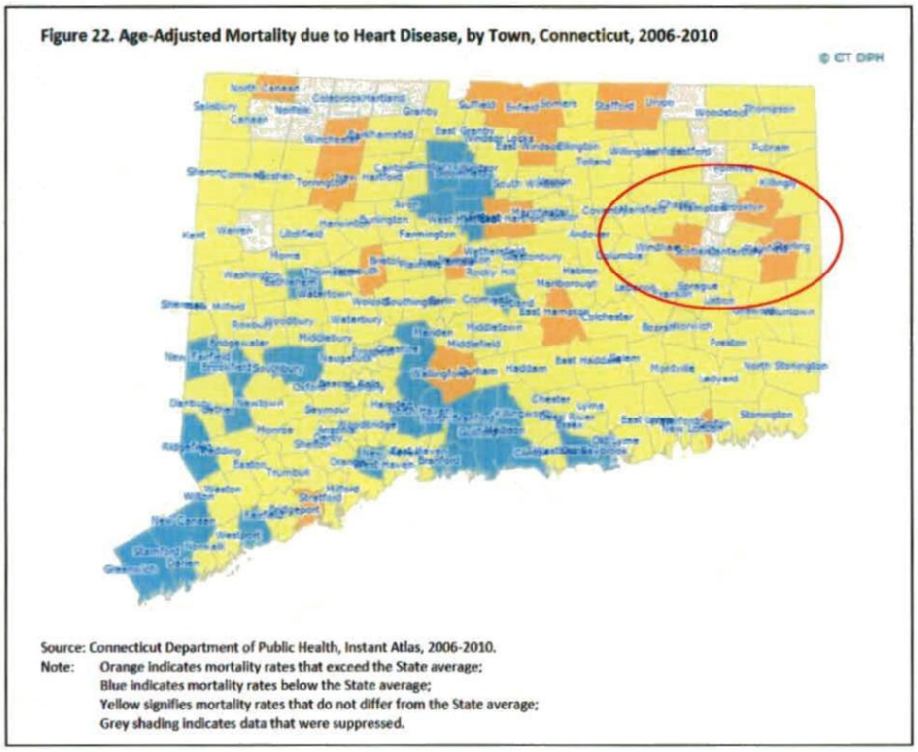


Figure 16 – Drive Time Chart (from 3d Health Assessment, Exhibit 8, p. 34)

	Brooklyn	***Plainfield***	***Windham***
Backus	*28 minutes*	*17 minutes*	*20 minutes*
Hartford	*55 minutes*	*57 minutes*	*43 minutes*
L+M	*47 minutes*	*36 minutes*	*39 minutes*

The Backus PCI program will meet the recommended minimum standards as outlined in the State Health Plan, § 3.4.3.1, "PCI without Surgical Backup." The physicians participating in the program practice, will or will continue to practice, at high volume institutions. All exceed the recommended 75 Elective and 11 Primary Angioplasties per year. Further, as described in later sections, Backus will exceed the recommended 200 institutional cases per year. Please see the 3d Health Assessment, pages 42-44, for a detailed breakdown of projected Primary and Elective procedure volume.

With Hartford Hospital providing oversight of these cardiac services at Backus, this proposal clearly meets all of the conditions as required in the ACCF/AHA/SCAI practice guidelines, and aligns with the State Health Plan.

> *§ "Whether there is a clear public need for the health care facility or services proposed by the applicant;" (Conn.Gen.Stat. § 19a-639(a)(3))*

8. With respect to the proposal, provide evidence and documentation to support clear public need:

    a. identify the target patient population to be served;

The 3d Health Assessment provides an overview of the demographics of the Backus Angioplasty Region, including age, gender and ethnic composition of residents, median household income and educational attainment. In order to estimate the current and five-year Angioplasty Region demographics, 3d Health utilized data obtained from The Nielsen Company, the industry leader in estimating demographic data for the past 35 years. In estimating census tract-level demographics, The Nielsen Company's base counts are calculated by utilizing both the 2010 U.S. Census and the annual American Community Survey, also conducted by the U.S. Census Bureau.

As a point of comparison and to validate The Nielsen Company estimates, 3d Health tested the 2015 Nielsen population for the Angioplasty Region to that of the 2010 U.S. Census as well as the 2014 American Community Survey and found both to have less than one-tenth of a percent variance (the census data from 2010 was lower by 136 residents while the 2014 ACS was higher by 99 residents). Upon validating the Nielsen estimates to two other sources of publicly available demographic data, 3d Health decided to utilize The Nielsen Company data in order to have the most current estimates and to best project five-year estimates at the age-gender level.

The Backus Angioplasty Region is compared on these measures to Connecticut and to the United States as a whole. Where relevant, 3d Health projected changes in demographic factors going forward. A number of these factors are directly relevant to the establishment for a PCI program at Backus.

Based on these statistics, the Backus Angioplasty Region population is expected to remain relatively similar over the next five years, with a majority of the population growth in the Norwich region, along Route 2. These areas account for 40% of the total Angioplasty Region population, or 90,000 residents. Also, total Angioplasty Region population over the age of 45 is greater than in the United States as a whole (3d Health Assessment, p. 6-7).

45% of the Backus Hospital Region's population is over age 45, which is higher than the Nation. The Angioplasty Region also has a slightly higher proportion of male residents as the State (3d Health Assessment, p.7). These factors suggest an increased future demand for cardiovascular services. 43% of the Angioplasty Region has a median household income less than $50,000 per year, and fewer residents in the Backus Angioplasty Region have completed an undergraduate degree or post-graduate degree (26% vs. 36% and 29% in the State and Nation, respectively) (3d Health Assessment, p. 9-10). The study "Widening of Socioeconomic Inequalities in the U.S. Death Rates, 1993-2001," by Jemal, et al., published in PLoS one (a multidisciplinary Open Access journal) in 2008, analyzed differences in death rates by disease and educational attainment, and showed that deaths from heart disease are three times more likely among this portion of the population compared to those that have at least a four-year degree.[18] Such statistics support the need for a PCI program to be established at Backus Hospital, to provide access to life-saving standard of care to vulnerable populations residing in eastern Connecticut.

b. discuss how the target patient population is currently being served;
c. document the need for the equipment and/or service in the community;

To complete the demand and market share analysis for Backus' Angioplasty Region for PCI, 3d Health analyzed Chime data for fiscal years 2009 through 2014. 3d Health also compared statistics for the Angioplasty Region and state of Connecticut to data from the National Center for Health Statistics' annual National Hospital Discharge Survey for 2010, the most current survey available. 3d Health found that overall acute MI volumes have increased in the defined Backus Angioplasty Region from FY 2009-2014. STEMI volume has remained consistent in the Backus Angioplasty Region since 2011. Using the 2010 National Center for Health Statistics' annual National Hospital Discharge Survey, 3d Health found that in that fiscal year the Backus Angioplasty Region experienced an incidence of 104.3/100,000 population STEMIs, compared to 83/100,000 population statewide, and 81.9/100,000 population nationally. The STEMI rate in the Backus Angioplasty Region is significantly higher than the State or Nation. Overall, acute MI volumes in the Backus Angioplasty Region increased 12.6% since FY 2009 (3d Health Assessment, p. 15). Further, the incidence of NSTEMI in the Angioplasty Region has increased by 31.5% since FY 2009 (568-747 cases) (3d Health Assessment, p. 15-16). Despite these

[18] *Jemal A, Ward E, Anderson RN, Murray T, Thun MJ (2008) Widening of Socioeconomic Inequalities in U.S. Death Rates, 1993–2001. PLoS ONE 3(5): e2181.*

figures, the rate of Primary and Elective PCI interventions for residents in the Angioplasty Region are 18% below the statewide level and 8% below the national level for Primary PCI, and 19% below the statewide levels and 41% below the national level Elective PCI.

In FY 2014 there were 947 discharges from an acute-care facility, originating from the defined Angioplasty Region, with the diagnosis of NSTEMI, NSTEMI with LBBB, or STEMI. In total, 514 of these discharges received a primary or elective PCI in 2014 (3d Health Assessment, p. 14-15). This indicates that the 2014 rate of Primary PCI as an intervention for STEMI or acute MI with LBBB originating from the Backus Angioplasty Region is about 18% below the statewide level, and 8% below the National level, as the rate of Primary PCI in the Angioplasty Region is 45%, compared to 53% statewide, and 48% nationally. Additionally, residents of the Angioplasty Region are receiving Elective PCI at a lower rate than the State or Nation (15% vs. 18% and 22%, respectively), despite suffering from NSTEMI conditions at a higher incidence than the Nation (3d Health Assessment, p. 16-17). Such statistics indicate an access to care issue for the residents of this region of Connecticut.

Over the past six years, there has been an average of 100 Primary PCI patients per year from the Backus Angioplasty Region treated at Connecticut or Massachusetts hospitals, with 84% of this volume originating from towns located within a 30 minute drive time of Backus (3d Health Assessment, p. 18). Hartford Hospital currently treats the most primary PCI patients originating within the Angioplasty Region, with 48% of the market in FY 2013 (3d Health Assessment, p. 22).

Similar to Primary PCI volumes, per CHIME data, on average 334 patients requiring Elective Inpatient PCI, who reside within the Backus Angioplasty Region, were treated at a Connecticut or Massachusetts hospital. 83% of this Angioplasty Region Elective Inpatient PCI volume originated from towns located within a 30 minute drive time to Backus (3d Health Assessment, p. 19). 58% of the Angioplasty Region Elective PCI patients currently travel to either Hartford Hospital or Yale New Haven Hospital to receive this care (3d Health Assessment, p. 23).

Further, the incidence of Primary and Elective PCI from the Angioplasty Region varies by demographic characteristics. In patients originating from the Backus Angioplasty Region over the past six years, PCI was more likely among males, older populations, and non-Hispanic populations (3d Health Assessment, p. 20). Incidence of Elective PCI in the Angioplasty Region is consistent with that of Primary PCI, and is heavily weighted toward Caucasian males aged 65 or older (3d Health Assessment p. 21).

Residents Going Out of Area for Necessary Care

The 3d Health Assessment revealed that a majority of cases originating in the Backus Angioplasty Region are being treated out of the area for Primary and Elective PCI to high-volume providers. In 2014, 48% of Primary cases were transferred to Hartford, and 11% of transfers went to Yale-New Haven Hospital ("YNHH") (3d Health Assessment, p. 22). While Hartford captured the greatest share of Primary PCIs, YNHH captured the greatest share of Elective PCIs (3d Health Assessment, p. 23). YNHH is a full-service cardiac provider and like Hartford Hospital has one of the busiest cardiac catheterization laboratories in the State of Connecticut. The remaining Primary and Elective PCI market is split between University of Massachusetts Memorial Hospital ("UMASS"), Lawrence and Memorial Hospital ("L+M") and St. Francis Hospital. In FY 2012 137 total cases went to UMASS, 22 cases from the Backus market went to L+M, and 45 cases went to St. Francis (3d Health Assessment, p. 32). All of these programs perform meet or exceed facility minimums each year, per the recommended guidelines, and the patient volume originating from the Backus market seeking care at these institutions is small enough to ensure that establishing a PCI program at Backus will not compromise the programs in existence at any of these providers. See ***Figure 17****, below, for more detailed information.*

Figure 17 – Current Market Share, Backus Angioplasty Region

FY 2014 Data[1]	*Hartford Hospital*	*Yale-New Haven Hospital*	*L+M Hospital*	*Saint Francis Hospital and Medical Center*	*UMass Memorial - University*
Angioplasty Region Cases / Market Share: ***Primary PCI***	*43 cases / 48% share*	*10cases / 11% share*	*2 cases / 2% share*	*6 cases / 7% share*	*27 cases / 30% share*
Angioplasty Region Cases / Market Share: ***Elective PCI***	*95 cases / 23% share*	*141 cases / 35% share*	*20 case / 5% share*	*39 cases / 9% share*	*110 cases / 25% share*
Total Estimated Primary PCI Cases	*267 cases*	*288 cases*	*97 cases*	*191 cases*	*347 cases*
Total Estimated Elective PCI Cases	*810 cases*	*1,180 cases*	*98 cases*	*664 cases*	*~753 cases (OP estimated)*
Total Coronary Angioplasty (inpatient and outpatient)[2]	*1,077 cases*	*1,468 cases*	*195 cases*	*855 cases*	*~1,100 cases (OP estimated)*
Percent of all Hospital's Coronary Angioplasty (Primary + Elective) from the Angioplasty Region	*14.6%*	*10.3%*	*11.3%*	*5.3%*	*12.5%*

[1]UMass-University data from FY 2012; 33% of all elective estimated to be performed on an outpatient basis
[2]L&M data from OCHA filing
[3]Hartford data obtained directly
[4]YNNH, and St. Francis data per the CHA's Patient Census Report from October 2013 through September 2014

Transfer of STEMI Patients to Primary PCI-Capable Hospitals Results in Door-To-Balloon Delays: Time is Muscle.

As detailed in ***Figure 17*** *above, residents who require a PCI are forced to leave the region to access PCI services. This is not ideal. Establishing a PCI program at Backus will help ensure that Angioplasty Region patients have timely access to comprehensive cardiac care locally. Because time is of the essence in emergency cardiac care, the ACC/AHA Guidelines for the Management of Patients with ST Segment Elevation Myocardial Infarction prescribe a timeframe within which reperfusion via Primary PCI should be achieved in patients suffering from STEMIs. The ACC/AHA STEMI Guidelines provide that "door-to-balloon" time ("DTB") – which is measured from when a patient presents at the emergency department to inflation of the balloon that opens the occluded artery – should not exceed 90 minutes.*

Delays in DTB times can compromise patient outcomes and it has been documented that "primary PCI, if performed in a timely fashion, is the reperfusion therapy of choice in patients with STEMI...In 13 trials evaluating the combined endpoint of death, reinfarction, or stroke at four to six weeks (4,946 patients), every additional 10 minute delay in door-to-balloon time beyond the door-to-needle time reduce the absolute benefit of primary PCI by 1.17%."[19] *In the Fracone, et al. 2009 study, "Impact of primary coronary angioplasty delay on myocardial salvage, infarct size, and microvascular damage in patients with ST-segment elevation myocardial infarction: insight from cardiovascular magnetic resonance," Francone and colleagues determined that in patients with STEMI treated with primary percutaneous coronary intervention, time to reperfusion determines the extent of reversible and irreversible myocardial injury assessed by cardiovascular magnetic resonance. In particular, salvaged myocardium is markedly reduced when reperfusion occurs in less than 90 minutes of coronary occlusion.*[20] *Terkelson et al. support this finding. In their 2010 study, Terkelson found that patients identified with STEMI who experienced a system delay in receiving a PCI had an increased long-term mortality rate. That is, a system delay of 0-60 minutes corresponded to a long term mortality rate of 15.4%; a delay of 61-120 minutes increased the long-term mortality rate to 23.3%; and a delay of 181-360 minutes created a long term mortality rate of 30.8%.*[21]

In 2006 McNamara et al. analyzed the effect of DTB time on mortality in patients with STEMI, and concluded that longer door to balloon times were associated with increased in-hospital mortality, compared to those who had DTB times less than or equal to 90 minutes. In a subgroup analysis, McNamara found increasing mortality with increasing DTB time was seen

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[19] *Gibson, Michael, C., Pinto, D.S, Cutlip, D. "Selecting a reperfusion strategy for acute ST elevation myocardial infarction." UpToDate, 2012.*

[20] *Francone, M., Bucciarelli-Ducci, C., Carbone, I., Canali, E., et al. "Impact of primary coronary angioplasty delay on myocardial salvage, infarct size, and microvascular damage in patients with ST-segment elevation myocardial infarction: insight from cardiovascular magnetic resonance." 2009. Journal American College of Cardiology. Dec 1: 54(23): 2145-53.*

[21] *Terkelsen, CJ, Sorenson J, Maeng, M, Jensen, L, et al. "System Delay and Mortality Among Patients with STEMI Treated with Primary Percutaneous Coronary Intervention." 2010. JAMA. Aug 18.*

regardless of symptom onset to door time, and regardless of the presence or absence of high-risk factors. Time to primary PCI is strongly associated with mortality risk and is important regardless of time from symptom onset to presentation, and regardless of baseline risk of mortality.[22] *To further support this argument, in 2009 Rathore et al. suggested reducing DTB time to as short a time period as possible will result in significant in-hospital mortality reduction. Rathore states, "Experimental models have shown that the continuous, progressive 'wave front of necrosis' largely depends on the duration of ischemia. Thus, patients with longer door-to-balloon times will experience longer periods of vessel occlusion, resulting in more ischemia and greater necrosis than patients with shorter times to treatment."*[23] *In the study, Rathore determined that "patients who died in hospital had a 14-minute longer median door-to-balloon time than patients who survived (96 vs. 82 minutes, P<.001)."*[24]

DTB times are often adversely impacted when a patient presents with a STEMI at a hospital without an angioplasty program. This is due in large part to the time it takes to transport the patient to a PCI-capable facility (as well as delays associated with the arranging for the transfer and receiving the patient). Case in point, current DTB times for Backus patients transferred to PCI-capable facilities do not consistently meet the AHA/ACC STEMI Guidelines recommended 90 minute DTB time. An analysis of 105 AMI patients who presented at Backus between FY 2011-2015 May, for which complete DTB time data was available, indicated that the median DTB time for patients transferred to either YNHH or Hartford Hospital was 134 minutes, with only 10% (11 cases) treated within the recommended 90 minute DTB time (3d Health Assessment, p. 26). Thirty percent (30%) of patients transferred exceeded the 90-minute DTB recommendation by an hour. Overall, 59% of DTB times were between 90 and 150 minutes (3d Health Assessment, p. 27).

The Rathore study indicates that any delay in DTB time is associated with mortality. In the study, the "estimated unadjusted mortality ranged from 2.8% for patients with door-to-balloon times of 30 minutes to 9.8% for patients with door-to-balloon times of 240 minutes."[25] *Thus, Rathore would suggest in the case of patients being transferred from Norwich to Hartford or New Haven, who have a DTB time of 134 minutes, the adjusted in-hospital mortality is estimated to be approximately 5%.*[26]

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[22] *McNamara, RL., Wang, Y., Herrin, J., Curtis, JP., "Effect of Door-To-Balloon Time on Mortality in Patients with ST-Segment Elevation Myocardial Infarction." 2006. Journal of American College of Cardiology, 6; 47(11):2180-6.*

[23] *Rathore, Saif S., Curtis, JP, Chen, J., et al., "Association of Door to Balloon Time and Mortality in Patients Admitted to Hospital with ST Elevation Myocardial Infarction: National Cohort Study." BMJ 2009; 338:b1807 doi: 10.1136/bmj.b1807*

[24] *Ibid.*

[25] *Rathore, Saif S., Curtis, JP, Chen, J., et al., "Association of Door to Balloon Time and Mortality in Patients Admitted to Hospital with ST Elevation Myocardial Infarction: National Cohort Study." BMJ 2009; 338:b1807 doi: 10.1136/bmj.b1807*

[26] *Ibid.*

Transport time accounts for over half of the DTB minutes associated with transfers from Backus to YNHH and Hartford Hospital. Backus collected a set of sample time data by detailed Primary PCI segment milestone from YNHH and Hartford Hospital for 105 cases from FY 2011 to FY 2015, May. Transport and travel time account for a significant portion of total DTB. Backus' affiliation with Hartford Healthcare has led to an increase in transfers for Primary PCI to Hartford Hospital with a corresponding reduction in travel time. Total DTB, however, still routinely exceeds the 90 minute guideline (3d Health Assessment, p. 29).

This is partly due to the capacity constraints existing at Hartford Hospital. A capacity analysis for Hartford Hospital's cardiac catheterization labs was conducted to understand whether there would be a benefit to Hartford if PCI volume was served locally at a Backus program, rather than transferred. The analysis indicated that during FY2014 Hartford Hospital was operating at approximately 92% of capacity (3d Health Assessment, p. 35). Thus, Hartford Hospital is at nearly full capacity within its existing infrastructure. The addition of a Backus program would therefore not only improve the DTB times for patients presenting locally, but would also help to ease some capacity constraints currently occurring at Hartford Hospital, as individuals currently requiring PCI who are traveling to Hartford for care would be able to receive the same care locally. This reduces the volume of patients treated at Hartford, without eroding the Hartford Hospital PCI program, and increases the capacity without increasing the number of catheterization labs at Hartford Hospital. Ultimately the establishment of a PCI program at Backus Hospital will improve access to care for individuals residing in the Hartford region who require a PCI.

Door-In-Door-Out ("DIDO") is the length of time from presentation at the emergency department to transport to a Primary PCI-capable hospital, and plays a major role in overall DTB time. A 2011 study appearing in JAMA recommends that DIDO should be limited to 30 minutes to regularly meet the 90-minute DTB guideline.[27] From FY 2011 to May 2015, the median DIDO for the 285 STEMI patients who presented to Backus was 73 minutes (3d Health Assessment, p. 28, ***Exhibit 8****). Only 11% of cases met the recommended DIDO time of 30 minutes. Backus has worked to minimize DIDO delays through multiple strategies in the Emergency Department, which are detailed below. Backus, however, has reached the limits of its ability to lower DIDO times for patients who must be transferred to another facility for Primary PCI. Further decrease will be difficult due to factors beyond Backus's control, including activation and arrival of EMS transportation, which adds substantial time to the total DIDO for STEMI patients arriving at the Backus ED (3d Health Assessment, p. 29).*

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[27] *Wang TY, Nallamothu BK, Krumholz HM, et al. Association of Door-In to Door-Out Time With Reperfusion Delays and Outcomes Among Patients Transferred for Primary Percutaneous Coronary Intervention. JAMA. 2011;305(24):2540-2547.*

Initiatives to Reduce DIDO for Primary PCI Patients

Bundled Medications

Thrombolytic medications are now "bundled" within the Pyxis system for easy administration and to facilitate rapid use. A "STEMI Medication Kit" was created and located within the Pyxis systems in the Emergency Department. Each kit contains the medications necessary for STEMI patients, and includes Aspirin, Plavix, Lopressor, Lipitor, and Heparin. Dosage information is also included on the label of each kit. These kits allow the provider to have instant access to STEMI medications, streamlining the order process and shaving critical minutes of the Door-In-Door-Out time. Rather than the physician needing to order five different medications through the pharmacy, a STEMI kit can be ordered and accessed within the ED, providing almost instant access to all necessary medications.

Emergency Department Response

When a STEMI is identified by a paramedic in the field (and is outside of a 30-minute drive to a PCI capable facility) a call is placed to alert the Hospital of the impending STEMI arrival. This call is made while the ambulance is en route to the facility, allowing ED staff and physicians to follow prescribed procedures to prepare for the STEMI, including preparation for transportation to a PCI-capable hospital. ED staff is able to take over the care of the STEMI patient immediately upon arrival. Knowing that time is of the essence when caring for a STEMI patient, the Emergency Department has developed and implemented "parallel processes," carrying out multiple operations simultaneously, to address STEMI in an efficient and effective manner. After arrival, the STEMI patient is seen by a physician and at that time a STEMI transfer order set is initiated. This order set activates different orders at once, including ancillary tests (laboratory and diagnostic imaging), nursing interventions, medications (the majority of which are included in the STEMI Medication Kit), consultations, and EMS transport (see ***Exhibit 21*** *for the ED CARD STEMI Transfer Order Set). Parallel processing allows each of these protocols to occur at the same time; one protocol does not have to be completed for the next necessary order to begin.*

Further, cardiology consultation is no longer called to confirm the STEMI prior to transporting. Historically cardiology consultation was called for every confirmed and suspected STEMI. Although cardiology response was rapid, many times it was not immediate, and ultimately added time onto a patient's transfer. With help and education provided by cardiac clinicians, Emergency Department physicians have been empowered to make the decision to transport due to STEMI to increase efficiencies. Cardiology consultation is only called if the patient is unstable or too sick for transport. Common situations include if the patient is in and out of ventricular fibrillation, is hypotensive, or has an unstable rhythm. Each of these parallel

processes and efficiency measures shaves minutes off of a patient's DIDO time, reduces their DTB time, and improves patient outcomes.

Unit Coordinator Communication

Unit Coordinators ("UC") in the Emergency Department are responsible for requesting transport for patients requiring treatment at a tertiary care facility. Prior to the STEMI Transfer Order Set and parallel processing, UCs were required to call for transport and communicate with the Charge Nurse or Emergency Physician if the desired method of transport is unavailable or delayed. After receiving the approval from the charge nurse or Emergency Physician the UC then requested transport from a second approved entity (i.e. ground transport through American Ambulance or LIFE STAR). Emergency Department leadership determined that requiring the UC to communicate to the charge nurse or ED physician before making the necessary transport arrangements was inefficient, as it added minutes onto a patient's DIDO time. As an efficiency measure, the Hospital has now empowered the UC to make the necessary transportation arrangements for a STEMI patient without input from the charge nurse or ED physician.

An analysis of the recorded conversations between the UC and transport dispatch revealed that the UC was not consistently alerting dispatch of the patient's STEMI diagnosis. This lack of communication caused delays in transport arrival, as EMS was not aware of the patient's time-sensitive condition. In response to this finding, ED UCs are now required to alert dispatch for both ground and air transport of the STEMI diagnosis when calling for EMS, as well as receiving an approximation of how long it will take for the EMS transport to arrive to the ED.

To further define the most efficient communication strategies, an algorithm was developed to guide UCs. This algorithm calls for UCs to immediately alert EMS dispatch to the need for transport for a STEMI as soon identification of the STEMI is possible. EMS dispatch should be called and appropriate transport arranged (ground or air) even if the STEMI has not yet arrived to the Emergency Department, but has been called in by EMS from the field. This allows for transport activation to occur prior to the patient arriving at the hospital, allowing the hand-off process for a patient to be transferred to a tertiary care facility to be as efficient as possible.

ED Education

STEMI identification, treatment, and protocols have been integrated into Emergency Department Clinical Competencies. ED competencies are mandatory trainings held on an annual basis for all clinical ED staff (UCs, Techs, RNs, and MDs). These trainings provide information on low volume but high risk identifiers or conditions as well as new initiatives. During the ED competencies, DIDO and DTB times are shared with ED staff, illustrating current DIDO/DTB times against the 90 minute DTB goal. This education has resulted in more awareness of STEMI

protocol, as well as outliers and fallouts (i.e. whether the EKG was done quickly, when the UC was notified of the STEMI so transport could be arranged). This training has been successful as it has made all ED staff acutely aware of the importance of early identification, treatment, and transfer of STEMI patients.

As previously mentioned, DTB delays result largely from the time associated with transport. Backus analyzed detailed milestone data for transport notification to departure for 79 STEMI cases. As illustrated by the timeline on page 28 of the 3d Health Assessment, 63% of DTB minutes are attributable to transport and travel times.

The addition of Angioplasty services at Backus will allow patients who present to the emergency department to obtain immediate treatment of their STEMIs. As noted on page 29 of the 3d Health Assessment, eliminating the steps associated with arranging for and completing transport of a patient to a Primary PCI-capable hospital will result in the saving of critical minutes from door to balloon, ultimately saving heart muscle. Door to Balloon Times for PCIs activated from the field and those walking into the Emergency Department will be less than 90 minutes (average DTB time is estimated to be 70 and 80 minutes, respectively). Reducing the average DTB time to less than 90 minutes will vastly improve both in-hospital and long term mortality. A PCI program at Backus will allow residents of the Angioplasty Region to obtain the care they require within the ACC/AHA STEMI Guidelines recommended timeframes, which will enhance the quality of cardiac care in eastern Connecticut and improve patient outcomes.

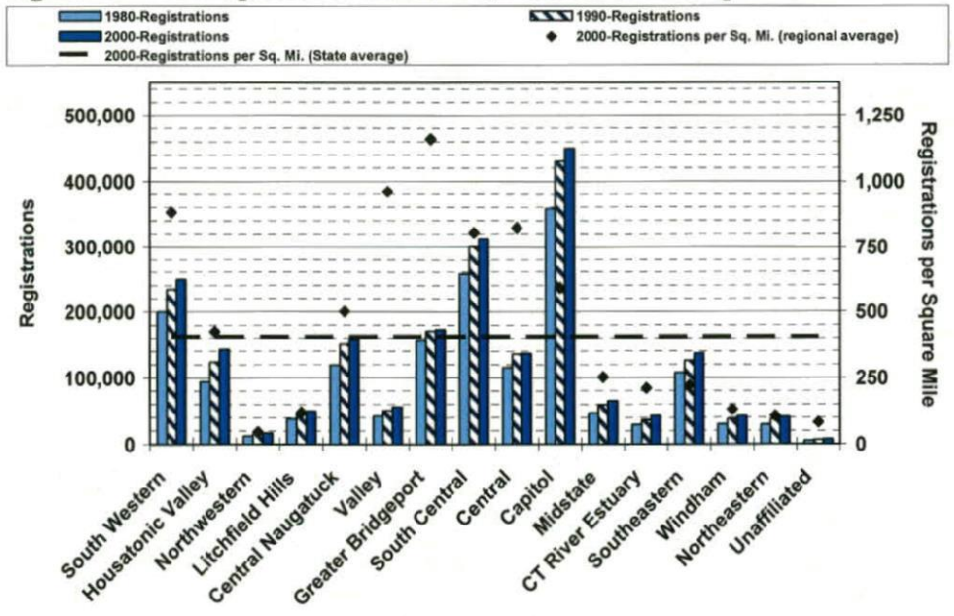
Elective Angioplasty – Reduces Duplicative Services and Promotes Care Coordination

The addition of Elective Angioplasty to the suite of cardiovascular services currently available at Backus Hospital will strengthen the care coordination, eliminate duplicative services, improve quality of care, and is responsive to the challenges faced by many residents of Eastern Connecticut. As described in other sections of the application, residents of Eastern Connecticut are older than the State or Nation, with a greater percentage of residents of the Angioplasty Region over the age of 45, fewer households in the Angioplasty Region have income levels greater than $50,000 than the State or Nation, and fewer residents in the Angioplasty Region have completed an undergraduate or post-graduate degree (3d Health Assessment, p. 7-10). Additionally, residents of the Angioplasty Region experience a high rate of NSTEMI, with a lesser rate receiving Elective PCI (3d Health Assessment, p. 16-17). There are no providers of Elective PCI within the defined Angioplasty Region, or its contiguous towns, which requires residents and their families to leave the region when requiring this care. In some instances this creates the need for duplicative services, and at times, puts the patient at a higher risk for

infection or complication. The need to leave the region, and many times the Hartford HealthCare system, disrupts care coordination and follow up care. Patients and their care givers must travel far distances for an Elective PCI, which is a burden on many residents who do not have transportation.

Transportation is a challenge for many residents of the region, as identified by the "Transportation in Connecticut: Trends & Planning Data" published by the Bureau of Transportation (attached as ***Exhibit 22****). When analyzing passenger vehicle registration by planning region Windham and Northeastern Connecticut have two of the lowest number of registrations (under 100,000), and two of the lowest number of registrations per square mile. Both regions have registrations far below the State average of 406 registrations per square mile. Residents in this region rely on limited public transportation services such as the Southeast Area Transit ("SEAT Bus"), the Northeastern Connecticut Transit District ("The District"), medical cab services, and taxi cabs for transportation. The SEAT Bus services nine municipalities in New London County, with a stop at Backus Hospital. The District provides both bus routes and dial-a-rides for elderly and disabled persons.*[28] *These transportation services, although widely used, are limited in scope and in operation. When individuals without their own vehicle must leave their home communities for medical care the travel arrangements and time can be onerous. The difficulty in securing reliable transportation impacts an individual's decision to seek care, and makes it difficult for an individual to receive regularly scheduled cardiac rehab or follow up after a procedure. See* ***Figure 18****, below, for detailed car registration data.*

Figure 18 – Transportation Statistics, Bureau of Transportation



Source: Connecticut Department of Motor Vehicles - Class 1 Auto Registrations (Passenger Cars).
Projections for years following 2000 is not available. Graphic revised as of August 2004.

[28] *http://www.nectd.org/*

Duplicative services occur when patients are undergoing a diagnostic catheterization procedure at in the Backus Hospital catheterization lab, and are found to have a thrombus. In the current model, these patients must have their procedure stopped. They then must be transported to another catheterization lab that provides Elective Angioplasty, and must have a second catheterization. This increases the risk of infection to the patient, and other arterial complications, as many times patients are transported with a sheath in place. It also duplicates the patient's exposure to radiation and sedation, as a repeat procedure must now take place. These duplicative services not only compromise the quality of care received and the clinical outcomes, but they increase the cost of care (see also the response to question 9c). In the proposed model, the patient would not need to be transported, and would not require a second catheterization, as the balloon could be inserted during the diagnostic procedure, when the thrombus is found. On average, these types of transfers occur 70 times per year in the Backus catheterization lab (see ***Figure 19*** *located after the response below).*

d. explain why the location of the facility or service was chosen;

Backus Hospital is an Ideal Location for a Primary and Elective PCI Program

As discussed, there is a clear public need for timely access to Primary and Elective PCI in the Backus Angioplasty Region. Time is of the essence in emergency cardiac care. With just one angioplasty provider in eastern Connecticut, outside of the Backus region, and located in an outlying section of New London along the shoreline, there is severely limited access to this life-saving service for area residents. Angioplasty Region residents are forced to leave their community to seek treatment for their cardiac conditions, which impact continuity of care, and puts the burden on the patient to travel at times more than one hour for subsequent treatment. Currently there are 146,000 residents of eastern Connecticut who do not have access to a Primary or Elective PCI-capable hospital within 30 minutes' drive time. Of these residents, 118,000 would have access within 30 minutes if Backus established a program, and 18,000 would have access to a Connecticut based provider. Additionally, more than 67,000 residents would experience improved access to Primary and Elective Angioplasty if this proposal is approved (3d Health Assessment, pg. 33-34). For these reasons, and as set forth more fully in other sections of this Application, the Backus Main Campus in Norwich is an ideal location for Primary and Elective PCI program. See ***Figure 19****, below, for a detailed description of the defined Angioplasty Region.*

Figure 19 – Backus Hospital Angioplasty Region Population by Town

Town / Town Part	2015 Population	2020 Population	Annual Growth
Within 30 Minutes			
Norwich	41,136	41,708	0.3%
Amston	4,271	4,258	(0.1%)
Bozrah	2,911	2,894	(0.1%)
Brooklyn	8,156	8,197	0.1%
Canterbury	5,033	4,965	(0.3%)
Chaplin	2,099	2,036	(0.6%)
Colchester	17,063	17,137	0.1%
Columbia	5,320	5,313	(0.0%)
Franklin	1,969	2,005	0.4%
Griswold-Lisbon	16,272	16,255	(0.0%)
Killingly	18,364	18,089	(0.3%)
Lebanon	7,138	7,075	(0.2%)
Mansfield Center	4,713	4,723	0.0%
Plainfield	14,730	14,700	(0.0%)
Preston	4,708	4,662	(0.2%)
Scotland	157	159	0.3%
Sprague	3,462	3,440	(0.1%)
Sterling	3,081	3,121	0.3%
Voluntown	2,523	2,522	(0.0%)
Windham	26,196	26,266	0.1%
Subtotal	**189,302**	**189,525**	**0.0%**
Outside 30 Minutes			
East Haddam	8,234	8,261	0.1%
Hampton	2,660	2,653	(0.1%)
Pomfret	4,544	4,544	-
Putnam	9,385	9,252	(0.3%)
Thompson	8,650	8,558	(0.2%)
Woodstock	8,644	8,538	(0.2%)
Subtotal	**42,117**	**41,806**	**(0.1%)**
Total Service Area	**231,419**	**231,331**	**(0.0%)**

e. provide incidence, prevalence or other demographic data that demonstrates community need;

Three towns within the defined Angioplasty Region, Putnam, Windham, and Danielson, are designated by the U.S. Department of Resources and Services Administration ("HRSA") as Health Professionals Shortage Areas ("HPSA")[29]. Specifically, these HPSAs are categorized as low income populations. A HPSA is "designated by HRSA as having shortages of primary care, dental care, or mental health providers and may be geographic (a county or Angioplasty Region), population (e.g. low income or Medicaid eligible), or facilities (e.g. federally qualified health centers, or state or federal prisons)."[30] Additionally, the towns of Killingly, Plainfield, Sterling, Bozrah, Franklin, Griswold, Lisbon, Norwich, Preston, Sprague, and Voluntown are identified by HRSA as Medically Underserved Populations. By definition this designation

[29] *http://datawarehouse.hrsa.gov/tools/analyzers/HpsaFindResults.aspx*
[30] *http://datawarehouse.hrsa.gov/tools/analyzers/HpsaFind.aspx*

indicates these towns "as those with economic barriers (specifically low-income or Medicaid eligible populations), or cultural and/or linguistic access barriers to primary medical care services."[31] *As discussed in the response to question 7, socioeconomic factors play a significant role in health outcomes and health status.*

In addition to the HPSA/MUP designation, Eastern Connecticut is disproportionately affected by risk factors that contribute to cardiovascular events. The Centers for Disease Control ("CDC") indicate three major risk factors for heart disease, and states that nationally 49% of adults report having at least one of the three risk factors. These include high blood pressure, high LDL cholesterol, and smoking. [32] *Other risk factors include diabetes, obesity, poor diet, physical inactivity, and excessive alcohol use. New London and Windham Counties suffer from all of these risk factors, many disproportionately when compared to the prevalence of these factors on a state and national level. These health indicators put residents of the region in danger of developing cardiovascular conditions necessitating the need for clinical intervention, such as PCI.*

The Robert Wood Johnson Foundation ("RWJF") compiles an annual report, "County Health Rankings and Roadmaps," which details the health status of states at a county-level. The report has been published annually since 2010, and highlights health factors such as mortality, morbidity, health behaviors, and socioeconomic indicators ***(Exhibit 4)****. Since 2010 Windham and New London Counties have been consistently ranked as two of the least healthy counties in the state. In 2010 Windham was ranked 8th/8 counties, and in the same year New London County was 5th/8. In 2015 Windham County was ranked 7th/8. New London County remained at 5th/8.*[33] *Thus, little change in ranking occurred over the five year period.*

To thoroughly understand the health status of its community, in 2015 Backus conducted a comprehensive community health needs assessment ("CHNA"), focusing on its Angioplasty Region ***(Exhibit 3)****. The Angioplasty Region analyzed encompassed all of New London and Windham Counties. Data gathered through the CHNA included primary data collected through 1,244 completed random telephone surveys. The survey instrument used consisted of approximately 100 questions covering a variety of health topics. Survey sampling was statistically significant to the geography, and represented the geographic distribution of the population, age cohorts, race, and gender. The CHNA also collected and analyzed secondary data sources, and conducted key informant interviews. These data points were compared to state and national benchmark data.*

The results of this CHNA determined that overweight and obesity rates are epidemic in both New London and Windham Counties, and continue to be the highest priority health challenges in the region. The survey determined that 66.2% of the adult population in New London and Windham

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[31] *http://www.hrsa.gov/shortage/mua/index.html*
[32] *www.cdc.gov/heartdisease/facts.htm/*
[33] *http://www.countyhealthrankings.org/app/#!/connecticut/2015/rankings/outcomes/overall*

Counties are classified as overweight, and 30.2% as obese. Both rates are significantly higher than the State of Connecticut (62.6% and 25%, respectively).

This result is supported by RWJF's 2015 report, which indicated that 30% of the adult population in Windham County is obese or overweight, reporting a Body Mass Index ("BMI") greater than or equal to 30, and 24% of adults as physically inactive. The RWJF reports in New London County 26% of the adults are obese or overweight, while 21% are sedentary.[34]

Obesity is an indicator of cardiovascular health, and a predictor of future cardiovascular events. Overweight and obesity is measured utilizing a BMI calculation. The BMI calculation indicates a relationship between body weight and height (kg/m^2). The National Institutes of Health's ("NIH") Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, the Evidence Report organizes BMI into a series of ranges, categorized into "underweight, normal, overweight, obesity, and extreme obesity" (attached as ***Exhibit 23****). Individuals are considered to be overweight if they have a BMI of 25 to 29.9, obese if their BMI is between 30 to 39.9, and extremely obese if their BMI is 40 or greater. In the same report, the NIH states that higher BMIs create an increased likelihood of developing co-morbid heath conditions. The NIH states that "higher morbidity in association with overweight and obesity has been observed for hypertension, type 2 diabetes, coronary heart disease ("CHD"), stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and some types of cancer (endometrial, breast, prostate, and colon)."*[35] *The NIH further asserts that obesity and hypertension (a co-morbid result of obesity) are risk factors for the development of cardiovascular disease, stating "the pathophysiology underlying the development of hypertension associated with obesity includes sodium retention and associated increases in vascular resistance, blood volume, and cardiac output. These cardiovascular abnormalities associated with obesity are believed to be related to a combination of increased sodium retention, increased sympathetic nervous system activity, alternations of the rennin-angiotension system and insulin resistance."*[36]

The Burden of Cardiovascular Diseases in Connecticut ("BCVD") 2010 Surveillance Report (found at http://www.ct.gov/dph/lib/dph/hisr/pdf/2010cvd_burdendoc_final.pdf) supports the evidence presented by the NIH, and identifies two different categories for risk factors relating to cardiovascular diseases: modifiable and non-modifiable. Non-modifiable risk factors include indicators such as age and family history, whereas modifiable risk factors include such indicators as high blood pressure, high cholesterol, smoking, diabetes, obesity, and physical inactivity.

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[34] *http://www.countyhealthrankings.org/app/#!/connecticut/2015/compare/snapshot?counties=011*
[35] *NIH pg. 12*
[36] *NIH pg. 13*

The BCVD in Connecticut 2010 Surveillance Report also identifies obesity as an independent risk factor for CVD, as well as a factor that increases the risk of obesity's co-morbid conditions such as "hypertension, dyslipidemia, CHD, and stroke."[37] *Obesity has a positive relationship with the risk of ischemic stroke, which increases as BMI increases.*[38]

The 2015 CHNA identified, for the same region, that the age-adjusted death rate due to diseases of the heart is 165.7, which is higher than the State rate, and higher than the Healthy People 2020 goal (153.4 and 156.9, respectively). Additionally, the survey revealed that 35.7% of individuals have been told they have high blood pressure, which is also higher than the State or the Health People 2020 target (31.3% and 26.9%, respectively) The age-adjusted death rate from Diabetes Mellitus is 15.8 which is higher than the State (14. 8), and 11% of individuals have diabetes or high blood sugar which is higher than the State (8.3%). Overall, 85.1% of individuals have 1 or more cardiovascular risk factor (**Exhibit 3**).

Further, the RWJF 2015 report indicates that 18% of adult individuals are classified as smokers in Windham County and New London County. This exceeds the State average of 15% and is well above the national benchmark of 14%. The 2015 Backus study revealed similar tobacco use trends in the region. Of CHNA survey respondents, 16.6% indicated they are current smokers. The Healthy People 2020 target 12.0% or lower. Of these current smokers, 68.2% were advised to quit smoking by a healthcare professional within the last year.[39]

The BCVD in Connecticut 2010 Surveillance Report lists smoking as a risk factor for cardiovascular diseases, stating "smoking causes reduced blood vessel elasticity by increasing arterial wall stiffness. Smoking increases the risk of heart attack two-fold. Smokers have higher congestive heart disease mortality than non-smokers and the risk of death increases with greater number of cigarettes smoked."[40]

The RWJF reports that 10% of individuals under the age of 65 residing in Windham County and 10% of individuals in New London County are uninsured. Further, Windham County has the largest population-to-primary care physician ratio in the State at 1,867:1. New London County also experiences a high population-to-primary care physician ratio at 1,594:1. Both indicators exceed the state average of 1,190:1. In Windham County the ratio of the population to primary care providers is almost double the national benchmark of 1,045:1, while New London far exceeds it.[41] *"A high ratio implies the reduced ability to meet demand for primary care services, which may negatively affect the health of a community, as treatment for needed services may be*

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[37] *The Burden of Cardiovascular Diseases in Connecticut 2010 Surveillance Report,* **pg. 31**
[38] *Ibid.*
[39] *Backus Hospital Community Health Needs Assessment, 2015.*
[40] *The Burden of Cardiovascular Disease in Connecticut – 2010, pg. 28.*
[41] *http://www.countyhealthrankings.org/app/#!/connecticut/2015/compare/snapshot?counties=015%2B011*

delayed or not sought at all. Residents with cardiovascular disease or coronary heart disease may remain undiagnosed without an adequate base of primary care to order diagnostics or refer patients to cardiologists."[42]

These health statistics and social determinants of health contribute to the morbidity and mortality experienced in Windham and New London County. Given the health indicators previously discussed, it is not surprising that Windham County has a higher rate of premature death than any other county in the state, with New London County not far behind. Both counties exceed the State average and national benchmark. The NIH states that "for persons with a BMI of 30 kg/m^2 or above, mortality rates from all causes, and especially from cardiovascular disease, are generally increased 50 to 100 percent above that of persons with BMIs in the range of 20-25 kg/m^2."[43]

RWJF considers premature death to be represented by the years of potential life lost before age 75. Every death occurring before the age of 75 contributes to the total number of years of potential life lost ("YPLL"). For example, a person dying at age 25 contributes 50 years of life lost, whereas a person who dies at age 65 contributes 10 years of life lost. In the 2015 study, Windham County reported 5,324 fewer deaths than Fairfield County (one of the healthiest counties in the State) but had 1,589 more YPLL. This means that on average, each 2015 death in Fairfield County contributed .68 YPLL to the overall rate, while in Windham County each death accounted for 4.91 YPLL. The Windham County figure was more than seven times the YPLL/death rate for Fairfield County. New London County has a similar issue; in 2015 there were 5,452 YPLL reported for New London County, which is attributed to 2,574 deaths. This means that each New London County death, on average, contributes 2.12 YPLL to the overall County rate. This is more than three times the YPLL/death rate for Fairfield County. These figures indicate that individuals in Windham and New London County, on average, are dying at a younger age than those in Fairfield County and the State overall, and that each death in these counties contributes more to the County's YPLL rate. Not surprisingly, each county exceeds the national benchmark of 5,200 YPLL.[44]

The careful analysis of the primary and secondary data collected indicate that multiple risk factors for cardiovascular events are epidemic in the region, with emphasis placed on the prevalence of obesity, its co-morbidities, and tobacco use. The BCVD report indicates that the "co-prevalence of risk factors places an individual at elevated risk of CHD and stroke," and complicates disease management.[45]

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[42] *Lawrence and Memorial Hospital, Docket Number 12-31768-CON, Agreed Settlement, pg. 12*
[43] *NIH pg. 23*
[44] *http://www.countyhealthrankings.org/app/#!/connecticut/2015/measure/outcomes/1/data?sort=sc-2*
[45] *The Burden of Cardiovascular Disease in Connecticut – 2010, pg. 34.*

Such cardiovascular risk in Windham and New London Counties supports the need for Backus to establish a life-saving PCI program as a necessary component of an effective and comprehensive cardiovascular service line. Patients with increased cardiovascular risks develop obstructive coronary artery disease that ultimately requires elective PCI for symptom control and treatment. Along with the need for an emergent PCI program, an elective PCI program allows patients to stay in their community for care. Providing highly trained and experienced Interventional Cardiologists in the Backus Catheterization Lab enables Backus to provide high quality care at the local level.

f. discuss how low income persons, racial and ethnic minorities, disabled persons and other underserved groups will benefit from this proposal;

When possible, residents of the Angioplasty Region are receiving PCI services at high volume institutions such as Yale New Haven Hospital, St. Francis, and Hartford Hospital, or at out of state at UMASS Memorial Hospital in Worcester Massachusetts (3d Health Assessment p. 22-23). The statistics presented in the 3d Health assessment indicate residents of the Backus service receive PCI at a lower rate than the State or Nation (3d Health Assessment p. 17). As highlighted in the response to questions 7, 8d and 8e, the Angioplasty Region population suffers from a lower socioeconomic status, multiple co-morbidities and a larger percentage of uninsured or underinsured. Therefore, seeking care outside of the region can be a hardship for patients and their families, who may be unable to travel to these hospitals easily due to age or other socioeconomic circumstances. In addition, receiving Angioplasty services at an out-of-state hospital distant from their homes makes follow-up care within the same institution more difficult. If approved, this proposal will bring access to care to an underserved and isolated region, ultimately enhancing the quality of healthcare available to low income persons, racial and ethnic minorities, disabled persons, and other underserved groups residing in the Backus community.

g. list any changes to the clinical services offered by the Applicant(s) and explain why the change was necessary;

The only change to clinical services offered by Backus will be the addition of Primary and Elective PCI to the suite of cardiovascular services offered by the Hospital. No other changes will occur due to the implementation of this proposal.

h. explain how access to care will be affected;

Access to Primary and Elective PCI procedures will now be readily available to all residents of eastern Connecticut. The establishment of this program will keep care close to home, improve coordination, and keep residents in-state when seeking this nationally recognized standard of care for acute cardiac conditions. See also the response to questions 7, 8 b,c,d.

i. discuss any alternative proposals that were considered.

*No other proposals were considered, as Primary and Elective Angioplasty is the nationally recommended standard for treating STEMI, LBBB and N-STEMI conditions, and residents of the Backus Angioplasty Region are receiving this standard of care at a lower rate than the rest of the State or Nation (**Exhibit 8**, p. 17).*

> § *"Whether the applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region, including, but not limited to, (A) provision of or any change in the access to services for Medicaid recipients and indigent persons, and (B) the impact upon the cost effectiveness of providing access to services provided under the Medicaid program;" (Conn.Gen.Stat. § 19a-639(a)(5))*

9. Describe how the proposal will:

   a. improve the quality of health care in the region;
   b. improve accessibility of health care in the region; and
   c. improve the cost effectiveness of health care delivery in the region.

A void currently exists in the east/northeast part of the State for Primary and Elective Angioplasty services. This proposal will fill that void and improve the quality and accessibility of health care for residents living in this geographically isolated region by making available critical life-saving procedures for which residents must now travel long distances to obtain. Timely access to PCI saves lives and improves health, and the people of this part of the State deserve the same standard of care and services that most all other Connecticut residents enjoy. Patients and their families, especially the more vulnerable populations that make up a considerable portion of this region, should not be forced to go out of State, or travel more than 30 minutes (and in most cases much more), or be transferred by LIFE STAR or EMS for these services. Rather, PCI services should be conveniently and readily available in their community. A PCI program at Backus Hospital will also significantly reduce healthcare costs - to both the State and patients- by eliminating duplicative procedures, and the need to transfer patients long distances, at times to more costly facilities, ultimately improving outcomes.

The 3d Health Assessment, a comprehensive cardiac assessment conducted in 2015, identified the need for Backus to establish a Primary and Elective PCI program as an integral part of its cardiac service line continuum, in order to improve the accessibility of cardiac services offered to the community. As discussed previously, Angioplasty Region demographics, incidence of STEMI and PCIs and documented delays associated with the lack of availability of this life-saving service in the Backus community support a clear public need for the proposal.

The establishment of a Primary and Elective PCI program at Backus will help to avoid downstream healthcare costs for STEMI and NSTEMI patients, and in doing so, will enhance the financial strength of the state's healthcare system, thus being a cost-effective alternative for patients and payors. For example, the establishment of this program avoids the cost of transportation and duplicative facilities and other fees for patients who present to Backus and are transferred to a PCI-capable hospital for treatment - and in the majority of cases, to a more costly academic medical center. These costs are not insignificant. The average charge for a LIFE STAR transport from Backus to Hartford Hospital is approximately $15,000 and an ambulance transfer to HH is approximately $1,500. In addition, when applying a 50% Ratio of Hospital Reimbursement to Hospital Charge, duplicate fees at two hospitals for a STEMI work up (a chest XRay, EKG, and lab work) can average $269 per patient.

Over the past 4 years Backus has transferred out an average of 70 diagnostic catheterization patients each year (see ***Figure 20****). These patients then undergo a repeat catheterization to clear the blockages found in the initial procedure. Often this requires another groin or radial puncture to the patient. By having an elective PCI program at Backus patients will be able to have the diagnostic and elective procedure completed together, reducing the exposure to radiation and intravenous contrast used during the procedure. This would also reduce the cost to the patient, as duplicative services would be eliminated. Each catheterization with contrast costs the patient approximately $4,300 (applying a 50% Ratio of Hospital Reimbursement to Hospital Charge). This conservatively equates to an approximate annual savings, for the average number of patients transferred from Backus each year, of $301,000.*

Figure 20 – Backus Hospital Diagnostic Catheterization Volume and Related Transfers

Fiscal Year	*Total Diagnostic Catheterizations*	*Transfers*	*% Transferred*
2012	*316*	*90*	*28.4%*
2013	*356*	*90*	*25.3%*
2014	*218*	*55*	*25.2%*
2015 (Annualized)	*214*	*47*	*21.9%*
4 Year Average	*276*	*70.5*	*25.5%*

Additionally, Patients from the Angioplasty Region who present to Backus ED (or to more distant Primary PCI hospitals) do not, for the most part, achieve reperfusion within 90 minutes of presentation as the ACC/AHA STEMI Guidelines require. Delays in treatment can adversely affect patient outcomes and lead to the need for additional healthcare services in the future. The result is added costs for patients and payors and can weaken the healthcare system. With a PCI program at Backus, patients will be able to obtain this life-saving service in a timely, cost-effective manner.

10. How will this proposal help improve the coordination of patient care (explain in detail regardless of whether your answer is in the negative or affirmative)?

This proposal, if approved, will greatly improve the coordination of patient care. The delays associated with transferring patients for PCI leads to increased patient anxiety and ultimately a worsened patient experience. Further, the physician who treats and evaluates the patient in the emergency department or in the Catheterization Lab, understands the patient history and current needs, and is in the best position to make the decision about the most appropriate next steps in the patient's care plan. When patients are transferred to other facilities for an Elective or Emergent PCI, this necessary information is not always communicated effectively. The investment in a PCI program at Backus Hospital will reduce anxiety associated with transport, leaving the local community, and will improve the patient experience. It will also improve patient outcomes and treatment plans, as the cardiologist who knows the patient best is performing the procedure, and providing the necessary follow up after the procedure is completed.

Hartford HealthCare's clinically integrated network, Integrated Care Partners ("ICP"), is another way continuity of care will be improved. ICP is a physician-led clinical organization, with the goal of bringing together all Hartford HealthCare physicians (employed and independent) to improve the health of the population, produce high-quality clinical outcomes, and shift contracts from fee-for-service to fee-for-value. ICP has a focus on enhanced care transitions for patients as a way to achieve its goals. The PCI program at Backus will benefit greatly from ICP's work in enhancing the standard of care, as well as providing access to data analytics that focus on quality.

Finally, Hartford HealthCare is currently deploying Epic throughout the System. By 2017 all Hartford HealthCare affiliates will be on Epic, which will create availability of clinical information across the health system. Community providers will have the option of joining the Epic platform through Hartford HealthCare's "Community Connect" initiative. "Community Connect is a reliable and affordable program allowing providers and practices associated with Hartford HealthCare access to the ambulatory suite of Epic products that are seamlessly linked to the inpatient and ancillary systems of Hartford HealthCare. This results in delivering the patient and provider with a unified patient record within a true community health record... Community Connect is offered to all providers who are members of the Active Staff in good standing at a Hartford HealthCare partner hospital." Key benefits of Hartford HealthCare's partnership with Epic are better coordination of patient care, avoidance of duplicative testing and procedures, as well as the ability to measure quality and ultimately manage cost.

These competencies and capabilities of Hartford HealthCare will support the proposed PCI program at Backus Hospital, ultimately improving patient care and coordination for all Hartford HealthCare patients, including the residents of the Backus Angioplasty Region.

11. Describe how this proposal will impact access to care for Medicaid recipients and indigent persons.

As described in the response to question 8f, above, the addition of Primary and Elective Angioplasty to the suite of cardiovascular services currently available at Backus will increase the access to care for the Medicaid population in the North Eastern region of the State, keeping care close to home. See also response under question 8 b and c.

> *§ "Whether an applicant, who has failed to provide or reduced access to services by Medicaid recipients or indigent persons, has demonstrated good cause for doing so, which shall not be demonstrated solely on the basis of differences in reimbursement rates between Medicaid and other health care payers;" (Conn.Gen.Stat. § 19a-639(a)(10))*

12. If the proposal fails to provide or reduces access to services by Medicaid recipients or indigent persons, provide explanation of good cause for doing so.

This proposal will not result in the reduction to access to services by Medicaid recipients. Conversely, this proposal will increase the access to services by Medicaid and indigent persons, as now this standard of care will be readily available within their community. Traveling out of area for Primary and Elective procedures is a burden on patients and their families, for both the initial intervention and any follow-up care that is required post procedure. Establishing this service at Backus eliminates this burden on community, and keeps lifesaving care close to home.

> *§ "Whether the applicant has satisfactorily demonstrated that any consolidation resulting from the proposal will not adversely affect health care costs or accessibility to care." (Conn.Gen.Stat. § 19a-639(a)(12))*

13. Will the proposal adversely affect patient health care costs in any way? Quantify and provide the rationale for any changes in price structure that will result from this proposal, including, but not limited to, the addition of any imposed facility fees.

As stated in the response to question 9c, this proposal will reduce health care costs to both patients and payors. The addition of Primary and Elective PCI at Backus will reduce transportation costs, duplicative clinical interventions, and improve outcomes preventing healthcare costs associated with future conditions.

Financial Information

§ *"Whether the applicant has satisfactorily demonstrated how the proposal will impact the financial strength of the health care system in the state or that the proposal is financially feasible for the application," (Conn.Gen.Stat. § 19a-639(a)(4))*

14. Describe the impact of this proposal on the financial strength of the state's health care system or demonstrate that the proposal is financially feasible for the applicant.

As stated previously in the response to question 9c, this service will ultimately reduce the cost to payors and patients. The savings is a result of the elimination of additional transport and duplication of services. When only considering the average 70 patients transferred from the Backus Catheterization Lab each year, the savings equates to approximately $301,000, which is not insignificant. Establishing a PCI program at Backus ultimately reduces cost the health care system, while simultaneously creating greater access closer to home for residents of eastern Connecticut. Although this program will run at a loss for Backus, it is viewed as a community benefit. Backus is willing to make this investment to improve the health outcomes of the communities it serves, given the results of the recent Community Health Needs Assessment and the Robert Wood Johnson Foundation County Health Rankings.

*As shown in **Exhibit 24**, the Hospital currently enjoys a positive margin that is projected to continue through FY 2019. Backus is able to afford this investment due to its historical financial performance, its projected financial performance, and the benefits it receives as being a part of the larger Hartford HealthCare system.*

15. Provide a final version of all capital expenditure/costs for the proposal using **OHCA Table 3.**

See Table 3.

16. List all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate; term; monthly payment; pledges and funds received to date; letter of interest or approval from a lending institution.

The establishment of a Primary PCI program at Backus will be financed through operations.

17. Include as an attachment:

    a. audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, provide other financial documentation (e.g., unaudited balance sheet, statement of operations, tax return, or other set of books.). Connecticut hospitals required to submit annual audited financial statements may reference that filing, if current;

Please see the FY2014 Audited Financial Statements for Backus Hospital and Hartford Hospital on file with OHCA.

    b. a complete **Financial Worksheet A (not-for-profit entity)** or **B (for-profit entity)**, available on OHCA's website under "OHCA Forms," providing a summary of revenue, expense, and volume statistics, "without the CON project," "incremental to the CON project," and "with the CON project." Note: the actual results reported in the Financial Worksheet must match the audited financial statement that was submitted or referenced.

*Please see Financial Worksheet A, **(Exhibit 24)**, for Backus Hospital financials with and without the proposed program.*

18. Complete **OHCA Table 4** utilizing the information reported in the attached Financial Worksheet.

Please see Table 4.

19. Explain all assumptions used in developing the financial projections reported in the Financial Worksheet.

Primary and Elective PCI case volume was calculated based on market projections completed by 3d Health for Backus' Angioplasty Region as outlined in the market assessment. Market data was gathered through the Connecticut Hospital Association CHIME Standard Data Extract, Hartford Hospital internal data, and L+M filings on record with OHCA.

Net revenue per case is based on current contract rates at Backus for the eight DRGs that account for >95% of primary PCI patients. A payor-weighted reimbursement by DRG was calculated based on the payer mix of all PCI patients originating the Backus Angioplasty Region. Outpatient rates are based on Hartford Hospital experience per case adjusted for Backus outpatient contracts.

Physician professional fees for performing the PCI cases are included in the net revenue. These fees are also included in the operating expenses with no markup.

Net revenue per case is assumed to remain flat in the forecast.

Operating expenses per case are based on Backus' ratio of cost-to-charges from FY 2014 by Revenue Center. Additional expenses were added for Bad Debt, a Medical Director to oversee the PCI program, and staff education and training.

Call team expenses include the addition of 2.6 new cardiology staff FTEs, on-call payments to the staff, and call-back pay for staff. Physician on-call expenses were included at $125 per hour for 24/7 coverage throughout the year.

Capital expenditures are estimated, and include $4.8M for an additional cath lab, software, and equipment upgrades as well as an allowance for ongoing capital needs estimated at 3% of net patient revenue.

20. Explain any projected incremental losses from operations resulting from the implementation of the CON proposal.

Backus is proposing to invest capital in a Primary and Elective PCI program with the intention of servicing primarily existing patients who present for care and need to be transferred, as well as those who are traveling to more distant PCI facilities for treatment. While this service shows a net loss on operations, Backus views the PCI program as a strategic investment to address a lack of access to life-saving cardiac services for its patients. As shown in ***Exhibit 24****, the Hospital currently enjoys a positive margin that will continue through FY 2019 despite the fact that the Primary PCI program will not show a gain.*

Moreover, it should be noted that a vast majority of the cost associated with the proposed PCI program is call-coverage expense. Net operating margin of the Primary PCI service before physician on-call expense is estimated at 9.4% by Year 4. The annual operating income of the service before physician on-call expense changes from $744K to $485K by the end of Year 4. Unlike larger hospitals in major urban areas, Backus does not have Interventional Cardiologists who take call without compensation. Because Backus is a community hospital, in order to offer this much-needed emergency service it must expend in excess of a million dollars annually for professional services. Without this cost, the program itself would not operate at a loss.

21. Indicate the minimum number of units required to show an incremental gain from operations for each projected fiscal year.

In order to show a gain from operations 385 procedures must be performed in year 5 of the program. Gains from operations are not possible in years 1-4, due to the assumptions utilized to project financial results. These assumptions include:

- *Net revenue per case remains flat*
- *Operating expenses were adjusted for inflation over the 5-years. An annual inflation rate of 2.68% was applied each year. This results in an assumption that the program will experience increasing expenses, and flat reimbursement.*

Please see ***Figure 21****, below, for more information:*

Figure 21 – Operating Expense Growth, Backus PCI Program, Years 1-5

	Year 1	*Year 2*	*Year 3*	*Year 4*	*Year 5*
Total Operating Expense Growth	-	*3.6%*	*4.5%*	*4.4%*	*4.6%*

Utilization

> § *"The applicant's past and proposed provision of health care services to relevant patient populations and payer mix, including, but not limited to, access to services by Medicaid recipients and indigent persons;" (Conn.Gen.Stat. § 19a-639(a)(6))*

21. Complete **OHCA Table 5** and **OHCA Table 6** for the past three fiscal years ("FY"), current fiscal year ("CFY") and first three projected FYs of the proposal, for each of the Applicant's existing and/or proposed services. Report the units by service, service type or service level.

Table 5 represents Hartford Hospital volume for PCI procedures originating from the Angioplasty Region, as this is a new service which Backus does not currently provide.

See Table 6 for projected utilization at Backus Hospital.

22. Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected service volume; explain any increases and/or decreases in volume reported in OHCA Tables 4 and 5.

To estimate future potential Primary and Elective PCI volume among Angioplasty Region residents, 3d Health prepared a set of market projections based on application of calculated utilization rates to the Angioplasty Region population. These utilization rates were calculated by age and gender using Primary PCI volume originating across the state of Connecticut from FY 2009 through FY 2014. These rates also include an estimate for Connecticut patients treated at

Massachusetts hospitals based on FY 2012 data. In modeling future volumes originating from the Angioplasty Region, 3d Health assumed no change in the underlying calculated utilization rates. Age-gender utilization rates were kept constant over the projection period, but were applied to population projections for the Angioplasty Region so the volumes account of the aging of the population (3d Health Assessment, p. 37).

Given expected demographic changes and aging of the population, Angioplasty Region 3d Health projects PCI volumes to increase 24% by FY 2020 over FY 2009 estimates, from to 512 market cases to 634 (3d Health Assessment, p. 41).

Since the typical Primary PCI patient presents at a hospital ED, 3d Health applied Backus and Windham combined FY2014 ED market share to the projections to estimate the potential for Primary PCI cases at Backus. Market share was calculated for each specific geographic region within the defined Backus Angioplasty Region, based on 30 minute drive time from Backus. For those cases from towns within 30 minutes of Backus 80% was applied to the total potential volume (the combined market share for Backus and Windham). For those cases from Angioplasty Region towns outside of 30 minutes away from Backus 11% was applied to total potential volume.
Finally, 3d Health assumed an in-migration rate of 5.4%, based on historic Emergency Department experience.

This methodology resulted in total projected Backus Primary PCI volume ranging from 79 primary cases in FY 2016 to 82 cases in FY 2020. This is well above the 36 case institutional minimum required by the ACC/AHA Guidelines (3d Health Assessment p.42).

*To estimate Elective PCI cases 3d Health employed a similar methodology. First, 3d Health calculated the total Angioplasty Region Elective PCI cases (inpatient and outpatient) based on Chime Data, as well as L+M OHCA filings (**Exhibit 20**). 3d Health then estimated the percentage of "complex" PCI cases (those with a history of previous cardiac event or intervention), and removed them from the total potential Backus case volume. It was assumed that these patients would require care at a tertiary institution offering on-site cardiac surgical backup and would not receive their Elective Angioplasty at Backus. 3d Health then stratified the remaining potential Angioplasty Region cases by those originating from within a 10 minute drive time of Backus, a 10-30 minute drive time from Backus, and those originating from greater than 30 minutes from Backus.*

To further predict the potential volume seeking care at Backus, 3d Health again calculated market share (inpatient only) for each specific geographic region within the defined Backus Angioplasty Region (based on the 10, 10-30, and 30+ drive times). This equates to 75% of cases

originating 10 minutes from Backus, 50% of cases originating 10-30 minutes from Backus, and 25% of cases originating 30+ minutes from Backus.

Further, an inmigration factor was assumed, based on historic inpatient market experience. This inmigration factor was equal to 3.2%.

Finally, acknowledging that L+M performs some Elective PCI cases on patients originating from the Backus Angioplasty Region, it was assumed that these cases would continue to be performed at L+M and were removed from the total Elective projections. Analyzing L+M filings on record with the Office of Health Care Access it is assumed L+M would continue to treat between 14-16 individuals residing in the Backus Angioplasty Region per year ***(Exhibit 20)****. This number was calculated using the volume of patients who sought this service at L+M over the most recent 12 months data was available.*

In total, 137 Elective cases are projected to occur at Backus in 2016, growing to 151 cases in 2020.

When Primary and Elective Angioplasty volumes are combined, Backus is projected to treat 216 cases in FY2016, growing to 233 by 2020 (3d Health Assessment, p.43). This volume is above the 200 case institutional minimum required by the ACC/AHA PCI Guideline, and as stated in Chapter 3 of the State Health Plan. See ***Figure 22*** *below for a detailed breakdown of projected volume.*

Figure 22 – Backus Hospital Projected PCI Volume

	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Total Service Area Elective PCI, Inpatient & Outpatient	**486**	**493**	**500**	**507**	**514**
% Complex Elective PCI	*39.5%*	*38.8%*	*38.1%*	*37.5%*	*36.9%*
Service Area Non-Complex Elective PCI	**295**	**302**	**309**	**317**	**324**
Service Area Volume Originating Within:					
10 Minutes of Backus	56	58	59	61	62
10-30 Minutes of Backus	180	184	189	193	198
More than 30 Minutes from Backus	58	60	61	63	64
Potential Backus Elective Cases from Towns Within:					
10 Minutes of Backus: 75% HHC East Region IP market share	42	43	45	46	47
10-30 Minutes of Backus: 50% HHC East Region IP market share	89	92	94	96	99
More than 30 Minutes from Backus: 25% Estimated Market Share	15	15	15	16	16
Potential Service Area Cases	146	150	154	158	162
Inmigration					
Total Potential Elective PCI Cases	**151**	**155**	**159**	**163**	**167**
Total Potential Primary PCI Cases	79	80	81	81	82
Less: Expected L&M Elective Service Area Cases	(14)	(15)	(15)	(15)	(16)
Primary & Elective Projected Cases	***216***	***220***	***225***	***229***	***233***

23. Provide the current and projected patient population mix (number and percentage of patients by payer) for the proposal using **OHCA Table 7** and provide all assumptions. **Note: payer mix should be calculated from patient volumes, not patient revenues.**

*See **Table 7** for projected patient population mix. This is a new service, and thus a current patient population mix is not available. Table 7 details projected population mix only.*

> *§ "Whether the applicant has satisfactorily identified the population to be served by the proposed project and satisfactorily demonstrated that the identified population has a need for the proposed services;" (Conn.Gen.Stat. § 19a-639(a)(7))*

24. Describe the population (as identified in question 8(a)) by gender, age groups or persons with a specific condition or disorder and provide evidence (i.e., incidence, prevalence or other demographic data) that demonstrates a need for the proposed service or proposal. ***Please note: if population estimates or other demographic data are submitted, provide only publicly available and verifiable information (e.g., U.S. Census Bureau, Department of Public Health, CT State Data Center) and document the source.***

In order to project volume, 3d Health developed age and gender-specific use rates for Primary and Elective PCI based on actual PCI volume across the state of Connecticut from FY2009-FY2014 (see 3d Health Assessment, p. 37). This data was derived from the Connecticut Hospital Association Standard Data Extract. In modeling future volumes originating from the Angioplasty Region, 3d Health assumed no change in the underlying calculated utilization rates. Annual Incidence Rate of Primary PCI in the State of CT per 100,000 Population (5-Year Rate):

Figure 23 – PCI Use Rates, Backus Angioplasty Region

	Elective PCI			Primary PCI	
Age Group	Female	Male	Age Group	Female	Male
0-17	-	-	0-17	-	-
18-44	6.5	17.2	18-44	4.6	15.9
45-64	74.0	217.6	45-64	32.2	133.4
65+	230.9	538.4	65+	95.3	192.8

Given the expected demographic changes and aging population, 3d Health projected a 24% increase in PCI cases originating from the Backus Angioplasty Region 512 in FY 2009 to 634 in FY 2020 (3d Health Assessment, p. 41).

The 3d Health Assessment provides an overview of the demographics of the Backus Angioplasty Region, including age, gender and ethnic composition of residents, median household income and educational attainment. The Backus Angioplasty Region is compared on these measures to Connecticut and to the United States as a whole. Where relevant, 3d Health has projected changes in demographic factors going forward. As previously discussed, a number of these factors are directly relevant to the establishment for a Primary PCI program at Backus.

45% of the Backus Hospital Region's population is over age 45, which is higher than the Nation. The Angioplasty Region also has a slightly higher proportion of male residents as the State and Nation. These factors suggest an increased future demand for cardiovascular services (3d Health Assessment, p.7).

25. Using **OHCA Table 8**, provide a breakdown of utilization by town for the most recently completed FY. Utilization may be reported as number of persons, visits, scans or other unit appropriate for the information being reported.

Table 8 represents market volume for PCI procedures performed at Hartford Hospital, as this proposal is for a new service that Backus Hospital does not yet offer.

> *§ "The utilization of existing health care facilities and health care services in the Angioplasty Region of the applicant;" (Conn.Gen.Stat. § 19a-639(a)(8))*

26. Using **OHCA Table 9**, identify all existing providers in the Angioplasty Region and, as available, list the services provided, population served, facility ID (see table footnote), address, hours/days of operation and current utilization of the facility. Include providers in the towns served or proposed to be served by the Applicant, as well as providers in towns contiguous to the Angioplasty Region.

Not applicable; there are no PCI-capable facilities within the defined Backus market, or within the contiguous towns.

27. Describe the effect of the proposal on these existing providers.

Not applicable; there are no PCI-capable facilities within the defined Backus market, or within the contiguous towns.

28. Describe the existing referral patterns in the area served by the proposal.
29. Explain how current referral patterns will be affected by the proposal.

Many of the projected Primary PCI volume at Backus are patients who already present to Backus for cardiac care. Ambulances transport patients to Backus because it is the closest facility for an unidentified STEMI, there is not a PCI capable provider within 30 minutes for an identified STEMI, or because a patient requests a transport to Backus. These referral patterns

are not expected to change if the proposal is approved. What will change is Backus' ability to provide timely access to PCI services to area residents rather than transferring them to facilities in New Haven or Hartford.

Residents of the Backus market are currently seeking PCI services at more distant Connecticut hospitals or out of state. Backus expects some of this volume to shift to its program in Norwich, which will be beneficial for patients in terms of receiving timely treatment of a life-threatening cardiac condition. The shift of volume will not be significant enough to have any appreciable impact on any other provider.

Elective cases will be generated by patient and physician selection, as well as those patients identified as requiring an Elective PCI while undergoing a diagnostic catherization at Backus. This occurs in approximately 25% of diagnostic catherizations done at Backus on an annual basis (averaging 70 per year over the last 4 years). In this circumstance, the diagnostic catheterization is stopped and the patient is referred to a facility that can provide the Elective Angioplasty. The patient must then undergo a second catheterization to complete the Angioplasty. This results in duplicative services and increases the cost of healthcare.

> § "Whether the applicant has satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities;" (Conn.Gen.Stat. § 19a-639(a)(9))

30. If applicable, explain why approval of the proposal will not result in an unnecessary duplication of services.

There are no existing providers of Primary or Elective PCI services within 30 minutes' drive time for 146,000 residents of eastern Connecticut. Establishing a Primary and Elective PCI program at Backus will improve access to life-saving emergency cardiac care for these individuals. This proposal will expand 30 minute access to a Connecticut PCI provider to 118,000 individuals, will improve access within 40-50 minutes for 28,000 Eastern Connecticut residents, and will provide access within 10 minutes to a PCI provider to 67,000 individuals (3d Health Assessment p. 34). The closest provider in Eastern Connecticut is outside of the Backus Angioplasty Region, and not an easily accessible hospital for a large number of patients in the Backus Angioplasty Region, particularly those in the North East corner of the State. Timely access to Primary PCI services is crucial. Establishing a program in Norwich will not be unnecessarily duplicative, but rather will enhance the quality and accessibility of cardiac care in the region.

§ *"Whether the applicant has satisfactorily demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the geographic region. . ." (Conn.Gen.Stat. § 19a-639(a)(11))*

31. How will the proposal impact the diversity of health care providers and patient choice or reduce competition in the geographic region?

If this proposal is approved, patients residing in the defined Backus Angioplasty Region will have a greater choice for PCI procedures, and will have the ability to receive this nationally recognized standard of care at the facility they most often choose for their other healthcare needs (see ***Figure 8****). Such access currently does not exist, and there are no providers within the defined region (or within the towns contiguous to the defined region) that provide this service.*

TABLES

	Description
1.	*Applicant's Services and Service Locations*
2.	*Angioplasty Region Towns*
3.	*Total Proposal Capital Expenditure*
4.	*Projected Incremental Revenues and Expenses*
5.	*Historical Utilization by Service*
6.	*Projected Utilization by Service*
7.	*Applicant's Current & Projected Payer Mix*
8.	*Utilization by Town*
9.	*Services and Service Locations of Existing Providers*

TABLE 1
APPLICANT'S SERVICES AND SERVICE LOCATIONS

Service	Street Address, Town	Population Served	Days/Hours of Operation	New Service or Proposed Termination
Primary & Elective Angioplasty	*326 Washington Street, Norwich*	*Residents of Northern Eastern Connecticut – Please see Table 2, below, for a detailed breakdown of the zip codes included.*	*24/7*	*New Service*

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TABLE 2
ANGIOPLASTY REGION TOWNS

List the official name of town* and provide the reason for inclusion.

Town*	Reason for Inclusion
Norwich *Amston* *Bozrah* *Brooklyn* *Canterbury* *Chaplin* *Colchester* *Columbia* *Franklin* *Griswold-Lisbon* *Killingly* *Lebanon* *Mansfield Center* *Plainfield* *Preston* *Scotland* *Sprague* *Sterling* *Voluntown* *Windham*	*Towns within 30 minute drive time to Backus Hospital*
East Haddam *Hampton* *Pomfret* *Putnam* *Thompson* *Woodstock*	*Towns outside of 30 minutes to Backus Hospital, but where Backus Hospital would be the closest Connecticut provider of Primary and Elective PCI services.*

* Village or place names are not acceptable.

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TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE

Purchase/Lease	Cost
Equipment (Medical, Non-medical Imaging)	*$344,000*
Land/Building Purchase*	
Construction/Renovation**	*$4,500,000*
Other (specify) (*estimated 3% of operating revenue for additional capital needs*)	*$138,053*
Total Capital Expenditure (TCE)	***$4,982,053***
Lease (Medical, Non-medical Imaging)***	
Total Capital Cost (TCO)	***$4,982,053***
Total Project Cost (TCE+TCO)	***$4,982,053***

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.
** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.
*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

*See **Exhibit 25** for vendor quotes. It is estimated that the Balloon Pump and Angio-Jet have 5 year useful life. The necessary software upgrades to current equipment is estimated to have a useful life of 3 years. Please also note, a vendor quote is not included for necessary software updates. Additionally, equipment cost estimates are included in the financial projections at full cost.*

*See **Exhibit 26** for the proposed floor plans. Gross square footage for the new Lab is estimated to be 3,300 square feet. Construction of the new Lab is approximately 18 weeks, with the operational date following about 3 weeks post construction completion.*

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TABLE 4
PROJECTED INCREMENTAL REVENUES AND EXPENSES

	*FY 2016**	*FY 2017**	*FY 2018**
Revenue from Operations	*$4,715,663*	*$4,750,913*	*$4,911,295*
Total Operating Expenses	*$5,071,026*	*$5,208,730*	*$5,470,996*
Gain/Loss from Operations	***($355,363)***	***($457,817)***	***($559,701)***

* Fill in years using those reported in the Financial Worksheet attached.

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TABLE 5
HISTORICAL UTILIZATION BY SERVICE

Service**	Actual Volume (Last 3 Completed FYs)			CFY Volume*
	FY 2012***	FY 2013***	FY 2014***	FY 2015***
Inpatient PCI	*99*	*90*	*104*	*109*
Outpatient PCI	*3*	*12*	*34*	*22*
Total	***102***	***102***	***138***	***131***

* For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than 6 months, report actual volume and identify the period covered.

** Identify each service type and level adding lines as necessary. Provide the number of visits or discharges as appropriate for each service type and level listed.

*** Fill in years. If the time period reported is not *identical* to the fiscal year reported in Table 4 of the application, provide the date range using the mm/dd format as a footnote to the table.

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TABLE 6
PROJECTED UTILIZATION BY SERVICE

Service*	Projected Volume		
	FY 2016**	FY 2017**	FY 2018**
Primary PCI	*79*	*80*	*81*
Elective PCI	*137*	*140*	*144*
Total	***216***	***220***	***225***

* Identify each service type by location and add lines as necessary. Provide the number of visits/discharges as appropriate for each service listed.

** If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary. If the time period reported is not *identical* to the fiscal year reported in Table 4 of the application, provide the date range using the mm/dd format as a footnote to the table.

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TABLE 7
APPLICANT'S CURRENT & PROJECTED PAYER MIX

Volume reflects both IP & OP, incremental volume projections for Backus Hospital PCI program. FY 2014 is not completed, as Backus does not currently operate a PCI program.

Payer	Current FY 20__**		Projected					
			FY 2016**		FY 2017**		FY 2018**	
	Discharges	%	Discharges	%	Discharges	%	Discharges	%
Medicare*			*109*	*50%*	*110*	*50%*	*113*	*50%*
Medicaid*			*25*	*11%*	*25*	*11%*	*26*	*11%*
CHAMPUS & TriCare			-	*0%*	-	*0%*	-	*0%*
Total Government			*2*	*1%*	*2*	*1%*	*2*	*1%*
Commercial Insurers			***135***	***62%***	***136***	***62%***	***140***	***62%***
Uninsured			*79*	*37%*	*80*	*37%*	*82*	*37%*
Workers Compensation			*2*	*1%*	*2*	*1%*	*2*	*1%*
Total Non-Government			-	*0%*	-	*0%*	-	*0%*
Total Payer Mix			***81***	***38%***	***82***	***38%***	***85***	***38%***
			216	***100%***	***218***	***100%***	***225***	***100%***

* Includes managed care activity.
** Fill in years. Ensure the period covered by this table corresponds to the period covered in the projections provided. New programs may leave the "current" column blank.

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TABLE 8 - UTILIZATION BY TOWN

PCI PROCEDURES PERFORMED AT HARTFORD HOSPITAL ON PATIENTS FROM THE BACKUS ANGIOPLASTY REGION FISCAL YEAR 2014 (10/1/2013-9/30/2014)

Town	ZIP Code	FY14
Bozrah	06334	1
Bozrah	06336	-
Brooklyn	06234	3
Canterbury	06331	1
Chaplin	06235	4
Colchester	06415	20
Colchester	06474	-
Columbia	06237	6
East Haddam	06423	4
East Haddam	06469	2
Franklin	06254	2
Franklin	06389	-
Griswold-Lisbon	06337	-
Griswold-Lisbon	06351	4
Hampton	06247	4
Hebron	06231	8
Killingly	06233	-
Killingly	06239	1
Killingly	06241	1
Killingly	06243	-
Killingly	06263	-
Killingly	06387	-
Lebanon	06249	9
Mansfield	06250	4
Norwich	06360	13
Norwich	06380	2
Plainfield	06332	1
Plainfield	06354	1
Plainfield	06374	6
Pomfret	06230	-
Pomfret	06258	-
Pomfret	06259	-
Pomfret	06267	-
Preston	06365	1
Putnam	06260	2
Scotland	06264	2
Sprague	06330	1
Sprague	06350	-
Sprague	06383	-
Sterling	06373	-
Sterling	06377	2
Thompson	06245	-

Thompson	*06246*	-
Thompson	*06255*	-
Thompson	*06277*	-
Voluntown	*06384*	*1*
Windham	*06226*	*19*
Windham	*06256*	*5*
Windham	*06266*	-
Windham	*06280*	*7*
Woodstock	*06244*	-
Woodstock	*06262*	-
Woodstock	*06281*	-
Woodstock	*06282*	*1*

* List inpatient/outpatient/ED volumes separately, if applicable

** Fill in year if the time period reported is not *identical* to the fiscal year reported on pg. 2 of the application; provide the date range using the mm/dd format as a footnote to the table.

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TABLE 9
SERVICES AND SERVICE LOCATIONS OF EXISTING PROVIDERS

Service or Program Name	Population Served	Facility ID*	Facility's Provider Name, Street Address and Town	Hours/Days of Operation	Current Utilization
N/A	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*

* Provide the Medicare, Connecticut Department of Social Services (DSS), or National Provider Identifier (NPI) facility identifier and label column with the identifier used.

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Supplemental CON Application Form

Establishment of Cardiac Services

Conn. Gen. Stat. § 19a-338(a)(9)

Applicants:	The William W. Backus Hospital & Hartford Hospital
Project Name:	Establishment of Primary and Elective Percutaneous Coronary Intervention at The William W. Backus Hospital

1. Clear Public Need

a. The record in this docket will include, in addition to other materials, the most recent American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines. The Applicants may submit any comments in response to this evidence, which they deem appropriate.

PLEASE NOTE ALL FIGURE AND EXHIBIT REFERENCES ARE TAKEN FROM THE CERTIFICATE OF NEED

Hartford Hospital and Backus (collectively, "Applicants") have determined, and demonstrate within the Certificate of Need main form, that there is a clear public need for a Primary and Elective PCI program in Eastern Connecticut, specifically at the Backus main campus in the City of Norwich. Many residents of the greater Norwich area, particularly those residing to the north and east, are without timely access to this life-saving intervention, which has long been the nationally recognized standard of care for treating a common form of heart attack known as a ST-Segment Elevation Myocardial Infarction ("STEMI"), as well as new or presumed new onset Left Branch Bundle Blockage ("LBBB"). Elective PCI is the standard for treating Acute Coronary Syndrome (Non ST-Elevation Myocardial Infarction, "NSTEMI") in people with intermediate to high risk factors. Elective PCI is also the standard for treating patients with symptoms of recurrent myocardial ischemia ("Unstable Angina" or "UA") and/or high risk findings on a non-invasive stress test. The Applicants have demonstrated how the proposed Primary and Elective Angioplasty program meets an identifiable need for these services in the Backus service area, and how operation of such a program will greatly enhance the quality of cardiovascular care in the Backus community.

As stated in section 3.4.3 of the Statewide Health Care Facilities and Services Plan, Primary and Elective PCI is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a diagnosed blockage in the heart. Primary PCI is used to treat emergency situations and Elective PCI is often a scheduled procedure post cardiac event (such as a NSTEMI AMI). In both cases, an expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

PCI is often combined with the permanent placement of a small wire mesh tube called a stent to help prop the artery open and decrease the chance of it narrowing again. Some stents are coated with medication to help keep the artery open (drug-eluting stents), while others are not (bare-metal stents).

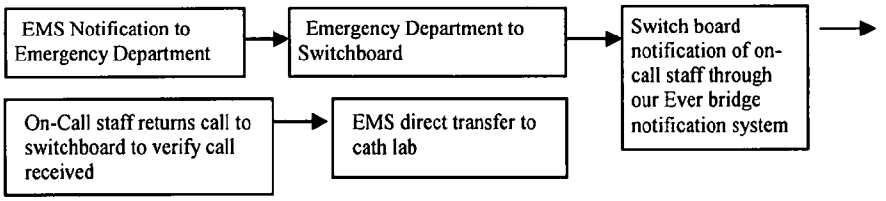
Myocardial infarction is defined by pathology as myocardial cell death due to prolonged ischemia. A ST-segment elevation myocardial infarction (STEMI) occurs when an acute coronary thrombosis totally occludes a coronary artery. In other words, a STEMI occurs when a vessel becomes blocked or closed, causing a decreased or interrupted blood flow to the heart. A STEMI requires immediate intervention to restore circulation to the vessel and to allow for reperfusion, or restoration of blood flow, of the cardiac muscle that became ischemic. Reperfusion therapy by primary percutaneous coronary intervention with stenting has proven the optimal approach to reduce morbidity and mortality in STEMIs.

Below is a chart that details how Backus will meet each of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention recommendations for PCI. These criteria are all consistent with national guidelines and best practice recommendations.

Figure 4 – Standards for Providing Primary and Elective PCI

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention	***How Backus Will Meet Standard***
4.1.1 Equipment	*The Cardiac Cath Lab has two defibrillators, one in the lab itself and one in the holding area outside the lab. Backus has POC testing for ACT and AVOX testing.* *The Digital Cine images are kept on file for 10 years. The X-ray equipment and staff lead is examined by a qualified physicist once a year. The X-Ray equipment also has yearly preventative maintenance preformed.*
4.1.2 Staffing	*There will be an Interventional Cardiologist performing all PCI cases. There will be one RN and two Radiologic Technologists in the room during each procedure. All the Catheterization Lab staff are BLS and ACLS certified. The Radiologic Technologists are credentialed by the American Society of Radiation Technologists.*
4.1.3 Time Out Procedures	*The Cardiac Catheterization Lab staff will follow the William W. Backus Hospital policy related to Universal Protocol.*
4.2.1 Informed Consent	*Informed consent will be obtained prior to each procedure. The Interventional Cardiologist will make every attempt to provide information regarding the risks and benefits of different strategies to the patient and family along with the benefits of rapid intervention for STEMI patients.*
4.3 Radiation Safety: Recommendations	*Total fluoro time is documented in the Backus electronic medical record and tracked quarterly in departmental QI. Low dose capability is now available on Phillips FD10. Radiation shielding for staff includes a full vest, thyroid, and skirt along with a radiation dose tracker.*

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention	*How Backus Will Meet Standard*
4.4 Contrast-Induced AKI (Acute Kidney Injury)	*A contrast questionnaire will be completed with all patients who will be having a cardiac cath to screen for potential contrast-induced AKI prior to the procedure. The RN will notify the physician for patients at risk for potential contrast induced AKI. Total contrast used intra-procedure is documented in the electronic medical record.*
4.7 Bleeding Risk	*The Lab utilizes many avenues to reduce the potential of bleeding. Each patient's treatment is individualized to minimize bleeding risk. Backus currently performs radial diagnostic catheterizations. Backus utilizes a variety of devices to obtain hemodynamic stability after the procedure.*
Procedural Considerations	
Personal and Facility Requirements for PCI Programs	• *See **Exhibit 2** for education plan.* • *The Lab will be staffed 24/7, 365 days per year with on-call personal available during off hours.* • *The Intensive Care Unit staff is competent in ventilator management, invasive hemodynamic monitoring, and operation of a temporary pacemaker. Training on the management of an IABP will take place to provide our ICU RN's the ability to care for an unstable patient coming from the Catheterization Lab.* • *Backus has Anesthesia available 24/7 in house to provide endotracheal intubation if necessary* • *LIFE STAR and Paramedics are available to handle endotracheal intubation and IABP during transport.* • *Backus has an agreement with Hartford Hospital for any patients who require cardiac surgery. See **Exhibit 13** for the Cardiac Surgery Transfer Agreement. Backus will test the transfer process to Hartford Hospital at least two times per year.* • *The Cardiac Cath Lab utilizes Philips FD10 X-Ray and Philips X-Per Monitoring Equipment. This equipment was installed in September 2011.* • *There will be two IABP's available. The Preventative Maintenance is completed on this equipment once a year. The IABP catheters are compatible with LIFE STAR transport.* • *There is currently real-time transfer of images with Hartford Hospital. This will be particularly important if Backus has patients who require surgical intervention. By 2017 Hartford HealthCare will be on one electronic medical record allowing for real time review of cases and documentation.*
Personal and Facility Requirements for PCI Programs Cont.	• *Backus has selected and will stock the appropriate inventory of interventional equipment. The inventory list is attached as **Exhibit 14**.* • *The hospital currently participates in the ACTION Registry with ACC NCDR and will participate in the ACC NCDR PCI registry*

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention	***How Backus Will Meet Standard***
Document Requirements for Off-Site Surgical Back-Up	• *Backus has written agreements for emergency transfer of patients to Hartford Hospital with Cardiac Surgery.* • *There have been transport protocols developed and approved. The transport protocols are attached as* ***Exhibit 15****. Backus will test transfer protocols at least two times each year.* • *Documentation of the transfers will take place along with areas for improvement in the transfer process. All patients transferred out after an intervention will be followed up and reviewed by the Catheterization Lab Medical Director, Catheterization Lab manager and the involved Interventional Cardiologist.*
Document Requirements for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals without On-site Cardiac Surgery	• *Detailed patient criteria for Primary PCI /Elective PCI interventions and patients requiring emergent transfer for coronary bypass surgery is discussed in response to question 5e.*
5.2.2.2 Primary PCI of the Infract Artery	*Backus has a system in place that will allow patients to have PCI performed within 90 minutes of the first medical contact.* *The systems in place are as follows:* *The on-call team is required to arrive at the hospital within 30 minutes of notification.* *Notification will occur in the following manner:*  *If there is no return call by the on-call staff to the switchboard within 5 minutes the switchboard operator will try the second number provided. If there still is no response after 5 minutes the operator will call the Cath Lab Medical Director and/or the manager of the Cath Lab notifying them of the delay.*

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention	***How Backus Will Meet Standard***
5.7 Interventional Pharmacotherapy	*All Registered Nurse staff is competent in the administration and monitoring of conscious sedation. The competency criteria are attaches as* ***Exhibit 16****. The physicians performing the procedure are also competent to administer conscious sedation*
6.4.3 Cardiac Rehabilitation	*Backus Hospital will offer enrollment to all patients post-PCI into its Cardiac Rehabilitation program.*
6.5 Secondary Prevention	*After the procedure, intensive education will take place while the patient is in the facility. As an outpatient the following services are available to our patients to utilize to their benefit: weight loss programs, smoking cessation, cardiac support group, diabetes management programs, blood pressure clinics, cholesterol screenings. See the response to question 1 for an overview of the services offered.*
7.1 Quality and Performance	*Monthly quality review will take place. Attached as* ***Exhibit 17*** *are the PCI Overall Outcome and Quality Measurements and the ACCF/AHA/SCAI/AMA-Convened Physician Consortium National Committee for Quality Assurance dated February 2013*

*Patient selection guidelines have been determined based upon the ACCF/SACI/STS/AATS /AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization, Focused Update (**Exhibit 12**) and the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.*

*Specifically, selection criteria are based on Tables 7 and 8 (page e596-e597, respectively) in the 2011 document (**Exhibit 9**), excerpts of which are included below - see **Figure 5** and **Figure 6**.*

Figure 5 – Primary PCI Patient Selection Guidelines

Table 7. SCAI Expert Consensus Document Requirements for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in patients with

- >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired
- Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography
- Lesions in other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms)
- Lesions with TIMI flow grade 3 that are not amenable to stenting in patients with left main or 3-vessel disease that will require coronary bypass surgery
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention

Transfer emergently for coronary bypass surgery patients with

- High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support
- Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer

IABP indicates intra-aortic balloon pump; LV, left ventricular; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis in Myocardial Infarction.

Adapted with permission from Dehmer et al.[352]

Figure 6 – Elective PCI Patient Selection Guidelines

Table 8. SCAI Expert Consensus Document Requirements for Patient and Lesion Selection and Backup Strategy for Nonemergency PCI by Experienced Operators at Hospitals Without On-Site Cardiac Surgery

Patient risk: expected clinical risk in case of occlusion caused by procedure

High patient risk: Patients with any of the following

- Decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders
- LVEF <25%
- Left main stenosis (≥50% diameter) or 3-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries)
- Single-target lesion that jeopardizes >50% of remaining viable myocardium

Lesion risk: probability that procedure will cause acute vessel occlusion

Increased lesion risk: lesions in open vessels with any of the following characteristics

- Diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments
- More than moderate calcification of a stenosis or proximal segment
- Location in an extremely angulated segment (>90%)
- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- Substantial thrombus in the vessel or at the lesion site
- Any other feature that may, in the operator's judgment, impede successful stent deployment

Aggressive measures to open CTOs are also discouraged because of an increased risk of perforation

Strategy for surgical backup based on lesion and patient risk

- High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.
- High-risk patients with non–high-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.
- Non–high-risk patients with high-risk lesions require no additional precautions.
- Non–high-risk patients with non–high-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.

CTO indicates chronic total occlusion; CVA, cerebrovascular accident; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

Adapted with permission from Dehmer et al.[352]

During the 1990s, PCI for STEMIs and thrombolytic therapy coexisted, with PCI common at PCI-equipped hospitals and thrombolytic therapy common at non-PCI hospitals. Two European publications in 2003 shifted this dynamic by documenting that

PCI is superior to thrombolytic therapy when performed quickly[1,2]. *Current American College of Cardiology/American Heart Association ("ACC/AHA") Guidelines call for reperfusion with PCI of STEMI patients within 90 minutes of first medical contact. U.S. hospitals have struggled to successfully implement the recommended course of treatment, particularly because only 25% of acute care hospitals in the nation provide PCI.*

Patients who undergo an Elective PCI have risk factors, or test results which show that if a PCI to correct the blockages causing the ischemia is not performed the patient would be more likely to have a fatal myocardial infarction in the future. Unlike primary PCI, this procedure is a scheduled, but ideally takes place within 24-48 hours of diagnosis to effectively reduce the risk of future cardiac events. Once these patients have their coronary intervention, their reoccurring symptoms are alleviated and they are able to return to their baseline health.

To evaluate the need for a Primary and Elective PCI program, Backus commissioned 3d Health, Inc., a healthcare consulting firm based in Chicago, to analyze the demand for and availability of Primary and Elective PCI in Eastern Connecticut, and whether Backus service area patients are able to access these nationally recognized life-saving services in a timely fashion and in accordance with standard of practice and OEMS guidelines. In conducting its needs assessment and market share analysis (see the Percutaneous Coronary Intervention Assessment by 3d Health, Inc. "3d Health" attached as ***Exhibit 8****), 3d Health defined a Backus Hospital Angioplasty Region, ("PCI Region," or "Angioplasty Region") (3d Health Assessment, p. 4). This Angioplasty Region was determined through analyzing eastern Connecticut zip codes, and assigning zip codes to regions based on the closest potential Connecticut PCI facility. See* ***Figure 7****, below, for a map of the Backus Angioplasty Region. This reflects the geography where Backus would be the closest PCI provider in the State for each zip code included in the shaded region.*

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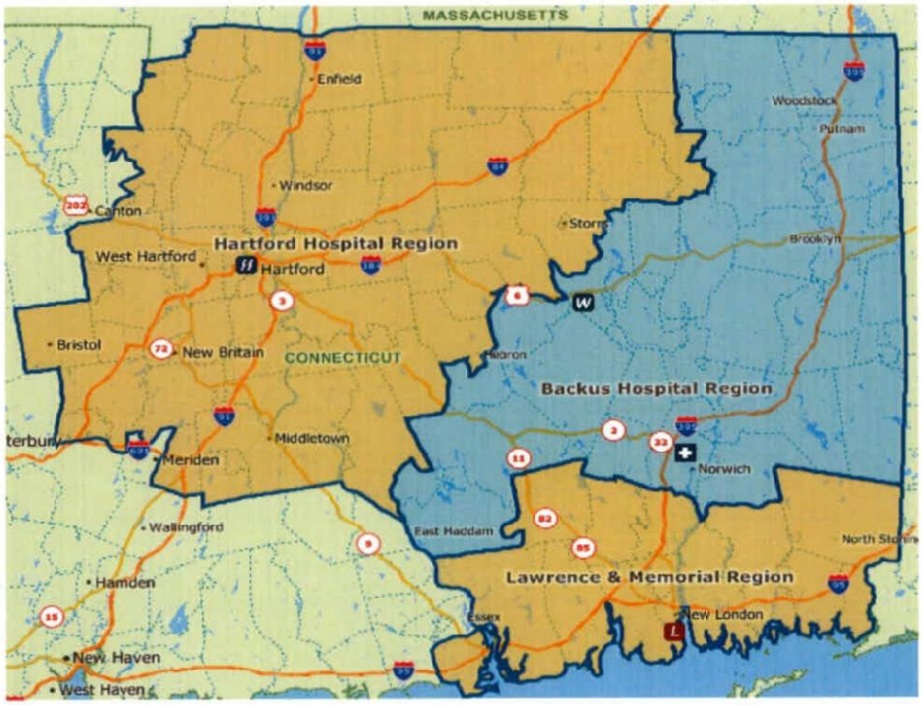
[1] *Widimsky P, Budesínsky T, Vorác D et al (2003) Long distance transport for primary angioplasty versus immediate thrombolysis in acute myocardial infarction European Heart Journal; 24:94–104*

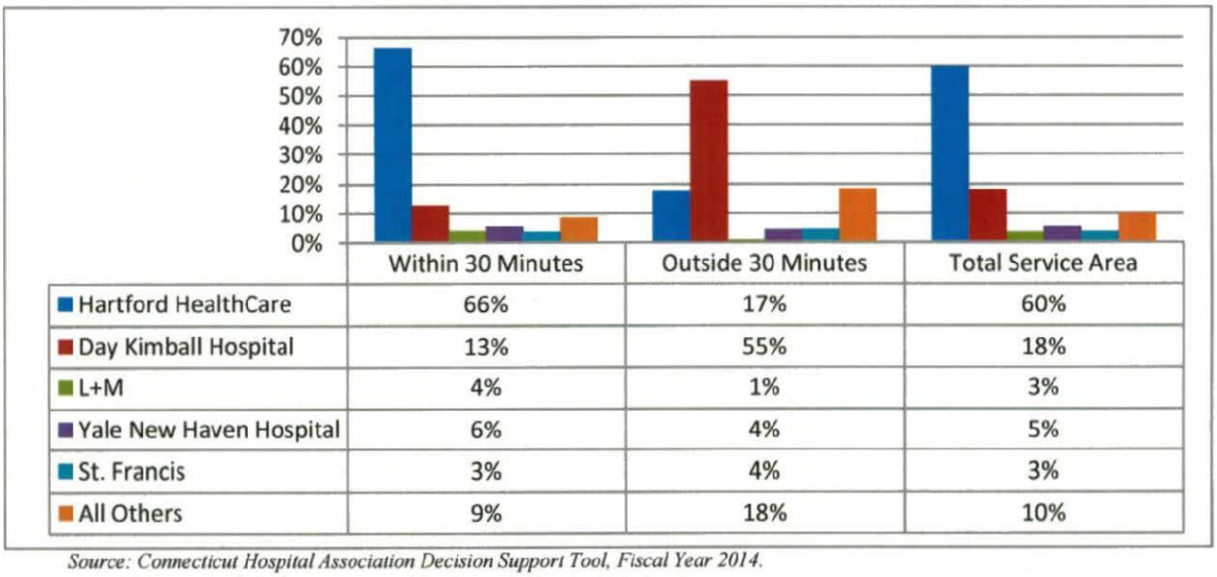
[2] *Keeley EC, Boura JA, Grines CL. (2003) Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials. Lancet; 361:13–20*

Figure 7 – Backus Hospital Angioplasty Region



The Angioplasty Region does not differ significantly from the traditionally defined Backus and Windham Hospital service area, with the exception of the inclusion of towns in the very far north east corner of the State (Thompson, Woodstock, Pomfret, and Putnam), and East Haddam. Additionally, it was determined that Hartford HealthCare providers (Backus, Windham and Hartford Hospital) hold dominate inpatient market share within the Angioplasty Region. When analyzing the geography identified by 3d Health by proximity to Backus (within a 30 minute drive time or outside a 30 minute drive time) it was determined that Hartford HealthCare providers hold 60% of the total market, followed by Day Kimball with 18% of the market. Other regional providers, such as L+M only hold approximately 3% of the market; Yale and St. Francis hold 5% and 3%, respectively. The remaining 10% of the Backus Angioplasty market is split between all other acute care facilities in Connecticut. See ***Figure 8****, below:*

Figure 8 – Angioplasty Region Inpatient Market Share



	Within 30 Minutes	Outside 30 Minutes	Total Service Area
Hartford HealthCare	66%	17%	60%
Day Kimball Hospital	13%	55%	18%
L+M	4%	1%	3%
Yale New Haven Hospital	6%	4%	5%
St. Francis	3%	4%	3%
All Others	9%	18%	10%

Source: Connecticut Hospital Association Decision Support Tool, Fiscal Year 2014.
Hartford HealthCare defined as Backus, Hartford, and Windham Hospitals

A list of the towns included in the Backus Angioplasty Region (defined as the geography where Backus would be the closest Connecticut PCI provider) is included in ***Figure 9****, below:*

Figure 9 – Towns within the Backus Hospital Angioplasty Region

Towns Within 30 Minutes Drivetime to Backus Hospital	*Norwich* *Amston* *Bozrah* *Brooklyn* *Canterbury* *Chaplin* *Colchester* *Columbia* *Franklin* *Griswold-Lisbon*	*Killingly* *Lebanon* *Mansfield Center* *Plainfield* *Preston* *Scotland* *Sprague* *Sterling* *Voluntown* *Windham*
Towns outside of 30 minutes to Backus Hospital, but where Backus Hospital would be the closest Connecticut provider of Primary and Elective PCI services.	*East Haddam* *Hampton* *Pomfret* *Putnam* *Thompson* *Woodstock*	

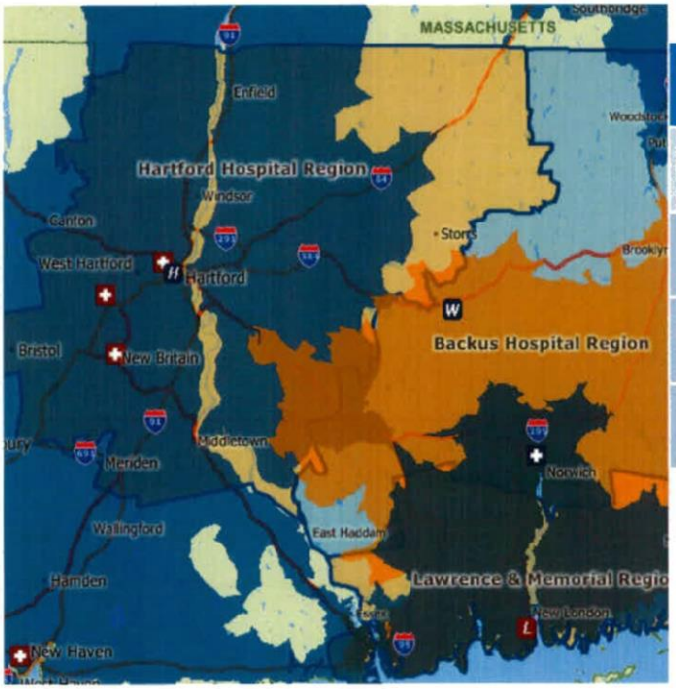
3d Health also looked at incidence/prevalence data, use rates, relative market share and outmigration and used this data to project volume for the proposed Primary and Elective Angioplasty program. 3d Health came to the conclusion that there is an unmet need for timely Primary and Elective PCI in the greater Backus service area, and that 231,419 people will benefit from more readily available interventional cardiac care if this proposal is approved. See the 3d Health Assessment, attached as ***Exhibit 8****, for detailed information.*

The need for rapid reperfusion for STEMI patients was acknowledged by DPH on January 23, 2012, when it published policy guidance regarding the transport of STEMI patients to Primary PCI-capable facilities (see Exhibit 18). The DPH Guidance requires the transport of patients identified in the field with a STEMI to a Primary PCI-capable hospital if the facility is within 30 minutes drive time. If there is not a facility within 30 minutes, EMS personnel must make a transport decision with direct medical oversight. DPH asserts that this transport guidance will ensure that a Primary PCI is received within 90 minutes from initial medical contact, as the standard of care requires.

Under the DPH Regulations, STEMI patients are identified in the field via an EKG performed in the ambulance. This can only occur if a paramedic is on-board the ambulance, either at the time of patient pick up or through interception en route to the hospital, and the ambulance has the ability to conduct an EKG. In the defined Service Area only three ambulance services have this ability: American Ambulance, the Mohegan Tribal Ambulance, and the Windham Hospital Paramedic Program ("American," "Mohegan," and "Windham Paramedics"). In total, there are 50 Backus sponsored paramedics working at Mohegan or American, which covers all of New London and Windham Counties. There are only 15 Advance Life Support ("ALS") vehicles available in the region. On average, there are 10 available ALS staffed vehicles during the day, and 6 during the night. The ALS service in the northeast region is provided by Windham Paramedics, which covers 13 towns and 330 square miles. The remaining ambulance services are mainly volunteer-based and only Basic Life Support ("BLS") capable. These services are not qualified to determine if a patient is experiencing a STEMI when picked up in the field. Thus, patients with unidentified STEMIs continue to arrive at Backus Hospital in need of Primary PCI, as there is not always a paramedic available to intercept a BLS ambulance in the field to diagnose a STEMI patient. Currently these STEMI arrivals necessitate a second transport to a PCI-capable facility, but if this proposal is approved, they will be able to receive immediate Primary Angioplasty at Backus.

Although there are multiple PCI providers in Connecticut, only one is located in eastern Connecticut, and none are within 30-minutes drive time for thousands of residents of the service area. As can be seen from the map on pages 33-34 of the 3d Health Assessment, towns to the surrounding and north of Norwich, do not have access to a PCI-capable Connecticut hospital within 30 minutes. If Backus Hospital establishes a Full Service PCI program at Backus, 51% of the service area, or 118,000 residents, would gain access to a facility that offers Angioplasty within 30 minutes, and an additional 67,000 residents would have improved access within 10 minutes. Backus would also be the closest PCI facility for an additional 28,000 residents in the Northeast portion of the state, and would become the closest Connecticut provider to 18,000 residents. Thus, the potential for a program at Backus would vastly improve regional access to cardiac care (3d Health Assessment, p. 33-34). See ***Figure 10****, below.*

Figure 12 – Backus Hospital Angioplasty Region by Segment



Future State: Improved Access for 231,000 Residents if Backus Provided PCI	
Access within 30 minutes if Backus offered	*118,000*
Access within 40-50 minutes if Backus offered	*28,000*
Improved Access; within 10 minutes of Backus	*67,000*
Access to a Connecticut Provider if Backus offered	*18,000*

30 Minute Drive Time, Existing PCI Providers

30 Minute Drive Time, Potential Backus Program

In addition to the geographic isolation of the defined service area, multiple other factors inform the need to establish a Primary and Elective PCI program at Backus. Three towns within the defined service area, Putnam, Windham, and Danielson, are designated by the U.S. Department of Resources and Services Administration ("HRSA") as Health

Professionals Shortage Areas ("HPSA")[3]. Specifically, these HPSAs are categorized as low income populations. A HPSA is "designated by HRSA as having shortages of primary care, dental care, or mental health providers and may be geographic (a county or service area), population (e.g. low income or Medicaid eligible), or facilities (e.g. federally qualified health centers, or state or federal prisons)."[4] Additionally, the towns of Killingly, Plainfield, Sterling, Bozrah, Franklin, Griswold, Lisbon, Norwich, Preston, Sprague, and Voluntown are identified by HRSA as Medically Underserved Populations. By definition this designation indicates these towns "as those with economic barriers (specifically low-income or Medicaid eligible populations), or cultural and/or linguistic access barriers to primary medical care services."[5] As discussed in the response to question 7 in the Certificate of Need Application Main Form, socioeconomic factors play a significant role in health outcomes and health status.

In addition to the HPSA/MUP designation, Eastern Connecticut is disproportionately affected by risk factors that contribute to cardiovascular events. The Centers for Disease Control ("CDC") indicate three major risk factors for heart disease, and states that nationally 49% of adults report having at least one of the three risk factors. These include high blood pressure, high LDL cholesterol, and smoking.[6] Other risk factors include diabetes, obesity, poor diet, physical inactivity, and excessive alcohol use. New London and Windham Counties suffer from all of these risk factors, many disproportionately when compared to the prevalence of these factors on a state and national level. These health indicators put residents of the region in danger of developing cardiovascular conditions necessitating the need for clinical intervention, such as PCI.

The Robert Wood Johnson Foundation ("RWJF") compiles an annual report, "County Health Rankings and Roadmaps," which details the health status of states at a county-level. The report has been published annually since 2010, and highlights health factors such as mortality, morbidity, health behaviors, and socioeconomic indicators (attached as Exhibit 4). Since 2010 Windham and New London Counties have been consistently ranked as two of the least healthy counties in the state. In 2010 Windham was ranked 8th/8 counties, and in the same year New London County was 5th/8. In 2015 Windham County was ranked 7th/8. New London County remained at 5th/8.[7] Thus, little change in ranking occurred over the five year period.

To thoroughly understand the health status of its community, in 2015 Backus conducted a comprehensive community health needs assessment ("CHNA"), focusing on New London

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[3] *http://datawarehouse.hrsa.gov/tools/analyzers/HpsaFindResults.aspx*
[4] *http://datawarehouse.hrsa.gov/tools/analyzers/HpsaFind.aspx*
[5] *http://www.hrsa.gov/shortage/mua/index.html*
[6] *www.cdc.gov/heartdisease/facts.htm/*
[7] *http://www.countyhealthrankings.org/app/#!/connecticut/2015/rankings/outcomes/overall*

*and Windham Counties (**Exhibit 3**). Data gathered through the CHNA included primary data collected through 1,244 completed random telephone surveys. The survey instrument used consisted of approximately 100 questions covering a variety of health topics. Survey sampling was statistically significant to the geography, and represented the geographic distribution of the population, age cohorts, race, and gender. The CHNA also collected and analyzed secondary data sources, and conducted key informant interviews. These data points were compared to state and national benchmark data.*

The results of this CHNA determined that overweight and obesity rates are epidemic in both New London and Windham Counties, and continue to be the highest priority health challenges in the region. The survey determined that 66.2% of the adult population in New London and Windham Counties are classified as overweight, and 30.2% as obese. Both rates are significantly higher than the State of Connecticut (62.6% and 25%, respectively).

This result is supported by RWJF's 2015 report, which indicated that 30% of the adult population in Windham County is obese or overweight, reporting a Body Mass Index ("BMI") greater than or equal to 30, and 24% of adults as physically inactive. The RWJF reports in New London County 26% of the adults are obese or overweight, while 21% are sedentary.[8]

Obesity is an indicator of cardiovascular health, and a predictor of future cardiovascular events. Overweight and obesity is measured utilizing a BMI calculation. The BMI calculation indicates a relationship between body weight and height (kg/m^2). The "National Institutes of Health ("NIH") Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, the Evidence Report," organizes BMI into a series of ranges, categorized into "underweight, normal, overweight, obesity, and extreme obesity" (see Exhibit 23, attached). Individuals are considered to be overweight if they have a BMI of 25 to 29.9, obese if their BMI is between 30 to 39.9, and extremely obese if their BMI is 40 or greater. In the same report, the NIH states that higher BMIs create an increased likelihood of developing co-morbid heath conditions. The NIH states that "higher morbidity in association with overweight and obesity has been observed for hypertension, type 2 diabetes, coronary heart disease ("CHD"), stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and some types of cancer (endometrial, breast, prostate, and colon)."[9] *The NIH further asserts that obesity and hypertension (a co-morbid result of obesity) are risk factors for the development of cardiovascular disease, stating "the pathophysiology underlying the development of hypertension associated with obesity includes sodium retention and associated increases in vascular resistance, blood volume,*

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[8] *http://www.countyhealthrankings.org/app/#!/connecticut/2015/compare/snapshot?counties=011*
[9] *NIH pg. 12.*

and cardiac output. These cardiovascular abnormalities associated with obesity are believed to be related to a combination of increased sodium retention, increased sympathetic nervous system activity, alternations of the rennin-angiotension system and insulin resistance."[10]

The Burden of Cardiovascular Diseases in Connecticut ("BCVD") 2010 Surveillance Report (found at http://www.ct.gov/dph/lib/dph/hisr/pdf/2010cvd_burdendoc_final.pdf) supports the evidence presented by the NIH, and identifies two different categories for risk factors relating to cardiovascular diseases: modifiable and non-modifiable. Non-modifiable risk factors include indicators such as age and family history, whereas modifiable risk factors include such indicators as high blood pressure, high cholesterol, smoking, diabetes, obesity, and physical inactivity.

The BCVD in Connecticut 2010 Surveillance Report also identifies obesity as an independent risk factor for CVD, as well as a factor that increases the risk of obesity's co-morbid conditions such as "hypertension, dyslipidemia, CHD, and stroke."[11] *Obesity has a positive relationship with the risk of ischemic stroke, which increases as BMI increases.*[12]

*The 2015 CHNA identified, for the same region, that the age-adjusted death rate due to diseases of the heart is 165.7, which is higher than the State rate, and higher than the Healthy People 2020 goal (153.4 and 156.9, respectively). Additionally, the survey revealed that 35.7% of individuals have been told they have high blood pressure, which is also higher than the State or the Health People 2020 target (31.3% and 26.9%, respectively) The age-adjusted death rate from Diabetes Mellitus is 15.8 which is higher than the State (14. 8), and 11% of individuals have diabetes or high blood sugar which is higher than the State (8.3%). Overall, 85.1% of individuals have 1 or more cardiovascular risk factor (**Exhibit 3**).*

Further, the RWJF 2015 report indicates that 18% of adult individuals are classified as smokers in Windham County and New London County. This exceeds the State average of 15% and is well above the national benchmark of 14%. The 2015 Backus study revealed similar tobacco use trends in the region. Of CHNA survey respondents, 16.6% indicated they are current smokers. The Healthy People 2020 target 12.0% or lower. Of these current smokers, 68.2% were advised to quit smoking by a healthcare professional within the last year.[13]

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[10] *NIH pg. 13.*
[11] *The Burden of Cardiovascular Diseases in Connecticut 2010 Surveillance Report,* ***pg. 31.***
[12] *Ibid.*
[13] *Backus Hospital Community Health Needs Assessment, 2015.*

The BCVD in Connecticut 2010 Surveillance Report lists smoking as a risk factor for cardiovascular diseases, stating "smoking causes reduced blood vessel elasticity by increasing arterial wall stiffness. Smoking increases the risk of heart attack two-fold. Smokers have higher congestive heart disease mortality than non-smokers and the risk of death increases with greater number of cigarettes smoked."[14]

The RWJF reports that 10% of individuals under the age of 65 residing in Windham County and 10% of individuals in New London County are uninsured. Further, Windham County has the largest population-to-primary care physician ratio in the State at 1,867:1. New London County also experiences a high population-to-primary care physician ratio at 1,594:1. Both indicators exceed the state average of 1,190:1. In Windham County the ratio of the population to primary care providers is almost double the national benchmark of 1,045:1, while New London far exceeds it.[15] *"A high ratio implies the reduced ability to meet demand for primary care services, which may negatively affect the health of a community, as treatment for needed services may be delayed or not sought at all. Residents with cardiovascular disease or coronary heart disease may remain undiagnosed without an adequate base of primary care to order diagnostics or refer patients to cardiologists."*[16]

These health statistics and social determinants of health contribute to the morbidity and mortality experienced in Windham and New London County. Given the health indicators previously discussed, it is not surprising that Windham County has a higher rate of premature death than any other county in the state, with New London County not far behind. Both counties exceed the State average and national benchmark. The NIH states that "for persons with a BMI of 30 kg/m^2 or above, mortality rates from all causes, and especially from cardiovascular disease, are generally increased 50 to 100 percent above that of persons with BMIs in the range of 20-25 kg/m^2."[17]

RWJF considers premature death to be represented by the years of potential life lost before age 75. Every death occurring before the age of 75 contributes to the total number of years of potential life lost ("YPLL"). For example, a person dying at age 25 contributes 50 years of life lost, whereas a person who dies at age 65 contributes 10 years of life lost. In the 2015 study, Windham County reported 5,324 fewer deaths than Fairfield County (one of the healthiest counties in the State) but had 1,589 more YPLL. This means that on average, each 2015 death in Fairfield County contributed .68 YPLL to the overall rate, while in Windham County each death accounted for 4.91 YPLL. The

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[14] *The Burden of Cardiovascular Disease in Connecticut – 2010, pg. 28.*
[15] *http://www.countyhealthrankings.org/app/#!/connecticut/2015/compare/snapshot?counties=015%2B011*
[16] *Lawrence and Memorial Hospital, Docket Number 12-31768-CON, Agreed Settlement, pg. 12.*
[17] *NIH pg. 23.*

Windham County figure was more than seven times the YPLL/death rate for Fairfield County. New London County has a similar issue; in 2015 there were 5,452 YPLL reported for New London County, which is attributed to 2,574 deaths. This means that each New London County death, on average, contributes 2.12 YPLL to the overall County rate. This is more than three times the YPLL/death rate for Fairfield County. These figures indicate that individuals in Windham and New London County, on average, are dying at a younger age than those in Fairfield County and the State overall, and that each death in these counties contributes more to the County's YPLL rate. Not surprisingly, each county exceeds the national benchmark of 5,200 YPLL.[18]

The careful analysis of the primary and secondary data collected indicate that multiple risk factors for cardiovascular events are epidemic in the region, with emphasis placed on the prevalence of obesity, its co-morbidities, and tobacco use. The BCVD report indicates that the "co-prevalence of risk factors places an individual at elevated risk of CHD and stroke," and complicates disease management.[19]

Such cardiovascular risks in Windham and New London Counties, and the need for rapid reperfusion for STEMI patients, supports the need for Backus to establish a PCI program as a necessary component of an effective and comprehensive cardiovascular service line. Patients with increased cardiovascular risks develop obstructive coronary artery disease that ultimately requires elective PCI for symptom control and treatment. Along with the need for an emergent PCI program, an elective PCI program allows patients to stay in their community for care. Providing highly trained and experienced Interventional Cardiologists in the Backus Catheterization Lab enables Backus to provide high quality care at the local level.

b. If applicable to the proposal (e.g., establishment of catheterization lab without a cardiac surgical program), provide a copy of a signed agreement between the Applicant and a tertiary care facility. Identify patient selection guidelines, the process and protocols involved in the transfer of a patient requiring cardiac surgery, and joint quality assurance reviews and joint training.

*See **Exhibit 13** for the transfer agreement between Backus and Hartford Hospitals, **Exhibit 15** for Transfer Protocols, **Exhibit 17** for Quality and Outcomes Measurements and **Exhibit 2** for the Applicants' Education Plan.*

See the response to CON Question 1 for patient selection criteria, as well as Backus' plan to adhere to national guidelines for the provision of PCI.

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[18] *http://www.countyhealthrankings.org/app/#!/connecticut/2015/measure/outcomes/1/data?sort=sc-2*
[19] *The Burden of Cardiovascular Disease in Connecticut – 2010, pg. 34.*

c. Has the Applicant held any discussions with the local emergency medical service ("EMS") regarding the proposed service? Describe.

There is tremendous support in the defined Angioplasty Region for Backus's proposal to develop a PCI program. Backus communicated its plans for the proposed program to the community through phone calls, emails, and face to face meetings with EMS, municipal leaders, physicians and patients. Fire department chiefs and assistant chiefs, ambulance personnel, physicians, and chief municipal leaders throughout the Angioplasty Region have been contacted. The response has been overwhelmingly positive and universally supportive. These stakeholders understand that there is a lack of adequate access to PCI services in the region and they can speak to the practical realities of this situation for area residents in need of care. Additionally, Day Kimball Hospital has provided a letter of support, citing barriers in its communities for needed access to PCI services. Residents of these communities cannot access a PCI capable facility in a timely fashion within the State of Connecticut. Letters of support from area fire departments, municipal leaders, physicians, patients and EMS personnel are attached as ***Exhibit 11****.*

2. Projected Volume

a. In table format, provide historical volumes (three full years and the current year-to-date) for each Applicant by service as applicable to the proposal.

This application is for the establishment of a new service; therefore ***historical volumes are only*** *reflective of Hartford Hospital volume from the defined Angioplasty Region. Backus Hospital has no historical utilization to provide.*

All data reflects the Applicant's Fiscal Year, which runs from October 1 – September 30.

TABLE A
CARDIAC HISTORICAL UTILIZATION BY ZIP CODE

HARTFORD HOSPITAL
Fiscal Year Volume, 10/1-9/30

Town	ZIP Code	FY12	FY13	FY14	FY 2015 Ann
Bozrah	*06334*	*2*	*1*	*1*	*-*
Bozrah	*06336*	*-*	*-*	*-*	*-*
Brooklyn	*06234*	*1*	*3*	*3*	*3*
Canterbury	*06331*	*1*	*1*	*1*	*1*
Chaplin	*06235*	*3*	*4*	*4*	*1*
Colchester	*06415*	*17*	*12*	*20*	*15*
Colchester	*06474*	*-*	*-*	*-*	*-*
Columbia	*06237*	*6*	*8*	*6*	*5*
East Haddam	*06423*	*9*	*5*	*4*	*8*
East Haddam	*06469*	*4*	*1*	*2*	*3*
Franklin	*06254*	*-*	*1*	*2*	*2*
Franklin	*06389*	*-*	*-*	*-*	*-*
Griswold-Lisbon	*06337*	*-*	*-*	*-*	*-*
Griswold-Lisbon	*06351*	*2*	*3*	*4*	*5*
Hampton	*06247*	*5*	*4*	*4*	*2*
Hebron	*06231*	*-*	*1*	*8*	*5*
Killingly	*06233*	*-*	*-*	*-*	*-*
Killingly	*06239*	*3*	*-*	*1*	*1*
Killingly	*06241*	*-*	*-*	*1*	*1*
Killingly	*06243*	*-*	*-*	*-*	*-*
Killingly	*06263*	*-*	*-*	*-*	*-*
Killingly	*06387*	*-*	*-*	*-*	*-*
Lebanon	*06249*	*5*	*5*	*9*	*11*
Mansfield	*06250*	*6*	*6*	*4*	*2*
Norwich	*06360*	*3*	*6*	*13*	*13*
Norwich	*06380*	*-*	*-*	*2*	*3*
Plainfield	*06332*	*-*	*-*	*1*	*-*
Plainfield	*06354*	*1*	*3*	*1*	*1*
Plainfield	*06374*	*2*	*2*	*6*	*4*
Pomfret	*06230*	*-*	*-*	*-*	*-*
Pomfret	*06258*	*-*	*1*	*-*	*-*
Pomfret	*06259*	*-*	*-*	*-*	*-*
Pomfret	*06267*	*-*	*-*	*-*	*-*
Preston	*06365*	*-*	*-*	*1*	*2*
Putnam	*06260*	*1*	*-*	*2*	*-*
Scotland	*06264*	*-*	*1*	*2*	*1*
Sprague	*06330*	*-*	*1*	*1*	*-*
Sprague	*06350*	*-*	*-*	*-*	*-*
Sprague	*06383*	*-*	*-*	*-*	*-*
Sterling	*06373*	*-*	*-*	*-*	*-*

Sterling	*06377*	-	*2*	*2*	*2*
Thompson	*06245*	-	-	-	-
Thompson	*06246*	-	-	-	-
Thompson	*06255*	-	-	-	-
Thompson	*06277*	-	*1*	-	-
Voluntown	*06384*	-	-	*1*	-
Windham	*06226*	*20*	*22*	*19*	*21*
Windham	*06256*	*5*	*3*	*5*	*5*
Windham	*06266*	-	-	-	*2*
Windham	*06280*	*5*	*5*	*7*	*5*
Woodstock	*06244*	-	-	-	-
Woodstock	*06262*	-	-	-	-
Woodstock	*06281*	-	-	-	*2*
Woodstock	*06282*	*1*	-	*1*	-
TOTAL		***102***	***102***	***138***	***131***

* For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

** Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g., July 1-June 30, calendar year, etc.).

Fiscal Year 2015 volume represents annualized volume, which is based on 11 months (through August) of actual PCI volume from the Angioplasty Region treated at Hartford Hospital.

TABLE B
CARDIAC HISTORICAL UTILIZATION BY INPATIENT/OUTPATIENT

HARTFORD HOSPITAL
Fiscal Year Volume, 10/1-9/30

Category – Inpatient/Outpatient	Actual Volume (Last 3 Completed FYs)			CFY Volume*
	FY12	**FY13**	**FY14**	**FY15**
Inpatient PCI	*99*	*90*	*104*	*109*
Outpatient PCI	*3*	*12*	*34*	*22*
Total	***102***	***102***	***138***	***131***

* For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

** Identify each service type and add lines as necessary. Provide the number of visits or discharges as appropriate for each service listed.

*** Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g., July 1-June 30, calendar year, etc.).

Fiscal Year 2015 volume represents annualized volume, which is based on 11 months (through August) of actual PCI volume from the Angioplasty Region treated at Hartford Hospital.

TABLE C
CARDIAC HISTORICAL UTILIZATION BY UNIQUE PHYSICIAN IDENTIFIER
Fiscal Year Volume, 10/1-9/30

Unique Physician Identifier	Actual Volume (Last 3 Completed FYs)			CFY Volume*
	FY 2012	FY 2013	FY 2014	FY 2015
Physician 1	*31*	*84*	*71*	*96*
Physician 2	*116*	*113*	*117*	*92*
Physician 3	*185*	*169*	*132*	*125*
Physician 4	*103*	*82*	*68*	*63*
Physician 5	*126*	*125*	*113*	*102*
Physician 6	*106*	*81*	*75*	*78*
Physician 7	-	-	*23*	*89*
Physician 8	-	-	-	-
Total	***679***	***678***	***638***	***699***

* For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

** Identify each service type and add lines as necessary. Provide the number of visits or discharges as appropriate for each service listed.

*** Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g., July 1-June 30, calendar year, etc.).

Current Fiscal Year data is current through May 2015 (8 months of the fiscal year), and annualized to estimate potential 2015 total volume.

All historical volumes pulled from the CHIME On-Demand Analytics Tool, included in the Decision Support suite of analytics. Volume is reflective of the following ICD-09 primary procedures:

- *3606 INS NONDRUG ELUT COR ST,*
- *3607 INS DRUG-ELUT CORONRY ST,*
- *3609 REM OF COR ART OBSTR NEC,*
- *0066 PTCA OR CORONARY ATHER,*
- *1755 TRANSLUM COR ATHERECTOMY*

Historical data is not available for all physicians, as some are new to the Connecticut market, and due to delays in data, historical volume is not yet available.

b. If applicable, for the most recently completed fiscal year, identify the number of:

i. Patients with a diagnosis of ST-segment elevation acute myocardial infarction (AMI) that presented at the Hospital's emergency room.

58 patients with a diagnosis of STEMI presented at the Backus Hospital Emergency Department in FY 2014.

ii. Doses of thrombolytic medication, issued through its pharmacy, to patients with a diagnosis of AMI.

Review of use of thrombolytics in STEMI patients in fiscal year 2014 (the most recently completed year) using charge data in the Backus Electronic Medical Record show the following:

FY 2014 – 0 doses

TABLE D
CARDIAC PROJECTED UTILIZATION BY INPATIENT/OUTPATIENT

Backus Hospital - Projected				
Category		*FY16*	*FY17*	*FY18*
Inpatient		***150***	***149***	***149***
Outpatient		***66***	***71***	***76***
Total		***216***	***220***	***225***

* Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g., July 1-June 30, calendar year, etc.).

All projected utilization of services is reflective of Backus Hospital volume only, and reflect the Hospital's fiscal year (10/1-9/30).

TABLE E
CARDIAC PROJECTED UTILIZATION BY UNIQUE PHYSICIAN IDENTIFIER

Unique Physician Identifier	Projected Volume		
	FY*	FY*	FY*
N/A	*N/A*	*N/A*	*N/A*
Total			

* Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g., July 1-June 30, calendar year, etc.).

There is no way to project Primary Angioplasty volume by physician because it is an emergency service. The Interventional Cardiologist on-call when the patient presents will perform the procedure. Elective Angioplasty also cannot be predicted by physician, as this has multiple factors, including patient/physician relationships, which will determine what physician performs the procedure.

c. Please identify the number of physicians that will be providing coverage for the proposed program. Explain whether the physicians will be full time with the proposed program or also providing coverage at other hospitals.

The physicians participating in the Backus PCI program will be an extension of the Hartford Hospital interventional physician team. All physicians covering the Backus program will work under the oversight of the Director of the Hartford Hospital Cardiac Lab and Interventional Cardiology Fellowship, Dr. Francis Kiernan (see CV attached as ***Exhibit 7****). The group providing PCI services at Hartford Hospital, Hartford Cardiac Laboratory, P.C., currently employs 7 physicians. Hartford Cardiac Laboratory, P.C. and has committed to provide clinical and administrative support to the Backus program. Additionally, a private physician, Dr. John Michael Chua Chiaco, has committed to provide PCI coverage at Backus (CV also attached as* ***Exhibit 7****). Dr. Chua Chiaco currently practices at Backus, and is located in Norwich Connecticut. Notably, recruitment efforts will take place upon approval of the proposal to add physician resources dedicating coverage at Backus, in partnership with the Hartford Cardiac Laboratory, P.C. This newly recruited physician will also rotate through the Hartford Hospital Cardiac Catheterization lab.*

These physicians all provide coverage, or will provide coverage (in the case of any newly recruited physicians), at other Hospitals, and will continue to do so after the Backus program is established. The rotation through programs at high-volume PCI centers will ensure the physicians providing coverage at Backus will meet all operator minimums (as specified by the ACC/AHA guidelines and the State Health Plan), and are highly technically skilled. Further, these physicians will be required to abide by pre-

determined quality standards. This strong connection with Hartford Hospital's program and physician leadership will ensure the services provided at Backus are of the highest quality and produce strong clinical outcomes.

LIST OF EXHIBITS

	Description
1.	*SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup*
2.	*Education Plan for Critical Care Staff*
3.	*2015 Community Health Needs Assessment, Eastern Region, Connecticut, Prepared for Hartford Healthcare by Professional Research Consultants, Inc. dated March 2015*
4.	*Community Health Rankings Excerpt from the R. W. Johnson Foundation* *2015 County Health Rankings Connecticut from the R. W. Johnson Foundation*
5.	*Department of Public Health License for Backus and Hartford*
6.	*Curriculum Vitae:* *Nader Bahadory, MD* *Mariane Carna* *Rebecca Durham* *John Foley, MD* *Dan Lohr* *Stuart Markowitz, MD* *Robert Sidman, MD* *Paul Thompson, MD* *Carolyn Trantalis* *David Whitehead*
7.	*Curriculum Vitae:* *John Michael Chua Chiaco, MD* *Francis Kiernan, MD*
8.	*Percutaneous Coronary Intervention Assessment prepared by 3d Health, Inc.* *dated September 1, 2015*
9.	*2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction* *2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention*
10.	*Scholarly Articles:* *CDC Heart Disease Facts* *Time Delay to Treatment and Mortality in Primary Angioplasty for Acute Myocardial Infarction: Every Minute of Delay Counts* *Widening of Socioeconomic Inequalities in U.S. Death Rates, 1993-2001* *Selecting a Reperfusion Strategy for Acute ST Elevation Myocardial Infarction*

	Description
	Scholarly Articles cont.: *Impact of Primary Coronary Angioplasty Delay on Myocardial Salvage, Infarct Size, and Microvascular Damage in Patients With ST-Segment Elevation Myocardial Infarction* *System Delay and Mortality Among Patients With STEMI Treated With Primary Percutaneous Coronary Intervention* *Effect of Door-to-Balloon Time on Mortality in Patients With ST-Segment Elevation Myocardial Infarction* *Association of Door-to-Balloon Time and Mortality in Patients Admitted to Hospital with ST Elevation Myocardial Infarction: National Cohort Study* *Association of Door-In to Door-Out Time With Reperfusion Delays and Outcomes Among Patients Transferred for Primary Percutaneous Coronary Intervention* *Composition of Coronary Thrombus in Acute Myocardial Infarction* *Universal Definition of Myocardial Infarction* *Clinical and Angiographic Predictors and Prognostic Value of Failed Thrombus Aspiration in Primary Percutaneous Coronary Intervention* *Long Distance Transport for Primary Angioplasty vs Immediate Thrombolysis in Acute Myocardial Infarction* *Primary Angioplasty Versus Intravenous Thrombolytic Therapy for Acute Myocardial Infarction: A Quantitative Review of 23 Randomised Trials*
11.	*Letters of Support*
12.	*ACCF/SACI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update*
13.	*Cardiac Surgery Transfer Agreement between Hartford and Backus*
14.	*Angioplasty Supply Costs*
15.	*Clinical Guideline for Transfer of Cath Lab Patients to and Acute Care Facility*
16.	*Registered Nurse Competency for Sedation Criteria*
17.	*PCI Overall Outcome and Quality Measurements* *ACCF/AHA/SCAI/AMA-Convened Physician Consortium National Committee for Quality Assurance dated February 2013*
18.	*DPH Policy Guidance for STEMI Patients Memorandum*
19.	*The Changing Demographics of Connecticut 1990-2000, Part 2: The Five Connecticuts*
20.	*Select Filings from Lawrence & Memorial Certificate of Need*
21.	*ED CARD STEMI Transfer Order Set*
22.	*Transportation in Connecticut: Trends & Planning Data dated June 2006*

	Description
23.	*Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, the Evidence Report*
24.	*Financial Worksheet A*
25.	*Vendor Quotes*
26.	*Construction Plans*
27.	*Documentation of Non-Profit Status for Hartford and Backus*

EXHIBIT 1

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association.

SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Gregory J. Dehmer, James C. Blankenship, Mehmet Cilingiroglu, James G. Dwyer, Dmitriy N. Feldman, Timothy J. Gardner, Cindy L. Grines and Mandeep Singh

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SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Gregory J. Dehmer, MD[1*]; James C. Blankenship, MD[2]; Mehmet Cilingiroglu, MD[3]; James G. Dwyer, MD[4]; Dmitriy N. Feldman, MD[5]; Timothy J. Gardner, MD[6]; Cindy L. Grines, MD[7]; and Mandeep Singh, MD, MPH[8]

Introduction

In 2007, the Society for Cardiovascular Angiography and Interventions (SCAI) published an Expert Consensus Document titled "The Current Status and Future Direction of Percutaneous Coronary Intervention without On-Site Surgical Backup."[1] This document summarized the available data on the performance of percutaneous coronary intervention (PCI) without on-site surgery in the United States (US), reviewed the existing literature, examined the recommendations for the performance of PCI in this setting from several professional organizations abroad and from experienced programs in the US, defined the best practices for facilities engaged in PCI without on-site surgery and made recommendations for the future role of PCI without on-site surgery.

Since publication of that document, new studies, meta-analyses, and randomized trials have been published comparing PCI with and without on-site surgery. In addition, the total number of PCIs performed annually has decreased, reports about the overuse of PCI have emerged, and appropriate use criteria for coronary revascularization have been published. A noteworthy change occurred in the 2011 PCI guideline in which elective PCI was upgraded to Class IIb and primary PCI was upgraded to Class IIa at facilities without on-site surgery.[2] Several tables on the structure and operation of programs without on-site surgery from the 2007 SCAI Expert Consensus Document were used in the 2011 PCI guideline recommendations. Finally, new updates of the ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards and the ACCF/AHA/SCAI Clinical Competence in Coronary Artery Interventional Procedures have been published.[3,4]

Although many of the concerns about the safety of PCI without on-site surgery have been resolved, there are new issues to consider as the delivery of PCI continues to evolve in the US. Accordingly, the SCAI, ACCF, and AHA have engaged in this effort to reevaluate the current status of PCI without on-site surgery in the US. The specific goals of this effort were to:

1. Determine current trends in the prevalence of PCI without on-site surgery in the US;
2. Summarize new literature related to the performance of PCI without on-site surgery;
3. Review existing guidelines, expert consensus documents, competency statements and other documents

[1] Baylor Scott & White Health, Central Texas, Temple, TX. SCAI Writing Committee Member and Chair
[2] Geisinger Health System, Danville, PA. SCAI Writing Committee Member
[3] Arkansas Heart Hospital, Little Rock, AR. SCAI Writing Committee Member
[4] Heart and Vascular Center of Northern Arizona, Flagstaff, AZ. SCAI Writing Committee Member.
[5] New York Presbyterian Hospital, New York, NY. SCAI Writing Committee Member
[6] Christiana Care Health System, Newark, DE. AHA Writing Committee Member
[7] Detroit Medical Center, Detroit, MI. SCAI Writing Committee Member
[8] Mayo Clinic, Rochester, MN. ACC Writing Committee Member
*Correspondence to: Gregory J. Dehmer, Cardiology Division [MS 33 ST156], Baylor Scott & White Health, Central Texas, 2401 South 31st Street, Temple, TX 76513. E-mail: gdehmer@sw.org.

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related to PCI without on-site surgery and summarize all relevant information into a single resource document;
4. Outline the current best practice methods and requirements for facilities engaged in performing PCI without on-site surgery; and
5. Evaluate the role of PCI without on-site surgery within the current US healthcare system.

Trends in the Performance of PCI

Although the use of PCI in the US had grown considerably since the early 1980s, data from the Nationwide Inpatient Sample cited by the Agency for Healthcare Research and Quality shows that the annual volume of PCI procedures peaked in 2006 and has since declined by over 30%.[5] Numerous factors have contributed to this decline, including a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, a reduction in the incidence of ST-segment elevation myocardial infarction (STEMI), the increasing use of techniques such as fractional flow reserve to better evaluate lesion severity and the development and application of appropriate use criteria.[5,6] As a result of these factors, many operators and hospitals now have low-volume practices. Using data from 2008, Maroney et al. estimated that 61% of interventional cardiologists performed 40 or fewer Medicare fee-for-service PCIs annually.[7] Clinical data from 1298 facilities reporting to the National Cardiovascular Data Registry (NCDR) show that 49% of facilities performed ≤400 PCIs and 26% performed ≤200 PCIs annually (Fig. 1).[8] Approximately 33% of facilities had no on-site surgery, and among these, 65% (282 facilities) had an annual case volume of ≤200 PCI procedures.

Across the US, PCI without on-site surgery has increased since 2007. The writing committee assessed the current use of PCI without on-site surgery from a survey of ACC Governors for each state, data from industry sources and direct contact with physicians in various states (Fig. 2). Currently, 45 states allow both primary and elective PCI without on-site surgery, 4 states allow only primary PCI without on-site surgery, and 1 state prohibits PCI without on-site surgery. PCI without on-site surgery is regulated by the State Department of Health in 34 states but is unregulated in the remaining 16 states.

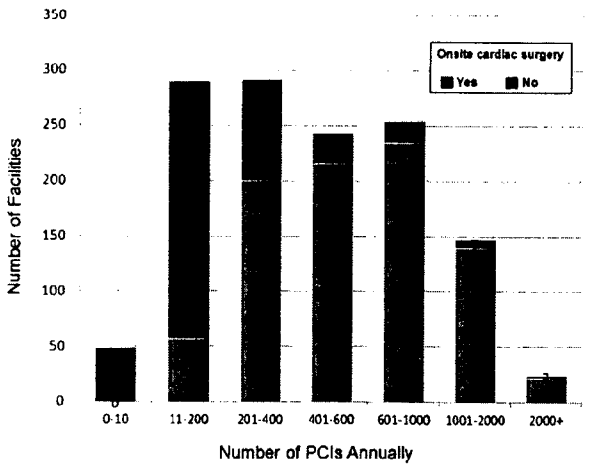

Figure 1. PCI volume at facilities with and without cardiac surgery. (Reproduced from Ref 8 with permission.)

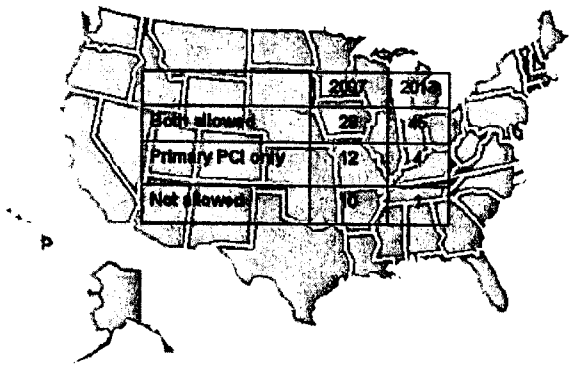

Figure 2. Change in the availability of PCI without on-site surgery from 2007 to 2013. The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

Elective PCI without on-site surgery was allowed at selected facilities in 9 states but only as part of statewide demonstration projects or to allow participation in the Cardiovascular Patient Outcomes Research Team (CPORT) Nonprimary PCI (CPORT-E) trial.[9] Since the conclusion of CPORT-E, the use of PCI without on-site surgery is being reevaluated in several of these states. PCI without on-site surgery is currently performed in 19 of the 65 cardiac catheterization laboratories within the Veterans Health Administration.[10]

Recent Literature on PCI Without On-site Surgery

Since 2006, 11 original studies and 3 meta-analyses on the topic of PCI without on-site surgery have been identified by a computerized systematic literature search using Medline (PubMed and Ovid) and Cochrane Databases.[9,11–23]

Primary PCI without on-site surgery

Seven studies and 2 meta-analyses of primary PCI showed no difference for in-hospital or 30-day mortality between sites with and without on-site surgery (Table 1). None of the individual studies examining the occurrence of emergency CABG surgery after primary PCI showed a difference between sites with and without on-site surgery. However, 1 meta-analysis showed that sites without on-site surgery had a lower occurrence of emergency CABG surgery after primary PCI (odds ratio, 0.53; 95% confidence interval 0.35–0.79).[20]

PCI without on-site surgery for conditions other than STEMI

Eight studies examined nonprimary PCI at sites with and without on-site surgery (Table 2). The majority of studies and meta-analyses showed no difference in mortality or a need for emergency CABG at sites without on-site surgery. One study at a high-volume facility performing only elective PCIs and staffed by high-volume interventionalists showed a lower mortality at the facility without on-site surgery (OR, 0.11; 95% CI 0.01–0.79).[21] However, the baseline clinical and angiographic characteristics of the study groups with and without on-site surgery were sufficiently different that a meaningful adjusted analysis could not be performed, and there is therefore the possibility of a case selection bias.

Two randomized trials of nonprimary PCI have now been published. The CPORT-E trial randomized over 18,000

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Table 1. Studies on Primary PCI Without On-site Surgery Published Since 2006

Author (Year)	Sites	On-site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007)[12]	Multicenter SCAAR Registry	No	857	7.0	1.05 (0.79–1.40)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	4,595	6.7		0.2		
Peels (2007)[13]	Single center	No	336	2.1	2.17 (0.26–17.8)	0	0.10 (0.00–2.51)	
		Yes	103	0.97		1.0		
Pereira (2008)[14]	Multicenter Portuguese Registry	No	1,214	5.0	0.79 (0.55–1.14)	1.8	1.52 (0.90–2.56)	Cardiogenic shock mortality was 53.4% with on-site surgery and 50.9% without (NS)
		Yes	1,470	4.0		2.7		
Kutcher (2009)[15]	Multicenter NCDR Registry	No	1,934	5.1	0.97 (0.79–1.20)	0.7	0.60 (0.35–1.03)	In-hospital mortality reported. Only 42% of sites without on-site surgery performed ≥36 primary PCIs annually compared with 80% of sites with on-site surgery
		Yes	31,099	5.2		1.2		
Pride (2009)[16]	Multicenter NRMI Database	No	1,795	3.3	0.86 (0.61–1.23)			Propensity matched patient cohort. In-hospital mortality reported and only for patients undergoing primary PCI. Incidence of emergency CABG not reported
		Yes	1,795	3.8				
Hannan (2009)[17]	Multicenter New York State Database	No	1,729	2.3	1.22 (0.76–1.94)	0.06	0.17 (0.02–1.38)	Propensity matched patient cohort. In-hospital/30-day mortality reported
		Yes	1,729	1.9		0.35		
Singh (2009)[18]	3 sites Mayo Clinic experience	No	667	2.5	0.80 (0.42–1.54)	0.7	1.25 (0.33–4.68)	Propensity matched patient cohort of nonelective PCI defined as acute MI within 24 h or cardiogenic shock.
		Yes	667	3.1		0.6		
Meta-analyses								
Zia [2011][19]		No	8,703	6.1	0.93 (0.83–1.05)	3.0	0.87 (0.68–1.11)	9 studies included in the analysis
		Yes	97,386	7.6		3.4		
Singh M [2011][20]		No	16,489	4.6	0.96 (0.88–1.05)	0.22	0.53 (0.35–0.79)	11 studies included in the analysis
		Yes	107,585	7.2		1.03		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

patients in a 1:3 ratio to undergo PCI at hospitals with and without on-site cardiac surgery, respectively.[9] High-risk patients were excluded, as was the use of atherectomy devices. The trial had 2 primary endpoints: 6-week mortality and 9-month incidence of major adverse cardiac events (composite of death, Q-wave myocardial infarction, or target-vessel revascularization). The 6-week mortality rate was 0.9% at hospitals without on-site surgery compared with 1.0% at those with on-site surgery ($P = 0.004$ for noninferiority). The 9-month rates of major adverse cardiac events were 11.2% and 12.1% at hospitals with and without on-site surgery, respectively ($P = 0.05$ for noninferiority). A similar, but smaller randomized study of nonemergency PCI was performed in Massachusetts hospitals.[11] The rates of major adverse cardiac events were 9.5% in hospitals without on-site cardiac surgery and 9.4% in hospitals with on-site cardiac surgery at 30 days (relative risk, 1.00; 95% one-sided upper confidence limit, 1.22; $P<0.001$ for noninferiority) and 17.3% and 17.8%, respectively, at 12 months (relative risk, 0.98; 95% one-sided upper confidence limit, 1.13; $P<0.001$ for noninferiority). The individual rates of death, myocardial infarction, repeat revascularization and stroke did not differ significantly between the groups at either time point.

Three meta-analyses conducted primarily with registry data have examined the use of nonprimary PCI at facilities with and without on-site surgery.[19,20,23] Overall, the mortality rate and need for emergency CABG surgery did not differ between hospitals with and without on-site surgery. In 1 meta-analysis, after adjusting for publication bias, the mortality rate for nonprimary PCI was 25% higher at centers without on-site surgery compared with centers that had on-site surgery (OR, 1.25; 95% CI, 1.01–1.53; $P=0.04$).[20] However, it is important to note that these meta-analyses preceded the publication of the 2 randomized trials.[9,11] Therefore, based on these recent studies, there is no indication of increased mortality or a greater need for emergency CABG for either primary or nonprimary PCI at sites without on-site cardiac surgery.

Guidelines, Competency Documents, Policy Statements, and Other Programs

Since 2007, there have been several new documents published that provide guidance for the performance of PCI without

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Table 2. Studies on Nonprimary PCI Without On-site Surgery Published Since 2006

Author (Year)	Sites	On-site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007)[12]	Multicenter SCAAR Registry	No	7,981	0.81	1.23 (0.91–1.65)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	20,930	0.66		0.2		
Frutkin (2008)[21]	2 sites	No	1,090	0.09	0.11 (0.01–0.79)	0.2	6.10 (0.55–67.3)	Nonrandomized comparison of 2 sites. Stable and unstable angina plus NSTEMI included. In-hospital mortality shown
		Yes	3,317	0.8		0.03		
Pereira (2008)[14]	Multicenter Portuguese Registry	No	4831	0.5	1.43 (0.85–2.41)	0.7	3.14 (2.13–4.63)	
		Yes	5584	0.7		2.1		
Kutcher (2009)[15]	Multicenter NCDR Registry	No	6,802	0.8	0.99 (0.76–1.30)	0.2	0.69 (0.40–1.16)	72% of sites without on-site surgery performed <200 PCIs annually compared with 6% among sites with on-site surgery
		Yes	268,312	0.8		0.3		
Pride (2009)[22]	Multicenter NRMI Registry	No	1,282	1.0	0.76 (0.37–1.58)			Only patients with NSTEMI included in study cohort
		Yes	1,282	1.3				
Singh (2009)[18]	3 sites Mayo clinic Experience	No	1,842	0.2	0.57 (0.17–1.95)	0	1.00 (0.02–50.4)	Propensity matched patient cohort
		Yes	1,842	0.4		0.2		
Aversano (2012)[9]	Multicenter Randomized Trial	No	14,149	0.9		0.1		Mortality reported after 6 weeks and incidence of emergency CABG shown.
		Yes	4,718	1.0		0.2		
Jacobs (2013)[11]	Multicenter Randomized Trial	No	2,774	0.7	1.96 (0.58–6.64)	0.3	2.30 (0.3–18.6)	All-cause and cardiac mortality at 30 days were no different. PCI without on-site surgery was not inferior
		Yes	917	0.3		0.1		
Meta-analyses								
Zia (2011)[19]		No	28,552	1.6	1.03 (0.64–1.66)	1.0	1.38 (0.65–2.95)	6 studies included in the analysis
		Yes	881,261	2.1		0.9		
Singh M (2011)[20]		No	30,423	0.9	1.15 (0.93–1.41)	0.17	1.21 (0.52–2.85)	9 studies included in the analysis
		Yes	883,865	0.8		0.29		
Singh PP (2011)[23]		No	1,812	0.17	2.3 (0.60–12.97)	0.11	0.47 (0.07–3.19)	4 studies included in the analysis but only 2 with data on mortality and CABG; Risk ratios rather than OR are reported in this analysis
		Yes	4,039	0.72		0.02		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

on-site surgery. Each new document builds incrementally upon the recommendations from prior documents with slight modifications based on new information. The recommendations for PCI programs without on-site surgery are maturing and becoming uniform over time through the vetting of these recommendations by numerous separate writing committees and undergoing extensive external reviews during document development. Key recommendations for PCI without on-site surgery from those documents are briefly summarized below and have been combined to develop the unified recommendations in this document.

2009 Focused Guideline Update on the Management of Patients with STEMI and Guideline Update on PCI

The 2009 focused update of the ACC/AHA guidelines for the management of patients with STEMI and the ACC/AHA/SCAI guidelines on PCI has been superseded by newer separate guidelines for STEMI and PCI.[2,24,25] However, a number of the recommendations from the 2009 document regarding triage and transfer of patients and the development of local STEMI systems have been incorporated into the current document.

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Compared with prior guidelines, the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention stipulated new classification ratings for both primary and elective PCI at hospitals without on-site cardiac surgery.[2] Primary PCI was assigned a class IIa recommendation (*Level of Evidence: B*) stating that primary PCI is "reasonable," provided appropriate planning for program development has been accomplished. Previously, this was assigned a class IIb recommendation. Elective PCI, previously assigned a class III recommendation, was given a class IIb recommendation (*Level of Evidence: B*) stating it "might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection". Elective PCI without on-site cardiac surgical

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backup was considered appropriate only when performed by experienced operators, with complication rates and outcomes equivalent or superior to national benchmarks. Importantly, the ACCF/AHA/SCAI PCI guidelines state, "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery." The guideline assigns a class III recommendation (*Level of Evidence: C*) to performing primary or elective PCI in hospitals without on-site cardiac surgery without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital and without appropriate hemodynamic support capability for transfers. The 2011 PCI guideline document adapted personnel, facility, operator and structural requirements for PCI without on-site surgery from the 2007 SCAI Expert Consensus document.[1] New facility and operator volume requirements were not addressed in the 2011 PCI guidelines but deferred to the 2013 PCI Clinical Competency document.[4] In 2011, ACCF/AHA also published a Guideline for Coronary Artery Bypass Surgery that did not discuss the performance of PCI without on-site surgery.[26]

2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

Similar to the 2011 PCI guidelines, this document presented requirements for PCI at facilities without on-site cardiac surgery that were derived from the 2007 SCAI expert consensus document with some modifications.[3] This document also presented criteria for excluding patients, based on risk and lesion characteristics, from PCI at facilities without on-site cardiac surgery. The document prescribed the quality assurance/quality improvement (QA/QI) program necessary for all cardiac catheterization laboratories with specific recommendations for structure, process, and outcome variables appropriate for monitoring. Moreover, it recommended that all major complications be reviewed by the QA/QI committee at least every 6 months and that any individual operator with complication rates above benchmarks for 2 consecutive 6-month intervals should have the issue directly addressed by the QA director with a written plan for remediation. The document also recommended that a random sample of cases from all operators should be reviewed at least annually.

2013 ACCF/AHA/SCAI Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

In addition to defining numerous requirements for operator competency, new operator, and facility PCI volume requirements were established.[4] Reflecting the overall decline in PCI volumes, this document recommended that laboratories performing both primary and elective PCI, with and without on-site cardiac surgery, should perform a minimum of 200 PCIs annually. Laboratories performing <200 cases annually must have stringent systems and process protocols in place with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. The existence of laboratories performing <200 PCIs annually that are not serving isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should be closed. This recommendation was based on an extensive review of studies that identified a signal suggesting worse outcomes in laboratories performing <200 PCIs annually. The writing committee recommended that operators perform a minimum of 50 PCIs annually [averaged over 2 years], including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually. However, it was emphasized that individual operator volume is but one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, the operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance. Operators who cannot maintain these case volume recommendations at their primary practice site should maintain privileges and continue to perform PCI procedures at a high-volume institution with on-site surgical backup to meet annual volume requirements. It was also recommended that operators should be board certified in interventional cardiology and maintain certification, with the exception of operators who have received equivalent training outside the US and are ineligible for board certification in the US.

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

This document did not specifically comment on PCI without on-site cardiac surgery but supported the 2011 ACCF/AHA/SCAI PCI guidelines recommendations.[25] It recommended that primary PCI be performed in high-volume, well-equipped centers with experienced interventional cardiologists, and skilled support staff.

2010 European Society of Cardiology and European Association for Cardio-Thoracic Surgery Guidelines

In contrast to the 2011 ACC/AHA/SCAI PCI guidelines, the 2010 European Society of Cardiology and the European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization do not comment on PCI without on-site surgery or issues related to institutional or operator competency.[27] However, the European guidelines continue to stress the importance of full disclosure regarding the lack of availability of on-site cardiac surgery and the inadvisability of performing PCI for high-risk patients/lesions at facilities that do not have on-site surgical backup.

The European guidelines for STEMI do not provide specific recommendations regarding PCI at centers without on-site surgery.[28] Rather, emphasis is placed on the development of networks between hospitals with differing levels of technology, connected by an efficient emergency transport system. To maximize staff experience, the guidelines recommend that primary PCI centers perform procedures 24 h a day, 7 days a week for all STEMI patients.

Other models mentioned in the European guidelines, although not ideal, include weekly or daily rotation of primary

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PCI centers or multiple primary PCI centers in the same region. Hospitals that cannot offer a 24/7 service for primary PCI should be allowed to perform primary PCI in patients already admitted for another reason and who develop STEMI during their hospital stay. These hospitals should, however, be discouraged from initiating a service limited to daytime or within-hours primary PCI, because this generates confusion with Emergency Medical Services (EMS) operators and is unlikely to match the door-to-balloon time and quality of intervention of focused 24/7 primary PCI centers. In a survey of European countries, the mean population served by a single primary PCI center varied between 0.3 and 7.4 million inhabitants. In countries offering primary PCI services to the majority of their STEMI patients, this population varied between 0.3 and 1.1 million per center.[29] In small service areas, experience can be suboptimal due to an insufficient number of STEMI patients, but the optimal size of a catchment area could not be clearly defined. For geographical areas where the expected transfer time to a primary PCI center makes it impossible to achieve satisfactory reperfusion times, thrombolysis with subsequent immediate transfer to a primary PCI center has been endorsed. Although there is a risk of intracranial bleeding, a potential role for this strategy in selected circumstances has been emphasized.[30]

Other Guidelines and Recommendations

The 2007 SCAI Expert Consensus Document summarized the recommendations from the British Cardiac Society and British Cardiovascular Intervention Society, the Cardiac Society of Australia and New Zealand (CSANZ), the Spanish Society of Cardiology, the Brazilian Society of Hemodynamics and Interventional Cardiology (*Sociedade Brasileira de Hemodinamica e Cardiologia Intervencionista*) and from several other countries.[31–39] Since 2007, only the guidelines from CSANZ have been updated, most recently in 2011.[32] CSANZ guidelines state that primary PCI without on-site surgery should be performed: (a) by operators and institutions meeting the overall requirements and standards of primary PCI centers; (b) by institutions with a proven plan for rapid transport to a cardiac surgical center; (c) in a timely fashion (<90 min); and (d) using rigorous case selection criteria. The CSANZ guidelines acknowledged that rural patients might have limited access to diagnostic angiography and PCI, and providing these services at institutions without on-site surgery by appropriately trained individuals facilitates equity of access, which should result in improved quality of care. However, the CSANZ guidelines also specifically state that rural and regional centers should not perform elective, high-risk PCI procedures if they are located more than 1 hour travel time from cardiac surgery centers.

AHA Policy Statement on PCI Without Surgical Backup

In March 2012, the AHA issued a policy statement on PCI without surgical backup defining two major reasons for providing PCI without on-site surgery.[40] First, PCI without on-site surgery is considered reasonable if the intent is to provide high quality timely primary PCI for patients with STEMI. The statement recommended that each community and facility in the community have an agreed-upon plan for how STEMI patients are to be treated. The plan should indicate hospitals that should receive STEMI patients from EMS units capable of obtaining diagnostic electrocardiograms, the management at the initial receiving hospital and written criteria and agreements for the expeditious transfer of patients from nonPCI-capable to PCI-capable facilities. Second, PCI without on-site surgery is a reasonable consideration for providing local care to patients and families who do not want to travel significant distances or who have certain preferred local physicians. This is an important consideration, but the policy statement emphasized that evolving evidence suggests that such centers should have mechanisms in place to ensure high quality care. In addition to emphasizing the current guideline classifications for PCI without on-site surgery, the AHA policy statement provided recommendations for states wishing to address the issue of PCI without on-site surgery through the regulation of legislation.

Mission Lifeline

The Mission Lifeline program developed in 2006 from a series of conferences sponsored by the AHA and has continued to mature.[41–43] The goal of Mission Lifeline is to improve the quality of care and outcomes for patients with STEMI and to improve healthcare system readiness and response to STEMI. An important focus of Mission Lifeline is to increase the number of patients with timely access to primary PCI. Criteria for the structure and operation of a STEMI referral and STEMI-receiving hospitals are part of the Mission Lifeline initiative and apply to facilities without on-site surgery.

Door-to-Balloon Alliance

The Door-to-Balloon [D2B™] effort began in January 2006 when the ACC recognized the need to reduce D2B times for patients with STEMI. This led to the development of a national initiative to achieve D2B times ≤90 min for at least 75% of nontransfer primary PCI patients with STEMI in participating hospitals performing primary PCI. This alliance consists of a nationwide network of hospitals, physician champions and strategic partners committed to improving D2B times. Participation in the Alliance provides the necessary tools; information and support for helping hospitals achieve the D2B treatment goals and encourages the use of real-time performance feedback on D2B times to drive the quality improvement effort.[44] The D2B program has been highly successful, having achieved its initial goals.[45]

Access to Primary PCI in the United States

Data from the American Hospital Association and the 2000 US Census were used to estimate the proportion of the adult population (≥18 years of age) who lived within 60 min of a PCI hospital.[46] An estimated 79.0% lived within a 1 hour drive of a PCI hospital, with a median driving time of 11.3 min. Even among those living closer to non-PCI hospitals, 74% would experience <30 min of additional delay with a direct referral to a PCI hospital. Approximately 5 years later, Concannon et al., using similar data sources and methodology, showed that despite a 44% relative increase in the number of facilities capable of performing PCI, the number of adults within a 1 hour drive of a PCI facility increased to

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only 79.9%, with the median driving time reduced by <1 min to 10.5 min.[47] Access in rural areas remained far less than in urban areas, with driving times reduced for only 9% of the population compared with the earlier survey. These findings mirrored a smaller experience in Michigan where expansion of primary PCI to 12 hospitals without on-site surgery increased access for only 4.8% of the population.[48] Finally, Horwitz et al. showed that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and confirmed that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access.[49] In total, these data support the argument that the addition of more PCI centers has not substantially improved access to PCI services for most patients.

Financial Considerations for Facilities Providing PCI Without On-site Surgery

Medicare payments to hospitals for invasive cardiac procedures have generally remained favorable, although physician reimbursement has decreased. Per-case revenue margins for PCI are typically higher than the overall hospital operating margins, and PCI improves the hospital case mix index. PCI programs bring prestige to an institution, and STEMI is one of the most prestigious diseases for treatment.[50,51] The push to develop rapid STEMI care has led many to currently advocate for EMS bypassing non-PCI hospitals; there is even consideration being given to triaging patients based on D2B metrics. Exclusion from providing STEMI care might be a lesser financial concern than the loss of downstream revenue from additional testing in patients suspected of having an acute coronary syndrome. This includes not only testing performed to exclude CAD as the cause of chest pain but also testing to evaluate noncardiac causes of chest pain. This can be an additional financial motivator for developing PCI facilities.[52] How the further bundling of payments and reimbursements on a global or capitated basis by accountable care organizations (ACO) will affect PCI programs is unclear at this time, but given the concerns about the cost of healthcare, increases in payments are unlikely.[53,54] However, even in an ACO environment, hospitals might benefit from keeping cardiovascular procedures in-house where they have the ability to control costs rather than transferring patients to tertiary hospitals.

The Volume-Outcome Relationship for PCI and the Certificate of Need

There are 26 states with Certificate of Need (CON) regulations for the development of cardiac catheterization laboratories, but the effect of such regulations is uncertain. Ho et al. found that the removal of state cardiac CON regulations was associated with an increase in the number of hospitals performing CABG and PCI, but the statewide number of procedures was unchanged. The average procedure volume per hospital for both CABG and PCI therefore declined.[55] Despite this, they found no evidence that CON regulations lowered procedural mortality rates for CABG or PCI. In other studies, CON regulation of cardiac catheterization was associated with care that was judged more appropriate, whereas the removal of CON regulation of cardiac surgery has been associated with an increase in low-volume cardiac surgical centers and increased mortality.[56,57] Concerns have been raised that the proliferation of small centers performing complex procedures that have a small but definite risk of important complications might dilute the ability to provide efficient high quality service.[52,58] Reduced mortality has been associated with an increased volume of primary PCI procedures in centers, higher volume operators, total volume of PCIs in centers, and the commitment of a center to provide PCI rather than fibrinolytic therapy.[59–63] Lieu et al. reported that redundant or low-volume primary PCI programs were cost ineffective.[64] Elective PCI at centers without on-site surgery was more expensive than PCI at centers with on-site surgery in one case-matched study.[65] In addition, the high fixed costs of a cardiac surgery program in the face of decreasing surgical volumes is leading to the consolidation of numerous smaller surgery programs, depriving some PCI programs of surgical backup.

The issue of a PCI volume-outcome relationship was extensively reviewed in the 2013 PCI Competency document for centers with and without on-site surgery and for primary and elective PCI.[4] The document concluded that in the current era, volume-outcome relationships are not as robust as in the past when balloon angioplasty was the only treatment modality. However, an institutional volume threshold of <200 PCIs annually appeared to be consistently associated with worse outcomes. Primary PCI volume ≤ the guideline-recommended minimum of 36 annually was associated with worse in-hospital mortality in a recent series of over 86,000 patients in the NCDR.[66] The cutoff points of <200 total PCIs annually and ≤36 primary PCIs annually has important implications because 26% of the PCI facilities submitting data to the NCDR performed ≤200 total PCIs annually and 38% performed ≤36 primary PCIs annually.[8,66] Recent data suggested a modest volume-outcome relationship for variables other than mortality, but these data have limitations and are not consistent across all studies.[4] Although there was an association between annual PCI volumes <200 and worse outcomes, there was no association between higher annual hospital volumes and improved outcomes at higher volume PCI centers. There was less evidence to support a threshold for individual operator volume for both elective and primary PCI.

Recommendations

We have provided recommendations for PCI without on-site surgery that are a composite of recommendations from the 2007 SCAI Expert Consensus Statement, the 2011 PCI guidelines, the 2012 Expert Consensus Document on Cardiac Catheterization Laboratory Standards, the 2013 PCI Competency statement and recommendations from the policy statement of the American Heart Association and requirements for the Mission Lifeline program and D2B Alliance.[1–4,40,43,44] Redundant recommendations from these documents were consolidated, and the writing committee included several new recommendations consistent with evolving practice standards.

Facility Requirements for PCI Programs Without On-Site Surgery

Facility requirements are similar to those presented in past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators, as described in the 2013 PCI competency document[4] (Table 3).

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Table 3. Facility Requirements for PCI Programs Without On-Site Surgery

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL, PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely 1) review quality and outcomes of the entire program; 2) review results of individual operators; 3) include risk adjustment; 4) provide peer review of difficult or complicated cases; and 5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS, AHA, PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of 2 times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤30 min *and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery.* Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery or intervention. *Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral.*	PCI-GL, AHA PCI-CS ECD *New*
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data [via T-1 transmission line] as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. *Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required.* Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL, PCI-CS *New*
Meticulous clinical and angiographic selection criteria for PCI (Table 5).	PCI-GL, AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based Class I therapies, both acutely and at discharge.	PCI-CS, ML
Full service laboratories [both primary and elective PCI, with and without on-site cardiac surgery] performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high volume center to enhance their skills. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
Geographic isolation exists if the emergency transport time to another facility is >30 min.	*New*
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL
STEMI Treatment Recommendations	
Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including: • Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes. • A process for prehospital identification and activation. • Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI-Receiving Center. • A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers. • Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.	2009 PCI-GL 2011 PCI-GL ML D2B
STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule.[a] The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.	PCI-GL, AHA ML

(Continued)

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Table 3. Continued

General Recommendations	Source
STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.	PCI-GL PCI-CS ML
Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high volume PCI facility to ensure good outcomes	PCI-GL PCI-CS
There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.	ML
The STEMI-Receiving Centers should participate in the Mission Lifeline-approved data collection tool, ACTION Registry-Get with the Guidelines™.	ML D2B
They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan	ML
Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis: a. Door-to-first device time, nontransfer patients b. STEMI Referral Hospital ED door-to-balloon [first device used] time c. First medical contact to balloon inflation [first device used] time, nontransfer patients d. First medical contact to balloon inflation [first device used] time, transfer patients e. Proportion of eligible patients receiving reperfusion therapy f. Proportion of eligible patients administered guideline-based class I therapies g. Proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization Laboratory for intended primary PCI who i. do not undergo acute catheterization because of misdiagnosis ii. undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 h h. In-hospital mortality	ML

[a]Required for U.S. facilities but might not be possible for all facilities worldwide.

ACC, American College of Cardiology; AHA, American Heart Association policy statement; CT, computed tomography; CTO, chronic total occlusion; D2B, Door-to-Balloon Alliance; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; EMS, emergency medical systems; GL, Guidelines; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; ML, Mission Lifeline; MR, magnetic resonance; New, New recommendation in this document; NCDR, National Cardiovascular Data Registry; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-segment elevation myocardial infarction.

Italics font: New or modified recommendation in the document.

Diagnostic modalities such as IVUS and especially fractional flow reserve previously considered desirable for facilities without on-site surgery have now increased in importance and are necessary for all PCI centers.

The 2013 PCI Competency Document identified a signal suggesting that an institutional volume threshold of <200 PCIs/year was associated with worse outcomes. Therefore, the 2013 Competency Document recommended that the continued

Table 4. Personnel Requirements for PCI Programs Without On-Site Surgery

Personnel Recommendations	Source
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	PCI GL PCI-CS
Coronary care unit nursing staff must be experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of IABP, *management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications.*	PCI-GL PCI-CS *New*
Personnel should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.	PCI-GL
Operators should have ABIM board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams.	PCI CS,
Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year [averaged over a 2-year period] to maintain competency.	PCI-CS
Primary PCI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 primary PCI procedures per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.	PCI-CS ML
Facilities should develop internal review processes to assess operators performing <50 PCIs annually. Individual operator level volume is one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.	PCI-CS
It is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by existing physicians until it is determined their skills, judgment and outcomes are acceptable.	*New*

ABIM, American Board of Internal Medicine; ML, Mission Lifeline; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; IABP, intra-aortic balloon pump; New, new recommendation in this document; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

Italics font: New or modified recommendation in the document.

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Table 5. Recommendations for Off-Site Surgical Backup and Case Selection

Recommendations–Cardiologist–Cardiac Surgeon Interactions	Source
Interventional cardiologists must establish a working relationship with cardiac surgeons at the receiving facility.	PCI-GL ECD
Cardiac surgeons should have privileges at the referring facility to allow review of treatment options as time allows.	PCI-GL ECD
Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis *(Heart Team approach) especially for the discussion of management of patients undergoing nonprimary PCI who have left main, three-vessel CAD or two-vessel CAD with involvement of the LAD or comorbidities such as diabetes, depressed LV function or complex anatomy.*	PCI-GL ECD *New*
Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.	PCI-GL ECD
Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at that time.	PCI-GL ECD
Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	PCI-GL ECD
Interventional cardiologist should be familiar with and have immediate access to appropriate life support devices, such an intraaortic balloon pumps, and should be qualified for handling emergencies such as pericardial tamponade and embolization.	PCI-GL ECD
Hospital administrations from both facilities endorse the transfer agreement.	PCI-GL ECD
Transferring physicians obtain consent for surgery from patients or appropriate surrogates.	PCI-GL ECD
Initial informed consent for PCI discloses that the procedure is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery and state that a written plan for transfer exists. *Consent for PCI should be obtained before the procedure and before any sedatives are given. Consent for PCI obtained while the patient is on the table is not informed consent and is unacceptable in non-emergency situations.*	PCI-GL ECD *New*
Recommendations - Case Selection and Management	
Avoid intervention in patients with: • >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired. • Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography. • Lesions in areas other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms). • Lesions with TIMI flow grade 3 in patients with left main or three-vessel disease where bypass surgery is likely a superior revascularization strategy compared with PCI. • Culprit lesions in more distal branches that jeopardize only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention. • *Chronic total occlusion.*	PCI-GL ECD *New*
The management of patients with STEMI resuscitated from sudden cardiac death is complex, and decisions about the need for immediate PCI with or without therapeutic hypothermia or possible transfer to a tertiary facility for treatment should be individualized.	
Emergency transfer for coronary bypass surgery patients with • High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support. • Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer.	PCI-GL ECD

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; IABP, intraaortic balloon pump; LV, left ventricle; New, new recommendation in this document; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

Italics font: New or modified recommendation in the document.

operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned and that any laboratory that cannot maintain satisfactory outcomes should be closed. Past documents have not specified any criteria for geographic isolation. The writing committee suggests it be defined not by distance but by the time required for emergency transport of a STEMI patient to another facility. Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access.[46–49] If the transfer time is ≤30 min, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital. For transport times longer than 30 min, performing PCI on-site is likely to be quicker than a transfer. The development of PCI facilities within a 30-min emergency transfer time to an established facility is therefore strongly discouraged.

What constitutes a reasonable transport time for a patient requiring emergency surgery has not been

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Table 6. Patient and Lesion Characteristics That Could Be Unsuitable for Nonemergency Procedures at Facilities Without On-Site Cardiac Surgery

High-risk patients	Source
• Decompensated congestive heart failure [Killip Class ≥3] without evidence for active ischemia.	PCI-GL
• Recent [<8 weeks] cerebrovascular accident.	AHA
• Advanced malignancy.	ECD
• Known clotting disorders.	
• LVEF ≤30%.	
• Chronic kidney disease [creatinine >2.0 mg/dL or creatinine clearance <60 mL/min].	
• Serious ongoing ventricular arrhythmias.	
• Patients with left main stenosis [>50% diameter] or three-vessel disease unprotected by prior bypass surgery [>70% stenoses in the proximal or mid segments of all major epicardial coronary arteries], treatment of any or all stenoses. Scoring systems, such as SYNTAX, may be useful in defining the extent of disease and type of revascularization procedure.	
• Patients with a single-target lesion that jeopardizes an extensive amount of myocardium.	
• Patients undergoing intervention on the last remaining conduit to the heart.	
High-risk lesions	
• Unprotected left main stenosis.	PCI-GL
• Diffuse disease [>20 mm in length].	ECD
• Extremely angulated segment [>90%] or excessive proximal or in-lesion tortuosity.	*New*
• More than moderate calcification of a stenosis or proximal segment	
• Inability to protect major side branches.	
• Degenerated older vein grafts with friable lesions.	
• Substantial thrombus in the vessel or at the lesion site.	
• Any other feature that could, in the operator's judgment, impede successful stent deployment.	
• Anticipated need for rotational or other atherectomy device, cutting balloon or laser.	
The characteristics listed above identify high-risk patient and lesion features but are not absolute contraindications to performing PCI at a facility without on-site surgery. For example, an elevated creatinine level increases the procedure risk for the patient, but this is not unique to facilities without on-site surgery and treatments to mitigate this complication can be used at all facilities. Ultimately, the operator should consider all factors and make a decision about the suitability of the patient for PCI at the facility.	*New*
Strategy for surgical backup based on lesion and patient risk	
• High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.	PCI-GL
• High-risk patients with nonhigh-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.	
• Non-high-risk patients with high-risk lesions require no additional precautions.	
• Non-high-risk patients with nonhigh-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.	

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; LVEF, left ventricular ejection fraction; New, new recommendation; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.

Italics font: New or modified recommendation in the document.

consistently addressed in prior documents. Both CPORT-E and MASS-COMM studies provide guidance contained in their on-line supplementary materials.[9,11] Both require a transport vehicle to be available to begin transport within 30 min and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery. MASS-COMM further recommends that surgical intervention begin within 120 min. Given the existing data on the distribution of PCI facilities in the US, the performance of elective PCI at facilities that cannot meet these transfer times is discouraged.[46,47]

The 2013 PCI competency document also states that any laboratory that cannot maintain satisfactory outcomes should be closed; however, there is currently no national definition for "satisfactory outcomes". The writing committee recommends that these be defined by each PCI center, including those with on-site surgery, as part of their quality review process, using national benchmark data. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their performance, engaging outside experts if necessary. Failure to improve quality metrics should lead to program closure regardless of the location. To ensure proper assessment and monitoring, laboratories are required to submit data to a national data registry, have regular meetings to discuss key performance metrics and develop plans for the correction of any deficiencies. Especially with facility PCI volumes decreasing, it becomes increasingly difficult to determine whether there are significant differences in the data reports from year to year. For example, to detect (with statistical certainty) a doubling of in-hospital mortality from 1% to 2% at a hospital with an annual case volume of 200 PCIs, nearly 4 years of continuous data collection would be required. This does not negate the importance of data submission to a national registry that can help identify trends, but it emphasizes why these same data must be carefully evaluated and adjudicated at the local facility. The importance of unbiased local or external peer review cannot be overemphasized.[67,68] Implementation of the SCAI Quality Toolkit and certification by Accreditation for Cardiovascular Excellence [ACE] are recommended as resources for improving quality.[69,70]

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Personnel Requirements for PCI Programs Without On-Site Surgery

Recognizing the potential for isolation and the advantage of clinical experience, the 2007 SCAI Expert Consensus Document included a recommendation that operators at PCI programs without on-site surgery perform at least 100 total and 18 primary PCIs annually, a recommendation that might not be achievable in the current environment. The 2013 PCI Competency Document moves away from strict volume requirements to focus more on achieving quality metrics for facilities and individual operators. As noted earlier, the 2013 Competency document recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually (Table 4). Again acknowledging the importance of experience, the 2007 SCAI Expert Consensus Document suggested that initial operators at a new program without on-site surgery should have a lifetime experience of >500 PCIs as primary operator after completing a fellowship. In the current environment of decreasing PCI volumes and in view of the recommendations of the 2013 PCI competence document, this number would be difficult to achieve. Nevertheless, it is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by more experienced physicians until it is determined that the skills, judgment and outcomes of these new cardiologists are acceptable.

Requirements for Off-Site Surgical Backup

Recommendations for the interactions between cardiologists and cardiac surgeons are listed in Table 5. A limitation of programs performing PCI without on-site surgery is the lack of on-site access to a cardiac surgeon for consultation about revascularization options. This makes the concept of a Heart Team consultation more difficult to achieve and could necessitate performing only diagnostic catheterization until a case review with a cardiac surgeon can be performed. The application of telemedicine consultations with a heart surgeon could facilitate these interactions. In reality, many of the nonemergency patients who merit discussion by a Heart Team are not optimal candidates for PCI at facilities without on-site cardiac surgery. It is important to emphasize that the role of the cardiac surgeon is not confined to the treatment of PCI complications but includes the participation in decisions about revascularization options. Recommendations for case selection at facilities without on-site surgery are shown in Table 5, and criteria for identifying high-risk lesions and patients are contained in Table 6. There are statistical models for identifying PCI patients at higher risk for mortality or emergency CABG that could be helpful for identifying patients who should not undergo PCI at facilities without on-site surgery.[18,71] However, these models have not been tested or applied on a large scale to determine the advisability of performing a PCI at facilities without on-site surgery.

The Delivery of PCI Services in the Future

As a result of the additional randomized studies on PCI without on-site surgery and the recent change in guideline recommendations, the performance of PCI without on-site surgery in the US has gained greater acceptance, and questions about its safety in the presence of a proven, well defined, and protocol driven approach have diminished. PCI programs should be evaluated based on their ability to: (a) sustain adequate quality metrics, (b) provide access to elective and emergency PCI procedures that would otherwise be unavailable in their service area, and (c) maintain the operator and institutional volumes recommended in the 2013 PCI Competency Document. For the future, the focus must now shift to developing a rational plan for the distribution of PCI services. Small PCI programs with large fixed costs are inefficient and unnecessary if they do not improve access in areas of need. However, it is unlikely that issues of system-wide efficiency will be addressed without central planning on the state or federal level. This writing group reaffirms the statement from the 2011 ACCF/AHA/SCAI PCI Guidelines that "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery" and suggests that new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations. The writing group recognizes the need for ongoing study and surveillance of all PCI programs through participation in national databases encourages public reporting of their results and acknowledges that further declines in PCI volumes might necessitate the closure of PCI programs in the future.

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KEY WORDS: AHA Scientific Statements ■ angioplasty ■ coronary artery bypass surgery ■ consensus

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Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
James C. Blankenship	Geisinger Medical Center—Director, Cardiac Catheterization Laboratory	None	None	None	• Abiomed* • Astra-Zeneca* • Boston Scientific* • Kai Pharmaceutical* • Novartis • Schering Plough • The Medicines Company* • Volcano	• SCAI—Vice President*	None
Mehmet Cilingiroglu	Arkansas Heart Hospital	None	None	None	None	None	None
Greg J. Dehmer (Chair)	Texas A&M College of Medicine, Scott & White Clinic Cardiology Division—Professor of Medicine; Director of Cardiology	None	None	None	None	None	None
James G. Dwyer	Heart and Vascular Center of Northern Arizona	None	None	None	None	None	None
Dmitriy N. Feldman	New York Presbyterian Hospital/Cornell	• Gilead • Maquet	• Abbott Vascular • Bristol-Myers Squibb* • Daiichi-Sankyo • Eli Lilly • Pfizer • The Medicines Company*	None	None	None	None
Timothy J. Gardner	Christiana Care Health System—Medical Director	None	None	None	None	None	None
Cindy L. Grines	Harper University Hospital—Vice President	• Abbott Vascular • Bristol-Myers Squibb • Lilly USA • Merck • The Medicines Company • Volcano*	None	None	None	• Journal of Interventional Cardiology†	None
Mandeep Singh	Mayo Clinic	None	None	None	None	None	None

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx for definitions of disclosure categories or additional information about the ACCF Disclosure Policy for Writing Committees.

*No financial benefit.

†Significant relationship.

ACC indicates American College of Cardiology; AMA, American Medical Association; FDA, U.S. Food and Drug Administration; NHLBI, National Heart, Lung, and Blood Institute; SCAI, Society for Cardiovascular Angiography and Interventions.

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Appendix 2. Peer Reviewer Relationships With Industry and Other Entities (Relevant)—SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Eric R. Bates	Content Reviewer—AHA and Content Reviewer—ACCF/ AHA/SCAI PCI Guideline	University of Michigan Hospitals and Health Centers—Professor of Medicine	• AstraZeneca • BMS • Daiichi-Sankyo • Eli Lilly • Merck/ Schering-Plough • Sanofi-aventis	None	None	None	None	None
Ashequl M. Islam	Official Reviewer—SCAI	Baystate Medical Center—Program Director, Interventional Cardiology Fellowship	• Edwards Lifesciences	• Daiichi-Sankyo • Eli Lilly	None	None	None	None
Hani Jneid	Official Reviewer—ACCF Task Force on Clinical Expert Consensus Documents	Baylor College of Medicine - MEDVAMC—Associate Professor of Medicine	None	None	None	None	None	None
Steven P. Marso	Official Reviewer—SCAI	Saint Luke's Mid America Heart Institute; University of Missouri-Kansas City—Professor of Medicine	None	None	None	None	• Amylin* • St. Jude Medical* • Terumo Medical* • The Medicines Company* • Volcano Corporation*	None
Laura Mauri	Official Reviewer—AHA	Harvard Medical School—Associate Professor of Medicine; Brigham & Women's Hospital	• Medtronic • St. Jude Medical	None	None	• Abbott Vascular* • Boston Scientific* • Bristol-Myers Squibb* • Cordis Corporation* • Daiichi-Sankyo* • Eli Lilly* • Medtronic* • Sanofi-aventis*	None	None
Srinivas Murali	Official Reviewer—ACC Board of Governors	Allegheny General Hospital—Director, Division of Cardiovascular Medicine	• Advisory Board • Actelion • Gilead Pharma	• Actelion	None	• Gilead Pharma • St. Jude Medical	None	None
Barry Uretsky	Official Reviewer—SCAI	University of Arkansas for Medical Sciences—Clinical Professor of Medicine	None	None	None	• St. Jude Medical*	None	None
Howard Walpole	Official Reviewer—ACCF Board of Trustees	Okyanos Heart Institute—Chief Medical Officer	None	None	None	None	None	None
Thomas M. Bashore	Content Reviewer—ACCF/ AHA/SCAI Clinical Competence Statement on CIP	Duke University Medical Center—Professor of Medicine; Clinical Chief, Division of Cardiology	None	None	None	None	None	None

(Continued)

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Appendix 2. Continued

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John G. Byrne	Content Reviewer—ACCF Interventional Section Leadership Council	Brigham & Women's Hospital—Chief, Division of Cardiac Surgery; Harvard Medical School—Professor	None	None	None	None	None	None
Joaquin E. Cigarroa	Content Reviewer—ACCF Interventional Section Leadership Council and ACCF/AHA CABG Guideline	Oregon Health & Science University—Associate Professor of Medicine	None	None	None	None	• Catheterization and Cardiovascular Intervention† • Portland Metro Area AHA†	None
Frederick E. Grover	Content Reviewer—ACCF Surgeons Section Leadership Council	University of Colorado—Professor and Chair, Department of Surgery	• Somahlution†	None	None	None	None	None
Maureen B. Julien	Content Reviewer—ACCF Interventional Section Leadership Council	Hospital of the University of Pennsylvania—Nurse Practitioner	None	None	None	None	None	None
Glenn N. Levine	Content Reviewer—ACCF/AHA/SCAI PCI Guideline and ACCF/AHA/SCAI Clinical Competence Statement on CIP	Baylor College of Medicine—Professor of Medicine	None	None	None	None	None	None
Pasala S. Ravichandran	Content Reviewer—ACCF Surgeons Section Leadership Council	Oregon Health & Science University—Associate Professor	None	None	None	None	None	None
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*Significant relationship.

†No financial benefit.

ACCF indicates American College of Cardiology; AHA, American Heart Association; CABG, Coronary Artery Bypass Graft Surgery; CIP, Coronary Interventional Procedures; PCI, Percutaneous Coronary Intervention; SCAI, Society of Cardiovascular Angiography & Interventions.

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Correction

In the article by Dehmer et al, "SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup," which published online March 17, 2014, and appears in the June 17, 2014, issue of the journal (*Circulation.* 2014;129:2610–2626), several corrections were needed.

1. On page 2611, in the second column, first paragraph, the second sentence read, "Since the conclusion of CPORT-E, the use of PCI without on-site surgery is being revaluated in several of these states." It has been changed to read, "Since the conclusion of CPORT-E, the use of PCI without on-site surgery is being reevaluated in several of these states."
2. On page 2620, in the second column, first paragraph, the fourth sentence read, "For example, to detect (with statistically certainty)...." It has been changed to read, "For example, to detect (with statistical certainty)...."
3. On page 2624, in Appendix 1, in the information for Cindy L. Grines, "Consultant" column, the second bullet read, "Bristol Meyers Squibb." It has been changed to read, "Bristol-Myers Squibb."
4. On page 2624, in Appendix 1, in the legend, first paragraph, the first sentence read, "This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development." It has been changed to read, "This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors at the time this document was under development."

These corrections have been made to the print version and to the current online version of the article, which is available at http://circ.ahajournals.org/lookup/doi/10.1161/CIR.0000000000000037.

(*Circulation.* 2014;130:e22.)
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Circulation is available at http://circ.ahajournals.org

DOI: 10.1161/CIR.0000000000000078

EXHIBIT 2

Education Plan for PCI

Catheterization Lab Staff

RN:

- 8 hours of total classroom time reviewing pathophisiology, EKG interpretation, pre-intra- post care of a PCI patient.
- 4 hour IABP course
- Up to 12 weeks of hands on training at Hartford Hospital in their cardiac catheterization lab.
- Case simulation prior to GO LIVE
- Signed off competencies indicating that expectations to care for the PCI patient have been met.

CV Tech:

- 6 hours of total classroom time reviewing pathophisiology, EKG interpretation, inter-procedural procedures and guidelines.
- 4 hour IABP course
- Up to 8 weeks of hands on training at Hartford Hospital in their cardiac catheterization lab
- Case simulation prior to GO LIVE
-
- Signed off competencies indicating that expectations to care for the PCI patient have been met.

Critical Care RN:

- 4 hours of classroom or on-line learning regarding PCI care, pre and post procedure
- 4 hour IABP course
- Case simulation prior to GO LIVE
- Signed off competencies indicating that expectations to care for the PCI patient have been met.

EXHIBIT 3

Executive Report

2015 Community Health Needs Assessment

Eastern Region, Connecticut

Prepared for:
HARTFORD HEALTHCARE

By:
Professional Research Consultants, Inc.
11326 P Street Omaha, NE 68136-2316
www.PRCCustomResearch.com

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Introduction

Professional Research Consultants, Inc.

Project Overview

Project Goals

This Community Health Needs Assessment is a systematic, data-driven approach to determining the health status, behaviors and needs of residents in the Eastern Region of Hartford HealthCare's service area. Subsequently, this information may be used to inform decisions and guide efforts to improve community health and wellness.

A Community Health Needs Assessment provides information so that communities may identify issues of greatest concern and decide to commit resources to those areas, thereby making the greatest possible impact on community health status. This Community Health Needs Assessment will serve as a tool toward reaching three basic goals:

- **To improve residents' health status, increase their life spans, and elevate their overall quality of life.** A healthy community is not only one where its residents suffer little from physical and mental illness, but also one where its residents enjoy a high quality of life.
- **To reduce the health disparities among residents.** By gathering demographic information along with health status and behavior data, it will be possible to identify population segments that are most at-risk for various diseases and injuries. Intervention plans aimed at targeting these individuals may then be developed to combat some of the socio-economic factors which have historically had a negative impact on residents' health.
- **To increase accessibility to preventive services for all community residents.** More accessible preventive services will prove beneficial in accomplishing the first goal (improving health status, increasing life spans, and elevating the quality of life), as well as lowering the costs associated with caring for late-stage diseases resulting from a lack of preventive care.

This assessment was conducted on behalf of Hartford HealthCare by Professional Research Consultants, Inc. (PRC). PRC is a nationally-recognized healthcare consulting firm with extensive experience conducting Community Health Needs Assessments such as this in hundreds of communities across the United States since 1994.

Methodology

This assessment incorporates data from both quantitative and qualitative sources. Quantitative data input includes primary research (the PRC Community Health Survey) and secondary research (vital statistics and other existing health-related data); these quantitative components allow for trending and comparison to benchmark data at the state and national levels. Qualitative data input includes primary research gathered through an Online Key Informant Survey of various community stakeholders.

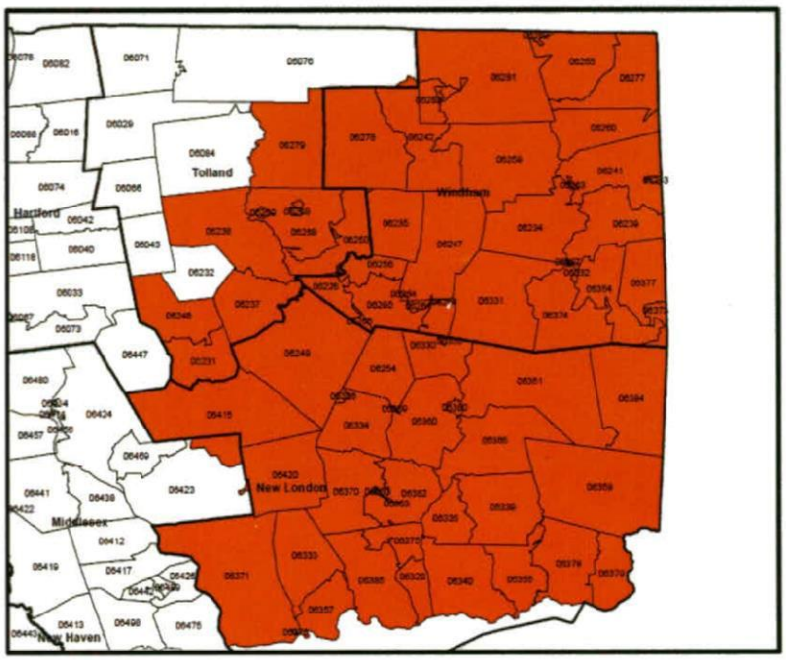
PRC Community Health Survey

Survey Instrument

The survey instrument used for this study is based largely on the Centers for Disease Control and Prevention (CDC) Behavioral Risk Factor Surveillance System (BRFSS), as well as various other public health surveys and customized questions addressing gaps in indicator data relative to health promotion and disease prevention objectives and other recognized health issues. The final survey instrument was developed by Hartford HealthCare and PRC.

Community Defined for This Assessment

The study area for the survey effort (referred to as the "Eastern Region" in this report) is defined by 67 residential ZIP Codes in Eastern Connecticut. This area definition is illustrated in the following map.



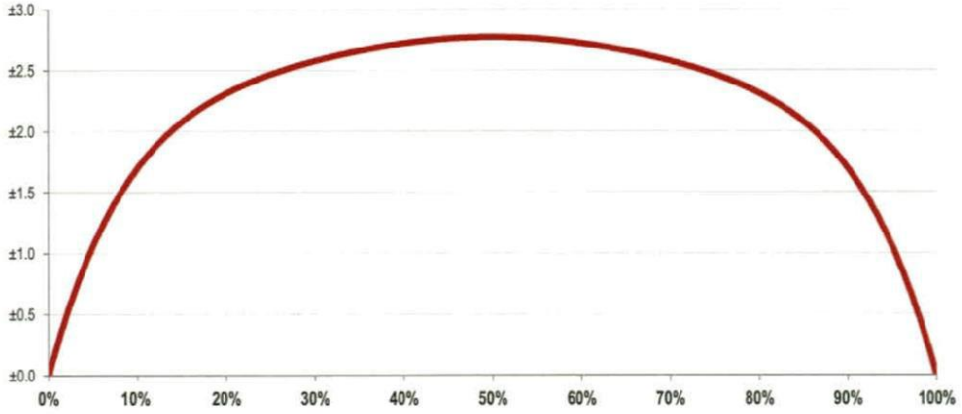
Sample Approach & Design

A precise and carefully executed methodology is critical in asserting the validity of the results gathered in the *PRC Community Health Survey*. Thus, to ensure the best representation of the population surveyed, a telephone interview methodology — one that incorporates both landline and cell phone interviews — was employed. The primary advantages of telephone interviewing are timeliness, efficiency and random-selection capabilities.

The sample design used for this effort consisted of a random sample of 1,244 individuals age 18 and older in the Eastern Region. Because this study is part of a larger effort involving multiple regions and hospital service areas, the surveys were distributed among various strata. Once the interviews were completed, these were weighted in proportion to the actual population distribution so as to appropriately represent the Eastern Region as a whole. All administration of the surveys, data collection and data analysis was conducted by Professional Research Consultants, Inc. (PRC).

For statistical purposes, the maximum rate of error associated with a sample size of 1,244 respondents is ±2.8% at the 95 percent level of confidence.

Expected Error Ranges for a Sample of 1,244 Respondents at the 95 Percent Level of Confidence



Note:
- The "response rate" (the percentage of a population giving a particular response) determines the error rate associated with that response. A "95 percent level of confidence" indicates that responses would fall within the expected error range on 95 out of 100 trials.

Examples:
- If 10% of the sample of 1,244 respondents answered a certain question with a "yes," it can be asserted that between 8.3% and 11.7% (10% ± 1.7%) of the total population would offer this response.
- If 50% of respondents said "yes," one could be certain with a 95 percent level of confidence that between 47.2% and 52.8% (50% ± 2.8%) of the total population would respond "yes" if asked this question.

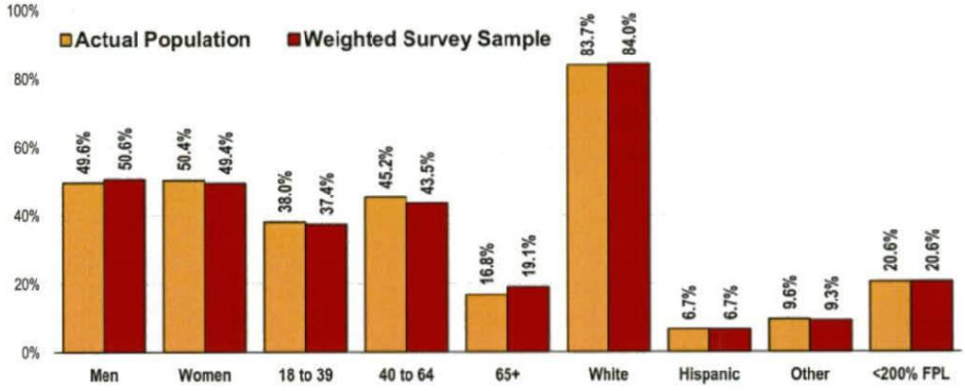
Sample Characteristics

To accurately represent the population studied, PRC strives to minimize bias through application of a proven telephone methodology and random-selection techniques. And, while this random sampling of the population produces a highly representative sample, it is a common and preferred practice to "weight" the raw data to improve this representativeness even further. This is accomplished by adjusting the results of a random sample to match the geographic distribution and demographic characteristics of the population surveyed

(poststratification), so as to eliminate any naturally occurring bias. Specifically, once the raw data are gathered, respondents are examined by key demographic characteristics (namely gender, age, race, ethnicity, and poverty status) and a statistical application package applies weighting variables that produce a sample which more closely matches the population for these characteristics. Thus, while the integrity of each individual's responses is maintained, one respondent's responses may contribute to the whole the same weight as, for example, 1.1 respondents. Another respondent, whose demographic characteristics may have been slightly oversampled, may contribute the same weight as 0.9 respondents.

The following chart outlines the characteristics of the Eastern Region sample for key demographic variables, compared to actual population characteristics revealed in census data. [Note that the sample consisted solely of area residents age 18 and older; data on children were given by proxy by the person most responsible for that child's healthcare needs, and these children are not represented demographically in this chart.]

Population & Survey Sample Characteristics
(Eastern Region, 2015)



Sources:
- Census 2010, Summary File 3 (SF 3). US Census Bureau.
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc.

Further note that the poverty descriptions and segmentation used in this report are based on administrative poverty thresholds determined by the US Department of Health & Human Services. These guidelines define poverty status by household income level and number of persons in the household *(e.g., the 2014 guidelines place the poverty threshold for a family of four at $23,850 annual household income or lower)*. In sample segmentation: "**very low income**" refers to community members living in a household with defined poverty status; "**low income**" refers to households with incomes just above the poverty level, earning up to twice the poverty threshold; and "**mid/high income**" refers to those households living on incomes which are twice or more the federal poverty level.

The sample design and the quality control procedures used in the data collection ensure that the sample is representative. Thus, the findings may be generalized to the total population of

community members in the defined area with a high degree of confidence.

Online Key Informant Survey

To solicit input from key informants, those individuals who have a broad interest in the health of the community, an Online Key Informant Survey was also implemented as part of this process. A list of recommended participants was provided by Hartford HealthCare; this list included names and contact information for physicians, public health representatives, other health professionals, social service providers, and a variety of other community leaders. Potential participants were chosen because of their ability to identify primary concerns of the populations with whom they work, as well as of the community overall.

Key informants were contacted by email, introducing the purpose of the survey and providing a link to take the survey online; reminder emails were sent as needed to increase participation. In all, 25 community stakeholders took part in the Online Key Informant Survey, as outlined below:

Online Key Informant Survey Participation		
Key Informant Type	**Number Invited**	**Number Participating**
Community/Business Leader	23	4
Health Provider	23	9
Public Health Expert	4	2
Social Services Representative	22	10

Final participation included representatives of the organizations outlined below:

- American Ambulance Service, Inc.
- American Red Cross Blood Services
- Backus Hospital
- Catholic Charities
- Generations Family Health Center, Inc.
- Mohegan Tribe
- Norwich Adult Education
- Reliance House, Inc.
- Rose City Senior Center
- Southeastern Regional Action Council
- St. Vincent de Paul Place Norwich
- Three Rivers Community College Nursing Program
- Town of Windham
- TVCCA
- Uncas Health District
- United Community and Family Services

- Windham Hospital
- Windham Region No Freeze Project

Through this process, input was gathered from several individuals whose organizations work with **low-income**, **minority populations** (African-Americans, American Indians, Asians, Cape Verdeans, Chinese residents, disabled elderly, French Creole residents, Haitian residents, Hispanics, persons with HIV/AIDS, the homeless, lesbian/gay/bisexual/transgender individuals, low-income residents, middle easterners, migrant farm workers, mixed race individuals, northern Europeans, unemployed residents, victims of crime), or **other medically underserved populations** (persons with behavioral health issues, children, diabetics, the disabled, the elderly, the homeless, lesbian/gays/bisexual/transgender individuals, low-income residents, Medicaid/Medicare recipients, those who are mentally ill, non-English speaking persons, persons with substance abuse issues, undocumented immigrants, uninsured/underinsured residents, veterans, women and children, young adults).

In the online survey, key informants were asked to rate the degree to which various health issues are a problem in their own community. Follow-up questions asked them to describe why they identify problem areas as such, and how these might be better addressed. Results of their ratings, as well as their verbatim comments, are included throughout this report as they relate to the various other data presented.

NOTE: These findings represent qualitative rather than quantitative data. The Online Key Informant Survey was designed to gather input from participants regarding their opinions and perceptions of the health of the residents in the area. Thus, these findings are based on perceptions, not facts.

Public Health, Vital Statistics & Other Data

A variety of existing (secondary) data sources was consulted to complement the research quality of this Community Health Needs Assessment. Data for the Eastern Region were obtained from the following sources (specific citations are included with the graphs throughout this report):

- Center for Applied Research and Environmental Systems (CARES)
- Centers for Disease Control & Prevention, Office of Infectious Disease, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
- Centers for Disease Control & Prevention, Office of Public Health Science Services, Center for Surveillance, Epidemiology and Laboratory Services, Division of Health Informatics and Surveillance (DHIS)
- Centers for Disease Control & Prevention, Office of Public Health Science Services, National Center for Health Statistics
- Community Commons
- Connecticut Department of Public Health
- ESRI ArcGIS Map Gallery

- National Cancer Institute, State Cancer Profiles
- OpenStreetMap (OSM)
- US Census Bureau, American Community Survey
- US Census Bureau, County Business Patterns
- US Census Bureau, Decennial Census
- US Department of Agriculture, Economic Research Service
- US Department of Health & Human Services
- US Department of Health & Human Services, Health Resources and Services Administration (HRSA)
- US Department of Justice, Federal Bureau of Investigation
- US Department of Labor, Bureau of Labor Statistics

Note that town-specific secondary data were sought and included where available; **the remainder of secondary data indicators for the "Eastern Region" reflect the combined counties of New London, Tolland and Windham counties**.

Benchmark Data

Connecticut Risk Factor Data

Statewide risk factor data are provided where available as an additional benchmark against which to compare local survey findings; these data are reported in the most recent *BRFSS (Behavioral Risk Factor Surveillance System) Prevalence and Trend Data* published by the Centers for Disease Control and Prevention and the US Department of Health & Human Services. State-level vital statistics are also provided for comparison of secondary data indicators.

Nationwide Risk Factor Data

Nationwide risk factor data, which are also provided in comparison charts, are taken from the *2013 PRC National Health Survey*; the methodological approach for the national study is identical to that employed in this assessment, and these data may be generalized to the US population with a high degree of confidence. National-level vital statistics are also provided for comparison of secondary data indicators.

Healthy People 2020

Healthy People provides science-based, 10-year national objectives for improving the health of all Americans. The Healthy People initiative is grounded in the principle that setting national objectives and monitoring progress can motivate action. For three decades, Healthy People has established benchmarks and monitored progress over time in order to:

- Encourage collaborations across sectors.
- Guide individuals toward making informed health decisions.
- Measure the impact of prevention activities.

Healthy People 2020 is the product of an extensive stakeholder feedback process that is

unparalleled in government and health. It integrates input from public health and prevention experts, a wide range of federal, state and local government officials, a consortium of more than 2,000 organizations, and perhaps most importantly, the public. More than 8,000 comments were considered in drafting a comprehensive set of Healthy People 2020 objectives.

Determining Significance

Differences noted in this report represent those determined to be significant. For survey-derived indicators (which are subject to sampling error), statistical significance is determined based on confidence intervals (at the 95 percent confidence level) using question-specific samples and response rates. For secondary data indicators (which do not carry sampling error, but might be subject to reporting error), "significance," for the purpose of this report, is determined by a 5% variation from the comparative measure.

Information Gaps

While this assessment is quite comprehensive, it cannot measure all possible aspects of health in the community, nor can it adequately represent all possible populations of interest. It must be recognized that these information gaps might in some ways limit the ability to assess all of the community's health needs.

For example, certain population groups — such as the homeless, institutionalized persons, or those who only speak a language other than English or Spanish — are not represented in the survey data. Other population groups — for example, pregnant women, lesbian/gay/bisexual/transgender residents, undocumented residents, and members of certain racial/ethnic or immigrant groups — might not be identifiable or might not be represented in numbers sufficient for independent analyses.

In terms of content, this assessment was designed to provide a comprehensive and broad picture of the health of the overall community. However, there are certainly a great number of medical conditions that are not specifically addressed.

Summary of Findings

Significant Health Needs of the Community

The following "areas of opportunity" represent the significant health needs of the community, based on the information gathered through this Community Health Needs Assessment and the guidelines set forth in Healthy People 2020. From these data, opportunities for health improvement exist in the area with regard to the following health issues (see also the summary tables presented in the following section).

Areas of Opportunity Identified Through This Assessment	
Access to Healthcare Services	• Primary Care Physician Ratio
Cancer	• *Cancer is the #2 Leading Cause of Death* • Colorectal Cancer Deaths • Female Breast and Cervical Cancer Incidence
Dementia, Including Alzheimer's Disease	• Alzheimer's Disease Deaths
Diabetes	• Diabetes Deaths • Diabetes Prevalence • Prevalence of Borderline/Pre-Diabetes
Heart Disease & Stroke	• *Heart Disease is the #1 Leading Cause of Death* • Heart Disease Deaths • Stroke Deaths • High Blood Pressure Prevalence
Injury & Violence	• Violent Crime Rate
Mental Health	• Suicide Deaths • *Mental Health ranked #1 as a "major problem" in the Online Key Informant Survey*
Nutrition, Physical Activity & Weight	• Overweight & Obesity [Adults] • Low Food Access • Leisure-Time Physical Activity • Meeting Physical Activity Guidelines • Access to Recreation/Fitness Facilities • *Nutrition, Physical Activity & Weight ranked #2 as a "major problem" in the Online Key Informant Survey*
Oral Health	• *Oral Health tied for #4 ranking as a "major problem" in the Online Key Informant Survey*
Potentially Disabling Conditions	• Activity Limitations • Sciatica/Back Pain Prevalence

– *continued next page* –

Areas of Opportunity (continued)	
Respiratory Diseases	• Chronic Lower Respiratory Disease (CLRD) Deaths • Chronic Obstructive Pulmonary Disease (COPD) Prevalence • Asthma Prevalence [Adults]
Substance Abuse	• Cirrhosis/Liver Disease Deaths • Overall Alcohol Use • Drug-Induced Deaths • Seeking Help for Alcohol/Drug Issues • *Substance Abuse ranked #3 as a "major problem" in the Online Key Informant Survey*
Tobacco Use	• *Tobacco Use tied for #4 ranking as a "major problem" in the Online Key Informant Survey*

Summary Tables: Comparisons With Benchmark Data

The following tables provide an overview of indicators in the Eastern Region. These data are grouped to correspond with the Focus Areas presented in Healthy People 2020.

Reading the Summary Tables

■ In the following charts, the Eastern Region results are shown in the larger, blue column.

■ The columns to the right of the Eastern Region column provide comparisons between local data and any available state and national findings, and Healthy People 2020 targets. Symbols indicate whether the Eastern Region compares favorably (☺), unfavorably (☹), or comparably (😐) to these external data.

Note that blank table cells signify that data are not available or are not reliable for that area and/or for that indicator.

Social Determinants	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Linguistically Isolated Population (Percent)	2.6	4.7	4.9	
Population in Poverty (Percent)	8.6	10.0	14.9	
Population Below 200% FPL (Percent)	20.8	22.4	33.6	
Children Below 200% FPL (Percent)	10.7	13.2	20.8	
No High School Diploma (Age 25+, Percent)	9.9	11.0	14.3	
Unemployment Rate (Age 16+, Percent)	5.8	5.7	5.4	
		better	similar	worse

Overall Health	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% "Fair/Poor" Physical Health	12.7	13.3	15.3	
% Activity Limitations	22.6	17.5	21.5	
		better	similar	worse

Access to Health Services	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% [Age 18-64] Lack Health Insurance	7.1	12.3	15.1	0.0
% [Insured] Went Without Coverage in Past Year	5.8		8.1	
% Difficulty Accessing Healthcare in Past Year (Composite)	36.9		39.9	
% Inconvenient Hrs Prevented Dr Visit in Past Year	14.6		15.4	
% Cost Prevented Getting Prescription in Past Year	9.0		15.8	
% Cost Prevented Physician Visit in Past Year	9.8		18.2	
% Difficulty Getting Appointment in Past Year	16.2		17.0	
% Difficulty Finding Physician in Past Year	10.3		11.0	
% Transportation Hindered Dr Visit in Past Year	6.5		9.4	
% Skipped Prescription Doses to Save Costs	8.6		15.3	
% Difficulty Getting Child's Healthcare in Past Year	2.8		6.0	
Primary Care Doctors per 100,000	58.9	84.0	74.5	
% [Age 18+] Have a Specific Source of Ongoing Care	77.2		76.3	95.0
% [Age 18-64] Have a Specific Source of Ongoing Care	77.4		75.6	89.4
% [Age 65+] Have a Specific Source of Ongoing Care	77.0		80.0	100.0
% Have Had Routine Checkup in Past Year	76.6	71.8	65.0	

Access to Health Services (continued)	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% Child Has Had Checkup in Past Year	95.6		84.1	
% Two or More ER Visits in Past Year	8.6		8.9	
% Rate Local Healthcare "Fair/Poor"	10.5		16.5	
		better	similar	worse

Arthritis, Osteoporosis & Chronic Back Conditions	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% [50+] Arthritis/Rheumatism	39.8		37.3	
% [50+] Osteoporosis	10.7		13.5	5.3
% Sciatica/Chronic Back Pain	22.9		18.4	
		better	similar	worse

Cancer	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Cancer (Age-Adjusted Death Rate)	155.5	153.0	166.2	161.4
Lung Cancer (Age-Adjusted Death Rate)	40.2	38.7	44.7	45.5
Prostate Cancer (Age-Adjusted Death Rate)	16.3	18.2	19.8	21.8
Female Breast Cancer (Age-Adjusted Death Rate)	20.1	19.2	21.3	20.7
Colorectal Cancer (Age-Adjusted Death Rate)	13.3	12.1	14.9	14.5

Cancer (continued)	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Prostate Cancer Incidence per 100,000	127.6	152.4	142.3	
Female Breast Cancer Incidence per 100,000	131.4	136.6	122.7	
Lung Cancer Incidence per 100,000	67.3	64.8	64.9	
Colorectal Cancer Incidence per 100,000	41.8	42.7	43.3	
Cervical Cancer Incidence per 100,000	10.2	6.2	7.8	
% Skin Cancer	6.2	5.8	6.7	
% Cancer (Other Than Skin)	6.3	7.5	6.1	
% [Women 50-74] Mammogram in Past 2 Years	85.3	81.5	83.6	81.1
% [Women 21-65] Pap Smear in Past 3 Years	86.4	80.1	83.9	93.0
% [Age 50+] Sigmoid/Colonoscopy Ever	85.6	74.5	75.2	
% [Age 50+] Blood Stool Test in Past 2 Years	35.4	16.4	36.9	
% [Age 50-75] Colorectal Cancer Screening	83.9		75.1	70.5
		better	similar	worse

Chronic Kidney Disease	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Kidney Disease (Age-Adjusted Death Rate)	12.6	12.5	13.2	
% Kidney Disease	2.7	2.1	3.0	
		better	similar	worse

Diabetes	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Diabetes Mellitus (Age-Adjusted Death Rate)	15.8	14.8	21.3	20.5
% Diabetes/High Blood Sugar	11.0	8.3	11.7	
% Borderline/Pre-Diabetes	7.5		5.1	
% [Non-Diabetes] Blood Sugar Tested in Past 3 Years	53.7		49.2	
		better	similar	worse

Dementias, Including Alzheimer's Disease	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Alzheimer's Disease (Age-Adjusted Death Rate)	19.4	16.5	24.0	
		better	similar	worse

Family Planning	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Births to Teenagers (Percent)	4.9	5.1	7.8	
		better	similar	worse

Hearing & Other Sensory or Communication Disorders	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% Deafness/Trouble Hearing	8.7		10.3	
		better	similar	worse

Heart Disease & Stroke	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Diseases of the Heart (Age-Adjusted Death Rate)	165.7	153.4	171.3	156.9
Stroke (Age-Adjusted Death Rate)	30.4	27.9	37.0	34.8
% Heart Disease (Heart Attack, Angina, Coronary Disease)	5.9		6.1	
% Stroke	2.7	2.3	3.9	
% Blood Pressure Checked in Past 2 Years	96.8		91.0	92.6
% Told Have High Blood Pressure (Ever)	35.7	31.3	34.1	26.9
% [HBP] Taking Action to Control High Blood Pressure	91.1		89.2	
% Cholesterol Checked in Past 5 Years	93.4	83.1	86.6	82.1
% Told Have High Cholesterol (Ever)	32.4	37.8	29.9	13.5
% [HBC] Taking Action to Control High Blood Cholesterol	84.6		81.4	
% 1+ Cardiovascular Risk Factor	85.1		82.3	
		better	similar	worse

HIV	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
HIV Prevalence per 100,000	187.0	359.7	340.4	
% [Age 18-44] HIV Test in the Past Year	18.9		19.3	
		better	similar	worse

Immunization & Infectious Diseases	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% [Age 65+] Flu Vaccine in Past Year	65.2	63.6	57.5	70.0
% [High-Risk 18-64] Flu Vaccine in Past Year	54.0		45.9	70.0
% [Age 65+] Pneumonia Vaccine Ever	75.5	67.8	68.4	90.0
% [High-Risk 18-64] Pneumonia Vaccine Ever	39.0		41.9	60.0
% Have Completed Hepatitis B Vaccination Series	48.9		44.7	
		better	similar	worse

Injury & Violence Prevention	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Unintentional Injury (Age-Adjusted Death Rate)	37.5	35.8	39.2	36.4
Motor Vehicle Crashes (Age-Adjusted Death Rate)	7.4	7.1	10.7	12.4
% "Always" Wear Seat Belt	91.8		84.8	92.0
% Child [Age 0-17] "Always" Uses Seat Belt/Car Seat	95.8		92.2	
% Child [Age 5-17] "Always" Wears Bicycle Helmet	68.7		48.7	

Injury & Violence Prevention (continued)	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Firearm-Related Deaths (Age-Adjusted Death Rate)	5.0	5.5	10.4	9.3
% Firearm in Home	22.7		34.7	
% [Homes With Children] Firearm in Home	20.8		37.4	
% [Homes With Firearms] Weapon(s) Unlocked & Loaded	8.8		16.8	
Homicide (Age-Adjusted Death Rate)	2.2	3.8	5.3	5.5
Violent Crime per 100,000	302.2	280.6	395.5	
% Victim of Violent Crime in Past 5 Years	0.8		2.8	
% Victim of Domestic Violence (Ever)	10.6		15.0	
		better	similar	worse

Maternal, Infant & Child Health	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
No Prenatal Care in First Trimester (Percent)	10.4	13.0		22.1
Low Birthweight Births (Percent)	7.4	7.8	8.0	7.8
Infant Death Rate	4.7	4.9	6.0	6.0
		better	similar	worse

Mental Health & Mental Disorders	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% "Fair/Poor" Mental Health	9.4		11.9	
% Diagnosed Depression	19.0		20.4	
% Symptoms of Chronic Depression (2+ Years)	26.4		30.4	
Suicide (Age-Adjusted Death Rate)	11.2	9.5	12.5	10.2
% Have Ever Sought Help for Mental Health	28.1		23.7	
% [Those With Diagnosed Depression] Seeking Help	85.1		76.6	
% Typical Day Is "Extremely/Very" Stressful	10.5		11.9	
% Member of HH Sought Help for Mental Health/Past Year	20.4			
% [Children <18] Child Has "Fair/Poor" Mental Health	6.0			
% [Children <18] Couldn't Get Mental Help for Child in Past Year	1.9			
		better	similar	worse

Nutrition & Weight Status	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% Eat 5+ Servings of Fruit or Vegetables per Day	37.4		39.5	
% "Very/Somewhat" Difficult to Buy Fresh Produce	24.2		24.4	
Population With Low Food Access (Percent)	30.6	29.8	23.6	
% Medical Advice on Nutrition in Past Year	43.9		39.2	

Nutrition & Weight Status (continued)	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% Healthy Weight (BMI 18.5-24.9)	32.0	35.6	34.4	33.9
% Overweight (BMI 25+)	66.2	62.6	63.1	
% Obese (BMI 30+)	30.2	25.0	29.0	30.5
% Medical Advice on Weight in Past Year	29.2		23.7	
% [Overweights] Counseled About Weight in Past Year	38.0		31.8	
% [Obese Adults] Counseled About Weight in Past Year	50.7		48.3	
% [Overweights] Trying to Lose Weight Both Diet/Exercise	35.1		39.5	
% Child [Age 5-17] Healthy Weight	57.8		56.7	
% Children [Age 5-17] Overweight (85th Percentile)	33.0		31.5	
% Children [Age 5-17] Obese (95th Percentile)	18.7		14.8	14.5
		better	similar	worse

Oral Health	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% [Age 18+] Dental Visit in Past Year	79.3	76.1	65.9	49.0
% Child [Age 2-17] Dental Visit in Past Year	92.2		81.5	49.0
% Have Dental Insurance	76.5		65.6	
		better	similar	worse

Physical Activity	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% No Leisure-Time Physical Activity	27.0	24.9	20.7	32.6
% Meeting Physical Activity Guidelines	45.2		50.3	
% Moderate Physical Activity	28.5		30.6	
% Vigorous Physical Activity	34.7		38.0	
Recreation/Fitness Facilities per 100,000	9.7	13.2	9.4	
% Medical Advice on Physical Activity in Past Year	53.7		44.0	
% Child [Age 2-17] Physically Active 1+ Hours per Day	45.4		48.6	
		better	similar	worse

Respiratory Diseases	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
CLRD (Age-Adjusted Death Rate)	41.8	30.9	42.0	
Pneumonia/Influenza (Age-Adjusted Death Rate)	13.1	12.9	15.3	
% COPD (Lung Disease)	11.0	5.9	8.6	
% [Adult] Currently Has Asthma	12.7	9.8	9.4	
% [Child 0-17] Currently Has Asthma	6.7		7.1	
		better	similar	worse

Sexually Transmitted Diseases	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Gonorrhea Incidence per 100,000	25.9	57.4	107.5	
Chlamydia Incidence per 100,000	220.3	364.9	456.7	
% [Unmarried 18-64] 3+ Sexual Partners in Past Year	8.8		11.7	
% [Unmarried 18-64] Using Condoms	35.0		33.6	
		better	similar	worse

Substance Abuse	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
Cirrhosis/Liver Disease (Age-Adjusted Death Rate)	9.0	7.6	9.9	8.2
% Current Drinker	63.4	62.6	56.5	
% Excessive Drinker (Heavy or Binge Drinking)	22.9		23.2	25.4
% Drinking & Driving in Past Month	3.1		5.0	
Drug-Induced Deaths (Age-Adjusted Death Rate)	15.4	13.5	14.1	11.3
% Illicit Drug Use in Past Month	2.4		4.0	7.1
% Ever Sought Help for Alcohol or Drug Problem	2.3		4.9	
		better	similar	worse

Tobacco Use	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% Current Smoker	16.6	15.5	14.9	12.0
% Someone Smokes at Home	10.6		12.7	
% [Non-Smokers] Someone Smokes in the Home	3.9		6.3	
% [Household With Children] Someone Smokes in the Home	8.2		9.7	
% [Smokers] Received Advice to Quit Smoking	68.2		67.8	
% [Smokers] Have Quit Smoking 1+ Days in Past Year	50.3		55.9	80.0
% Smoke Cigars	4.7		4.1	0.2
% Use Smokeless Tobacco	2.8		4.0	0.3
		better	similar	worse

Vision	Eastern Region	Eastern Region vs. Benchmarks		
		vs. CT	vs. US	vs. HP2020
% Blindness/Trouble Seeing	8.0		8.5	
% Eye Exam in Past 2 Years	68.0		56.8	
		better	similar	worse

Community Description

Professional Research Consultants, Inc.

Population Characteristics

Total Population

The Eastern Region*, the focus of this Community Health Needs Assessment, encompasses 1,587.58 square miles and houses a total population of 543,906 residents, according to latest census estimates.

Total Population
(Estimated Population, 2008–2012)

	Total Population	Total Land Area (Square Miles)	Population Density (Per Square Mile)
Eastern Region	**543,906**	**1,587.58**	**342.6**
Connecticut	3,572,213	4,841.1	737.89
United States	309,138,709	3,530,997.6	87.55

Sources:
- US Census Bureau American Community Survey 5-year estimates (2008-2012).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Population Change 2000-2010

A significant positive or negative shift in total population over time impacts healthcare providers and the utilization of community resources.

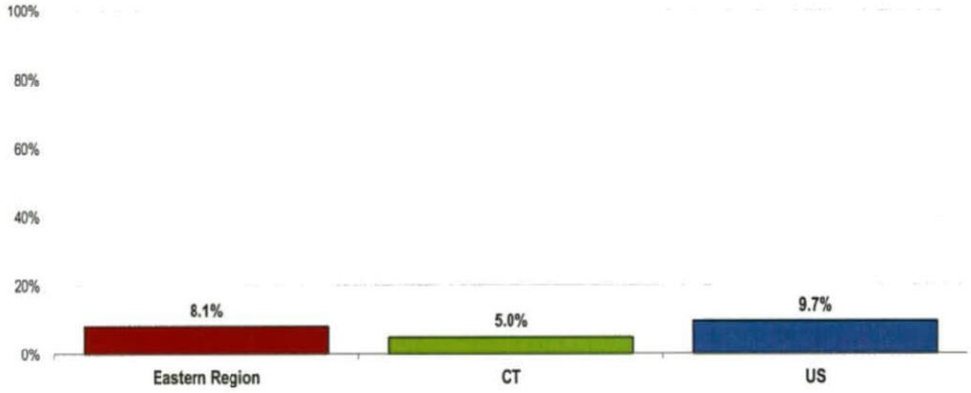
Between the 2000 and 2010 US Censuses, the population of the Eastern Region increased by 8.1%.

- A higher proportional increase than seen across the state.
- A lower proportional increase than seen nationwide.

* Here, as for all secondary data (non-survey data) indicators presented in this report, "Eastern Region" reflects data for the combined area of New London, Tolland and Windham counties. Survey data reflect the ZIP Code-defined region described in the Methodology section of this report.

Change in Total Population

(Percentage Change Between 2000 and 2010)

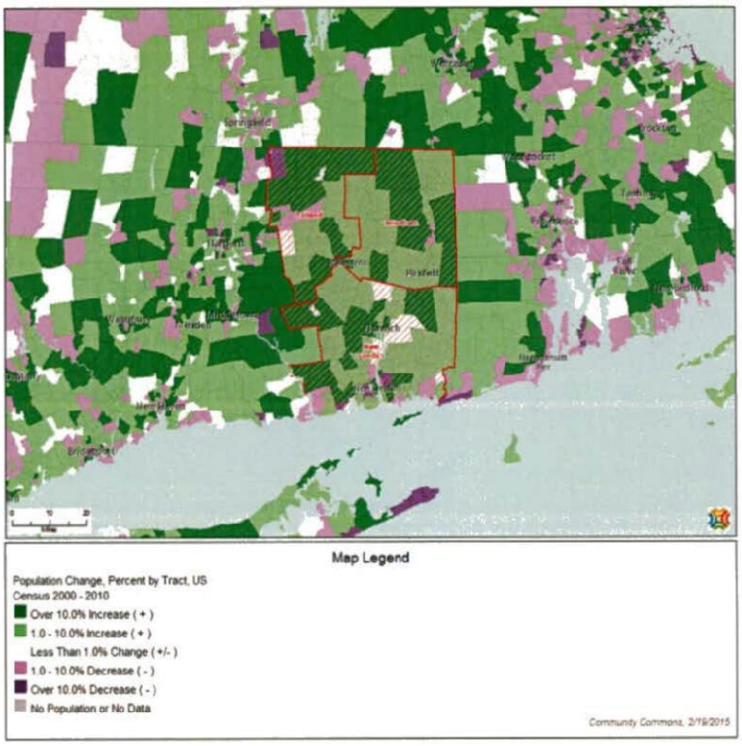


Sources:
- Retrieved February 2015 from Community Commons at http://www.chna.org.
- US Census Bureau Decennial Census (2000-2010).

Notes:
- A significant positive or negative shift in total population over time impacts healthcare providers and the utilization of community resources.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Note that the Eastern Region showed areas of population increases as well as decreases.

Population Change, Percent by Tract, US Census 2000–2010



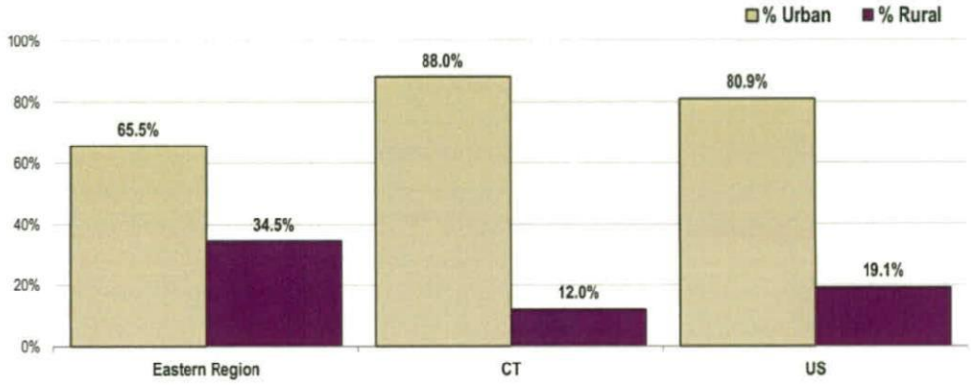
Urban/Rural Population

Urban areas are identified using population density, count, and size thresholds. Urban areas also include territory with a high degree of impervious surface (development). Rural areas are all areas that are not urban.

Nearly two-thirds of the Eastern Region are urban (65.5% of the population lives in areas designated as urban).

- Note that a much-higher proportion of the state and national populations live in urban areas.

Urban and Rural Population
(2010)

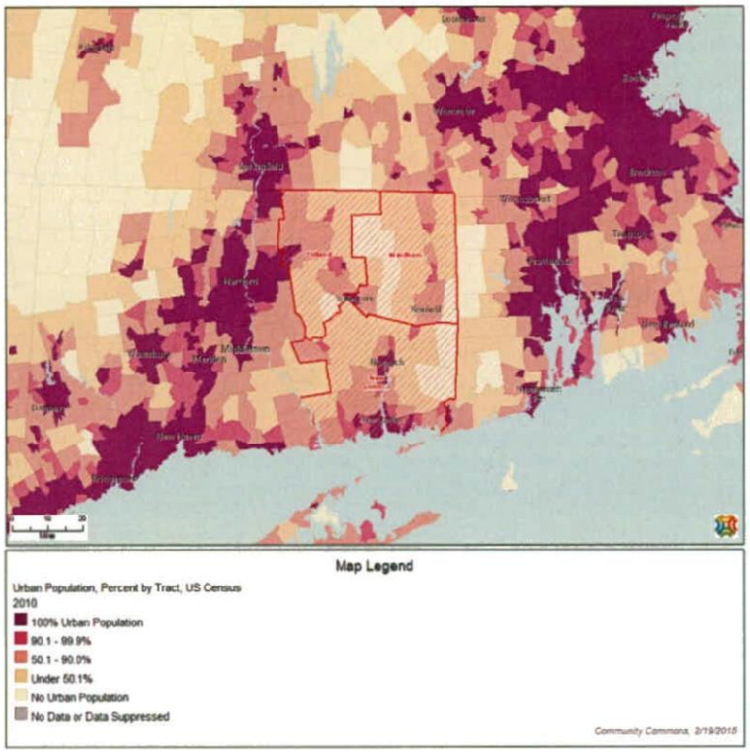


Sources:
- US Census Bureau Decennial Census (2010).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator reports the percentage of population living in urban and rural areas. Urban areas are identified using population density, count, and size threshoids. Urban areas also include territory with a high degree of impervious surface (development). Rural areas are all areas that are not urban.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- Note the following map outlining the urban population in the Eastern Region census tracts as of 2010.

Urban Population,
Percent by Tract, US Census 2010



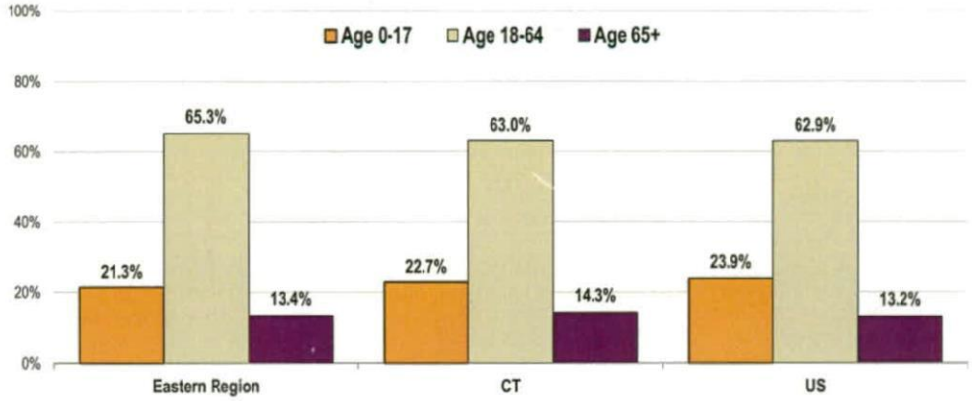
Age

It is important to understand the age distribution of the population as different age groups have unique health needs which should be considered separately from others along the age spectrum.

In the Eastern Region, 21.3% of the population are infants, children or adolescents (age 0-17); another 65.3% are age 18 to 64, while 13.4% are age 65 and older.

- The percentage of older adults (65+) is lower than that found statewide.
- The percentage of older adults (65+) is nearly identical to the US figure.

Total Population by Age Groups, Percent
(2008-2012)



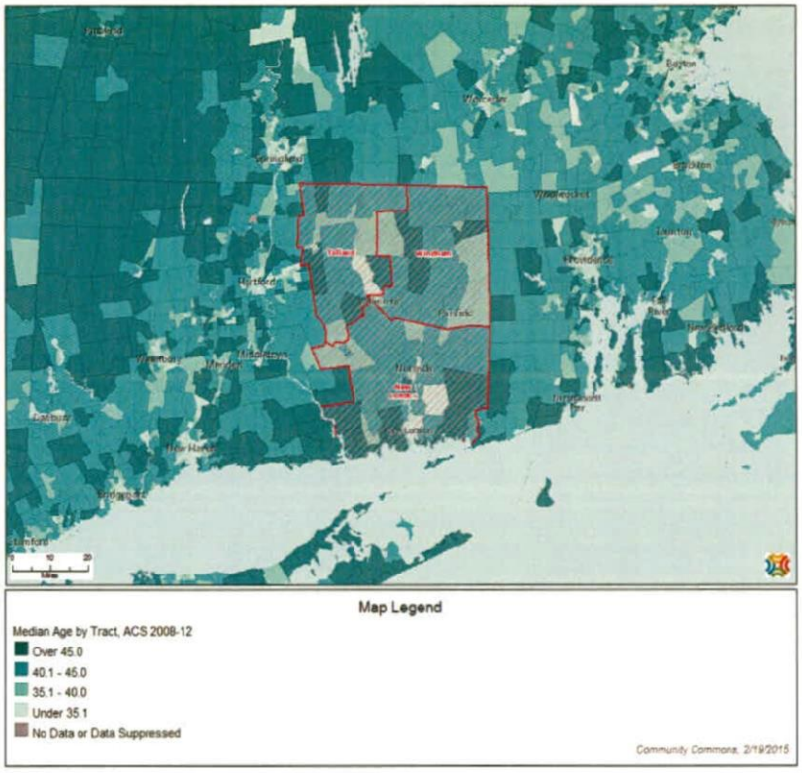
Sources:
- US Census Bureau American Community Survey 5-year estimates (2008-2012).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Median Age

The following map provides an illustration of the median age in the Eastern Region, segmented by census tract.

Median Age, by Tract, ACS 2008–2012



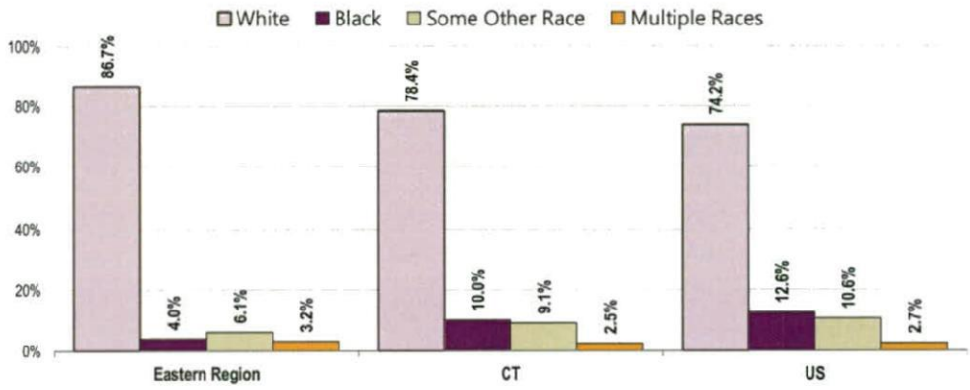
Race & Ethnicity

Race

In looking at race independent of ethnicity (Hispanic or Latino origin), 86.7% of residents of the Eastern Region are White and 4.0% are Black.

- Across the state and nation, the population is less White, more Black, and more "Other" race.

Total Population by Race Alone, Percent
(2008-2012)



Sources:
- US Census Bureau American Community Survey 5-year estimates (2008-2012).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

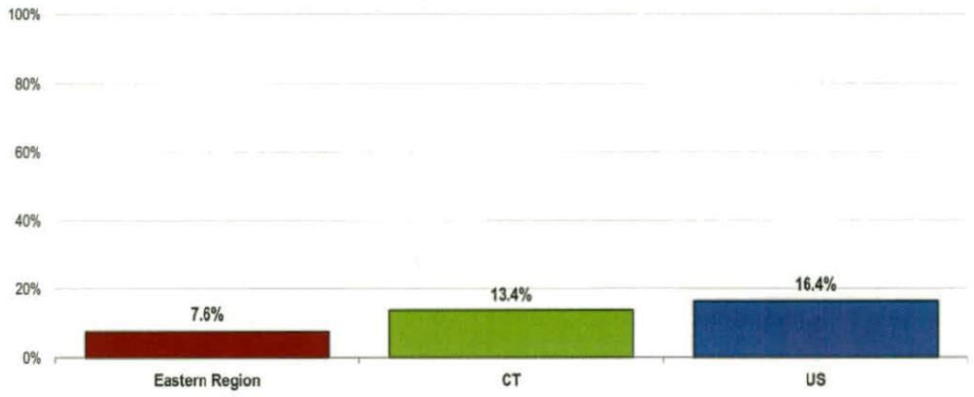
Notes:
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Ethnicity

A total of 7.6% of Eastern Region residents are Hispanic or Latino.

- Lower than found statewide.
- Lower than found nationally.

Percent Population Hispanic or Latino
(2008-2012)

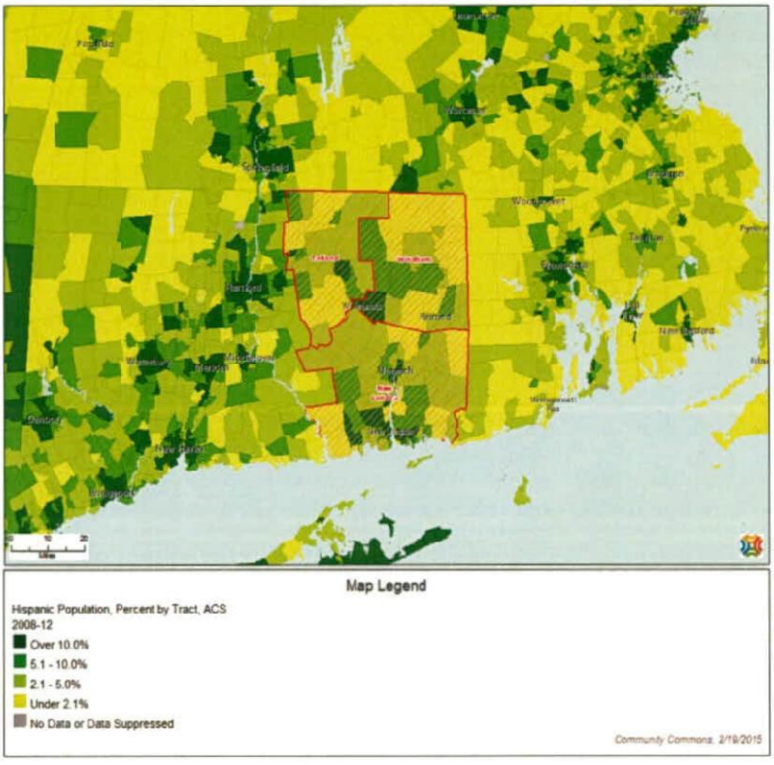


Sources:
- US Census Bureau American Community Survey 5-year estimates (2008-2012).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- Origin can be viewed as the heritage, nationality group, lineage, or country of birth of the person or the person's parents or ancestors before their arrival in the United States. People who identify their origin as Hispanic, Latino, or Spanish may be of any race.

- The map below illustrates the concentration of Hispanic/Latino residents in the area.

Population Hispanic or Latino, Percent by Tract, ACS 2008–2012

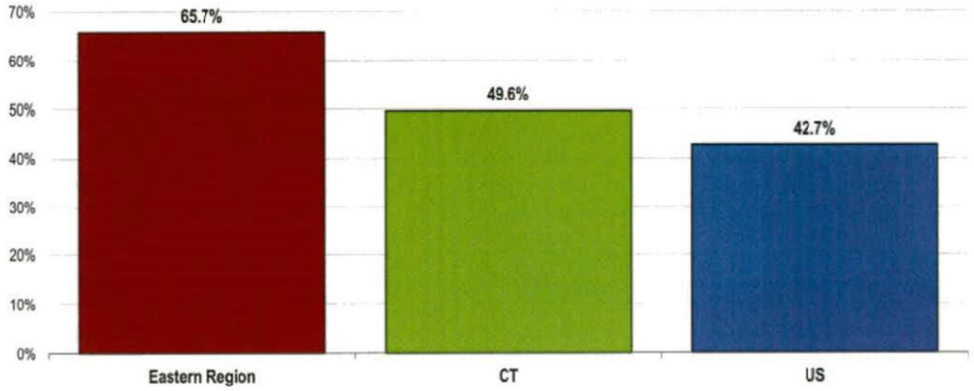


Between 2000 and 2010, the Hispanic population in the Eastern Region increased by 65.7%.

- Higher (in terms of percentage growth) than found statewide.
- Higher (in terms of percentage growth) than found nationally.

Hispanic Population Change

(Percentage Change in Hispanic Population Between 2000 and 2010)



Sources:
- US Census Bureau Decennial Census (2000-2010).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

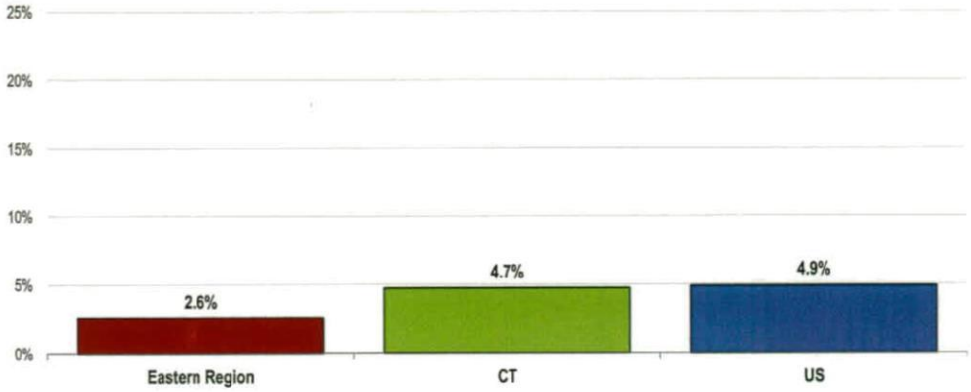
Notes:
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Linguistic Isolation

A total of 2.6% of the Eastern Region population age 5 and older live in a home in which no persons age 14 or older is proficient in English (speaking only English, or speaking English "very well").

- Lower than found statewide.
- Lower than found nationally.

Linguistically Isolated Population
(2008-2012)

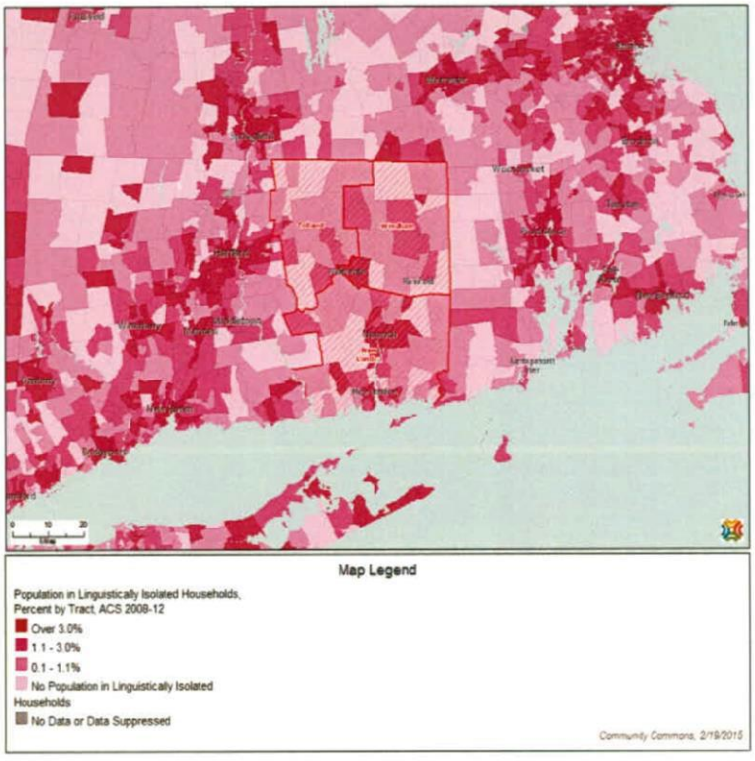


Sources:
- US Census Bureau American Community Survey 5-year estimates (2008-2012).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator reports the percentage of the population aged 5 and older who live in a home in which no person 14 years old and over speaks only English, or in which no person 14 years old and over speak a non-English language and speak English "very well."
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- Note the following map illustrating linguistic isolation in the Eastern Region.

Population in Linguistically Isolated Households, Percent by Tract, ACS 2007-2011



Social Determinants of Health

About Social Determinants

Health starts in our homes, schools, workplaces, neighborhoods, and communities. We know that taking care of ourselves by eating well and staying active, not smoking, getting the recommended immunizations and screening tests, and seeing a doctor when we are sick all influence our health. Our health is also determined in part by access to social and economic opportunities; the resources and supports available in our homes, neighborhoods, and communities; the quality of our schooling; the safety of our workplaces; the cleanliness of our water, food, and air; and the nature of our social interactions and relationships. The conditions in which we live explain in part why some Americans are healthier than others and why Americans more generally are not as healthy as they could be.

- Healthy People 2020 (www.healthypeople.gov)

Poverty

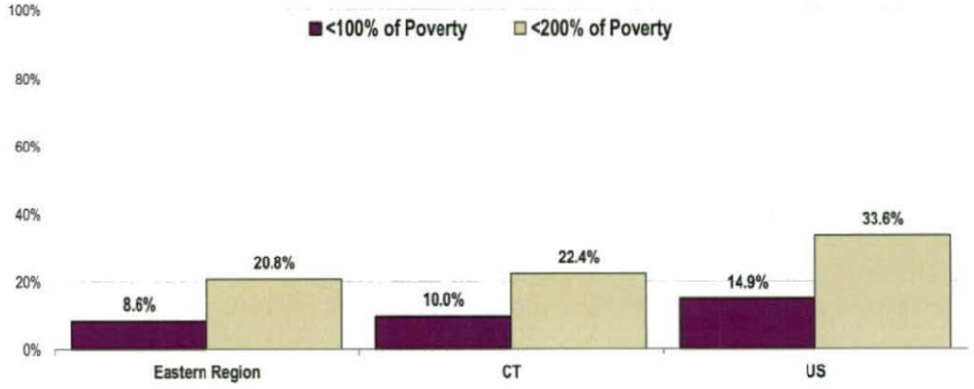
The latest census estimate shows 8.6% of the Eastern Region population living below the federal poverty level.

In all, 20.8% of Eastern Region residents live below 200% of the federal poverty level.

- Lower than the proportion reported statewide.
- Much lower than found nationally.

Population in Poverty

(Populations Living Below 100% and Below 200% of the Poverty Level; 2008-2012)

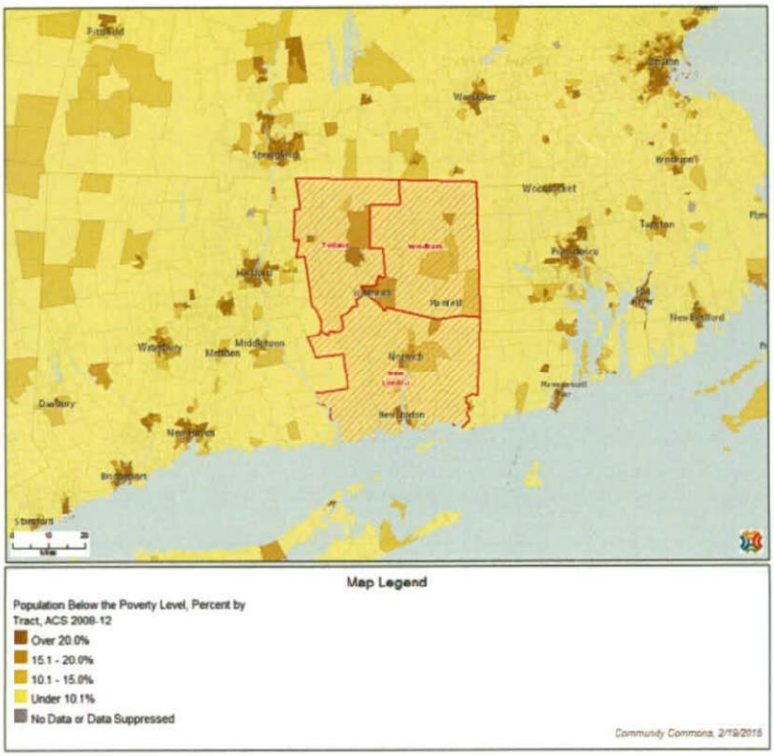


Sources:
- US Census Bureau American Community Survey 5-year estimates (2008-2012).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

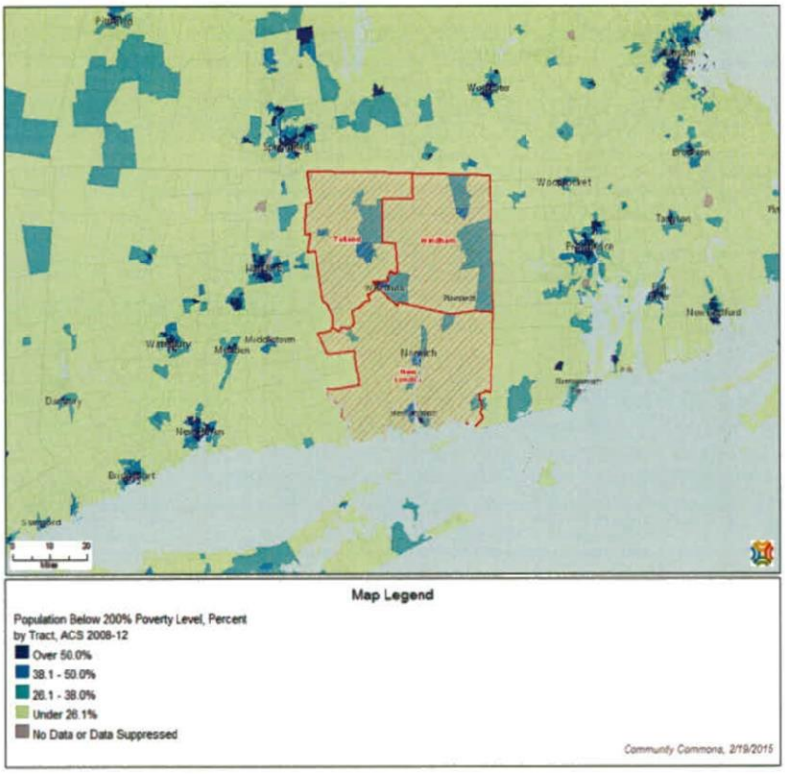
Notes:
- Poverty is considered a key driver of health status. This indicator is relevant because poverty creates barriers to access including health services, healthy food, and other necessities that contribute to poor health status.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- Note the following maps illustrating the concentration of poverty in the area.

Population Below the Poverty Level, Percent by Tract, ACS 2008–2012



Population Below 200% of Poverty, Percent by Tract, ACS 2008–2012



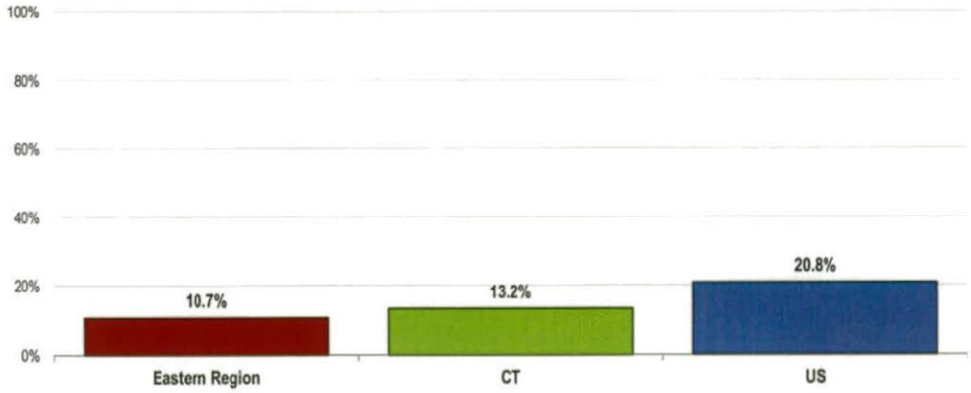
Children in Low-Income Households

Additionally, 10.7% of Eastern Region children age 0-17 live below the 200% poverty threshold.

- Lower than the proportion found statewide.
- Lower than the proportion found nationally.

Percent of Children in Low-Income Households

(Children 0-17 Living Below 200% of the Poverty Level, 2008-2012)

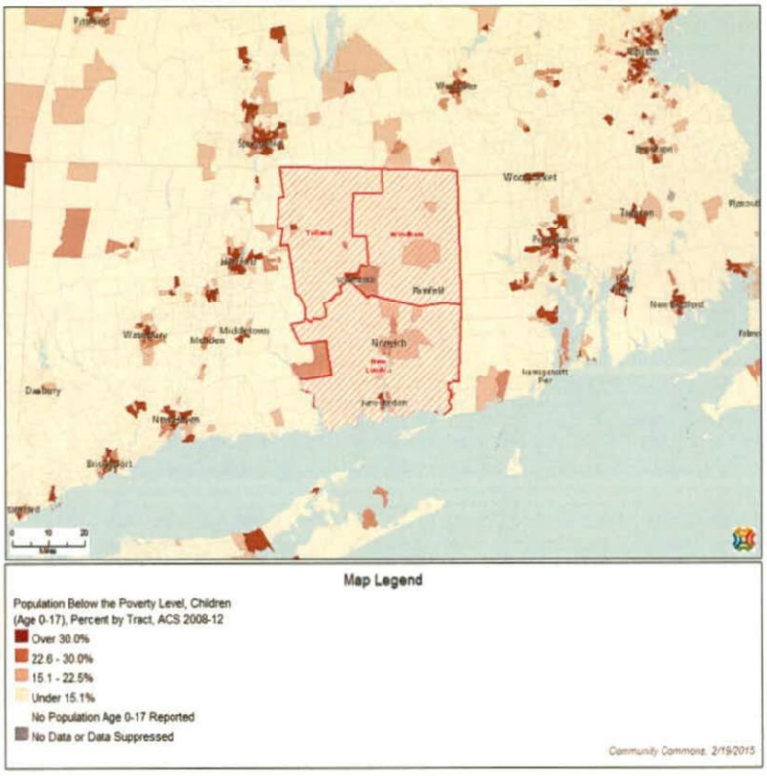


Sources:
- US Census Bureau American Community Survey 5-year estimates (2008-2012).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator reports the percentage of children aged 0-17 living in households with income below 200% of the Federal Poverty Level (FPL). This indicator is relevant because poverty creates barriers to access including health services, healthy food, and other necessities that contribute to poor health status.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- The following map illustrates the geographic distribution of children living below the poverty level in the area.

Children (0-17) Living Below 200% of Poverty, Percent by Tract, ACS 2008–2012



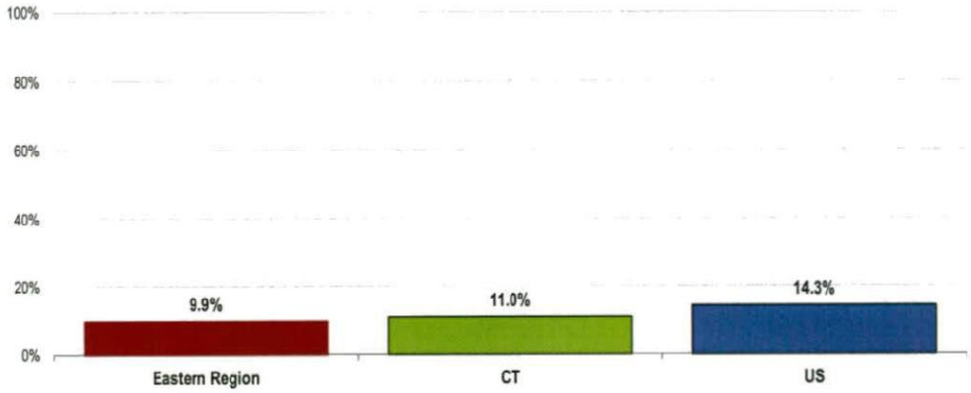
Education

Among the Eastern Region population age 25 and older, 9.9% do not have a high school education.

- More favorable than found statewide.
- More favorable than found nationally.

Population With No High School Diploma

(Population Age 25+ Without a High School Diploma or Equivalent, 2008-2012)

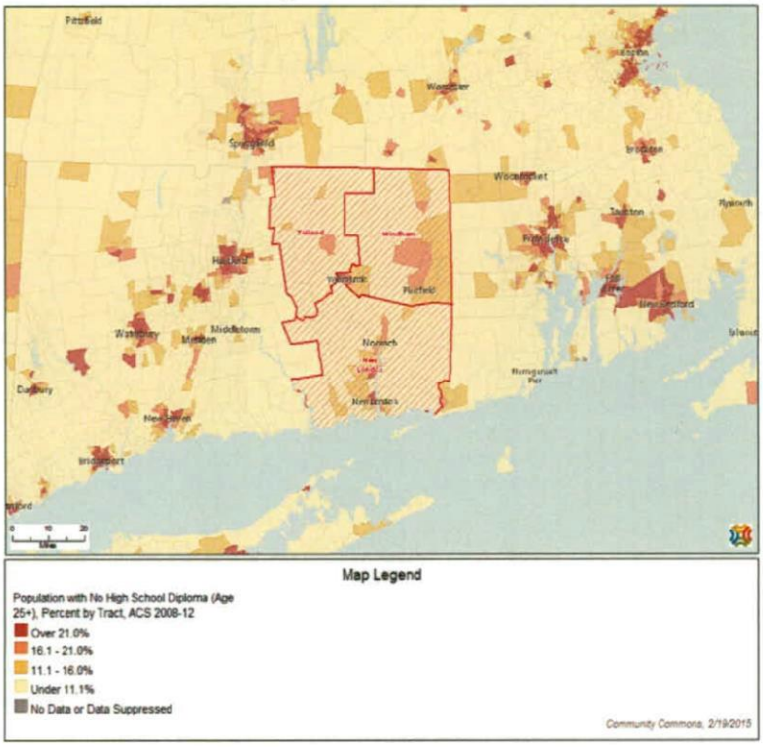


Sources:
- US Census Bureau American Community Survey 5-year estimates (2008-2012).
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator is relevant because educational attainment is linked to positive health outcomes.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- The concentration of those without a high school education is represented geographically in the following map.

Population With No High School Diploma, Percent by Tract, ACS 2008-2012



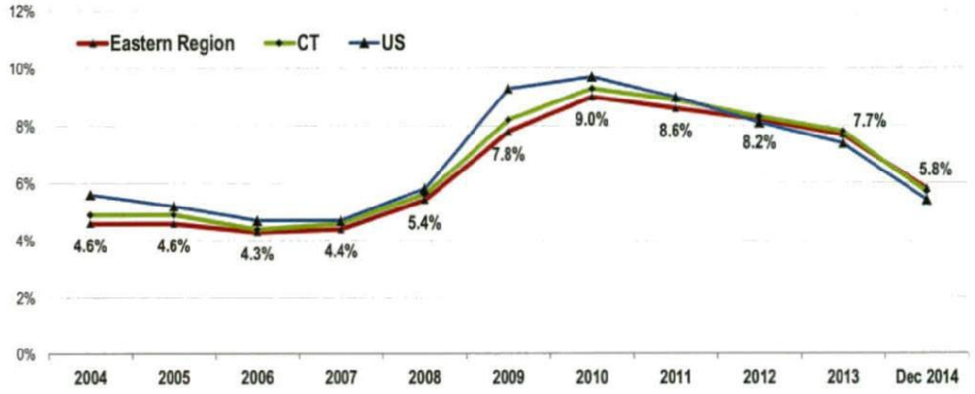
Employment

According to data derived from the US Department of Labor, the unemployment rate in the Eastern Region in December 2014 was 5.8%.

- Comparable to the statewide unemployment rate.
- Comparable to the national unemployment rate.
- TREND: After significant increases in the late 2000s, the unemployment rate in the Eastern Region has decreased since 2010.

Unemployment Rate

(Percent of Non-Institutionalized Population Age 16+ Unemployed, Not Seasonally-Adjusted)



Sources:
- US Department of Labor, Bureau of Labor Statistics.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator is relevant because unemployment creates financial instability and barriers to access including insurance coverage, health services, healthy food, and other necessities that contribute to poor health status.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

General Health Status

Professional Research Consultants, Inc.

Overall Health Status

Self-Reported Health Status

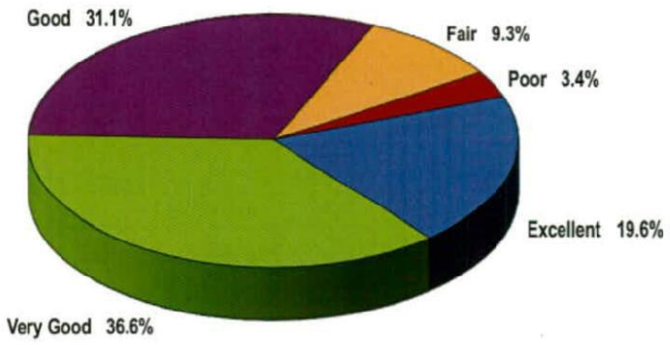
The initial inquiry of the PRC Community Health Survey asked respondents the following:

"Would you say that in general your health is: excellent, very good, good, fair or poor?"

A total of 56.2% of Eastern Region adults rate their overall health as "excellent" or "very good."

- Another 31.1% gave "good" ratings of their overall health.

Self-Reported Health Status
(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 5]
Notes: • Asked of all respondents.

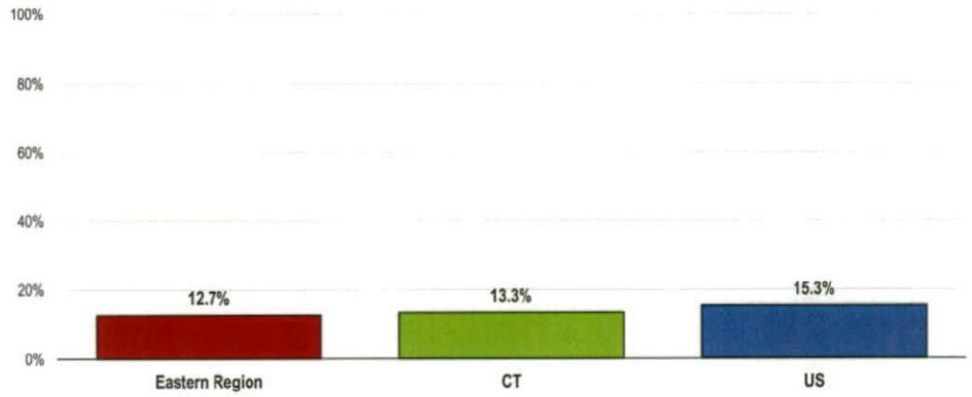
NOTE:

Differences noted in the text represent significant differences determined through statistical testing.

However, 12.7% of Eastern Region adults believe that their overall health is "fair" or "poor."

- Similar to statewide findings.
- Similar to the national percentage.

Experience "Fair" or "Poor" Overall Health



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 5]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

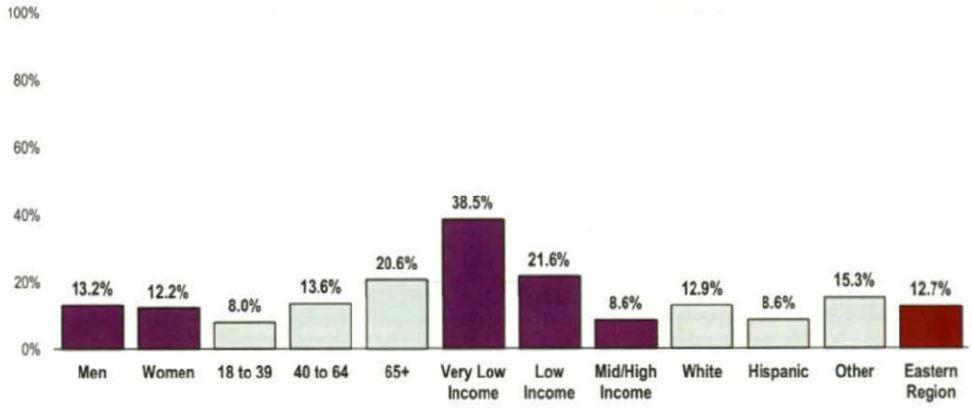
Notes:
- Asked of all respondents.

Adults more likely to report experiencing "fair" or "poor" overall health include:

- Adults age 40 and older (note the positive correlation with age).
- Residents living at very low incomes (note the negative correlation with income).
- Other differences by demographic characteristics (such as gender or race/ethnicity) are not statistically significant in this case.

Charts throughout this report (such as that here) detail survey findings among key demographic groups – namely by gender, age groupings, income (based on poverty status), and race/ethnicity.

Experience "Fair" or "Poor" Overall Health
(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 5]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Activity Limitations

RELATED ISSUE:
See also *Potentially Disabling Conditions* in the **Death, Disease & Chronic Conditions** section of this report.

About Disability & Health

An individual can get a disabling impairment or chronic condition at any point in life. Compared with people without disabilities, people with disabilities are more likely to:

- Experience difficulties or delays in getting the health care they need.
- Not have had an annual dental visit.
- Not have had a mammogram in past 2 years.
- Not have had a Pap test within the past 3 years.
- Not engage in fitness activities.
- Use tobacco.
- Be overweight or obese.
- Have high blood pressure.
- Experience symptoms of psychological distress.
- Receive less social-emotional support.
- Have lower employment rates.

There are many social and physical factors that influence the health of people with disabilities. The following three areas for public health action have been identified, using the International Classification of Functioning, Disability, and Health (ICF) and the three World Health Organization (WHO) principles of action for addressing health determinants.

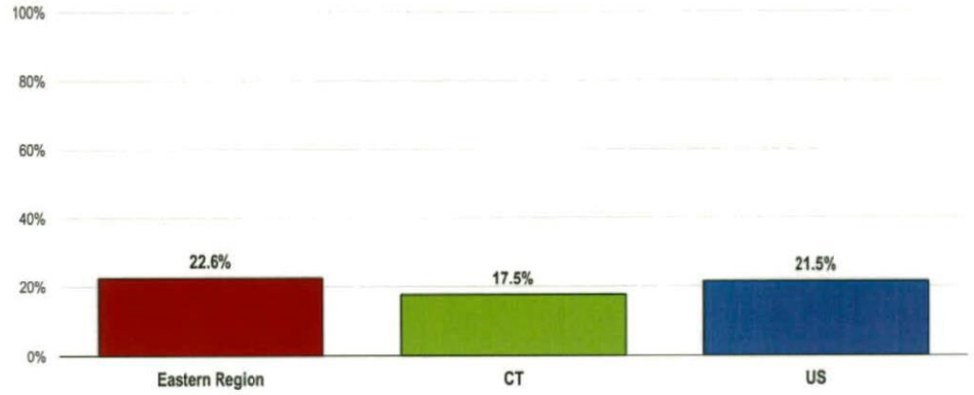
- **Improve the conditions of daily life** by: encouraging communities to be accessible so all can live in, move through, and interact with their environment; encouraging community living; and removing barriers in the environment using both physical universal design concepts and operational policy shifts.
- **Address the inequitable distribution of resources among people with disabilities and those without disabilities** by increasing: appropriate health care for people with disabilities; education and work opportunities; social participation; and access to needed technologies and assistive supports.
- **Expand the knowledge base and raise awareness about determinants of health for people with disabilities** by increasing: the inclusion of people with disabilities in public health data collection efforts across the lifespan; the inclusion of people with disabilities in health promotion activities; and the expansion of disability and health training opportunities for public health and health care professionals.

- Healthy People 2020 (www.healthypeople.gov)

A total of 22.6% of Eastern Region adults are limited in some way in some activities due to a physical, mental or emotional problem.

- Worse than the statewide prevalence.
- Similar to the national prevalence.

Limited in Activities in Some Way Due to a Physical, Mental or Emotional Problem



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 105]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

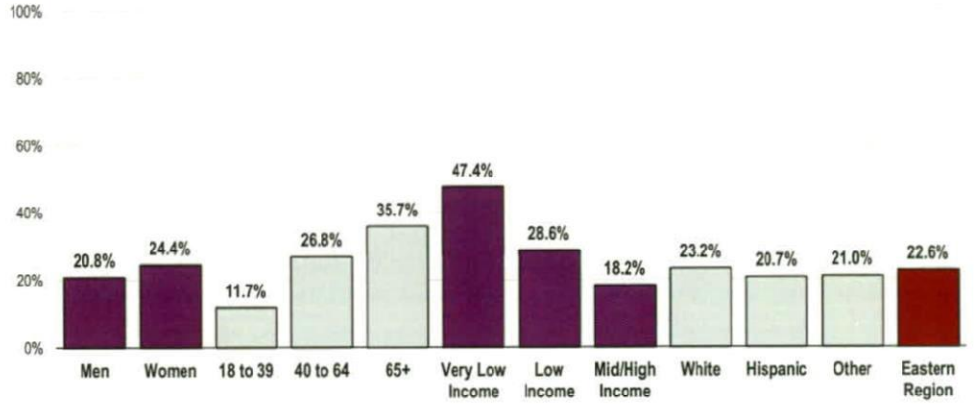
Notes:
- Asked of all respondents.

In looking at responses by key demographic characteristics, note the following:

- Adults age 40 and older are much more often limited in activities (note the positive correlation with age).
- Those with very low incomes are much more likely than those with higher incomes to report activity limitations.

Limited in Activities in Some Way Due to a Physical, Mental or Emotional Problem

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 105]

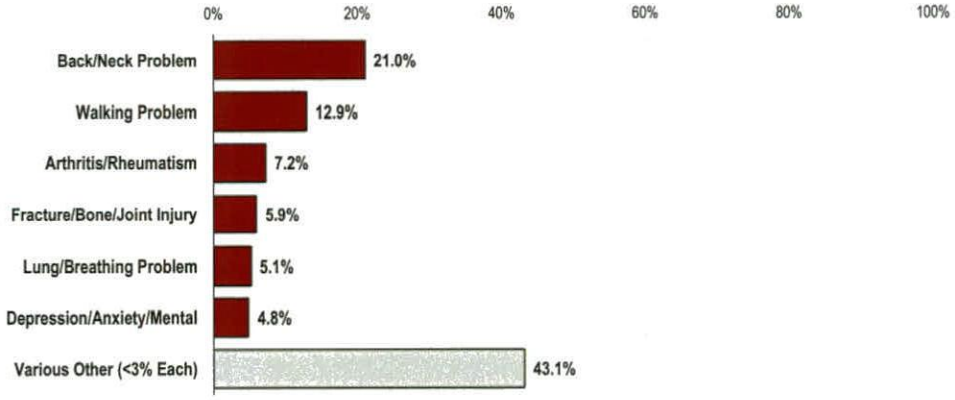
Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Among persons reporting activity limitations, these are most often attributed to musculo-skeletal issues, such as back/neck problems, problems walking, arthritis/ rheumatism, or fractures or bone/joint injuries.

Other limitations mentioned with some frequency included lung/breathing problems and depression/mental health issues.

Type of Problem That Limits Activities

(Among Those Reporting Activity Limitations; Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 106]
Notes: • Asked of those respondents reporting activity limitations.

Mental Health

RELATED ISSUE:

See also *Potentially Disabling Conditions* in the **Death, Disease & Chronic Conditions** section of this report.

About Mental Health & Mental Disorders

Mental health is a state of successful performance of mental function, resulting in productive activities, fulfilling relationships with other people, and the ability to adapt to change and to cope with challenges. Mental health is essential to personal well-being, family and interpersonal relationships, and the ability to contribute to community or society. Mental disorders are health conditions that are characterized by alterations in thinking, mood, and/or behavior that are associated with distress and/or impaired functioning. Mental disorders contribute to a host of problems that may include disability, pain, or death. Mental illness is the term that refers collectively to all diagnosable mental disorders. Mental disorders are among the most common causes of disability. The resulting disease burden of mental illness is among the highest of all diseases.

Mental health and physical health are closely connected. Mental health plays a major role in people's ability to maintain good physical health. Mental illnesses, such as depression and anxiety, affect people's ability to participate in health-promoting behaviors. In turn, problems with physical health, such as chronic diseases, can have a serious impact on mental health and decrease a person's ability to participate in treatment and recovery.

The existing model for understanding mental health and mental disorders emphasizes the interaction of social, environmental, and genetic factors throughout the lifespan. In behavioral health, researchers identify: **risk factors**, which predispose individuals to mental illness; and **protective factors**, which protect them from developing mental disorders. Researchers now know that the prevention of mental, emotional, and behavioral (MEB) disorders is inherently interdisciplinary and draws on a variety of different strategies. Over the past 20 years, research on the prevention of mental disorders has progressed. The major areas of progress include evidence that:

- MEB disorders are common and begin early in life.
- The greatest opportunity for prevention is among young people.
- There are multiyear effects of multiple preventive interventions on reducing substance abuse, conduct disorder, antisocial behavior, aggression, and child maltreatment.
- The incidence of depression among pregnant women and adolescents can be reduced.
- School-based violence prevention can reduce the base rate of aggressive problems in an average school by 25 to 33%.
- There are potential indicated preventive interventions for schizophrenia.
- Improving family functioning and positive parenting can have positive outcomes on mental health and can reduce poverty-related risk.
- School-based preventive interventions aimed at improving social and emotional outcomes can also improve academic outcomes.
- Interventions targeting families dealing with adversities, such as parental depression or divorce, can be effective in reducing risk for depression in children and increasing effective parenting.
- Some preventive interventions have benefits that exceed costs, with the available evidence strongest for early childhood interventions.
- Implementation is complex, it is important that interventions be relevant to the target audiences.
- In addition to advancements in the prevention of mental disorders, there continues to be steady progress in treating mental disorders as new drugs and stronger evidence-based outcomes become available.

- Healthy People 2020 (www.healthypeople.gov)

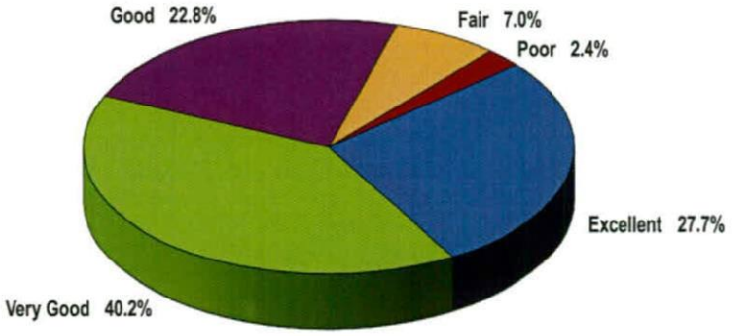
Self-Reported Mental Health Status

"Now thinking about your mental health, which includes stress, depression and problems with emotions, would you say that, in general, your mental health is: excellent, very good, good, fair or poor?"

A total of 67.9% of Eastern Region adults rate their overall mental health as "excellent" or "very good."

- Another 22.8% gave "good" ratings of their own mental health status.

Self-Reported Mental Health Status
(Eastern Region, 2015)

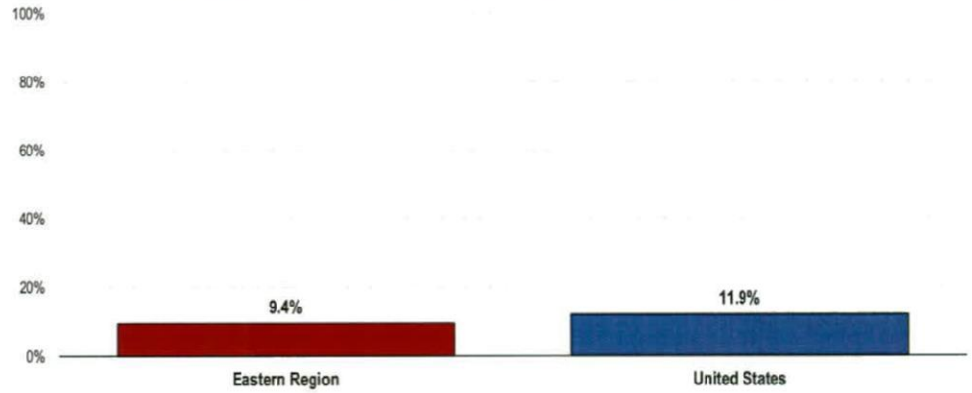


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 100]
Notes: • Asked of all respondents.

A total of 9.4% of Eastern Region adults, however, believe that their overall mental health is "fair" or "poor."

- Better than the "fair/poor" response reported nationally.

Experience "Fair" or "Poor" Mental Health

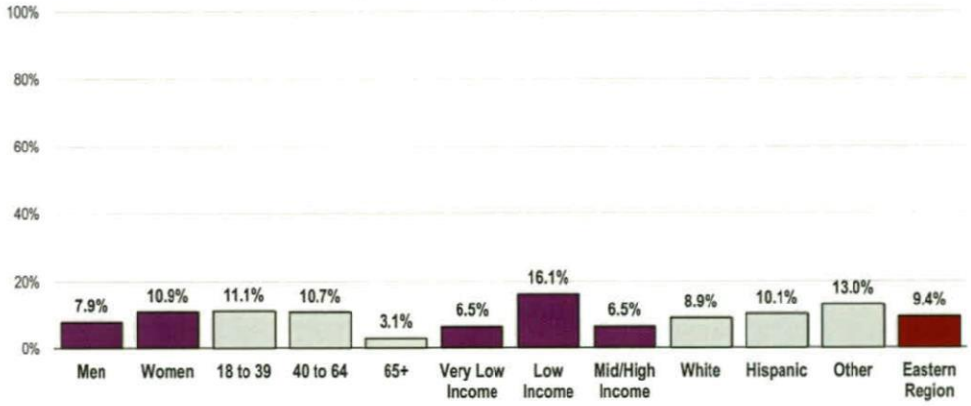


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 100]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

- Adults under 65 and those living just above the federal poverty level are much more likely to experience "fair" or "poor" mental health.

Experience "Fair" or "Poor" Mental Health

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 100]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

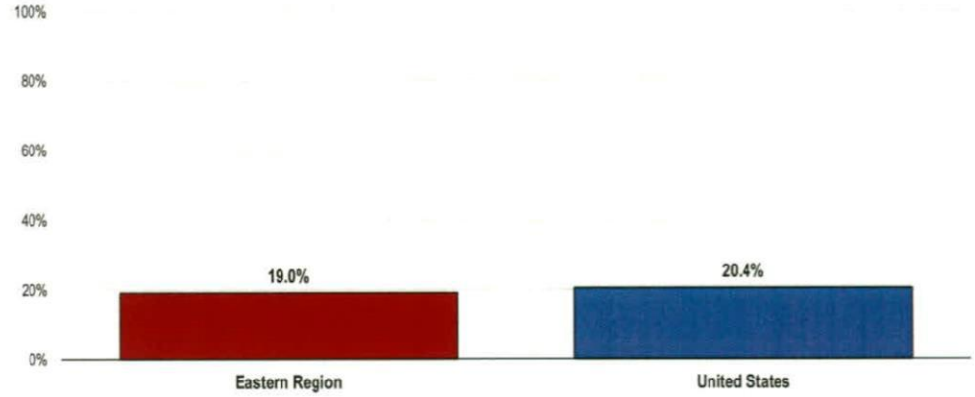
Depression

Diagnosed Depression

A total of 19.0% of Eastern Region adults have been diagnosed by a physician as having a depressive disorder (such as depression, major depression, dysthymia, or minor depression).

- Statistically similar to the national finding.

Have Been Diagnosed With a Depressive Disorder



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 103]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

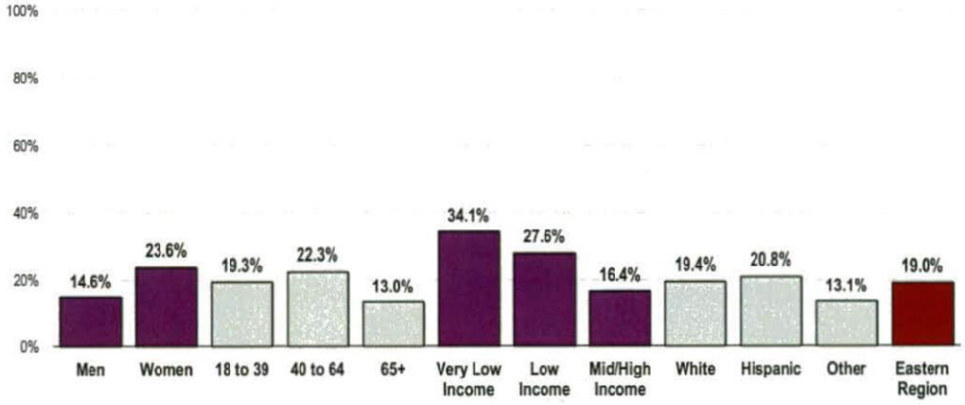
Notes:
- Asked of all respondents.
- Depressive disorders include depression, major depression, dysthymia, or minor depression.

The prevalence of diagnosed depression is higher among:

- Women.
- Adults younger than 65.
- Community members living at lower incomes (negative correlation).

Have Been Diagnosed With a Depressive Disorder

(Eastern Region, 2015)



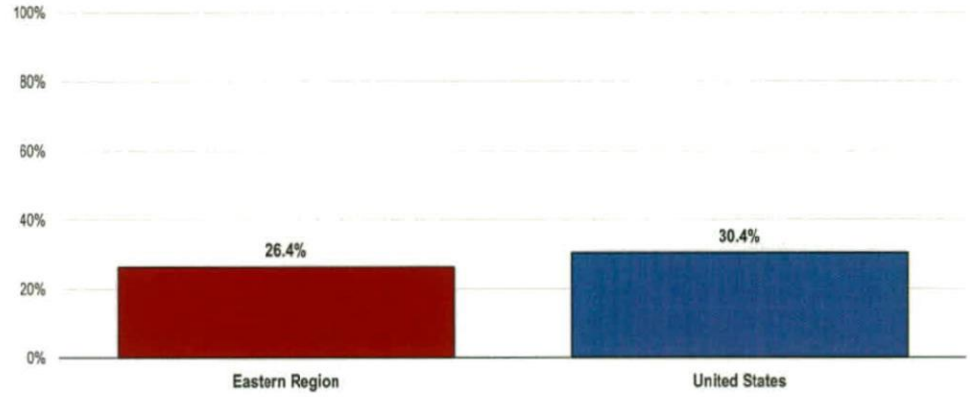
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 103]
Notes: • Asked of all respondents.
• Depressive disorders include depression, major depression, dysthymia, or minor depression.
• Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Symptoms of Chronic Depression

A total of 26.4% of Eastern Region adults have had two or more years in their lives when they felt depressed or sad on most days, although they may have felt okay sometimes (symptoms of chronic depression).

- More favorable than the national findings.

Have Experienced Symptoms of Chronic Depression



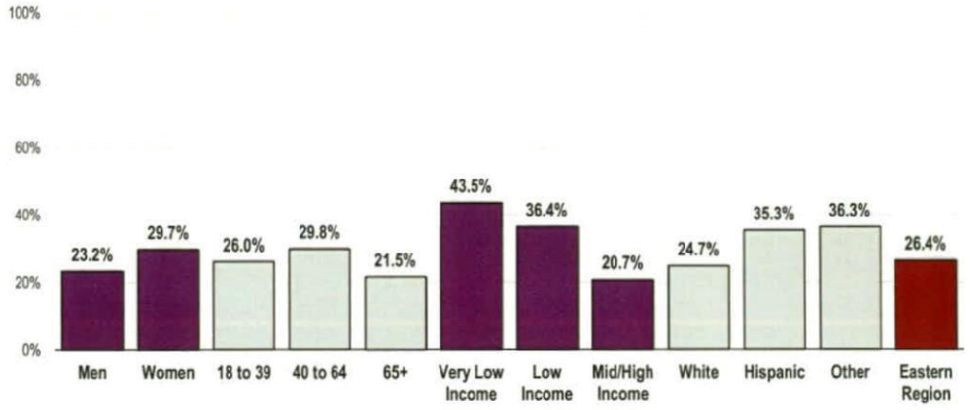
Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 101]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.
- Chronic depression includes periods of two or more years during which the respondent felt depressed or sad on most days, even if (s)he felt okay sometimes.

Note that the prevalence of chronic depression is notably higher among:

- Women.
- Adults age 40 to 64.
- Adults with lower incomes (negative correlation with income).
- Hispanics and residents of "Other" races.

Have Experienced Symptoms of Chronic Depression
(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 101]

Notes:
- Asked of all respondents.
- Chronic depression includes periods of two or more years during which the respondent felt depressed or sad on most days, even if (s)he felt okay sometimes.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level. level.

Stress

A total of 42.2% of Eastern Region adults consider their typical day to be "not very stressful" (29.1%) or "not at all stressful" (13.1%).

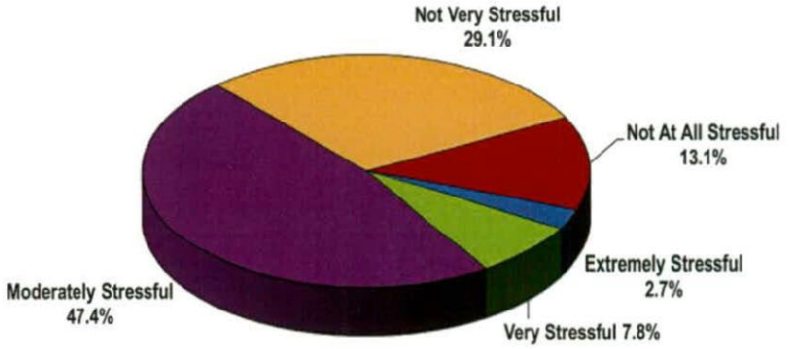
RELATED ISSUE:

See also *Substance Abuse* in the **Modifiable** Health Risks section of this report.

- Another 47.4% of survey respondents characterize their typical day as "moderately stressful."

Perceived Level of Stress On a Typical Day

(Eastern Region, 2015)

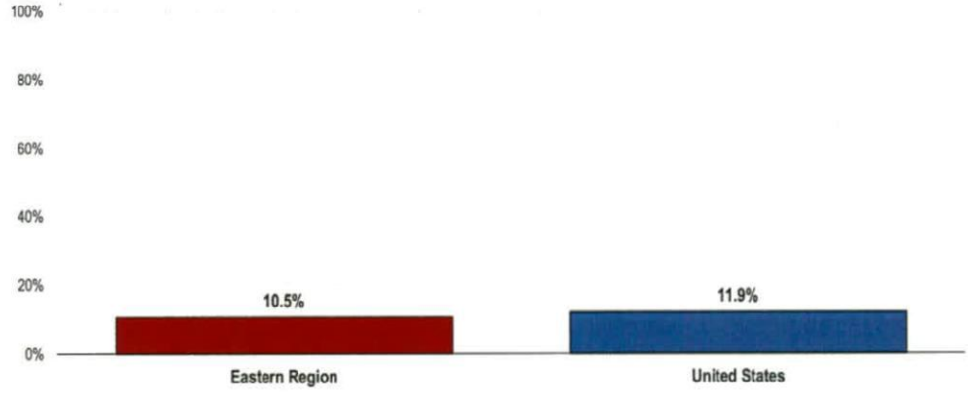


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 102]
Notes: • Asked of all respondents.

In contrast, 10.5% of Eastern Region adults experience "very" or "extremely" stressful days on a regular basis.

- Similar to national findings.

Perceive Most Days As "Extremely" or "Very" Stressful

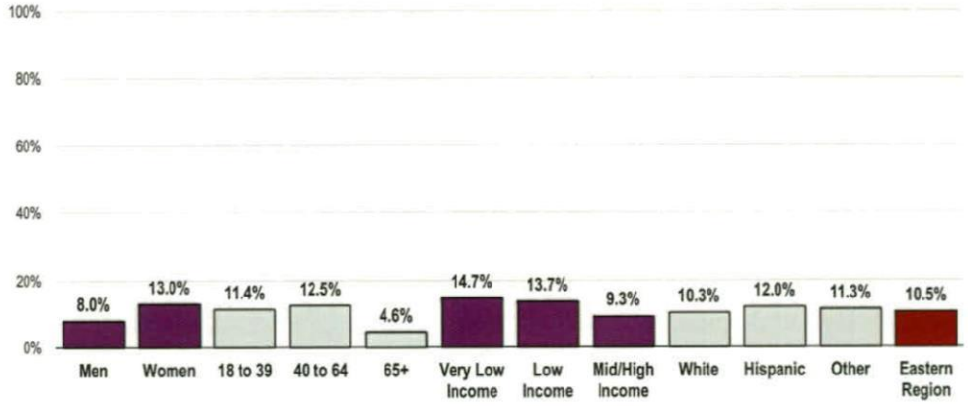


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 102]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

- Note that high stress levels are more prevalent among women and adults younger than 65.

Perceive Most Days as "Extremely" or "Very" Stressful

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 102]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Suicide

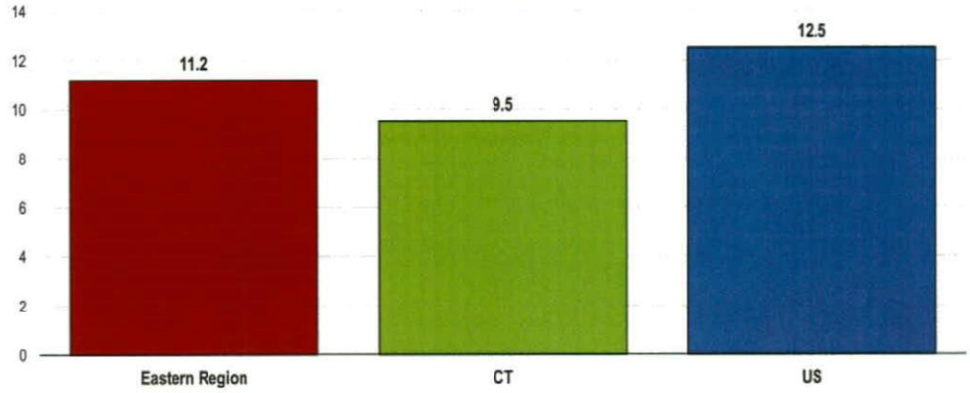
Between 2011 and 2013, there was an annual average age-adjusted suicide rate of 11.2 deaths per 100,000 population in the Eastern Region.

- Higher than the statewide rate.
- Lower than the national rate.
- Fails to satisfy the Healthy People 2020 target of 10.2 or lower.

Suicide: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 10.2 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective MHMD-1]

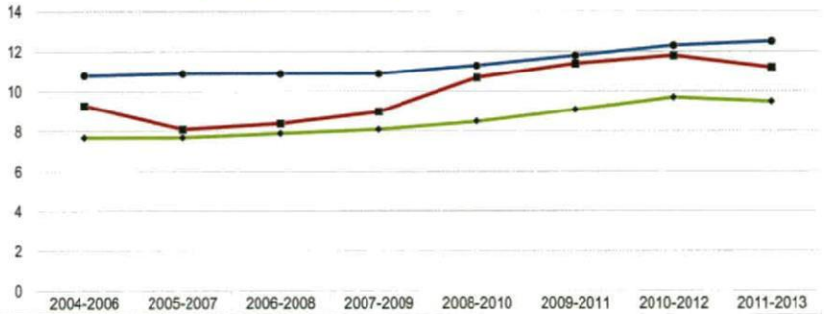
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The area suicide rate has increased from 2004-2006 benchmark data.

Suicide: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 10.2 or Lower



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	9.3	8.1	8.4	9.0	10.7	11.4	11.8	11.2
Connecticut	7.7	7.7	7.9	8.1	8.5	9.1	9.7	9.5
United States	10.8	10.9	10.9	10.9	11.3	11.8	12.3	12.5

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective MHMD-1]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Mental Health Treatment

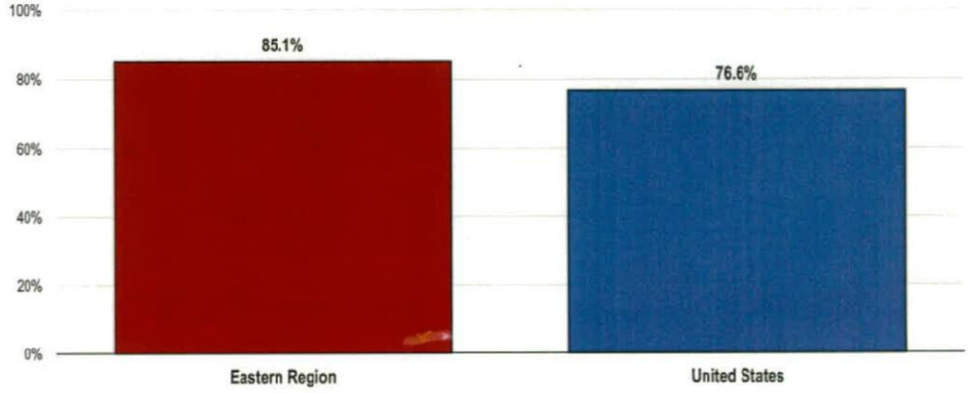
Among adults with a diagnosed depressive disorder, 85.1% acknowledge that they have sought professional help for a mental or emotional problem.

"Diagnosed depressive disorder" includes respondents reporting a past diagnosis of a depressive disorder by a physician (such as depression, major depression, dysthymia, or minor depression).

- Higher than national findings.

Adults With Diagnosed Depression Who Have Ever Sought Professional Help for a Mental or Emotional Problem

(Among Adults With Diagnosed Depressive Disorder)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 123]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Reflects those respondents with a depressive disorder diagnosed by a physician (such as depression, major depression, dysthymia, or minor depression).

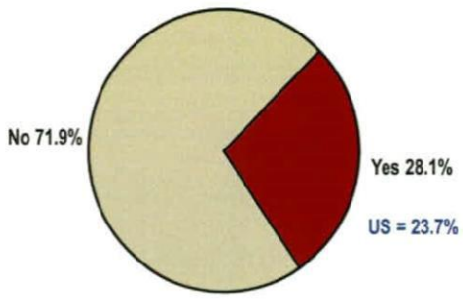
Treatment for Self

In all, 28.1% of Eastern Region adults have sought help from a professional for a mental or emotional problem. Of these adults, 43.8% have sought treatment within the past 12 months.

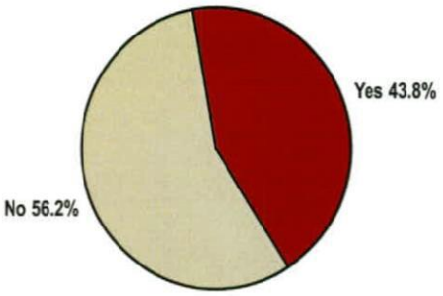
- The national percentage for seeking mental health treatment is 23.7% (lower than the Eastern Region percentage).

Adults Seeking Professional Help for Mental Health Issues

(Eastern Region, 2015)



Have Sought Professional Help for Mental Health Issues



Sought Help in the Past Year
(Among Those Seeking Help)

Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 104, 310]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

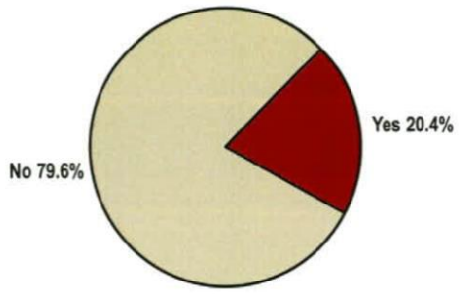
Treatment for Household Member

A total of 20.4% of Eastern Region adults said a household member has sought mental health services within the past 12 months. Of this group, 95.0% received the services they needed.

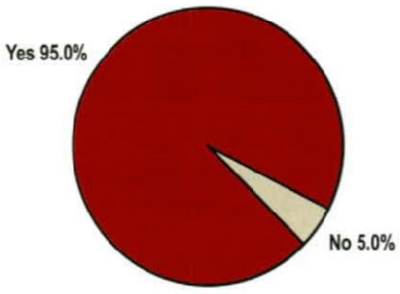
Those who were unable to get mental health services most often cited lack of available services, stigma, difficulty in getting an appointment, no information on where to seek help, and insurance reasons as the main barriers to care.

Member of Household Sought Mental Health Services in the Past Year

(Eastern Region, 2015)



Member of Household Sought Professional Help for Mental Health Issues in the Past Year



Received the Care That Was Needed
(Among Those Seeking Help in Past Year)

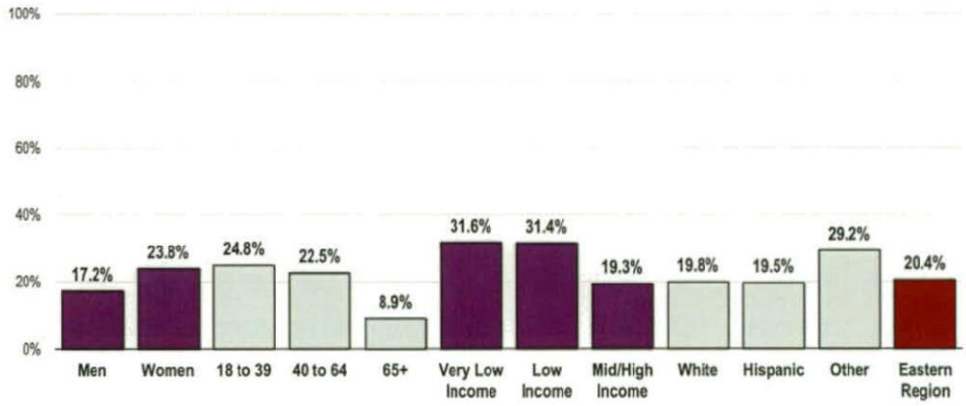
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 311, 312]
Notes: • Asked of all respondents.

Those more likely to mention that someone in the household sought mental health services include:

- Women.
- Adults younger than 65.
- Residents with lower incomes.

Member of Household Sought Professional Help for Mental Health in the Past Year

(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 311]
Notes: • Asked of all respondents.
• Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

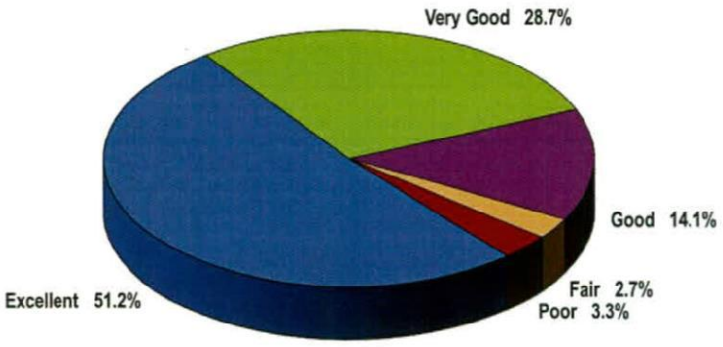
Pediatric Mental Health Treatment

Eastern Region households with children were asked to rate their child's mental health status. A total of 8 in 10 (79.9%) said "excellent" or "very good."

- Another 14.1% gave "good" ratings of their child's mental health.

Child's Reported Mental Health Status

(Eastern Region Children <18, 2015)



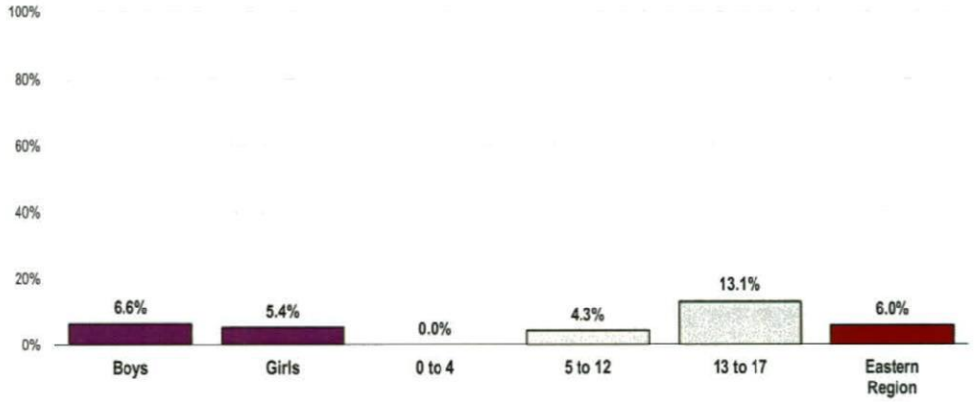
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 315]
Notes: • Asked of all respondents with children under 18 at home.

A total of 6.0%, however, reported that their child's mental health was "fair" or "poor."

- "Fair" and "poor" evaluations were notably higher for children age 5 and older (positive correlation with age) but were statistically similar by gender.

Child Experiences "Fair" or "Poor" Mental Health

(Eastern Region Children <18, 2015)

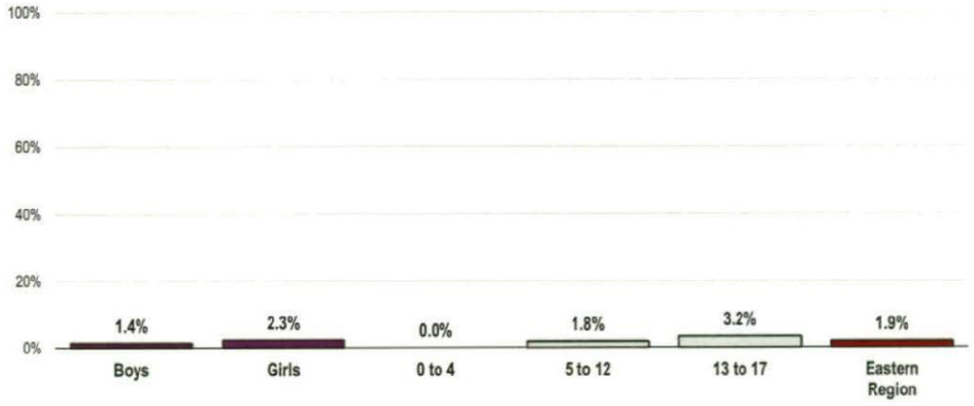


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 315]
Notes: • Asked of all respondents with children under 18 at home.
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Of Eastern Region households with children, 1.9% said there was a time in the past 12 months when their child needed mental health treatment but could not get it.

- Those more likely to experience difficulty in getting pediatric mental health care were children age 5 and older (note the correlation with age).

Could Not Get Necessary Mental Health Services for Child in the Past Year
(Eastern Region Children <18, 2015)

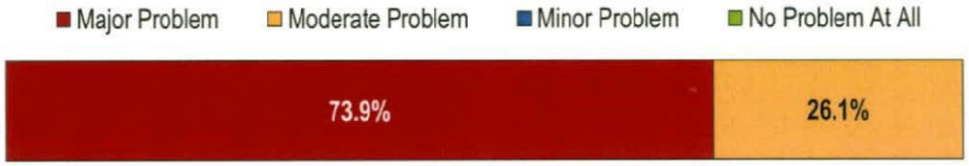


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 316]
Notes: • Asked of all respondents with children under 18 at home.
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Key Informant Input: Mental Health

The greatest share of key informants taking part in an online survey characterized *Mental Health* as a "major problem" in the community.

Perceptions of Mental Health as a Problem in the Community
(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Challenges

Among those rating this issue as a "major problem," the following represent what key informants see as the main challenges for persons with mental illness:

Lack of Services, Coordinated Long-Term Care

> *Not enough services and the way that services are provided. The mental health system especially for low income people is very limited and often does not provide services in the way that people need them. - Social Services Representative*

Lack of access, lack of providers, cost, specialist work with youth. - Social Services Representative

Our area cannot recruit enough providers to meet the need for all ages. Not enough capacity. - Health Provider

Reimbursement rates and coverage for individuals and agencies providing services. Lack of treatment facilities and programs for severe behavioral health issues and individuals struggling to function in society. - Public Health Expert

Accessing a variety of treatment resources and various levels of care. There is a gap in mid-level care. - Health Provider

Lack of coordinated care. - Public Health Expert

I think one of the biggest challenges for those with mental health in this area is lack of long-term care. In other words, I think we do a great job in identifying and treating those in an acute phase of their illness, but after the initial 30 to 60 days the clients seem to fall off their treatment plans and there is no way to follow up until they re-enter the system in another acute episode. There is also a lack of resources at the school system level. Early identification of illness within families could help get clients directed to treatment resources before it becomes a crisis. - Public Health Expert

Housing and consistent health care. - Community/Business Leader

Adequate mental health services for young children, especially those on the Autism Spectrum or with other behavioral disorders. Prevalence is increasing, and the number of professionals trained to provide the broad scope of services that can help is inadequate. Since these disorders cover such a broad spectrum, there needs to be a wide array of treatment options, and those need to be covered by insurance. Once kids "age out" of school, there is virtually no help for them unless they are so disabled that they fall into the DDS range of services. - Health Provider

Access to Care

Access to treatment and identifying of mental health issues. - Social Services Representative

One of the biggest challenges would be to look for treatment and maintain it. As far as I know there isn't that much information open to the community regarding organizations and or programs that help out with mental health. - Social Services Representative

Mental health outpatient services at Backus are not doing well. Inpatient is adequate. - Social Services Representative

Insurance limitations, including limiting the number of visits, preauthorization requirements and especially the fear people have that if they access mental health services, they'll be stigmatized. Also, given our diverse community, truly understanding cultural values and views regarding mental health issues is a gap. - Health Provider

Access to quality psychiatric care, including physicians and clinicians - and those who are available are not always very skilled or well qualified. For chronically mentally ill, a lack of financial resources compounds the problem and they have significant issues with basic needs, and difficulties with their physical health, and managing day to day concerns. Case management resources for helping with this and their mental health concerns is lacking. More supportive housing is needed. - Social Services Representative

Not knowing where to go when in crisis. - Health Provider

Stigma

There is a skepticism of mental health being seen negatively. For example, among the Latino community and/or Haitian, mental health issues are a sign of weakness and/or punishment on the family (disgrace). Therefore individuals in this community, do not foresee any treatment options and or even think about getting treated. - Social Services Representative

Stigma. - Public Health Expert

Stigma. - Social Services Representative

Stigma, poor communication between area hospital and community services, lack of appropriately funded outreach services, lack of accessible, integrative treatment. - Social Services Representative

Limited Funding

Mental health is of epidemic proportions with little focus on funding. - Health Provider

Death, Disease & Chronic Conditions

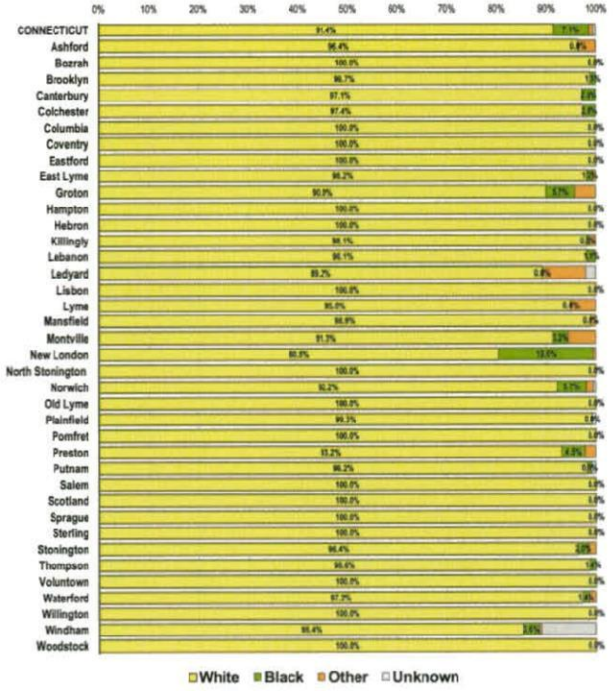
Professional Research Consultants, Inc.

Characteristics of Death

Deaths by Race & Ethnicity

The following graph illustrates the distribution of deaths by race. Note that significant shares of deaths in New London were among Black residents.

Resident Deaths by Race
(By Select Towns in the East Region, 2011)

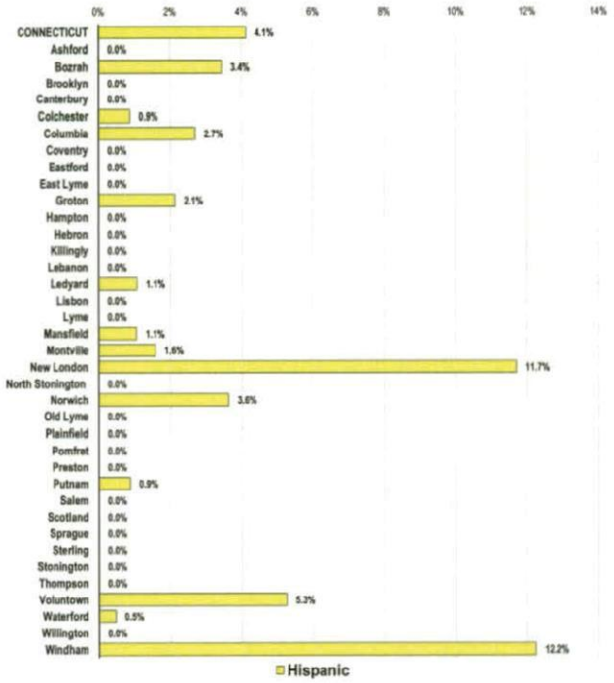


Source: • Connecticut Department of Public Health

By ethnicity, New London and Windham had among the highest proportions of deaths that were among Hispanics.

Resident Deaths by Ethnicity

(By Select Towns in the East Region 2011)



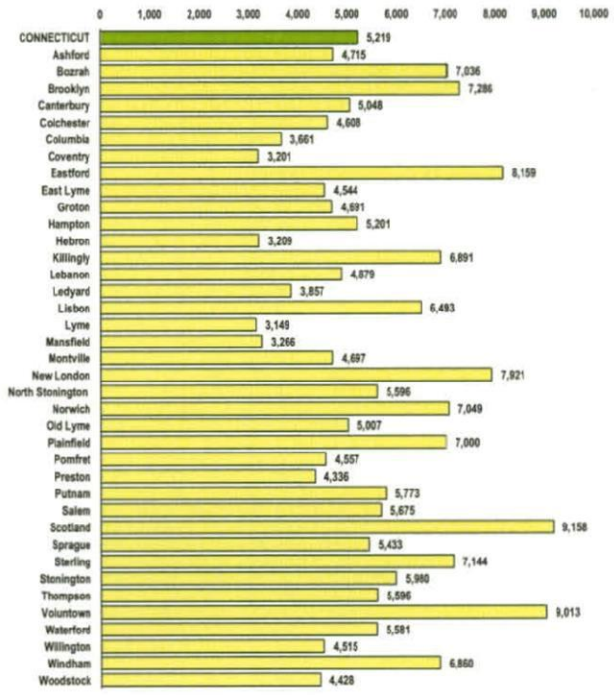
Source: • Connecticut Department of Public Health

Years of Potential Life Lost Before Age 75 (YPLL75)

Scotland led select towns in total years of potential life lost from all causes from 2006 to 2010. Multiple other towns in the region were also above the statewide value.

Years of Potential Life Lost Before Age 75 (YPLL75): All Causes

(By Select Towns in the East Region, 2006-2010)



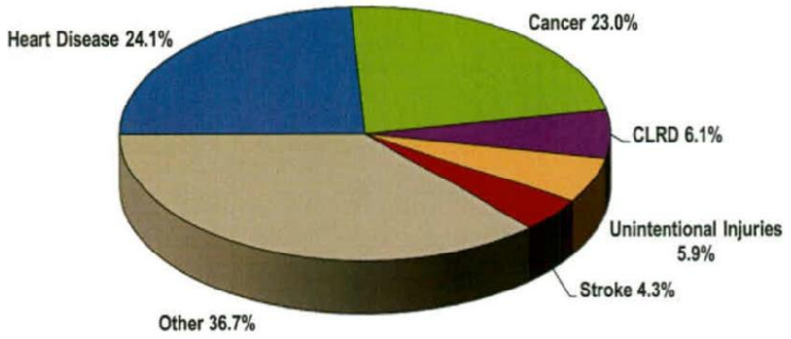
Source: • Connecticut Department of Public Health

Leading Causes of Death

Distribution of Deaths by Cause

Together, cardiovascular disease (heart disease and stroke) and cancers accounted for over one-half of all deaths in the Eastern Region from 2011 to 2013.

Leading Causes of Death
(Eastern Region, 2011-2013)



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- CLRD is chronic lower respiratory disease.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Age-Adjusted Death Rates for Selected Causes

In order to compare mortality in the region with other localities (in this case, Connecticut and the United States), it is necessary to look at *rates* of death — these are figures which represent the number of deaths in relation to the population size (such as deaths per 100,000 population, as is used here).

Furthermore, in order to compare localities without undue bias toward younger or older populations, the common convention is to adjust the data to some common baseline age distribution. Use of these "age-adjusted" rates provides the most valuable means of gauging mortality against benchmark data, as well as *Healthy People 2020* targets.

The following chart outlines 2011-2013 annual average age-adjusted death rates per 100,000 population for selected causes of death in the Eastern Region.

For infant mortality data, see *Birth Outcomes & Risks* in the **Births** section of this report.

Note that the age-adjusted mortality rate in the Eastern Region is worse than the national rate for drug-induced deaths.

Eastern Region mortality is worse than state rates for heart disease, CLRD, stroke, Alzheimer's disease, diabetes, drug-induced deaths, pneumonia/influenza, suicide and liver disease.

Of the causes outlined in the following chart for which Healthy People 2020 objectives have been established, the Eastern Region rates fail to satisfy the related goals for suicide, heart disease, cirrhosis, and drug-induced deaths.

Age-Adjusted Death Rates for Selected Causes

(2011-2013 Deaths per 100,000 Population)

	Eastern Region	Connecticut	US	HP2020
Diseases of the Heart	165.7	153.4	171.3	156.9*
Malignant Neoplasms (Cancers)	155.5	153.0	166.2	161.4
Chronic Lower Respiratory Disease (CLRD)	41.8	30.9	42.0	n/a
Unintentional Injuries	37.5	35.8	39.2	36.4
Cerebrovascular Disease (Stroke)	30.4	27.9	37.0	34.8
Alzheimer's Disease	19.4	16.5	24.0	n/a
Diabetes Mellitus	15.8	14.8	21.3	20.5*
Drug-Induced	15.4	13.5	14.1	11.3
Pneumonia/Influenza	13.1	12.9	15.3	n/a
Kidney Diseases	12.6	12.5	13.2	n/a
Intentional Self-Harm (Suicide)	11.2	9.5	12.5	10.2
Cirrhosis/Liver Disease	9.0	7.6	9.9	8.2
Motor Vehicle Deaths	7.4	7.1	10.7	12.4
Firearm-Related	5.0	5.5	10.4	9.3
Homicide/Legal Intervention	2.2	3.8	5.3	5.5

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov.

Note:
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population and coded using ICD-10 codes.
- *The Healthy People 2020 Heart Disease target is adjusted to account for all diseases of the heart; the Diabetes target is adjusted to reflect only diabetes mellitus-coded deaths.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Cardiovascular Disease

About Heart Disease & Stroke

Heart disease is the leading cause of death in the United States, with stroke following as the third leading cause. Together, heart disease and stroke are among the most widespread and costly health problems facing the nation today, accounting for more than $500 billion in healthcare expenditures and related expenses in 2010 alone. Fortunately, they are also among the most preventable.

The leading modifiable (controllable) risk factors for heart disease and stroke are:

- High blood pressure
- High cholesterol
- Cigarette smoking
- Diabetes
- Poor diet and physical inactivity
- Overweight and obesity

The risk of Americans developing and dying from cardiovascular disease would be substantially reduced if major improvements were made across the US population in diet and physical activity, control of high blood pressure and cholesterol, smoking cessation, and appropriate aspirin use.

The burden of cardiovascular disease is disproportionately distributed across the population. There are significant disparities in the following based on gender, age, race/ethnicity, geographic area, and socioeconomic status:

- Prevalence of risk factors
- Access to treatment
- Appropriate and timely treatment
- Treatment outcomes
- Mortality

Disease does not occur in isolation, and cardiovascular disease is no exception. Cardiovascular health is significantly influenced by the physical, social, and political environment, including: maternal and child health; access to educational opportunities; availability of healthy foods, physical education, and extracurricular activities in schools; opportunities for physical activity, including access to safe and walkable communities; access to healthy foods; quality of working conditions and worksite health; availability of community support and resources; and access to affordable, quality healthcare.

- Healthy People 2020 (www.healthypeople.gov)

Age-Adjusted Heart Disease & Stroke Deaths

Heart Disease Deaths

The greatest share of cardiovascular deaths is attributed to heart disease.

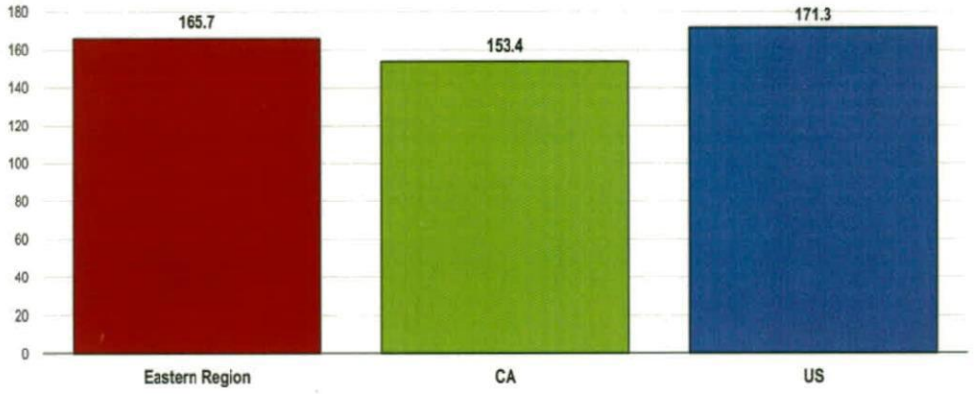
Between 2011 and 2013, there was an annual average age-adjusted heart disease mortality rate of 165.7 deaths per 100,000 population in the Eastern Region.

- Worse than the statewide rate.
- Similar to the national rate.
- Fails to satisfy the Healthy People 2020 target of 156.9 or lower (as adjusted to account for all diseases of the heart).

Heart Disease: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 156.9 or Lower (Adjusted)



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-2]

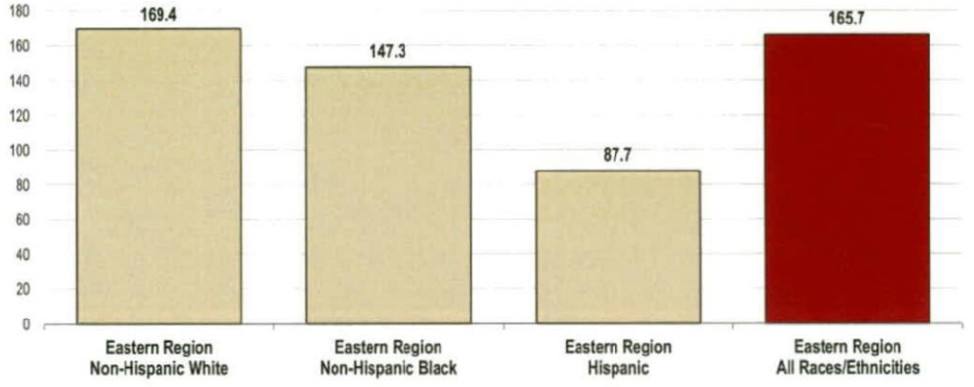
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- The Healthy People 2020 Heart Disease target is adjusted to account for all diseases of the heart.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- By race, the heart disease mortality rate is higher among Non-Hispanic Whites and Blacks than Hispanics in the Eastern Region.

Heart Disease: Age-Adjusted Mortality by Race

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 156.9 or Lower (Adjusted)



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-2]

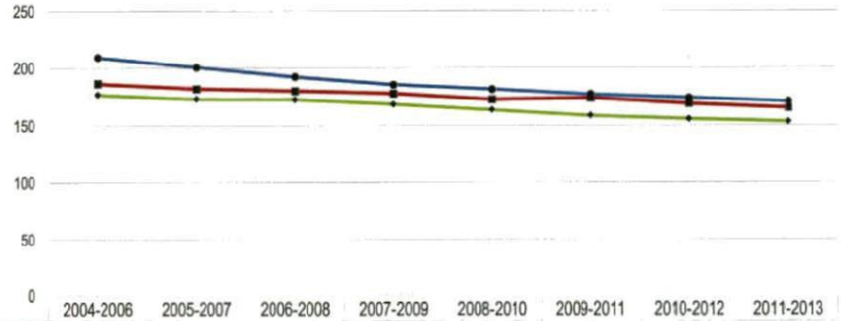
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- The Healthy People 2020 Heart Disease target is adjusted to account for all diseases of the heart.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The heart disease mortality rate has decreased in the Eastern Region, echoing the decreasing trends across Connecticut and the US overall.

Heart Disease: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 156.9 or Lower (Adjusted)



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	186.9	182.5	180.6	178.3	173.2	174.4	169.4	165.7
Connecticut	177.6	173.7	173.1	168.9	163.8	158.7	155.6	153.4
United States	209.4	200.7	192.5	185.8	181.9	177.6	174.4	171.3

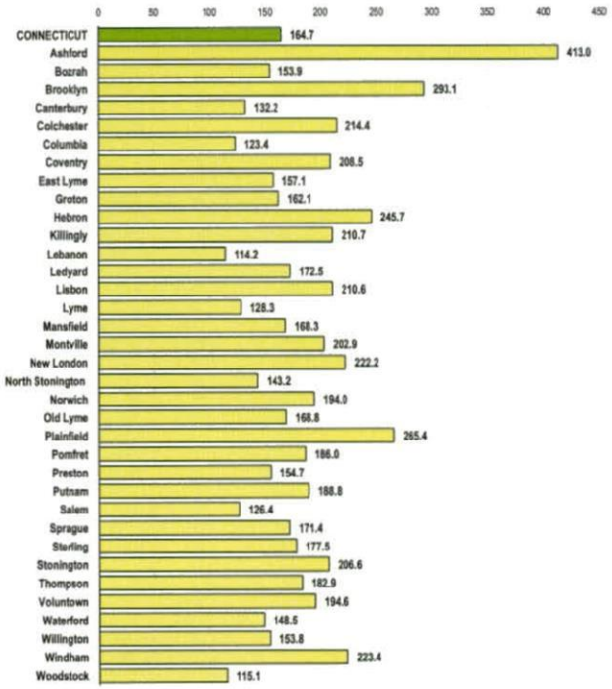
Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-2]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- Local, state and national data are simple three-year averages.
- The Healthy People 2020 Heart Disease target is adjusted to account for all diseases of the heart.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2006 to 2010, Ashford recorded the highest age-adjusted heart disease mortality rate among select towns in the Eastern Region.

Heart Disease: Age-Adjusted Mortality

(By Select Towns in the East Region, 2006-2010)

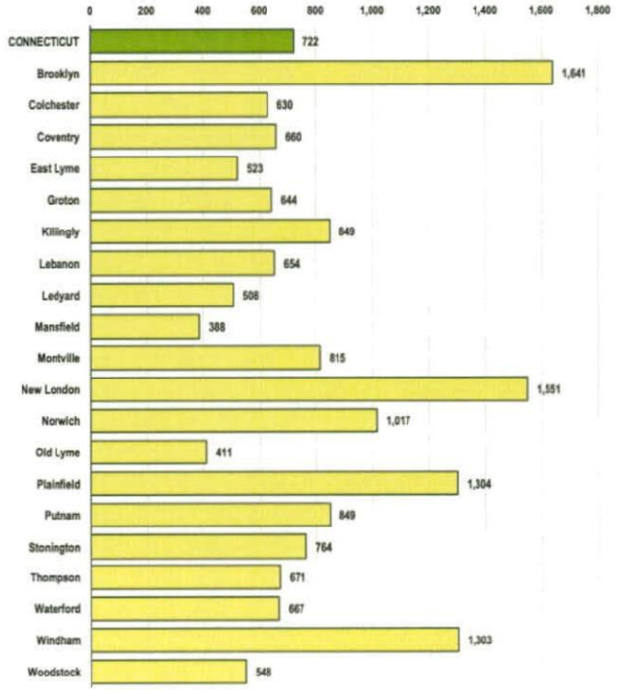


Source:
- Connecticut Department of Public Health

Heart Disease YPLL75

Brooklyn and New London led select towns in total years of potential life lost from heart disease from 2006 to 2010.

Heart Disease: YPLL75
(By Select Towns in the East Region, 2006-2010)



Source: • Connecticut Department of Public Health

Age-Adjusted Stroke Deaths

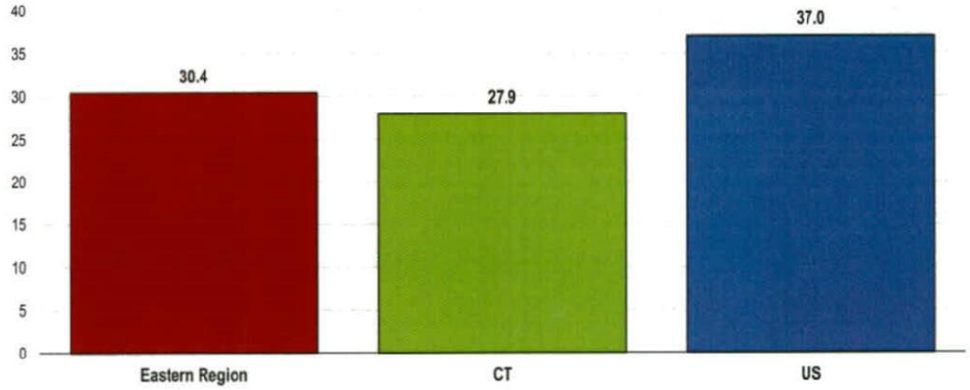
Between 2011 and 2013, there was an annual average age-adjusted stroke mortality rate of 30.4 deaths per 100,000 population in the Eastern Region.

- Less favorable than the Connecticut rate.
- More favorable than the national rate.
- Satisfies the Healthy People 2020 target of 34.8 or lower.

Stroke: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 34.8 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-3]

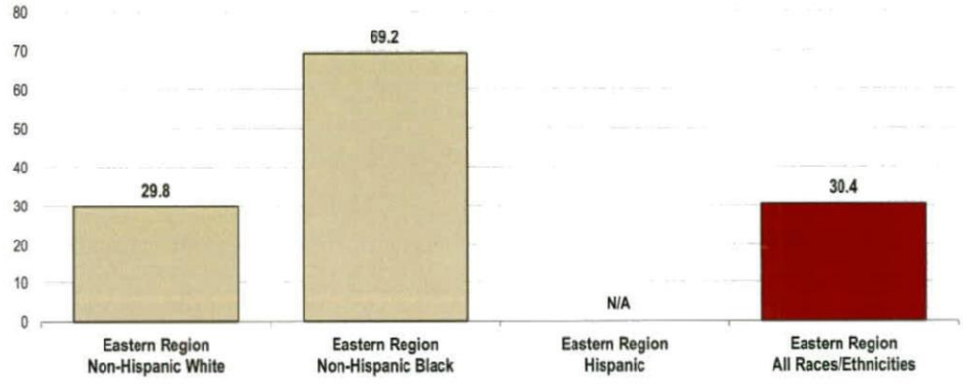
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- Stroke mortality is much higher among Blacks than among Whites in the Eastern Region (Hispanic data is not available).

Stroke: Age-Adjusted Mortality by Race

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 34.8 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-3]

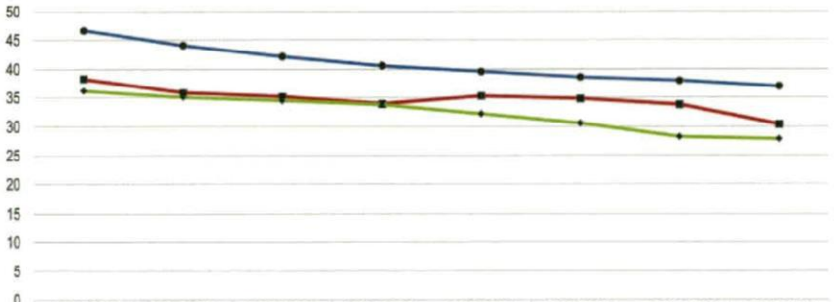
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The stroke rate has declined in recent years, echoing the trends reported across Connecticut and the US overall.

Stroke: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 34.8 or Lower



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	38.3	35.9	35.2	33.9	35.3	34.8	33.8	30.4
Connecticut	36.2	35.1	34.5	33.8	32.2	30.6	28.3	27.9
United States	46.7	44.1	42.2	40.6	39.6	38.6	38.0	37.0

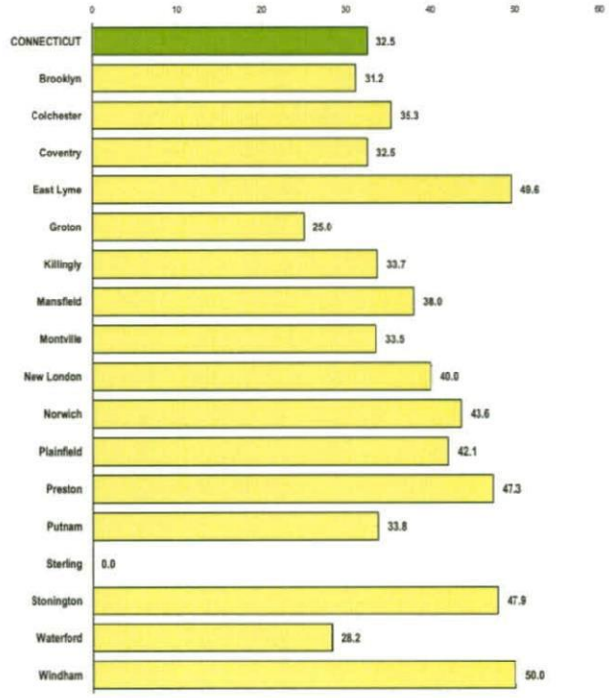
Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention., Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-3]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2006 to 2010, Windham recorded the highest age-adjusted stroke mortality rate among select towns in the Eastern Region, followed by East Lyme, Stonington, and Preston.

Stroke: Age-Adjusted Mortality

(By Select Towns in the East Region, 2006-2010)



Source:
- Connecticut Department of Public Health

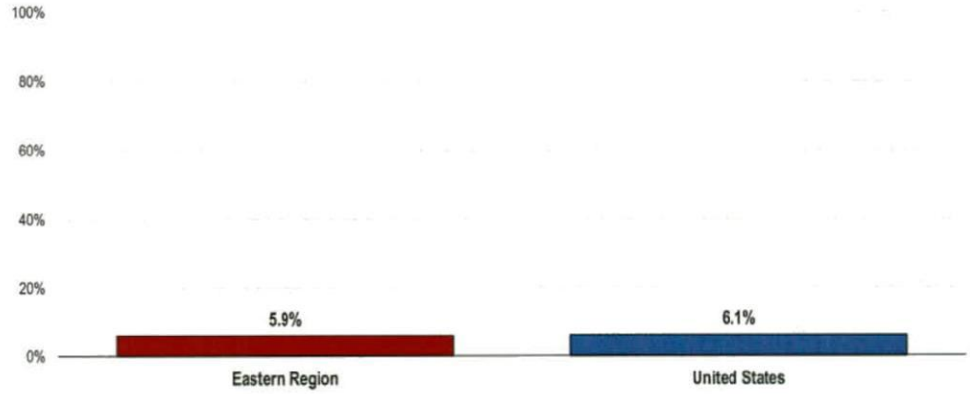
Prevalence of Heart Disease & Stroke

Prevalence of Heart Disease

A total of 5.9% of surveyed adults report that they suffer from or have been diagnosed with heart disease, such as coronary heart disease, angina or heart attack.

- Similar to the national prevalence.

Prevalence of Heart Disease



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 124]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

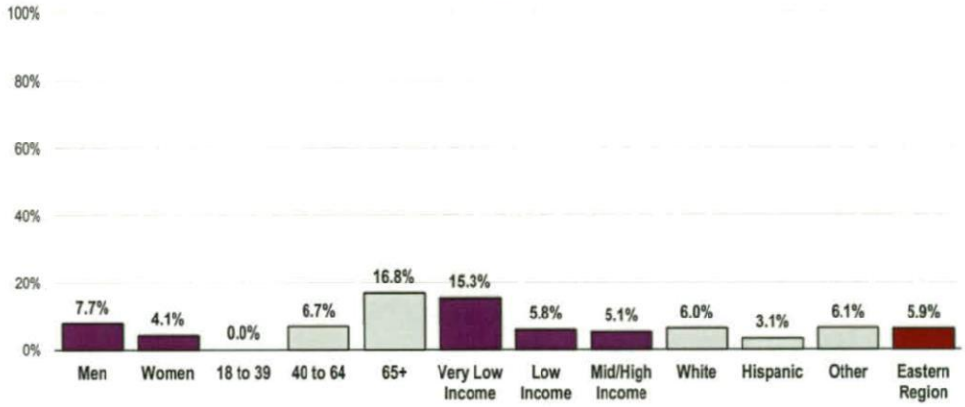
Notes:
- Asked of all respondents.
- Includes diagnoses of heart attack, angina or coronary heart disease.

Adults more likely to have been diagnosed with chronic heart disease include:

- Men.
- Those age 40 and older.
- Residents with very low incomes.

Prevalence of Heart Disease

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 124]

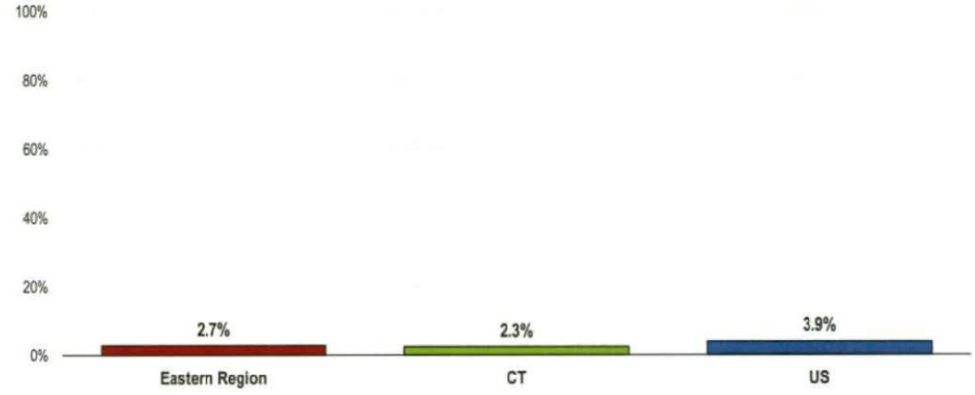
Notes:
- Asked of all respondents.
- Includes diagnoses of heart attack, angina or coronary heart disease.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Prevalence of Stroke

A total of 2.7% of surveyed adults report that they suffer from or have been diagnosed with cerebrovascular disease (a stroke).

- Similar to statewide findings.
- Similar to national findings.

Prevalence of Stroke



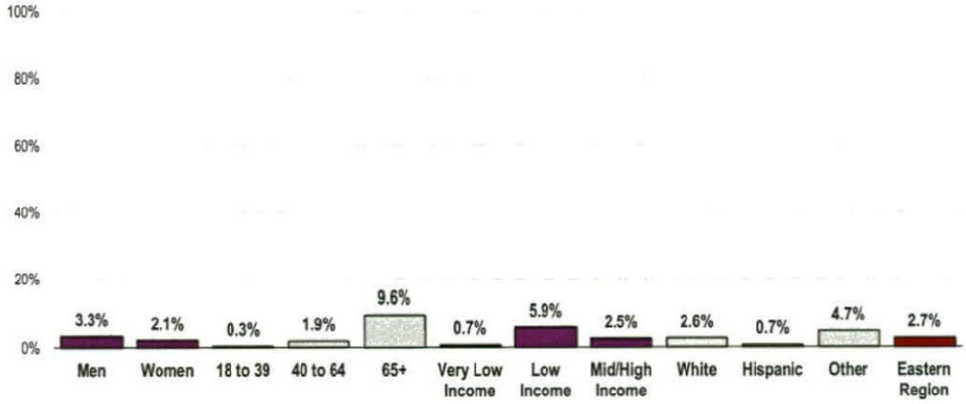
Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 36]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.

Notes:
- Asked of all respondents.

Adults more likely to have been diagnosed with stroke include:

- Those age 65 and older (positive correlation with age).
- Residents living just above the federal poverty level.

Prevalence of Stroke
(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 36]
Notes: • Asked of all respondents.
• Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Cardiovascular Risk Factors

About Cardiovascular Risk

Controlling risk factors for heart disease and stroke remains a challenge. High blood pressure and cholesterol are still major contributors to the national epidemic of cardiovascular disease. High blood pressure affects approximately 1 in 3 adults in the United States, and more than half of Americans with high blood pressure do not have it under control. High sodium intake is a known risk factor for high blood pressure and heart disease, yet about 90% of American adults exceed their recommendation for sodium intake.

- Healthy People 2020 (www.healthypeople.gov)

Hypertension (High Blood Pressure)

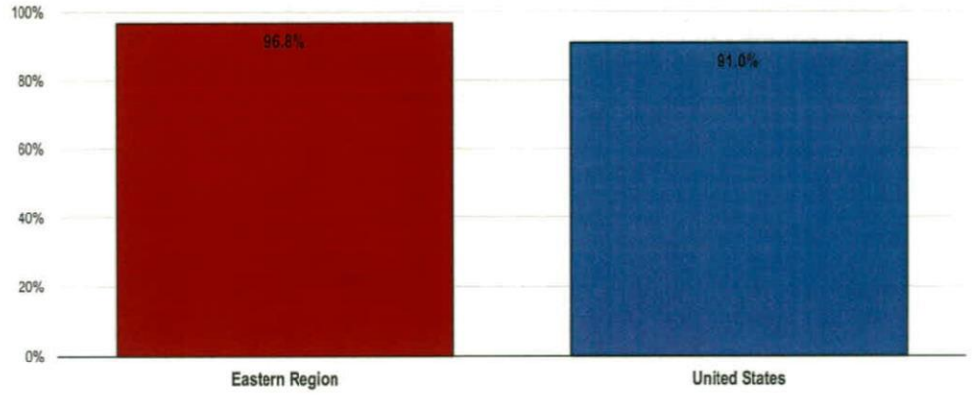
High Blood Pressure Testing

A total of 96.8% of Eastern Region adults have had their blood pressure tested within the past two years.

- Higher than national findings.
- Satisfies the Healthy People 2020 target (92.6% or higher).

Have Had Blood Pressure Checked in the Past Two Years

Healthy People 2020 Target = 92.6% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 45]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-4]

Notes:
- Asked of all respondents.

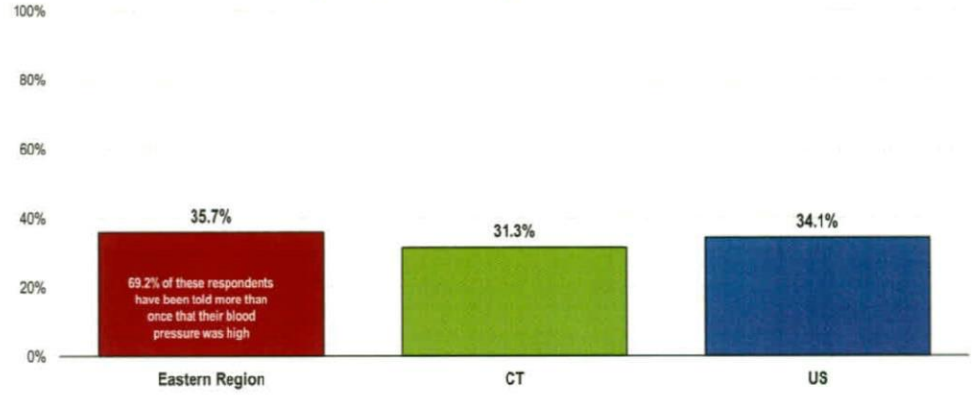
Prevalence of Hypertension

A total of 35.7% of adults have been told at some point that their blood pressure was high.

- Less favorable than the Connecticut prevalence.
- Similar to the national prevalence.
- Fails to satisfy the Healthy People 2020 target (26.9% or lower).
- Among hypertensive adults, 69.2% have been diagnosed with high blood pressure more than once.

Prevalence of High Blood Pressure

Healthy People 2020 Target = 26.9% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 43, 125]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-5.1]

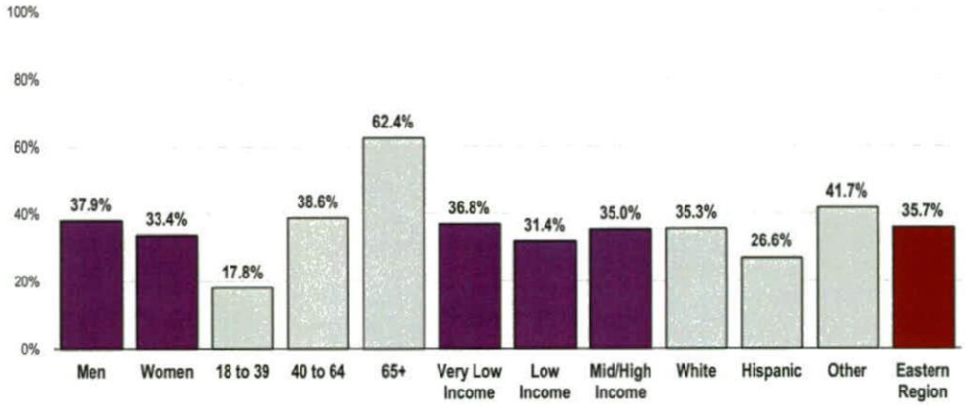
Notes:
- Asked of all respondents.

- Hypertension diagnoses are higher among adults age 40 and older, and especially those age 65+.

Prevalence of High Blood Pressure

(Eastern Region, 2015)

Healthy People 2020 Target = 26.9% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 125]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-5.1]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Hypertension Management

Among respondents who have been told that their blood pressure was high, 91.1% report that they are currently taking actions to control their condition.

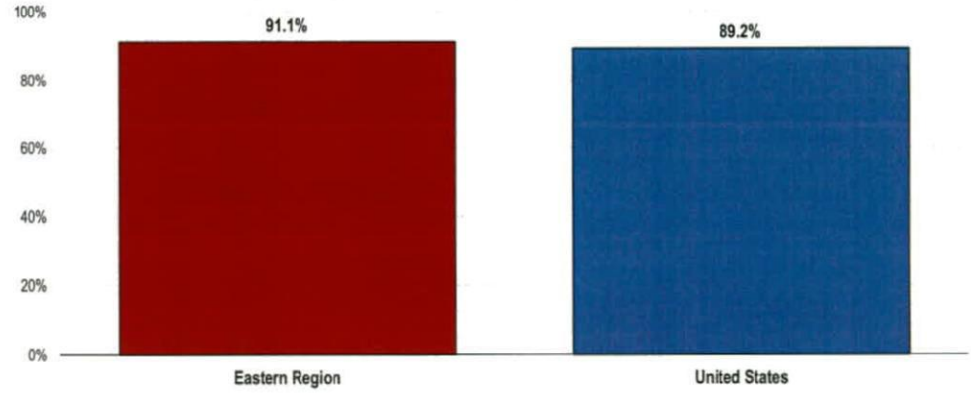
- Similar to national findings.

Respondents reporting high blood pressure were further asked:

"Are you currently taking any action to help control your high blood pressure, such as taking medication, changing your diet, or exercising?"

Taking Action to Control Hypertension

(Among Adults With High Blood Pressure)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 44]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents who have been diagnosed with high blood pressure.
- In this case, the term "action" refers to medication, change in diet, and/or exercise.

High Blood Cholesterol

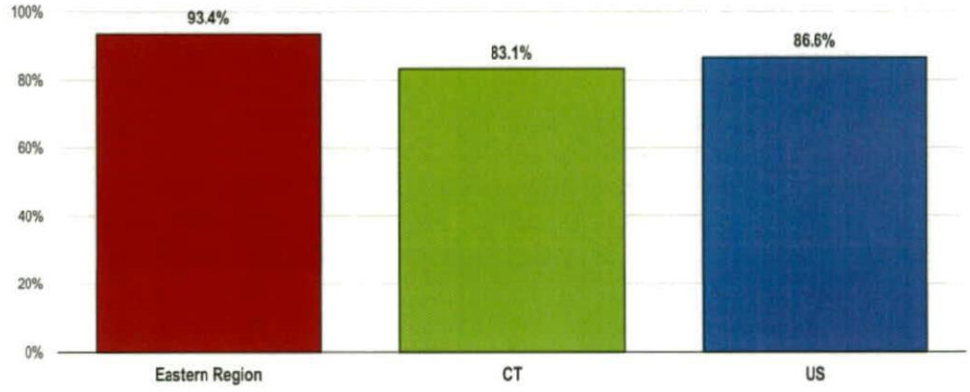
Blood Cholesterol Testing

A total of 93.4% of Eastern Region adults have had their blood cholesterol checked within the past five years.

- More favorable than Connecticut findings.
- More favorable than the national findings.
- Satisfies the Healthy People 2020 target (82.1% or higher).

Have Had Blood Cholesterol Levels Checked in the Past Five Years

Healthy People 2020 Target = 82.1% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 48]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-6]

Notes:
- Asked of all respondents.

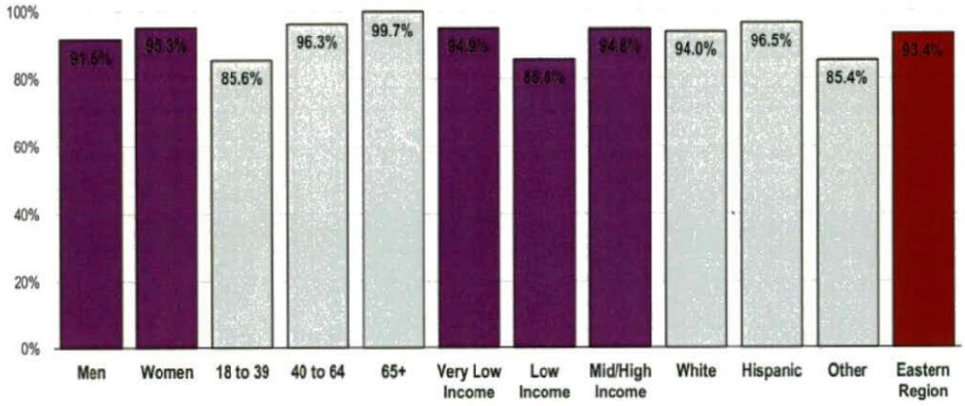
The following demographic segments report lower screening levels:

- Men.
- Adults younger than 40 (positive correlation with age).
- Residents living in the low-income breakout.
- "Other" races.

Have Had Blood Cholesterol Levels Checked in the Past Five Years

(Eastern Region, 2015)

Healthy People 2020 Target = 82.1% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 48]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-6]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

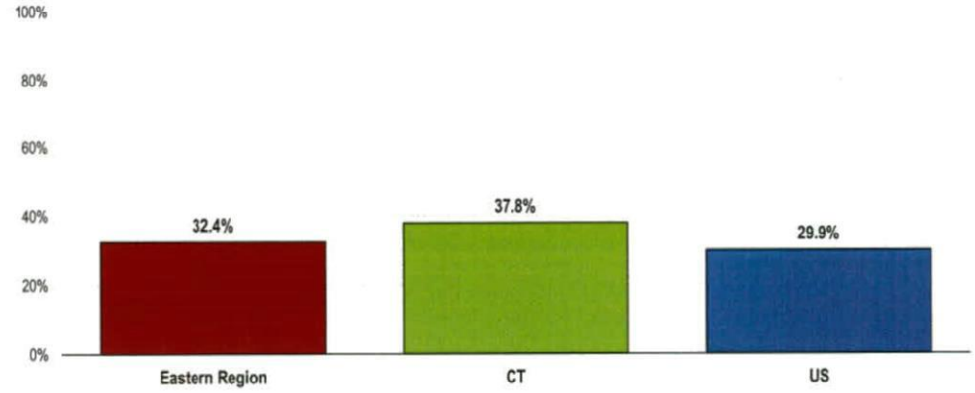
Self-Reported High Blood Cholesterol

A total of 32.4% of adults have been told by a health professional that their cholesterol level was high.

- More favorable than the Connecticut findings.
- Similar to the national prevalence.
- More than twice the Healthy People 2020 target (13.5% or lower).

Prevalence of High Blood Cholesterol

Healthy People 2020 Target = 13.5% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 126]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-7]

Notes:
- Asked of all respondents.
- *The Connecticut data reflects those adults who have been tested for high cholesterol and who have been diagnosed with it.

Note that 12.3% of Eastern Region adults report not having high blood cholesterol, but: 1) have never had their blood cholesterol levels tested; 2) have not been screened in the past 5 years; or 3) do not recall when their last screening was. For these individuals, current prevalence is unknown.

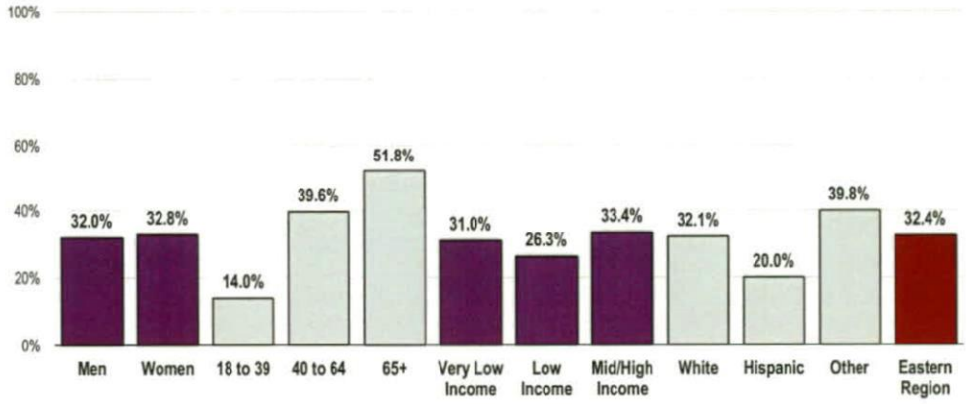
Further note the following:

- There is a positive correlation between age and high blood cholesterol.
- Whites and "Other" races more often report high cholesterol levels.
- Keep in mind that "unknowns" are relatively high in young adults, lower-income residents, and "Other" races.

Prevalence of High Blood Cholesterol

(Eastern Region, 2015)

Healthy People 2020 Target = 13.5% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 126]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective HDS-7]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

High Cholesterol Management

Respondents reporting high cholesterol were further asked:

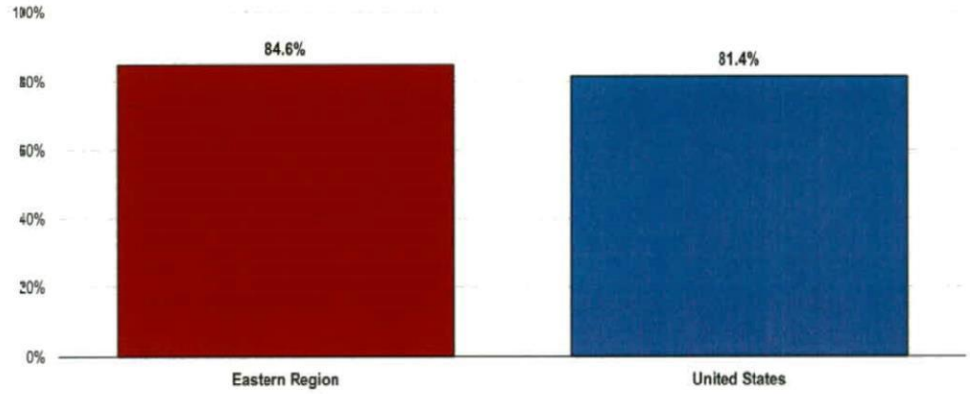
"Are you currently taking any action to help control your high cholesterol, such as taking medication, changing your diet, or exercising?"

Among adults who have been told that their blood cholesterol was high, 84.6% report that they are currently taking actions to control their cholesterol levels.

- Comparable to that found nationwide.

Taking Action to Control High Blood Cholesterol Levels

(Among Adults With High Cholesterol)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 47]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents who have been diagnosed with high blood cholesterol levels.
- In this case, the term "action" refers to medication, change in diet, and/or exercise.

About Cardiovascular Risk

Individual level risk factors which put people at increased risk for cardiovascular diseases include:

- High Blood Pressure
- High Blood Cholesterol
- Tobacco Use
- Physical Inactivity
- Poor Nutrition
- Overweight/Obesity
- Diabetes

- National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention

Three health-related behaviors contribute markedly to cardiovascular disease:

Poor nutrition. People who are overweight have a higher risk for cardiovascular disease. Almost 60% of adults are overweight or obese. To maintain a proper body weight, experts recommend a well-balanced diet which is low in fat and high in fiber, accompanied by regular exercise.

Lack of physical activity. People who are not physically active have twice the risk for heart disease of those who are active. More than half of adults do not achieve recommended levels of physical activity.

Tobacco use. Smokers have twice the risk for heart attack of nonsmokers. Nearly one-fifth of all deaths from cardiovascular disease, or about 190,000 deaths a year nationally, are smoking-related. Every day, more than 3,000 young people become daily smokers in the US

Modifying these behaviors is critical both for preventing and for controlling cardiovascular disease. Other steps that adults who have cardiovascular disease should take to reduce their risk of death and disability include adhering to treatment for high blood pressure and cholesterol, using aspirin as appropriate, and learning the symptoms of heart attack and stroke.

- National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention

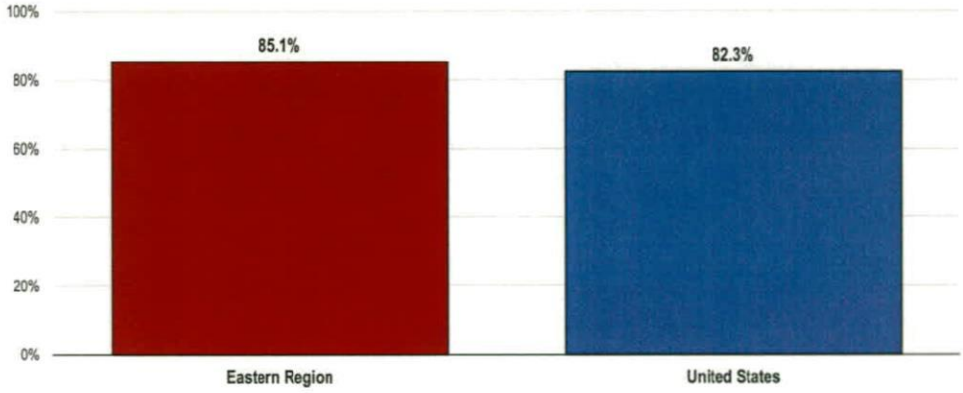
Total Cardiovascular Risk

RELATED ISSUE: See also Nutrition & Overweight, Physical Activity & Fitness and Tobacco Use in the Modifiable Health Risk section of this report.

A total of 85.1% of Eastern Region adults report one or more cardiovascular risk factors, such as being overweight, smoking cigarettes, being physically inactive, or having high blood pressure or cholesterol.

- Statistically similar to the national findings.

Present One or More Cardiovascular Risks or Behaviors



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 127]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

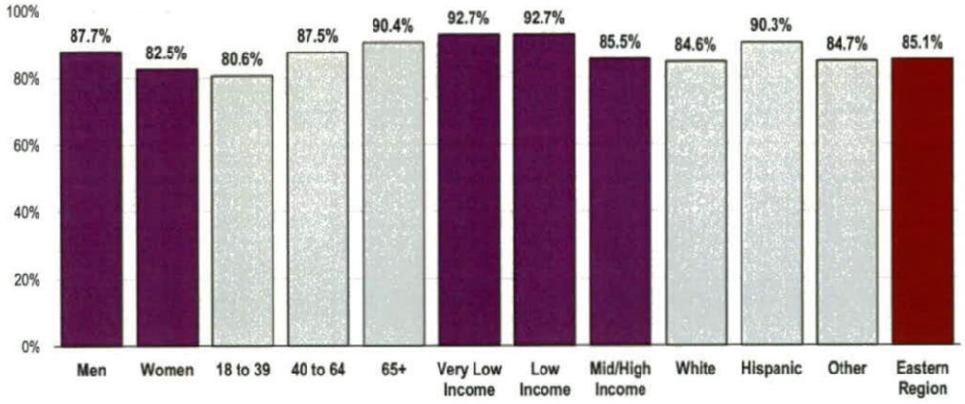
Notes:
- Asked of all respondents.
- Cardiovascular risk is defined as exhibiting one or more of the following: 1) no leisure-time physical activity; 2) regular/occasional cigarette smoking; 3) hypertension; 4) high blood cholesterol; and/or 5) being overweight/obese.

Adults more likely to exhibit cardiovascular risk factors include:

- Men.
- Adults age 40 and older, and especially seniors.
- Those with lower incomes.

Present One or More Cardiovascular Risks or Behaviors

(Eastern Region, 2015)



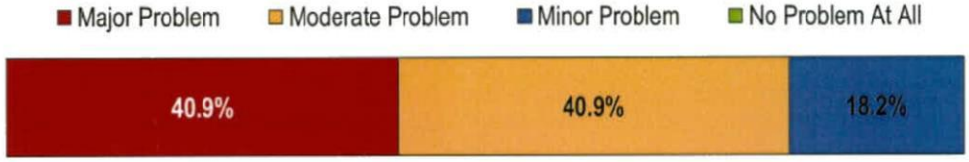
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 127]
Notes: • Asked of all respondents.
• Cardiovascular risk is defined as exhibiting one or more of the following: 1) no leisure-time physical activity; 2) regular/occasional cigarette smoking; 3) hypertension; 4) high blood cholesterol; and/or 5) being overweight/obese.
• Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Key Informant Input: Heart Disease & Stroke

Equal shares of key informants taking part in an online survey characterized *Heart Disease & Stroke* as a "major problem" and as a "moderate problem" in the area.

Perceptions of Heart Disease and Stroke as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Access to Health Care

> *Access to healthcare, transportation, office hours that do not extend beyond the normal work day. Cost of medications, cost of healthier choices at the grocery store, excessive tobacco use. - Public Health Expert*
>
> *The majority of our population does not have affordable, appropriate, and reliable access and information about these conditions. Translators and translation services that really work and are appropriate, are not in place for our population in need. We see students every day that suffer from conditions related to heart disease. Many of our students see a doctor/clinic initially but then cannot or do not follow up. Often times they do not use their medicine due to misunderstanding or miss-*

information or lack of Health Literacy. The information may be there, but their ability to understand and access it is quite limited. Accessible community health educators that speak their languages are desperately needed. We continue to teach Health Literacy within the context of ESOL education and look to community health resources for information, support and guidance. - Social Services Representatives

Leading Cause of Death, Prevalence

Number-one killer of men and women. - Health Provider

Based on mortality statistics and experience in the community. - Health Provider

This is a major problem in the US in every community. - Social Services Representative

Unhealthy Lifestyles

Similar to diabetes, heart disease and stroke require major lifestyle changes to prevent and treat. Many residents, particularly low income, are not equipped to make and maintain those changes. - Health Provider

Too many people and unfortunately children are obese and this leads to heart problems as well as others. - Community/Business Leader

Poor Hospital Care

Backus Neurology is in disarray and in The Hartford HealthCare system as a whole is weak. Effective stroke support at Backus is nonexistent and in Hartford HealthCare is poor. - Social Services Representative

Cancer

About Cancer

Continued advances in cancer research, detection, and treatment have resulted in a decline in both incidence and death rates for all cancers. Among people who develop cancer, more than half will be alive in five years. Yet, cancer remains a leading cause of death in the United States, second only to heart disease.

Many cancers are preventable by reducing risk factors such as: use of tobacco products; physical inactivity and poor nutrition; obesity; and ultraviolet light exposure. Other cancers can be prevented by getting vaccinated against human papillomavirus and hepatitis B virus. In the past decade, overweight and obesity have emerged as new risk factors for developing certain cancers, including colorectal, breast, uterine corpus (endometrial), and kidney cancers. The impact of the current weight trends on cancer incidence will not be fully known for several decades. Continued focus on preventing weight gain will lead to lower rates of cancer and many chronic diseases.

Screening is effective in identifying some types of cancers (see US Preventive Services Task Force [USPSTF] recommendations), including:

- Breast cancer (using mammography)
- Cervical cancer (using Pap tests)
- Colorectal cancer (using fecal occult blood testing, sigmoidoscopy, or colonoscopy)

- Healthy People 2020 (www.healthypeople.gov)

Cancer Deaths

Age-Adjusted Cancer Deaths

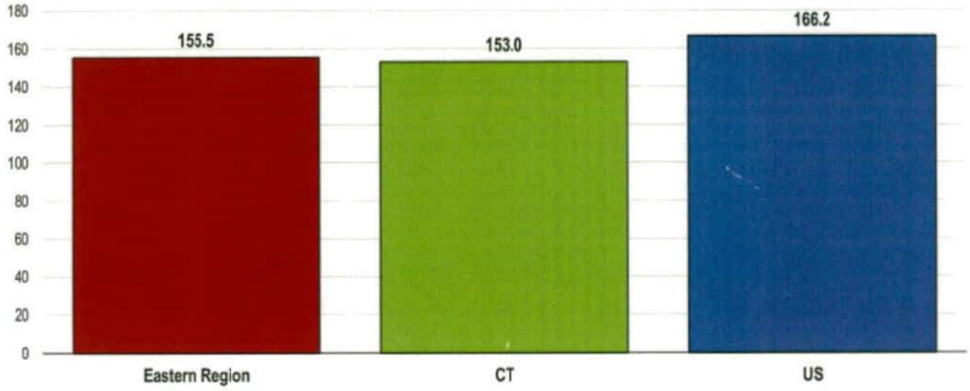
Between 2011 and 2013, there was an annual average age-adjusted cancer mortality rate of 155.5 deaths per 100,000 population in the Eastern Region.

- Similar to the statewide rate.
- More favorable than the national rate.
- Similar to the Healthy People 2020 target of 161.4 or lower.

Cancer: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 161.4 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective C-1]

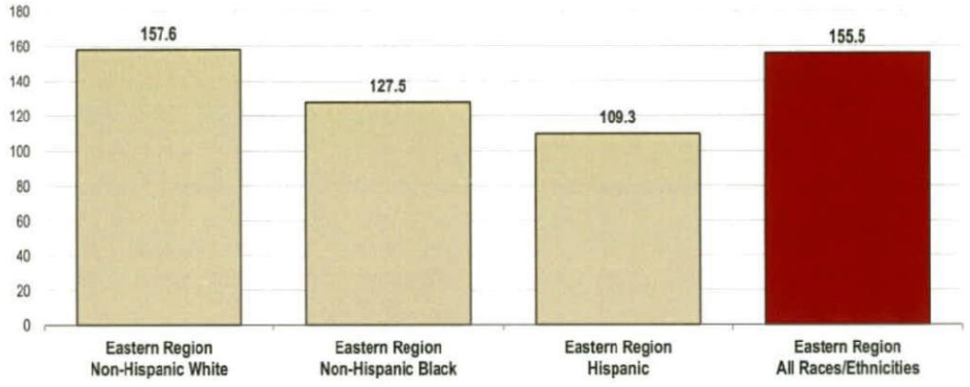
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- The cancer mortality rate is notably higher among Whites than among Blacks and Hispanics.

Cancer: Age-Adjusted Mortality by Race

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 161.4 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective C-1]

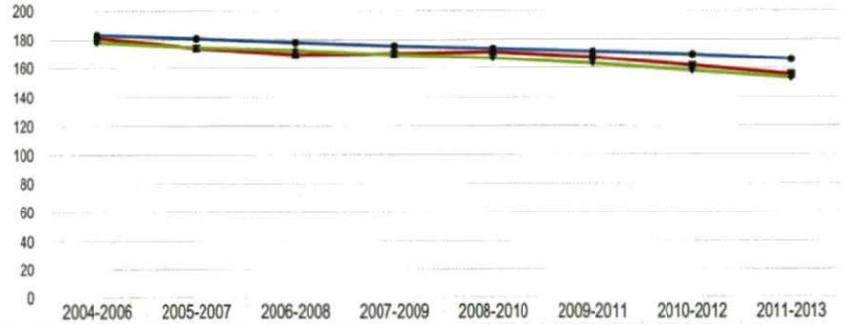
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: Cancer mortality has decreased over the past decade in the Eastern Region; the same trend is apparent both statewide and nationwide.

Cancer: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 161.4 or Lower



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	181.3	174.3	169.5	170.2	171.3	167.6	161.6	155.5
Connecticut	178.3	174.7	172.7	169.3	166.9	163.2	158.0	153.0
United States	183.4	181.0	178.1	175.6	173.8	171.7	169.4	166.2

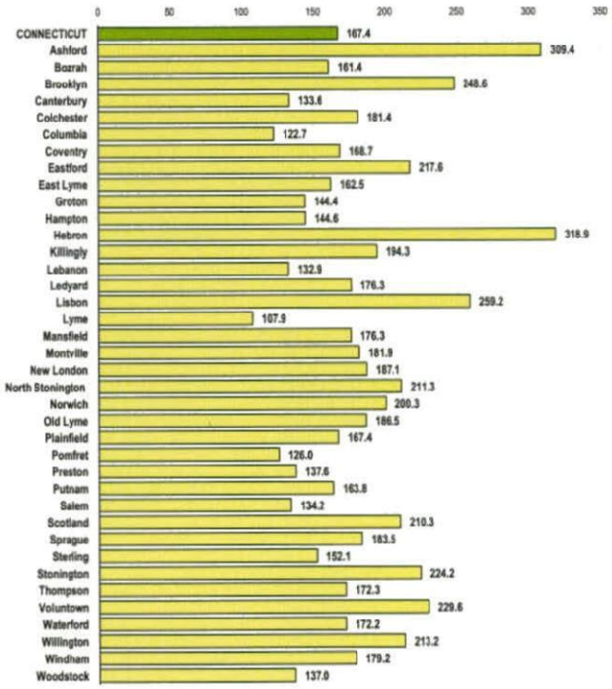
Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective C-1]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- State and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2006 to 2010, Hebron and Ashford recorded the highest age-adjusted cancer mortality rates among select towns in the Eastern Region.

Cancer: Age-Adjusted Mortality

(By Select Towns in the East Region, 2006-2010)

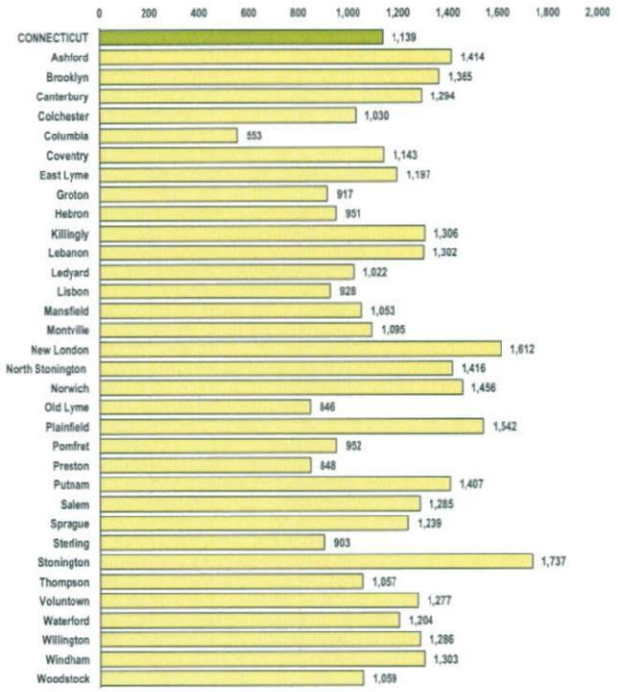


Source:
- Connecticut Department of Public Health

Cancer YPLL75

From 2006 to 2010, the total years of potential life lost before age 75 from cancer was found to be highest in Stonington, New London, and Plainfield.

Cancer: YPLL75
(By Select Towns in the East Region, 2006-2010)



Source: • Connecticut Department of Public Health

Cancer Deaths by Site

Lung cancer is by far the leading cause of cancer deaths in the Eastern Region.

Other leading sites include breast cancer among women, prostate cancer among men, and colorectal cancer (both genders).

As can be seen in the following chart (referencing 2011-2013 annual average age-adjusted death rates):

- The Eastern Region **lung cancer** death rate is similar to the state rate and more favorable than the national rate.
- The Eastern Region **female breast cancer** death rate is similar to the state rate and more favorable than the national rate.
- The Eastern Region **prostate cancer** death rate is better than both the state and national rates.
- The Eastern Region **colorectal cancer** death rate is worse than the state rate but better than the national rate.

Note that each of the Eastern Region cancer death rates detailed below satisfies the related Healthy People 2020 target, with the possible exception of female breast cancer (the death rate is statistically similar to the 2020 goal).

Age-Adjusted Cancer Death Rates by Site

(2011-2013 Annual Average Deaths per 100,000 Population)

	Eastern Region	Connecticut	US	HP2020
Lung Cancer	40.2	38.7	44.7	45.5
Female Breast Cancer	20.1	19.2	21.3	20.7
Prostate Cancer	16.3	18.2	19.8	21.8
Colorectal Cancer	13.3	12.1	14.9	14.5

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov

Notes:
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Cancer Incidence

Incidence rates reflect the number of newly diagnosed cases in a given population in a given year, regardless of outcome. Here, these rates are also age-adjusted.

"Incidence rate" or "case rate" is the number of new cases of a disease occurring during a given period of time.

It is usually expressed as cases per 100,000 population per year.

Between 2007 and 2011, the Eastern Region had an annual average age-adjusted incidence rate of 131.4 female breast cancer cases per 100,000.

- Similar to the statewide incidence rate.
- Higher than the national incidence rate.

There was an annual average age-adjusted incidence rate of prostate cancer of 127.6 cases per 100,000 population in the Eastern Region.

- Lower than the statewide incidence rate.
- Lower than the national incidence rate.

There was an annual average age-adjusted incidence rate of 67.3 lung cancer cases per 100,000 in the Eastern Region.

- Similar to the statewide incidence rate.
- Similar to the national incidence rate.

There was an annual average age-adjusted incidence rate of colorectal cancer of 41.8 cases per 100,000 in the Eastern Region.

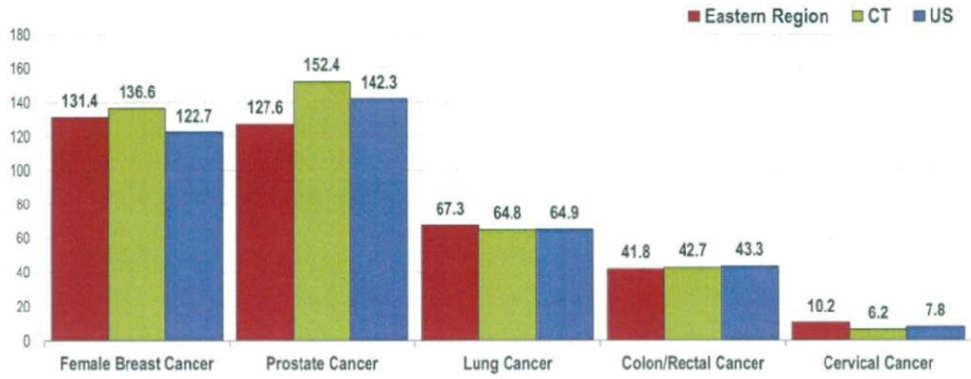
- Similar to the statewide incidence rate.
- Similar to the national incidence rate.

There was an annual average age-adjusted incidence rate of cervical cancer of 10.2 cases per 100,000 in the Eastern Region.

- Worse than the statewide incidence rate.
- Worse than the national incidence rate.

Cancer Incidence Rates by Site

(Annual Average Age-Adjusted Incidence per 100,000 Population, 2007-2011)



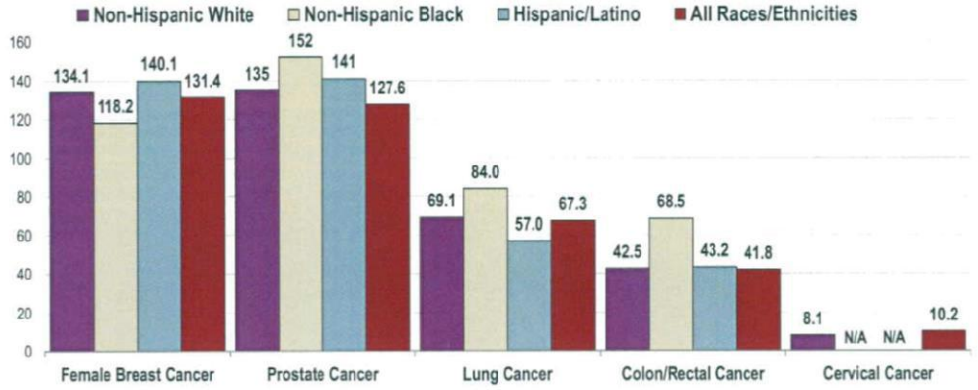
Sources:
- State Cancer Profiles: 2007-11.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator reports the age adjusted incidence rate (cases per 100,000 population per year) of cancers, adjusted to 2000 US standard population age groups (under age 1, 1-4, 5-9, ..., 80-84, 85 and older). This indicator is relevant because cancer is a leading cause of death and it is important to identify cancers separately to better target interventions.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- By available race data, Non-Hispanic Whites and Hispanics experience a higher incidence of female breast cancer than Blacks in the Eastern Region.
- On the other hand, Blacks experience a higher incidence of prostate, lung, and colorectal cancer than Whites and Hispanics in the area.

Cancer Incidence Rates by Site and Race/Ethnicity

(Annual Average Age-Adjusted Incidence per 100,000 Population, Eastern Region 2007-2011)



Sources:
- State Cancer Profiles: 2007-11.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator reports the age adjusted incidence rate (cases per 100,000 population per year) of cancers, adjusted to 2000 US standard population age groups (under age 1, 1-4, 5-9, ..., 80-84, 85 and older). This indicator is relevant because cancer is a leading cause of death and it is important to identify cancers separately to better target interventions.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

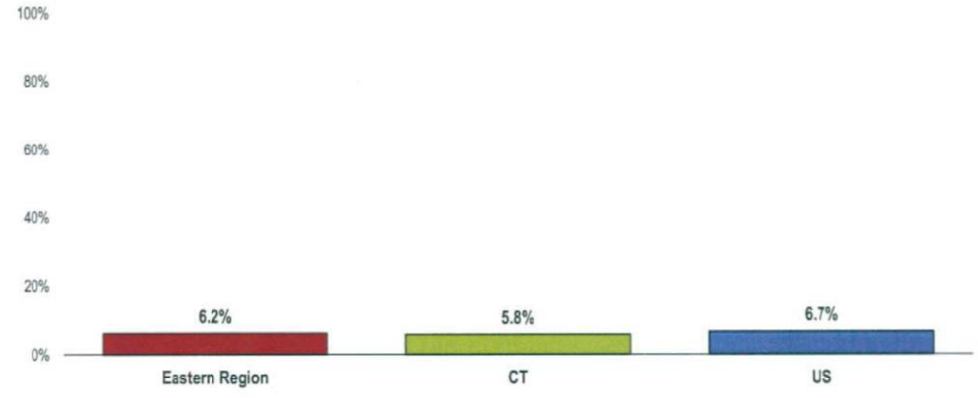
Prevalence of Cancer

Skin Cancer

A total of 6.2% of surveyed Eastern Region adults report having been diagnosed with skin cancer.

- Similar to what is found statewide.
- Similar to the national average.

Prevalence of Skin Cancer



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 31]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

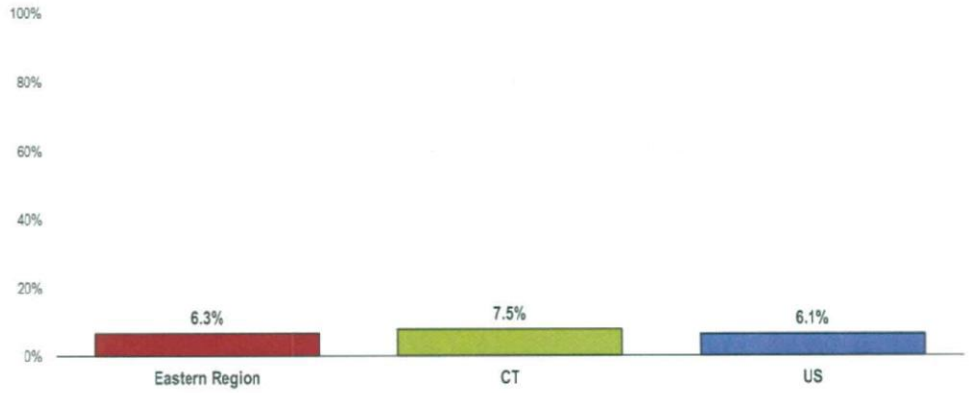
Notes:
- Asked of all respondents.

Other Cancer

A total of 6.3% of respondents have been diagnosed with some type of (non-skin) cancer.

- Similar to the statewide prevalence.
- Similar to the national prevalence.

Prevalence of Cancer (Other Than Skin Cancer)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 30]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.

Cancer Risk

RELATED ISSUE: See also *Nutrition & Overweight*, *Physical Activity & Fitness* and *Tobacco Use* in the **Modifiable Health Risk** section of this report.

About Cancer Risk

Reducing the nation's cancer burden requires reducing the prevalence of behavioral and environmental factors that increase cancer risk.

- All cancers caused by cigarette smoking could be prevented. At least one-third of cancer deaths that occur in the United States are due to cigarette smoking.
- According to the American Cancer Society, about one-third of cancer deaths that occur in the United States each year are due to nutrition and physical activity factors, including obesity.

- National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention

Cancer Screenings

The American Cancer Society recommends that both men and women get a cancer-related checkup during a regular doctor's checkup. It should include examination for cancers of the thyroid, testicles, ovaries, lymph nodes, oral cavity, and skin, as well as health counseling about tobacco, sun exposure, diet and nutrition, risk factors, sexual practices, and environmental and occupational exposures.

Screening levels in the community were measured in the PRC Community Health Survey relative to three cancer sites: female breast cancer (mammography); cervical cancer (Pap smear testing); and colorectal cancer (sigmoidoscopy and fecal occult blood testing).

Female Breast Cancer Screening

About Screening for Breast Cancer

The US Preventive Services Task Force (USPSTF) recommends screening mammography, with or without clinical breast examination (CBE), every 1-2 years for women age 40 and older.

Rationale: The USPSTF found fair evidence that mammography screening every 12-33 months significantly reduces mortality from breast cancer. Evidence is strongest for women age 50-69, the age group generally included in screening trials. For women age 40-49, the evidence that screening mammography reduces mortality from breast cancer is weaker, and the absolute benefit of mammography is smaller, than it is for older women. Most, but not all, studies indicate a mortality benefit for women undergoing mammography at ages 40-49, but the delay in observed benefit in women younger than 50 makes it difficult to determine the incremental benefit of beginning screening at age 40 rather than at age 50.

The absolute benefit is smaller because the incidence of breast cancer is lower among women in their 40s than it is among older women. The USPSTF concluded that the evidence is also generalizable to women age 70 and older (who face a higher absolute risk for breast cancer) if their life expectancy is not compromised by comorbid disease. The absolute probability of benefits of regular mammography increase along a continuum with age, whereas the likelihood of harms from screening (false-positive results and unnecessary anxiety, biopsies, and cost) diminish from ages 40-70. The balance of benefits and potential harms, therefore, grows more favorable as women age. The precise age at which the potential benefits of mammography justify the possible harms is a subjective choice. The USPSTF did not find sufficient evidence to specify the optimal screening interval for women age 40-49.

- US Preventive Services Task Force, Agency for Healthcare Research and Quality, US Department of Health & Human Services

Note that other organizations (e.g., American Cancer Society, American Academy of Family Physicians, American College of Physicians, National Cancer Institute) may have slightly different screening guidelines.

Mammography

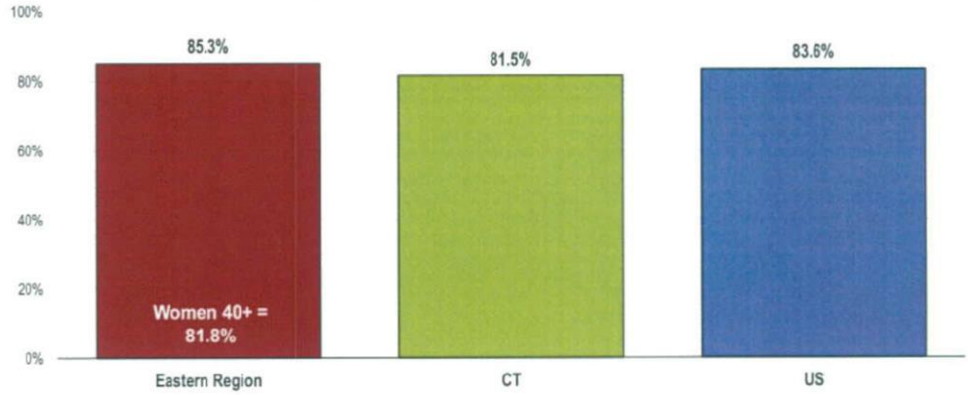
Among women age 50-74, 85.3% have had a mammogram within the past two years.

- Similar to statewide findings (which represent all women 50+).
- Similar to national findings.
- Satisfies the Healthy People 2020 target (81.1% or higher).
- Among women 40+, 81.8% have had a mammogram in the past two years.

Have Had a Mammogram in the Past Two Years

(Among Women Age 50-74)

Healthy People 2020 Target = 81.1% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 128-129]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2012 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective C-17]

Notes:
- Reflects female respondents 50-74.
- *Note that state data reflects all women 50 and older (vs. women 50-74 in local, US and Healthy People data).

Cervical Cancer Screenings

About Screening for Cervical Cancer

The US Preventive Services Task Force (USPSTF) strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix.

Rationale: The USPSTF found good evidence from multiple observational studies that screening with cervical cytology (Pap smears) reduces incidence of and mortality from cervical cancer. Direct evidence to determine the optimal starting and stopping age and interval for screening is limited. Indirect evidence suggests most of the benefit can be obtained by beginning screening within 3 years of onset of sexual activity or age 21 (whichever comes first) and screening at least every 3 years. The USPSTF concludes that the benefits of screening substantially outweigh potential harms.

The USPSTF recommends against routinely screening women older than age 65 for cervical cancer if they have had adequate recent screening with normal Pap smears and are not otherwise at high risk for cervical cancer.

Rationale: The USPSTF found limited evidence to determine the benefits of continued screening in women older than 65. The yield of screening is low in previously screened women older than 65 due to the declining incidence of high-grade cervical lesions after middle age. There is fair evidence that screening women older than 65 is associated with an increased risk for potential harms, including false-positive results and invasive procedures. The USPSTF concludes that the potential harms of screening are likely to exceed benefits among older women who have had normal results previously and who are not otherwise at high risk for cervical cancer.

The USPSTF recommends against routine Pap smear screening in women who have had a total hysterectomy for benign disease.

Rationale: The USPSTF found fair evidence that the yield of cytologic screening is very low in women after hysterectomy and poor evidence that screening to detect vaginal cancer improves health outcomes. The USPSTF concludes that potential harms of continued screening after hysterectomy are likely to exceed benefits.

- US Preventive Services Task Force, Agency for Healthcare Research and Quality, US Department of Health & Human Services

Note that other organizations (e.g., American Cancer Society, American Academy of Family Physicians, American College of Physicians, National Cancer Institute) may have slightly different screening guidelines.

Pap Smear Testing

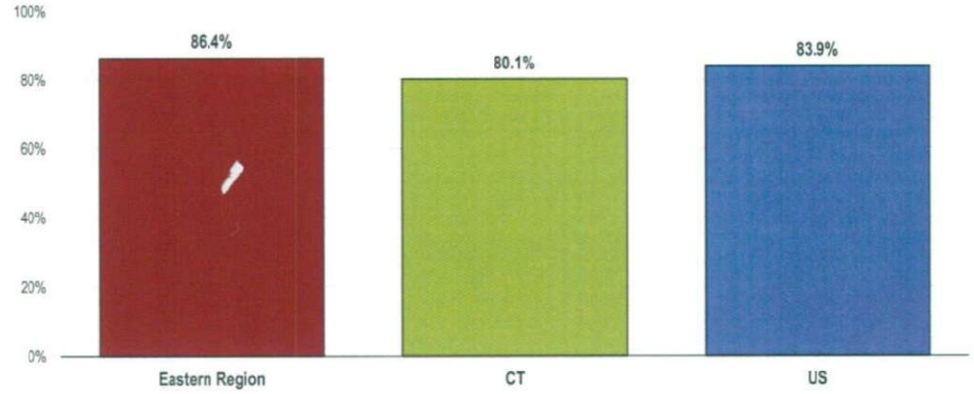
Among women age 21 to 65, 86.4% have had a Pap smear within the past three years.

- Better than Connecticut findings (which represents all women 18+).
- Statistically similar to national findings.
- Fails to satisfy the Healthy People 2020 target (93% or higher).

Have Had a Pap Smear in the Past Three Years

(Among Women Age 21-65)

Healthy People 2020 Target = 93.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 130]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2012 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective C-15]

Notes:
- Reflects female respondents age 21 to 65.
- *Note that the Connecticut percentage represents all women age 18 and older.

Colorectal Cancer Screenings

About Screening for Colorectal Cancer

The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults, beginning at age 50 years and continuing until age 75 years.

The evidence is convincing that screening for colorectal cancer with fecal occult blood testing, sigmoidoscopy, or colonoscopy detects early-stage cancer and adenomatous polyps. There is convincing evidence that screening with any of the three recommended tests (FOBT, sigmoidoscopy, colonoscopy) reduces colorectal cancer mortality in adults age 50 to 75 years. Follow-up of positive screening test results requires colonoscopy regardless of the screening test used.

- US Preventive Services Task Force, Agency for Healthcare Research and Quality, US Department of Health & Human Services

Note that other organizations (e.g., American Cancer Society, American Academy of Family Physicians, American College of Physicians, National Cancer Institute) may have slightly different screening guidelines.

Colorectal Cancer Screening

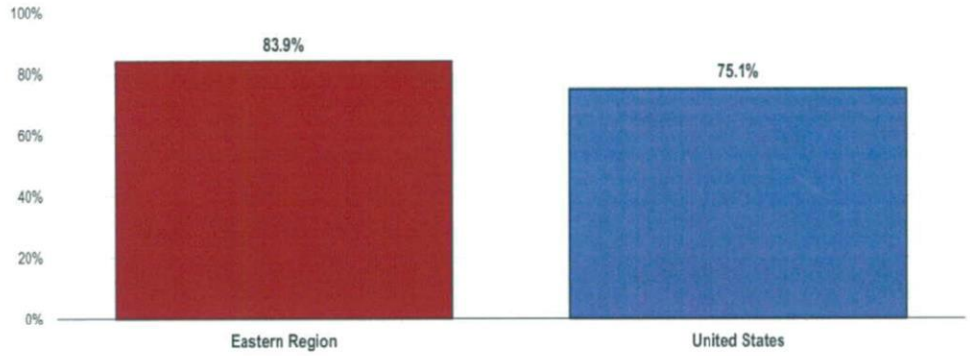
Among adults age 50-75, 83.9% have had an appropriate colorectal cancer screening (fecal occult blood testing within the past year and/or sigmoidoscopy/colonoscopy [lower endoscopy] within the past 10 years).

- Better than national findings.
- Satisfies the Healthy People 2020 target (70.5% or higher).

Have Had a Colorectal Cancer Screening

(Among Adults Age 50-75)

Healthy People 2020 Target = 70.5% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 133]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective C-16]

Notes:
- Asked of all respondents age 50 through 75.
- In this case, the term "colorectal screening" refers to adults age 50-75 receiving a FOBT (fecal occult blood test) in the past year and/or a lower endoscopy (sigmoidoscopy/colonoscopy) in the past 10 years.

Lower Endoscopy

Among adults age 50 and older, 85.6% have had a lower endoscopy (sigmoidoscopy or colonoscopy) at some point in their lives.

- More favorable than Connecticut findings.
- More favorable than national findings.

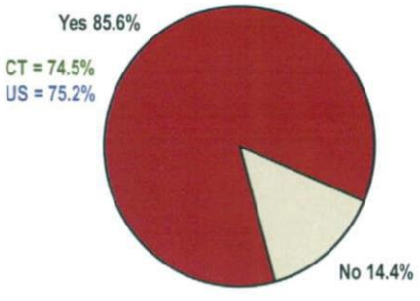
Blood Stool Testing

Among adults age 50 and older, 35.4% have had a blood stool test (aka "fecal occult blood test") within the past two years.

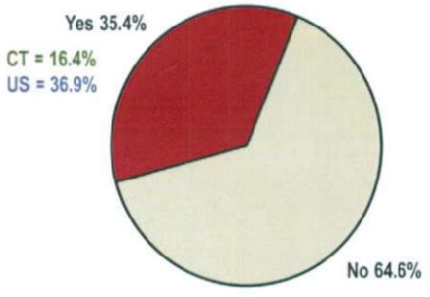
- Better than Connecticut findings.
- Comparable to national findings.

Colorectal Cancer Screenings

(Among Eastern Region Adults Age 50 and Older, 2015)



Ever Had Lower Endoscopy



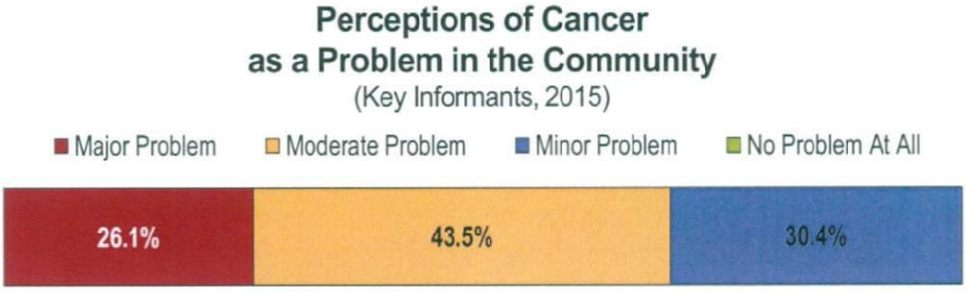
Blood Stool Test in Past 2 Years

Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 131-132]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2012 Connecticut data.

Notes:
- Asked of respondents age 50 and older.
- Lower endoscopy includes either sigmoidoscopy or colonoscopy.

Key Informant Input: Cancer

The largest share of key informants taking part in an online survey characterized *Cancer* as a "moderate problem" in the community



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Prevalence

> *Seems to be a high incidence of cancer in our region of the state. - Social Services Representative*
>
> *High incidence - Social Services Representative*
>
> *Cancer is highly prevalent and early detection and intervention may not always be happening. - Community/Business Leader*
>
> *There seems to be a significant diagnosis of cancer in our region and I'm not sure if everyone has access to treatment. There are new affiliations in our region but again I am not sure if transportation is an issue and I am not sure if payment is an issue. - Health Provider*

Transportation/Distance

> *A person must travel minimum 25 miles to nearest cancer treatment. Little or no public transportation available. - Social Services Representative*

Respiratory Disease

About Asthma & COPD

Asthma and chronic obstructive pulmonary disease (COPD) are significant public health burdens. Specific methods of detection, intervention, and treatment exist that may reduce this burden and promote health.

Asthma is a chronic inflammatory disorder of the airways characterized by episodes of reversible breathing problems due to airway narrowing and obstruction. These episodes can range in severity from mild to life threatening. Symptoms of asthma include wheezing, coughing, chest tightness, and shortness of breath. Daily preventive treatment can prevent symptoms and attacks and enable individuals who have asthma to lead active lives.

COPD is a preventable and treatable disease characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases (typically from exposure to cigarette smoke). Treatment can lessen symptoms and improve quality of life for those with COPD.

The burden of respiratory diseases affects individuals and their families, schools, workplaces, neighborhoods, cities, and states. Because of the cost to the healthcare system, the burden of respiratory diseases also falls on society; it is paid for with higher health insurance rates, lost productivity, and tax dollars. Annual healthcare expenditures for asthma alone are estimated at $20.7 billion.

Asthma. The prevalence of asthma has increased since 1980. However, deaths from asthma have decreased since the mid-1990s. The causes of asthma are an active area of research and involve both genetic and environmental factors.

Risk factors for asthma currently being investigated include:

- Having a parent with asthma
- Sensitization to irritants and allergens
- Respiratory infections in childhood
- Overweight

Asthma affects people of every race, sex, and age. However, significant disparities in asthma morbidity and mortality exist, in particular for low-income and minority populations. Populations with higher rates of asthma include: children; women (among adults) and boys (among children); African Americans; Puerto Ricans; people living in the Northeast United States; people living below the Federal poverty level; and employees with certain exposures in the workplace.

While there is not a cure for asthma yet, there are diagnoses and treatment guidelines that are aimed at ensuring that all people with asthma live full and active lives.

- Healthy People 2020 (www.healthypeople.gov)

[NOTE: COPD was changed to chronic lower respiratory disease (CLRD) with the introduction of ICD-10 codes. CLRD is used in vital statistics reporting, but COPD is still widely used and commonly found in surveillance reports.]

Respiratory Disease Deaths

Age-Adjusted Chronic Lower Respiratory Disease Deaths (CLRD)

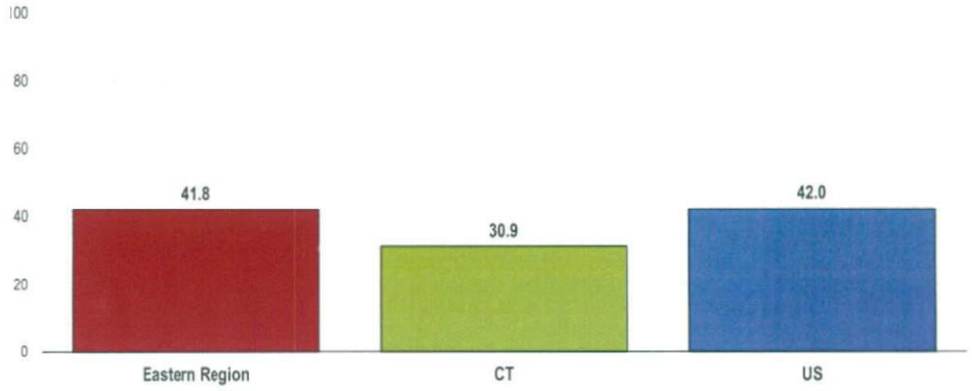
Note: COPD was changed to chronic lower respiratory disease (CLRD) in 1999 with the introduction of ICD-10 codes. CLRD is used in vital statistics reporting, but COPD is still widely used and commonly found in surveillance reports.

Between 2011 and 2013, there was an annual average age-adjusted CLRD mortality rate of 41.8 deaths per 100,000 population in the Eastern Region.

- Worse than the statewide prevalence.
- Similar to the national rate.

CLRD: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)



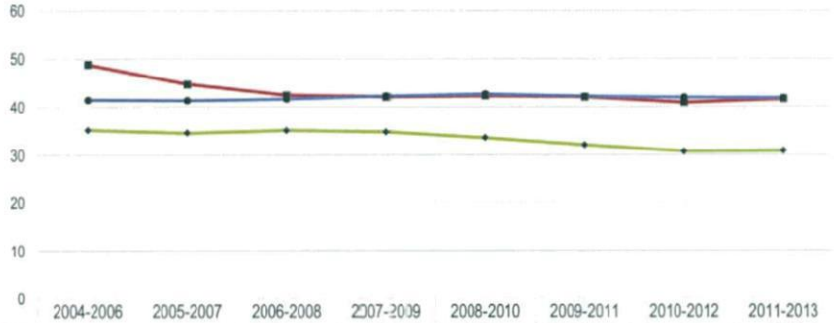
Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- CLRD is chronic lower respiratory disease.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: CLRD mortality in the Eastern Region has decreased over time.

CLRD: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	48.9	44.9	42.6	42.2	42.5	42.2	41.0	41.8
Connecticut	35.2	34.6	35.1	34.8	33.6	32.1	30.8	30.9
US	41.6	41.5	41.8	42.4	42.8	42.3	42.1	42.0

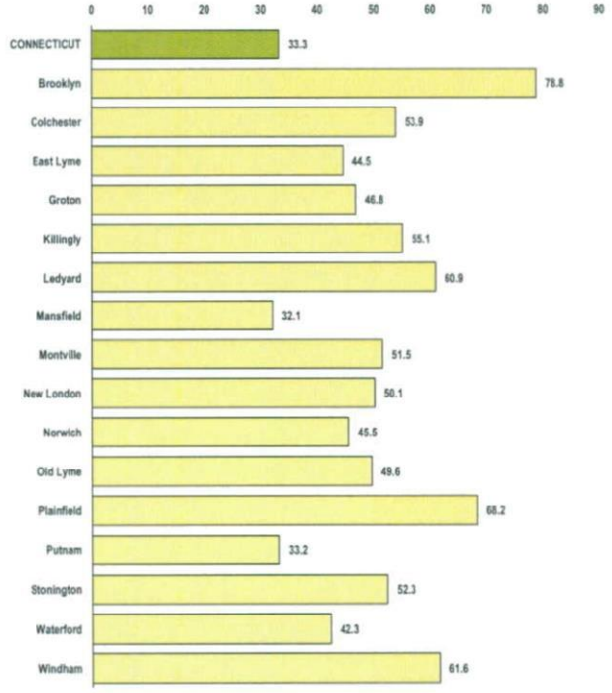
Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- State and national data are simple three-year averages.
- CLRD is chronic lower respiratory disease.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2006 to 2010, Brooklyn recorded the highest age-adjusted CLRD mortality rate among select towns in the Eastern Region.

CLRD: Age-Adjusted Mortality

(By Select Towns in the East Region, 2006-2010)



Source:
- Connecticut Department of Public Health

Age-Adjusted Pneumonia/Influenza Deaths

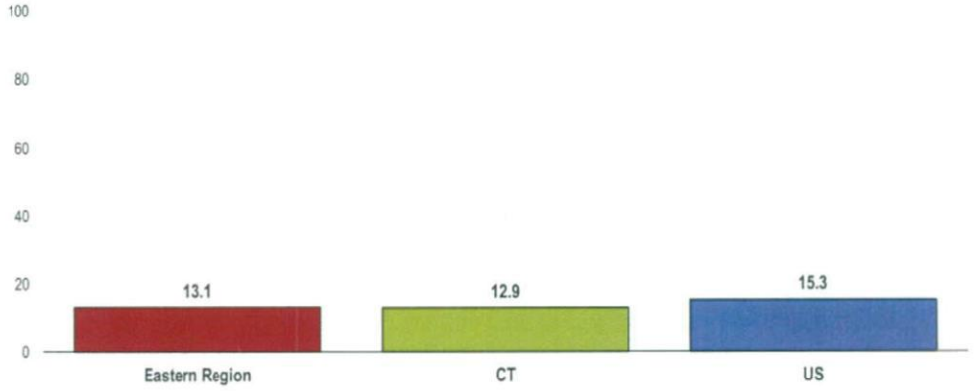
Between 2011 and 2013, there was an annual average age-adjusted pneumonia influenza mortality rate of 13.1 deaths per 100,000 population in the Eastern Region.

- Similar to that found statewide.
- Lower than the national rate.

For prevalence of vaccinations for pneumonia and influenza, see also *Immunization & Infectious Disease*.

Pneumonia/Influenza: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)



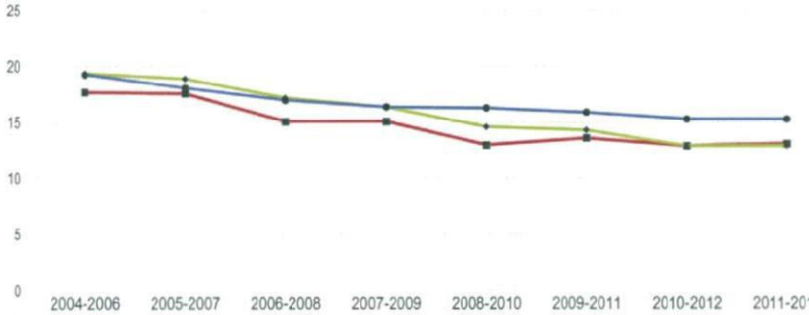
Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: Pneumonia/influenza mortality in the Eastern Region shows a decreasing trend, similar to the state and national trends.

Pneumonia/Influenza: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)



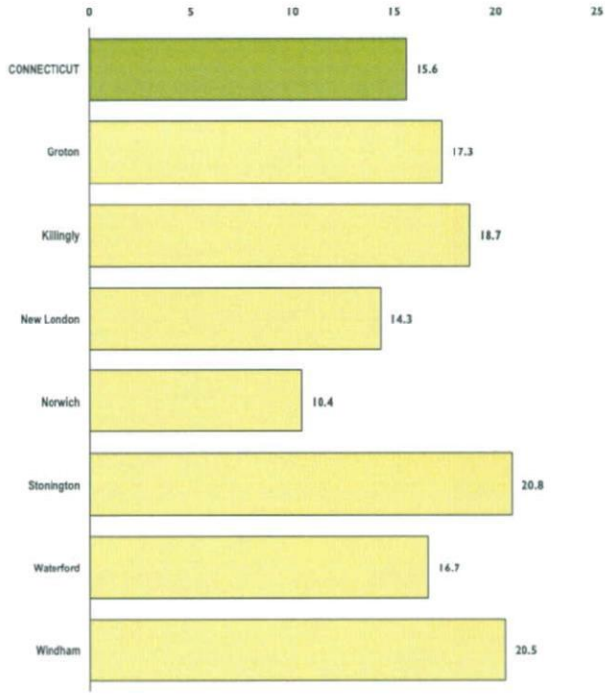
	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	17.7	17.6	15.1	15.1	13.0	13.6	12.9	13.1
Connecticut	19.4	18.9	17.2	16.4	14.6	14.3	12.9	12.9
US	19.3	18.1	17.0	16.4	16.3	15.9	15.3	15.3

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- State and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2006 to 2010, Stonington and Windham recorded the highest age-adjusted pneumonia/ influenza mortality rates among select towns in the Eastern Region.

Influenza/Pneumonia: Age-Adjusted Mortality
(By Select Towns in the East Region, 2006-2010)



Source: • Connecticut Department of Public Health

Respiratory Disease Prevalence

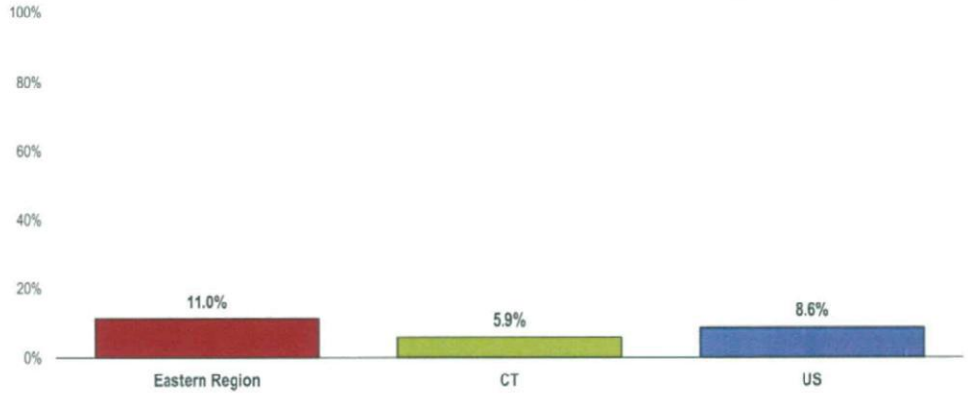
Chronic Obstructive Pulmonary Disease (COPD)

Survey respondents were next asked to indicate whether they suffer from or have been diagnosed with various respiratory conditions, including asthma and COPD.

A total of 11.0% of Eastern Region adults suffer from chronic obstructive pulmonary disease (COPD, including emphysema and bronchitis).

- Worse than the state prevalence.
- Worse than the national prevalence.

Prevalence of Chronic Obstructive Pulmonary Disease (COPD)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 25]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.

Notes:
- Asked of all respondents.
- Includes those having ever suffered from or been diagnosed with COPD or chronic obstructive pulmonary disease, including bronchitis or emphysema.

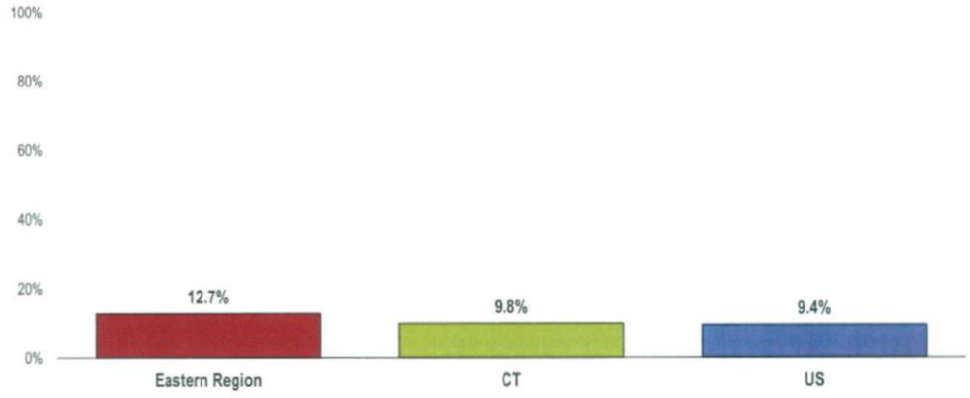
Asthma

Adults

A total of 12.7% of Eastern Region adults currently suffer from asthma.

- Worse than the statewide prevalence.
- Worse than the national prevalence.

Adult Asthma: Current Prevalence



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 134]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.

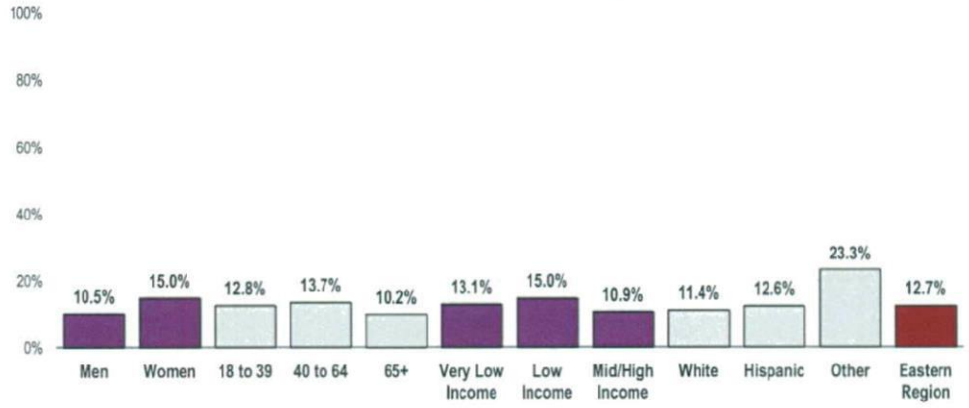
Notes:
- Asked of all respondents.
- Includes those who have ever been diagnosed with asthma, and who report that they still have asthma.

The following adults are more likely to suffer from asthma:

- Women.
- "Other" races.

Currently Have Asthma

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 134]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

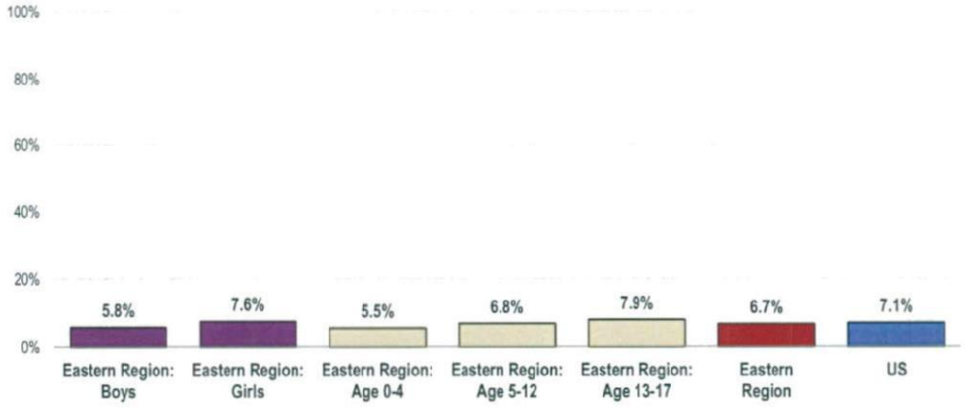
Children

Among the Eastern Region children under age 18, 6.7% currently have asthma.

- Comparable to national findings.
- Viewed by age and gender, results are similar among children in the Eastern Region.

Childhood Asthma: Current Prevalence

(Among Parents of Children Age 0-17)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 135]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

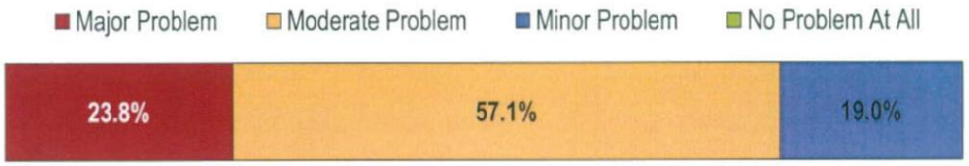
Notes:
- Asked of all respondents with children 0 to 17 in the household.
- Includes children who have ever been diagnosed with asthma, and whom are reported to still have asthma.

Key Informant Input: Respiratory Disease

The majority of key informants taking part in an online survey characterized *Respiratory Disease* as a "moderate problem" in the community.

Perceptions of Respiratory Diseases as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Prevalence

> *Extremely high prevalence in northeastern CT. - Health Provider*
>
> *High incidence of COPD and asthma - Social Services Representative*

Tobacco Use

> *Tobacco use. Adults who are smokers, smoking in the presence of children, who develop asthma or other Reactive Airway Disease. - Public Health Expert*

Humidity/Mold

> *There are areas of high humidity and/or mold nearby, as a result causing sinus infections, asthma and other respiratory diseases. Nearby complexes and apartments instead of looking for funding to upgrade their buildings and reduce the impact that these living conditions create in their residents, make tenants sign a waiver that releases them of any liability. - Social Services Representative*

Injury & Violence

About Injury & Violence

Injuries and violence are widespread in society. Both unintentional injuries and those caused by acts of violence are among the top 15 killers for Americans of all ages. Many people accept them as "accidents," "acts of fate," or as "part of life." However, most events resulting in injury, disability, or death are predictable and preventable.

Injuries are the leading cause of death for Americans ages 1 to 44, and a leading cause of disability for all ages, regardless of sex, race/ethnicity, or socioeconomic status. More than 180,000 people die from injuries each year, and approximately 1 in 10 sustains a nonfatal injury serious enough to be treated in a hospital emergency department.

Beyond their immediate health consequences, injuries and violence have a significant impact on the well-being of Americans by contributing to:

- Premature death
- Disability
- Poor mental health
- High medical costs
- Lost productivity

The effects of injuries and violence extend beyond the injured person or victim of violence to family members, friends, coworkers, employers, and communities.

Numerous factors can affect the risk of unintentional injury and violence, including individual behaviors, physical environment, access to health services (ranging from pre-hospital and acute care to rehabilitation), and social environment (from parental monitoring and supervision of youth to peer group associations, neighborhoods, and communities).

Interventions addressing these social and physical factors have the potential to prevent unintentional injuries and violence. Efforts to prevent unintentional injury may focus on:

- Modifications of the environment
- Improvements in product safety
- Legislation and enforcement
- Education and behavior change
- Technology and engineering

Efforts to prevent violence may focus on:

- Changing social norms about the acceptability of violence
- Improving problem-solving skills (for example, parenting, conflict resolution, coping)
- Changing policies to address the social and economic conditions that often give rise to violence

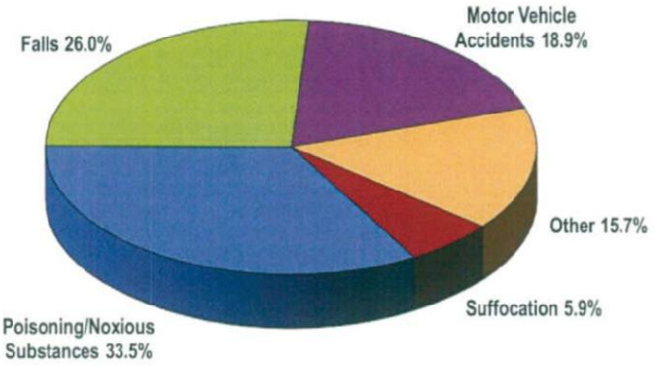
- Healthy People 2020 (www.healthypeople.gov)

Leading Causes of Accidental Death

Poisoning (including accidental drug overdose) was the leading cause of accidental deaths in the Eastern Region from 2011 to 2013.

Leading Causes of Accidental Death

(Eastern Region, 2011-2013)



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Unintentional Injury

Unintentional Injury Deaths

Age-Adjusted Unintentional Injury Deaths

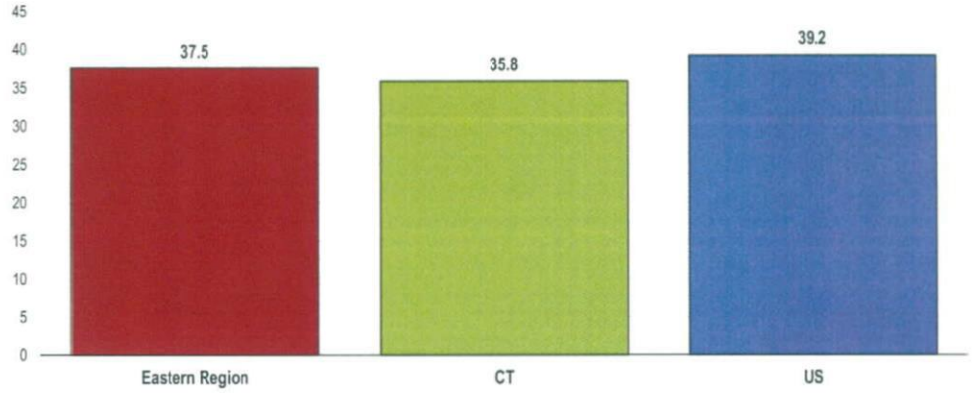
Between 2011 and 2013, there was an annual average age-adjusted unintentional injury mortality rate of 37.5 deaths per 100,000 population in the Eastern Region.

- Similar to the Connecticut rate.
- Similar to the national rate.
- Similar to the Healthy People 2020 target (36.4 or lower).

Unintentional Injuries: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 36.4 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-11]

Notes:
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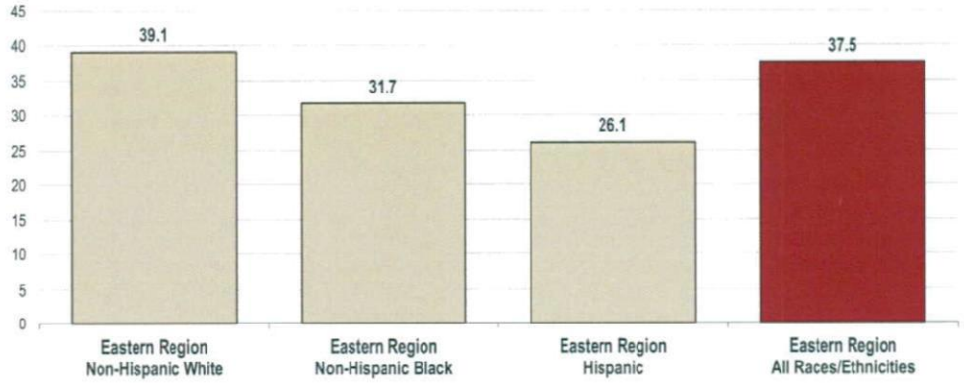
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- The mortality rate is notably higher among Non-Hispanic Whites when compared with Blacks and Hispanics in the Eastern Region.

Unintentional Injuries: Age-Adjusted Mortality by Race

(2010-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 36.4 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-11]

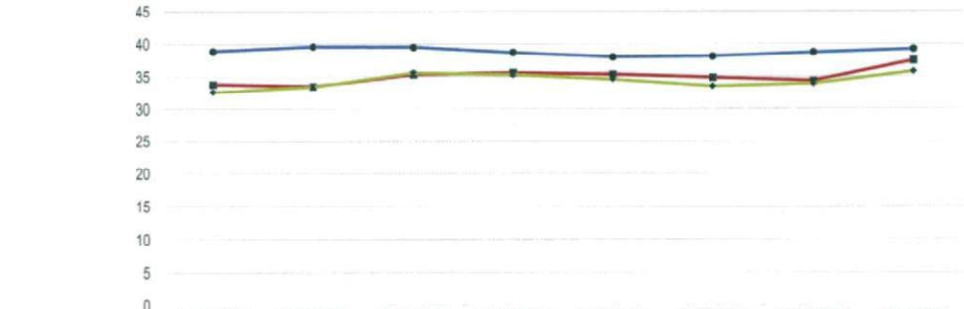
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: Despite fluctuations, there is an overall upward trend in the unintentional injury mortality rate in the Eastern Region.

Unintentional Injuries: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 36.4 or Lower



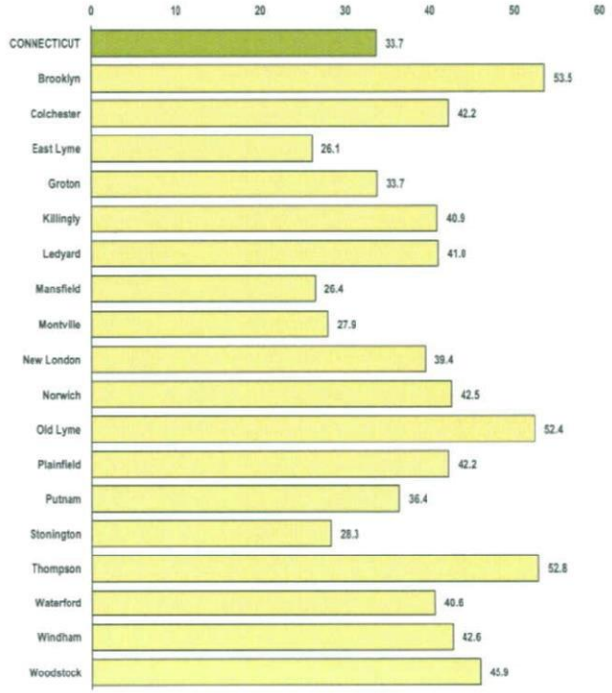
	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	33.8	33.5	35.4	35.6	35.4	34.9	34.4	37.5
Connecticut	32.6	33.4	35.6	35.3	34.6	33.5	33.9	35.8
United States	38.9	39.6	39.5	38.7	38.0	38.1	38.7	39.2

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-11]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2006 to 2010, Brooklyn recorded the highest unintentional injury mortality rate among select towns in the Eastern Region, followed by Thompson and Old Lyme.

Unintentional Injury: Age-Adjusted Mortality
(By Select Towns in the East Region, 2006-2010)



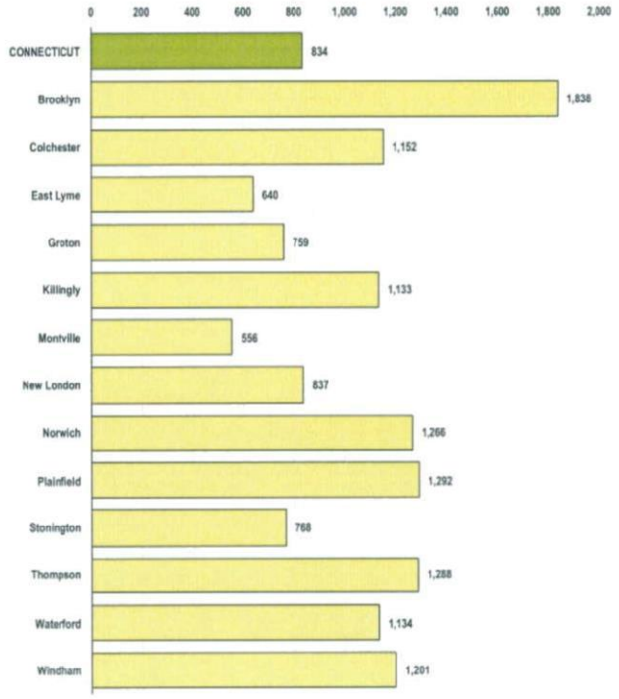
Source: • Connecticut Department of Public Health

Unintentional Injury YPLL75

As shown, Brooklyn recorded the highest total of years of potential life lost from unintentional injury among select towns in the area.

Unintentional Injuries: YPLL75

(By Select Towns in the East Region, 2006-2010)



Source: • Connecticut Department of Public Health

Motor Vehicle Safety

Age-Adjusted Motor-Vehicle Related Deaths

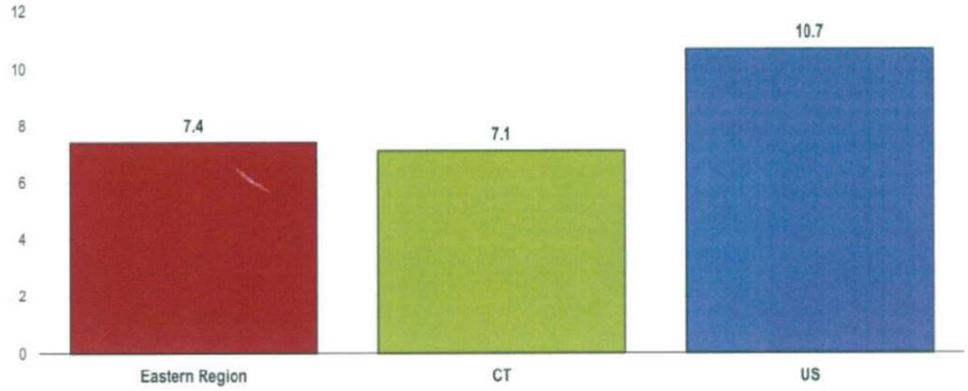
Between 2011 and 2013, there was an annual average age-adjusted motor vehicle crash mortality rate of 7.4 deaths per 100,000 population in the Eastern Region.

- Similar to that found statewide.
- Lower than found nationally.
- Satisfies the Healthy People 2020 target (12.4 or lower).

Motor Vehicle Crashes: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 12.4 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-13.1]

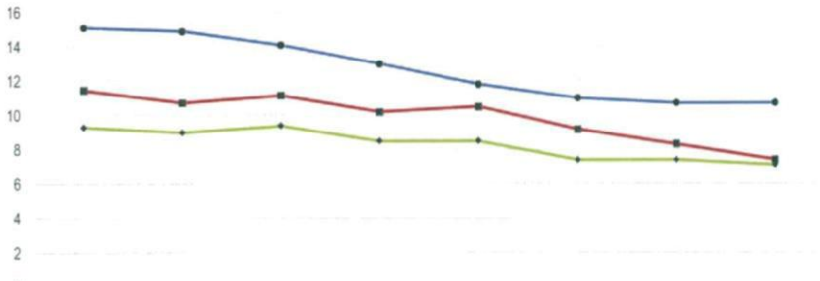
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The motor vehicle–related mortality rate in the Eastern Region has been decreasing over time, in keeping with state and national trends.

Motor Vehicle Crashes: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 12.4 or Lower



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	11.5	10.7	11.2	10.2	10.5	9.2	8.3	7.4
Connecticut	9.3	9.0	9.4	8.5	8.5	7.4	7.4	7.1
United States	15.1	14.9	14.1	13.0	11.8	11.0	10.7	10.7

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-13.1]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Seat Belt Usage - Adults

Most Eastern Region adults (91.8%) report "always" wearing a seat belt when driving or riding in a vehicle.

- More favorable than the national percentage.
- Comparable to the Healthy People 2020 target of 92.0% or higher.

Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 49]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-15]

Notes:
- Asked of all respondents.

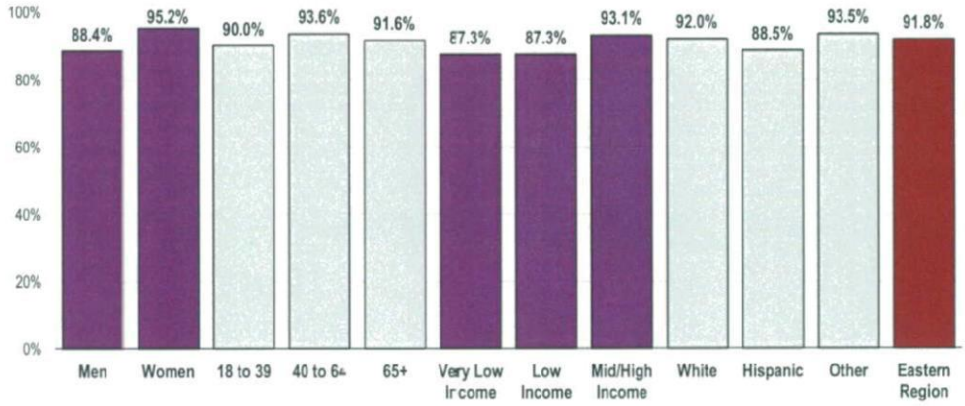
These population segments are <u>less</u> likely to report consistent seat belt usage:

- Men.
- Lower-income residents.

"Always" Wear a Seat Belt When Driving or Riding in a Vehicle

(Eastern Region, 2015)

Healthy People 2020 Target = 92.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 49]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-15]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

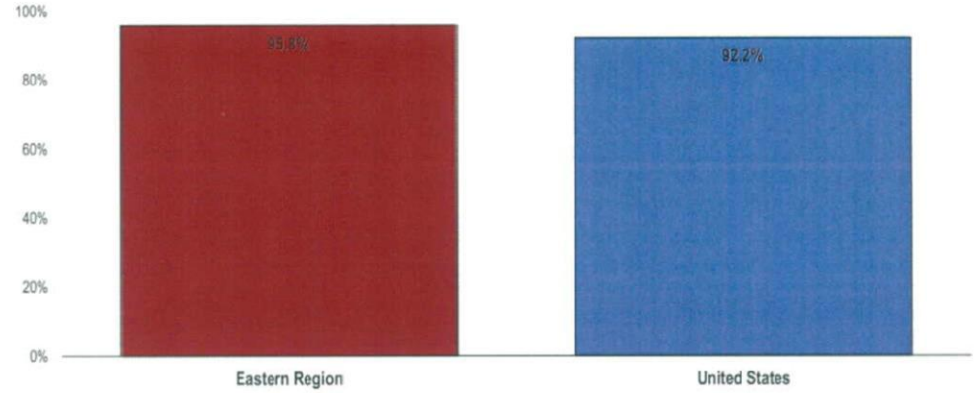
Seat Belt Usage - Children

A full 95.8% of the Eastern Region parents report that their child (age 0 to 17) "always" wears a seat belt (or appropriate car seat for younger children) when riding in a vehicle.

- Better than what is found nationally.

Child "Always" Wears a Seat Belt or Appropriate Restraint When Riding in a Vehicle

(Among Parents of Children Age 0-17)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 122]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents with children 0 to 17 in the household.

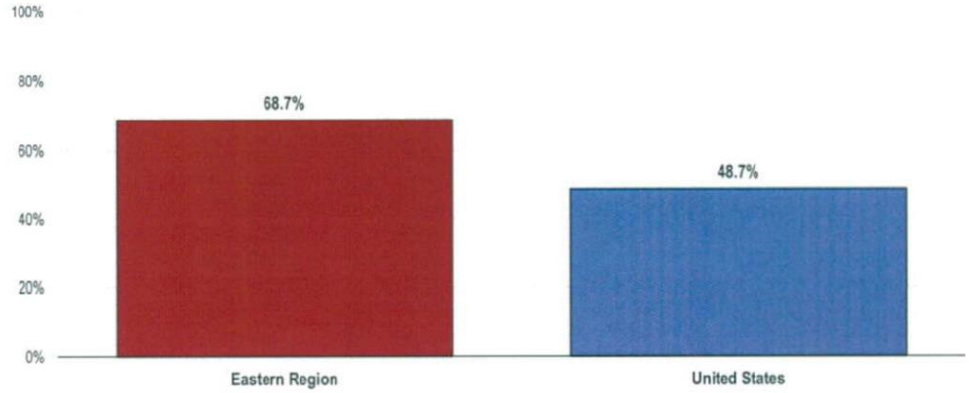
Bicycle Safety

More than 2 in 3 the Eastern Region children age 5 to 17 (68.7%) are reported to "always" wear a helmet when riding a bicycle.

- Better than the national prevalence.

Child "Always" Wears a Helmet When Riding a Bicycle

(Among Parents of Children Age 5-17)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 121]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents with children age 5 to 17 at home.

Firearm Safety

Age-Adjusted Firearm-Related Deaths

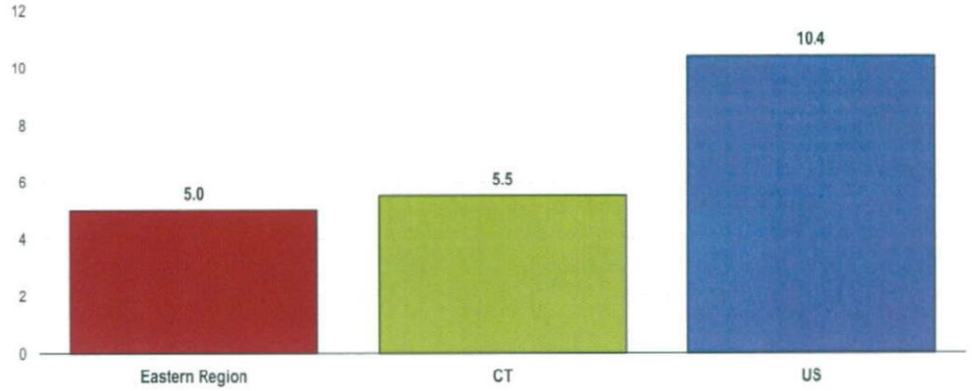
Between 2011 and 2013, there was an annual average age-adjusted rate of 5.0 deaths per 100,000 population due to firearms in the Eastern Region.

- Lower than found statewide.
- Half the rate than found nationally.
- Satisfies the Healthy People 2020 objective (9.3 or lower).

Firearms-Related Deaths: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 9.3 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-30]

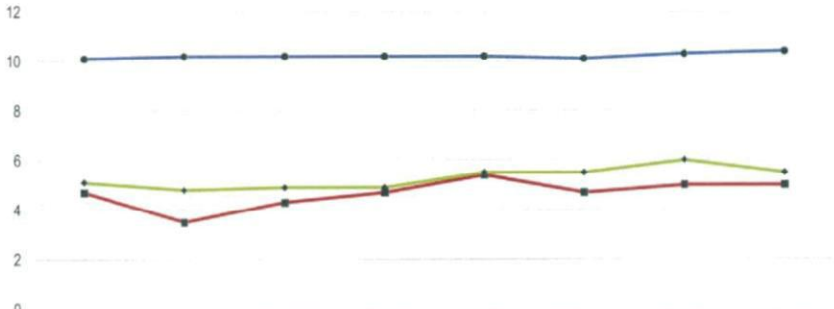
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The mortality rate in the Eastern Region has generally increased over time.

Firearms-Related Deaths: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 9.3 or Lower



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	4.7	3.5	4.3	4.7	5.4	4.7	5.0	5.0
Connecticut	5.1	4.8	4.9	4.9	5.5	5.5	6.0	5.5
United States	10.1	10.2	10.2	10.2	10.2	10.1	10.3	10.4

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-30]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Presence of Firearms in Homes

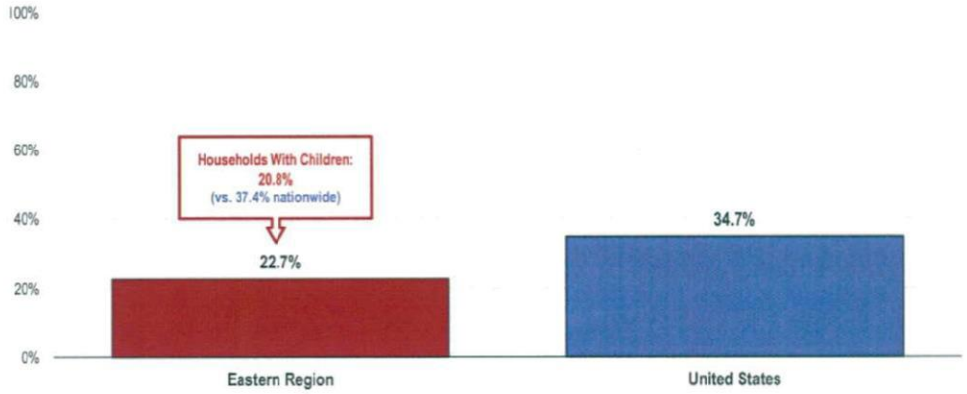
Survey respondents were further asked about the presence of weapons in the home:

"Are there any firearms now kept in or around your home, including those kept in a garage, outdoor storage area, truck, or car? For the purposes of this inquiry, 'firearms' include pistols, shotguns, rifles, and other types of guns, but do NOT include starter pistols, BB guns, or guns that cannot fire."

Overall, 22.7% of Eastern Region adults have a firearm kept in or around their home.

- Much lower than the national prevalence.
- Among Eastern Region households with children, 20.8% have a firearm kept in or around the house (lower than reported nationally).

Have a Firearm Kept in or Around the Home



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 52, 137]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

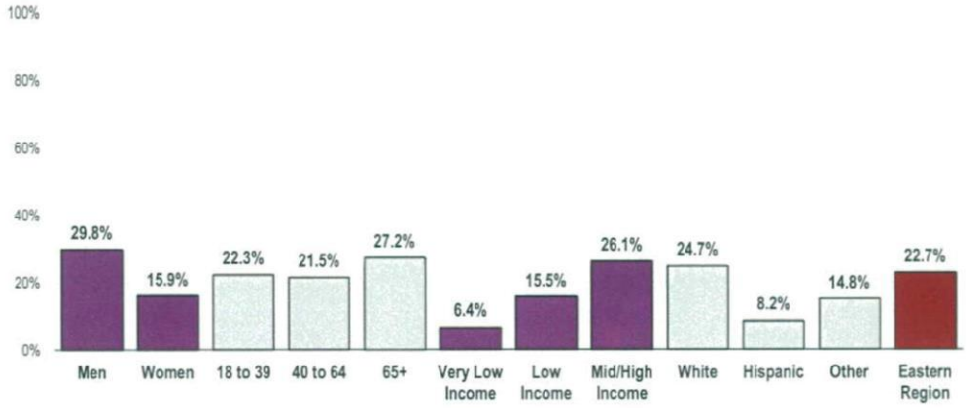
Notes:
- Asked of all respondents.
- In this case, firearms include pistols, shotguns, rifles, and other types of guns; this does not include starter pistols, BB guns, or guns that cannot fire.

Reports of firearms in or around the home are more prevalent among the following respondent groups:

- Men.
- Seniors.
- Upper-income residents (positive correlation).
- White respondents.

Have a Firearm Kept in or Around the House

(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 52]
Notes: • Asked of all respondents.
• In this case, firearms include pistols, shotguns, rifles, and other types of guns; this does not include starter pistols, BB guns, or guns that cannot fire.
• Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100--199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Among Eastern Region households with firearms, 8.8% report that there is at least one weapon that is kept unlocked and loaded.

- Lower than national rate.

Household Has An Unlocked, Loaded Firearm

(Among Respondents Reporting a Firearm in or Around the Home)

Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 138]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents with a firearm in or around the home.
• In this case, firearms include pistols, shotguns, rifles, and other types of guns; this does not include starter pistols, BB guns, or guns that cannot fire.

Intentional Injury (Violence)

Age-Adjusted Homicide Deaths

Between 2011 and 2013, there was an annual average age-adjusted homicide rate of 2.2 deaths per 100,000 population in the Eastern Region.

- More favorable than the rate found statewide.
- More favorable than the national rate.
- Satisfies the Healthy People 2020 target of 5.5 or lower.

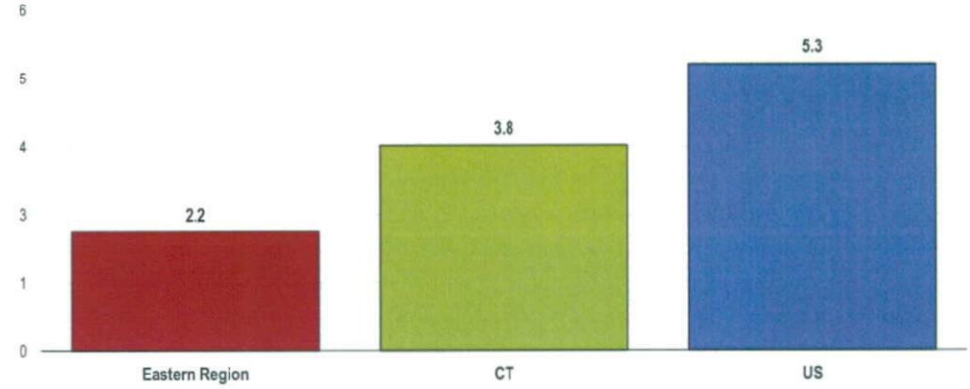
RELATED ISSUE:

See also *Suicide* in the **Mental Health** section of this report.

Homicide: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 5.5 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-29]

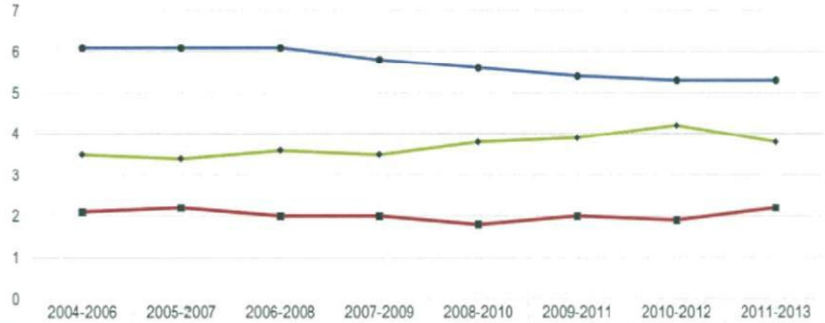
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: Over the past decade, the homicide rate in the Eastern Region has been fairly stable.

Homicide: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 5.5 or Lower



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	2.1	2.2	2.0	2.0	1.8	2.0	1.9	2.2
Connecticut	3.5	3.4	3.6	3.5	3.8	3.9	4.2	3.8
United States	6.1	6.1	6.1	5.8	5.6	5.4	5.3	5.3

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IVP-29]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Violent Crime

Violent Crime Rates

Violent crime is composed of four offenses (FBI Index offenses): murder and non-negligent manslaughter; forcible rape; robbery; and aggravated assault.

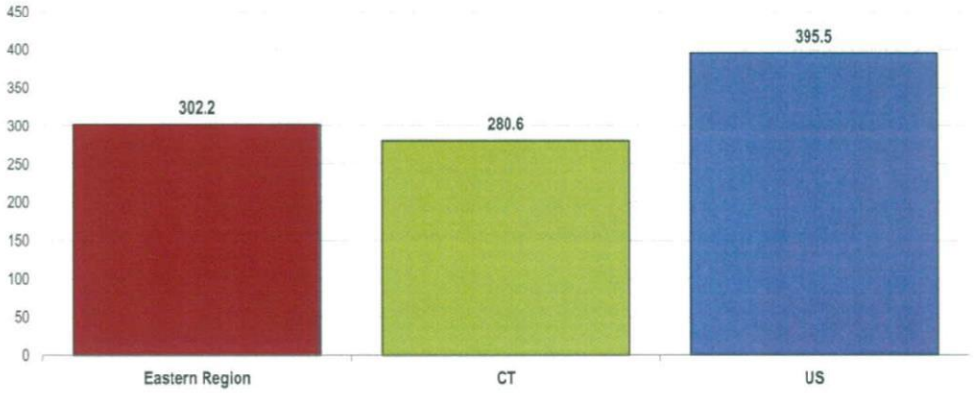
Note that the quality of crime data can vary widely from location to location, depending on the consistency and completeness of reporting among various jurisdictions.

From 2010 to 2012, there were a reported 302.2 violent crimes per 100,000 population in the Eastern Region.

- Worse than the statewide rate.
- Better than the national rate.

Violent Crime

(Rate per 100,000 Population, 2010-2012)



Sources:
- Federal Bureau of Investigation, FBI Uniform Crime Reports: 2012.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator reports the rate of violent crime offenses reported by the sheriff's office or county police department per 100,000 residents. Violent crime includes homicide, rape, robbery, and aggravated assault. This indicator is relevant because it assesses community safety.
- Participation by law enforcement agencies in the UCR program is voluntary. Sub-state data do not necessarily represent an exhaustive list of crimes due to gaps in reporting. Also, some institutions of higher education have their own police departments, which handle offenses occurring within campus grounds; these offenses are not included in the violent crime statistics, but can be obtained from the Uniform Crime Reports Universities and Colleges data tables.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Self-Reported Violence

Just 0.8% of Eastern Region adults acknowledges being the victim of a violent crime in the past five years.

- Well below the national prevalence.

Victim of a Violent Crime in the Past Five Years

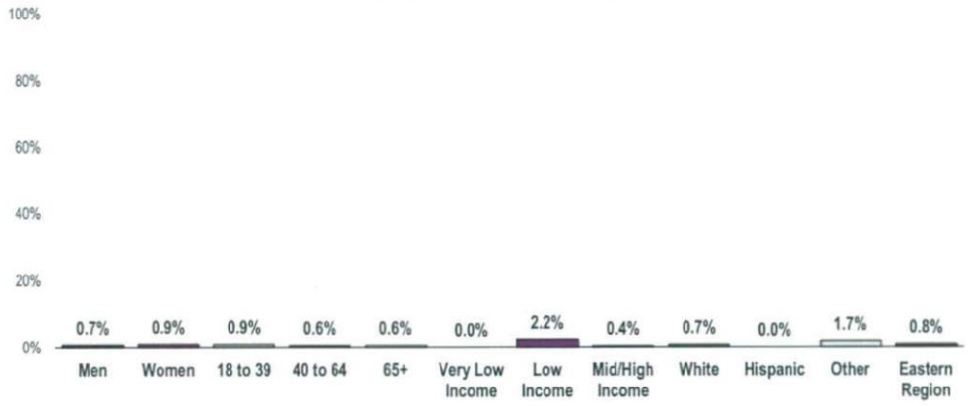
Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 50]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.

- Reports of violence do not vary significantly among Eastern Region survey respondents.

Victim of a Violent Crime in the Past Five Years

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 50]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Self-Reported Family Violence

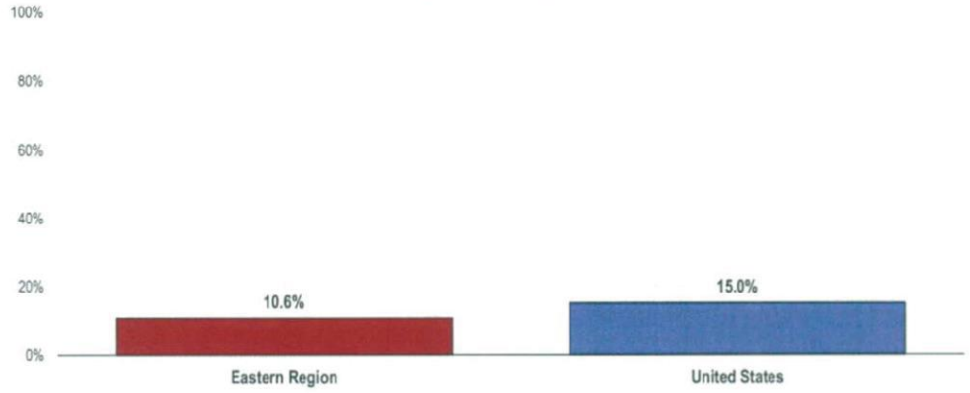
Respondents were told:

"By an intimate partner, I mean any current or former spouse, boyfriend, or girlfriend. Someone you were dating, or romantically or sexually intimate with would also be considered an intimate partner."

A total of 10.6% of respondents acknowledge that they have ever been hit, slapped, pushed, kicked, or otherwise hurt by an intimate partner.

- More favorable than national findings.

Have Ever Been Hit, Slapped, Pushed, Kicked, or Hurt in Any Way by an Intimate Partner



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 51]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

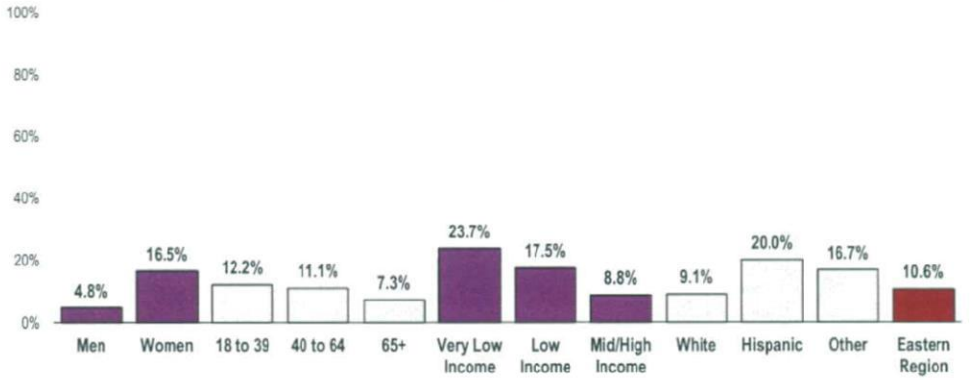
Notes:
- Asked of all respondents.

Reports of domestic violence are notably higher among:

- Women.
- Those with lower incomes (negative correlation with income).
- Hispanics and those of "Other" races.

Have Ever Been Hit, Slapped, Pushed, Kicked, or Hurt in Any Way by an Intimate Partner

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 51]

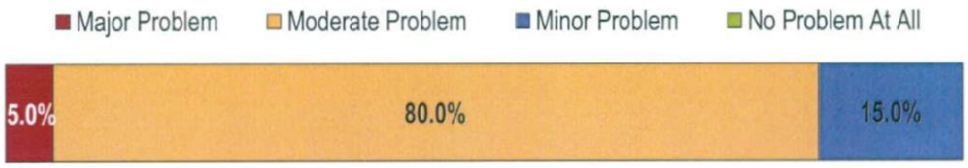
Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Key Informant Input: Injury & Violence

The vast majority of key informants taking part in an online survey characterized *Injury & Violence* as a "moderate problem" in the community.

Perceptions of Injury and Violence as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Diabetes

About Diabetes

Diabetes mellitus occurs when the body cannot produce or respond appropriately to insulin. Insulin is a hormone that the body needs to absorb and use glucose (sugar) as fuel for the body's cells. Without a properly functioning insulin signaling system, blood glucose levels become elevated and other metabolic abnormalities occur, leading to the development of serious, disabling complications. Many forms of diabetes exist; the three common types are Type 1, Type 2, and gestational diabetes. Effective therapy can prevent or delay diabetic complications.

Diabetes mellitus:

- Lowers life expectancy by up to 15 years.
- Increases the risk of heart disease by 2 to 4 times.
- Is the leading cause of kidney failure, lower limb amputations, and adult-onset blindness.

The rate of diabetes mellitus continues to increase both in the United States and throughout the world. Due to the steady rise in the number of persons with diabetes mellitus, and possibly earlier onset of type 2 diabetes mellitus, there is growing concern about the possibility that the increase in the number of persons with diabetes mellitus and the complexity of their care might overwhelm existing healthcare systems.

People from minority populations are more frequently affected by type 2 diabetes. Minority groups constitute 25% of all adult patients with diabetes in the US and represent the majority of children and adolescents with type 2 diabetes.

Lifestyle change has been proven effective in preventing or delaying the onset of type 2 diabetes in high-risk individuals.

- Healthy People 2020 (www.healthypeople.gov)

Age-Adjusted Diabetes Deaths

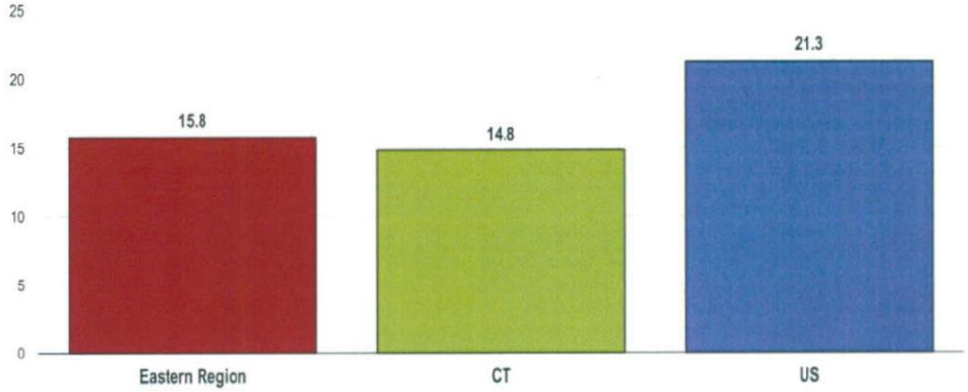
Between 2011 and 2013, there was an annual average age-adjusted diabetes mortality rate of 15.8 deaths per 100,000 population in the Eastern Region.

- Less favorable than that found statewide.
- More favorable than the national rate.
- Satisfies the Healthy People 2020 target (20.5 or lower, adjusted to account for diabetes mellitus-coded deaths).

Diabetes: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 20.5 or Lower (Adjusted)



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective D-3]

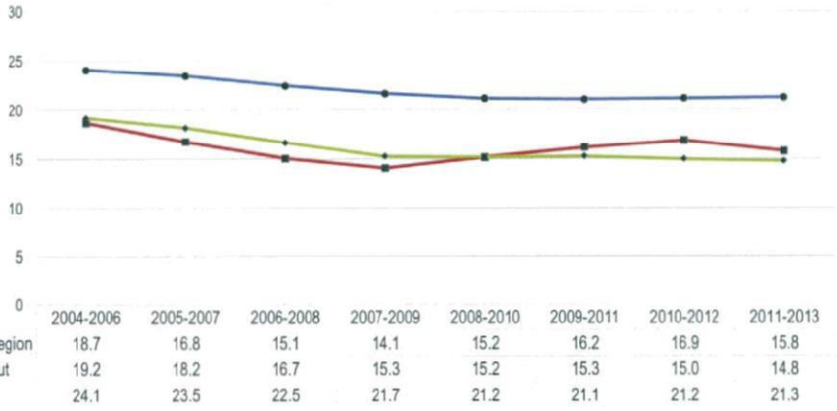
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- The Healthy People 2020 target for Diabetes is adjusted to account for only diabetes mellitus coded deaths.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The diabetes mortality rate in the Eastern Region has fallen and risen.

Diabetes: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 20.5 or Lower (Adjusted)



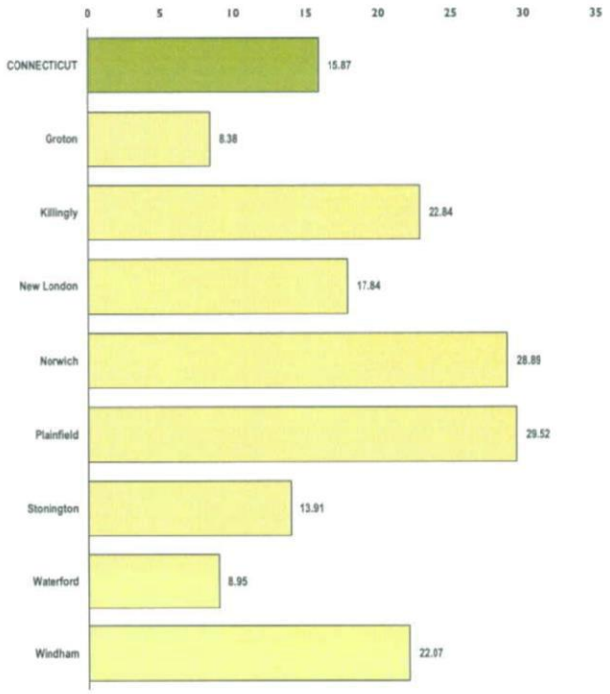
	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	18.7	16.8	15.1	14.1	15.2	16.2	16.9	15.8
Connecticut	19.2	18.2	16.7	15.3	15.2	15.3	15.0	14.8
US	24.1	23.5	22.5	21.7	21.2	21.1	21.2	21.3

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective D-3]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- Local, state and national data are simple three-year averages.
- The Healthy People 2020 target for Diabetes is adjusted to account for only diabetes mellitus coded deaths.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2006 to 2010, Plainfield and Norwich recorded the highest age-adjusted diabetes mortality rates among select towns in the region.

Diabetes: Age-Adjusted Mortality
(By Select Towns in the East Region, 2006-2010)



Source: • Connecticut Department of Public Health

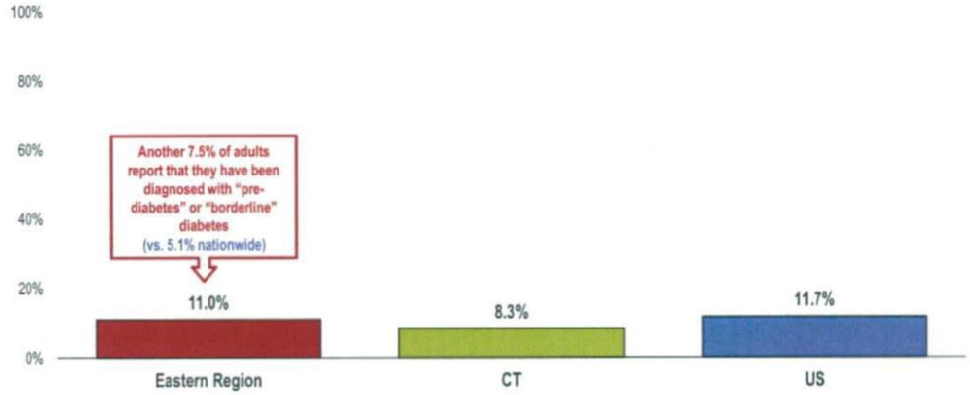
Prevalence of Diabetes

A total of 11.0% of Eastern Region adults report having been diagnosed with diabetes.

- Higher than the statewide proportion.
- Similar to the national proportion.

In addition to the prevalence of diagnosed diabetes referenced above, another 7.5% of Eastern Region adults report that they have "pre-diabetes" or "borderline diabetes."

Prevalence of Diabetes



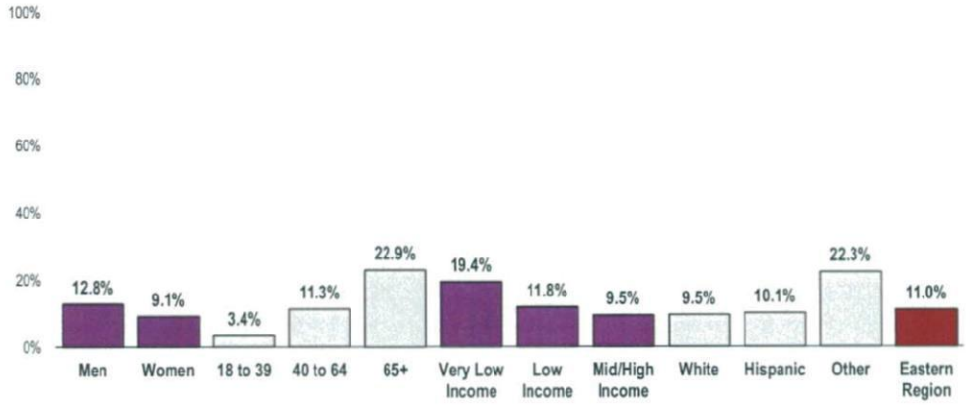
Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 136]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.

Notes:
- Asked of all respondents.
- Local and national data exclude gestation diabetes (occurring only during pregnancy).

A higher prevalence of diagnosed diabetes (excluding pre-diabetes or borderline diabetes) is reported among:

- Men.
- Adults age 40 and older (note the strong positive correlation between diabetes and age, with 22.9% of seniors with diabetes).
- Residents with lower incomes (negative correlation with income).
- "Other" respondents.

Prevalence of Diabetes
(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 136]

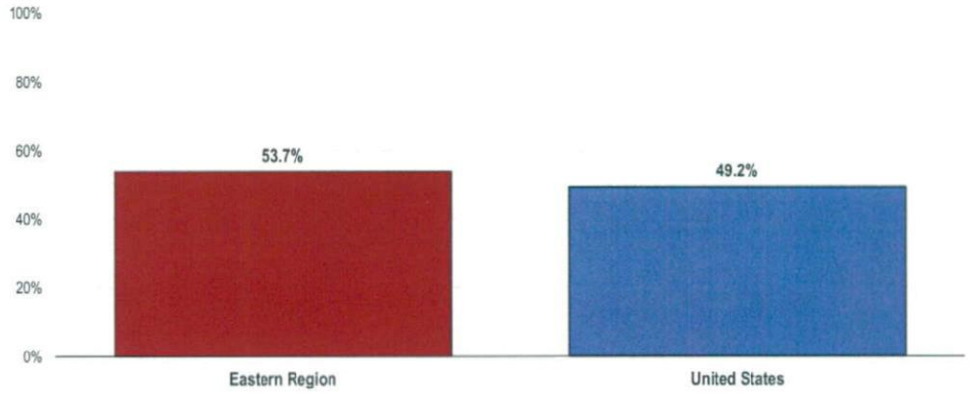
Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.
- Excludes gestation diabetes (occurring only during pregnancy).

Diabetes Testing

Of the Eastern Region adults who have not been diagnosed with diabetes, 53.7% report having had their blood sugar level tested within the past three years.

- Better than the national proportion.

Have Had Blood Sugar Tested in the Past Three Years
(Among Non-Diabetics)

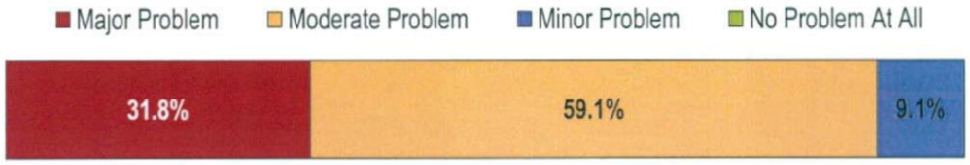


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 40]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of respondents who have not been diagnosed with diabetes.

Key Informant Input: Diabetes

A high percentage of key informants taking part in an online survey characterized *Diabetes* as a "moderate problem" in the community

Perceptions of Diabetes as a Problem in the Community
(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Challenges

Among those rating this issue as a "major problem," the biggest challenges for people with diabetes are seen as:

Cost

> *Some major issues would be affordability of the treatments, and especially clients that do not have current health coverage and cannot afford treatments to keep them out of relapse. Our area has quite*

> *a group of undocumented residents that unfortunately due to their status cannot obtain the necessary high priced treatments for themselves. Also, access to healthy fruits and vegetables in our area. There aren't that many points of access for families. Many families rely on canned fruit and high processed foods. - Social Services Representative*
>
> *For those without health insurance the cost of testing supplies and medication as well as access to healthier choices for food are significant. There also seems to be a disconnect between those who need education about their disease and those who actually receive it. - Public Health Expert*

Disease Management

> *Self-management, and the disproportionate impact on minorities and the poor. Diabetics have to change so much about their lives to manage their conditions, and it is overwhelming for even someone of means with adequate family and social support. - Health Provider*
>
> *Once diagnosed, limited staying healthy services, or disease progression prevention services are available - much more emphasis should be put on this to avoid significant disease complications - Social Services Representative*

Prevalence

> *High prevalence and insufficient resources which are accessible with or without insurance. - Health Provider*

Alzheimer's Disease

About Dementia

Dementia is the loss of cognitive functioning—thinking, remembering, and reasoning—to such an extent that it interferes with a person's daily life. Dementia is not a disease itself, but rather a set of symptoms. Memory loss is a common symptom of dementia, although memory loss by itself does not mean a person has dementia. Alzheimer's disease is the most common cause of dementia, accounting for the majority of all diagnosed cases.

Alzheimer's disease is the 6th leading cause of death among adults age 18 years and older. Estimates vary, but experts suggest that up to 5.1 million Americans age 65 years and older have Alzheimer's disease. These numbers are predicted to more than double by 2050 unless more effective ways to treat and prevent Alzheimer's disease are found.

- Healthy People 2020 (www.healthypeople.gov)

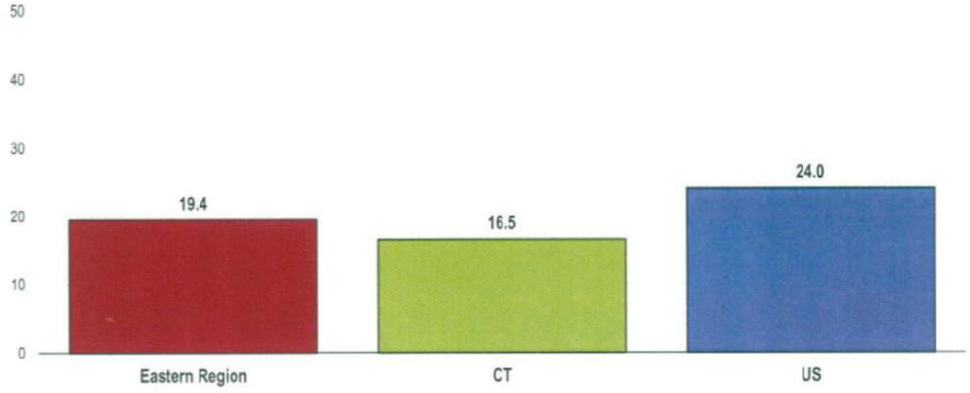
Age-Adjusted Alzheimer's Disease Deaths

Between 2011 and 2013, there was an annual average age-adjusted Alzheimer's disease mortality rate of 19.4 deaths per 100,000 population in the Eastern Region.

- Higher than the statewide rate.
- Lower than the national rate.

Alzheimer's Disease: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)



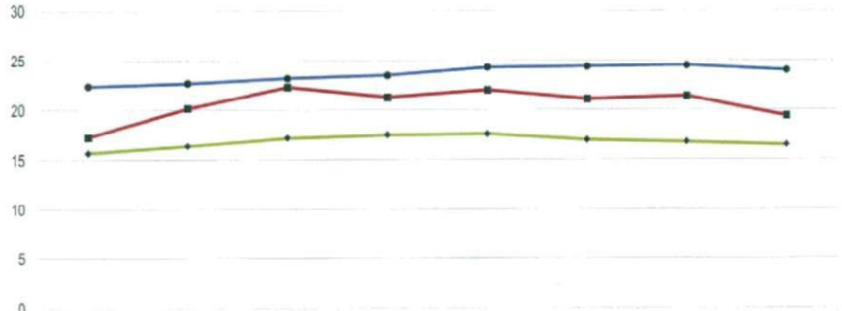
Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The Alzheimer's disease mortality rate in the Eastern Region has not shown a clear trend over the past decade.

Alzheimer's Disease: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	17.3	20.2	22.3	21.3	22.0	21.1	21.4	19.4
Connecticut	15.7	16.4	17.2	17.5	17.6	17.0	16.8	16.5
United States	22.4	22.7	23.2	23.5	24.3	24.4	24.5	24.0

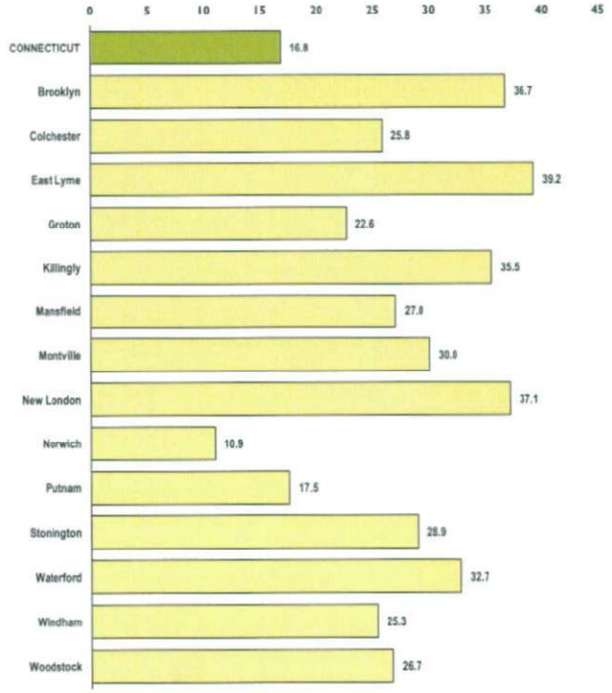
Sources: • CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes: • Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
• Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
• Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2006 to 2010, East Lyme, New London and Brooklyn recorded the highest Alzheimer's mortality rates among select towns in the Eastern Region.

Alzheimer's Disease: Age-Adjusted Mortality

(By Select Towns in the East Region, 2006-2010)



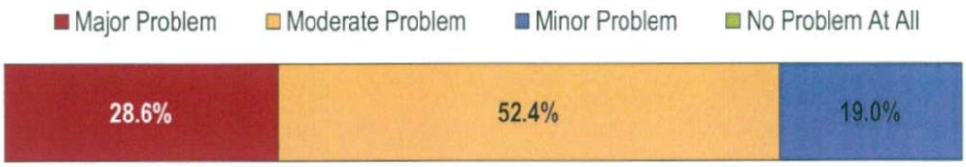
Source: • Connecticut Department of Public Health

Key Informant Input: Dementias, Including Alzheimer's Disease

Key informants taking part in an online survey are most likely to consider *Dementias, Including Alzheimer's Disease* as a "moderate problem" in the community.

Perceptions of Dementia/Alzheimer's Disease as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Caregiver Support

> *It is becoming more prevalent and working caregivers are often best positioned to provide care that can keep people at home as long as possible and out of more expensive, and less nurturing, nursing home. However, caregivers need respite and support to enable them to provide that level of care, to keep both themselves and the patient as healthy as possible. - Health Provider*
>
> *This disease does not get enough attention, nor resources. Most people cannot access caregiver support in an affordable way and we need more medical expertise locally. - Health Provider*

Awareness of Available Services

> *I am not sure that everybody is aware of the services that are available to them if they are having a crisis. - Health Provider*

Limited Resources

> *Aging population; limited resources to handle the problem. - Social Services Representative*

Kidney Disease

About Chronic Kidney Disease

Chronic kidney disease and end-stage renal disease are significant public health problems in the United States and a major source of suffering and poor quality of life for those afflicted. They are responsible for premature death and exact a high economic price from both the private and public sectors. Nearly 25% of the Medicare budget is used to treat people with chronic kidney disease and end-stage renal disease.

Genetic determinants have a large influence on the development and progression of chronic kidney disease. It is not possible to alter a person's biology and genetic determinants; however, environmental influences and individual behaviors also have a significant influence on the development and progression of chronic kidney disease. As a result, some populations are disproportionately affected. Successful behavior modification is expected to have a positive influence on the disease.

Diabetes is the most common cause of kidney failure. The results of the Diabetes Prevention Program (DPP) funded by the national Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) show that moderate exercise, a healthier diet, and weight reduction can prevent development of type 2 diabetes in persons at risk.

- Healthy People 2020 (www.healthypeople.gov)

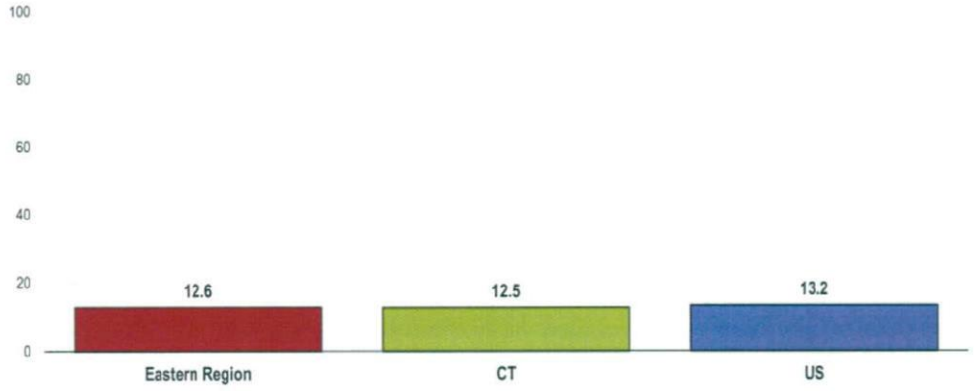
Age-Adjusted Kidney Disease Deaths

Between 2011 and 2013, there was an annual average age-adjusted kidney disease mortality rate of 12.6 deaths per 100,000 population in the Eastern Region.

- Comparable to the rate found statewide.
- Comparable to the national rate.

Kidney Disease: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)



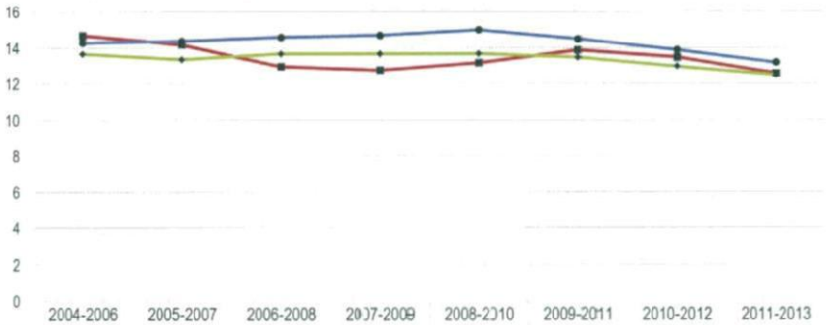
Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: Rates have largely decreased over the past decade.

Kidney Disease: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	14.7	14.2	13.0	12.8	13.2	13.9	13.5	12.6
Connecticut	13.7	13.4	13.7	13.7	13.7	13.5	13.0	12.5
United States	14.3	14.4	14.6	14.7	15.0	14.5	13.9	13.2

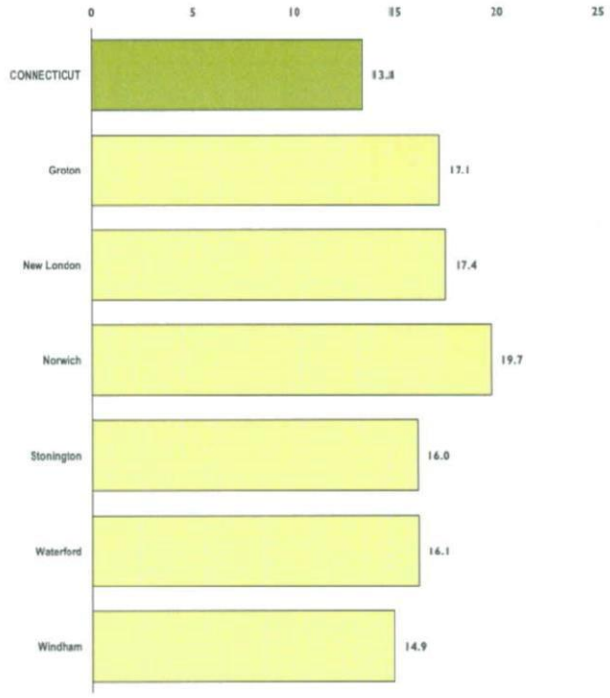
Sources: • CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.

Notes: • Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
• Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
• State and national data are simple three-year averages.
• Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2006 to 2010, Norwich recorded the highest kidney disease mortality rate among select towns in the area.

Kidney Disease: Age-Adjusted Mortality

(By Select Towns in the East Region, 2006-2010)



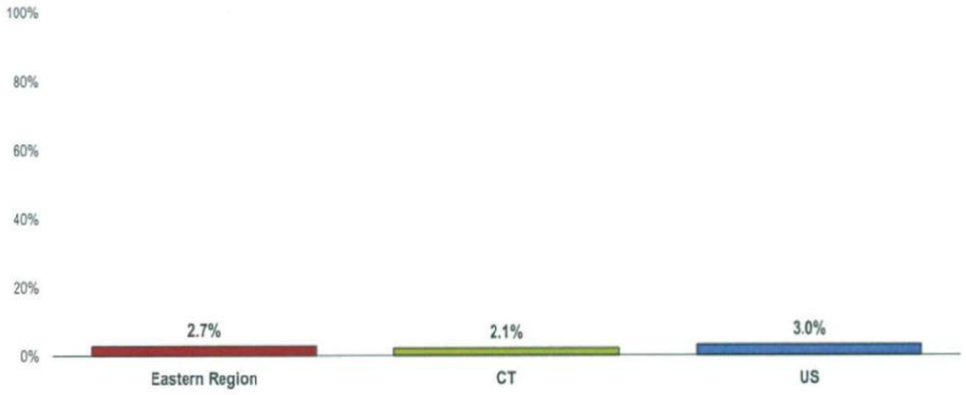
Source: • Connecticut Department of Public Health

Prevalence of Kidney Disease

A total of 2.7% of Eastern Region adults report having been diagnosed with kidney disease.

- Similar to the national proportion.
- Similar to the state proportion.

Prevalence of Kidney Disease

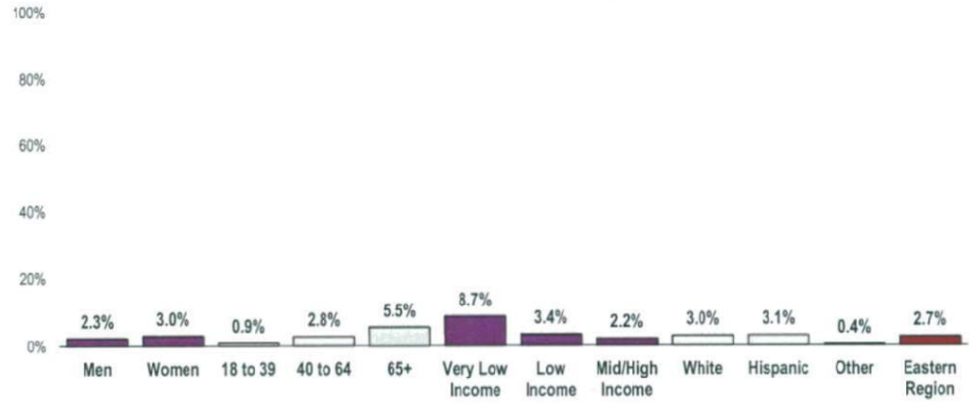


Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 33]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.

Notes:
- Asked of all respondents.

- A higher prevalence of kidney disease is reported among adults age 40 and older in the Eastern Region, along with lower-income residents, Whites, and Hispanics.

Prevalence of Kidney Disease
(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 33]

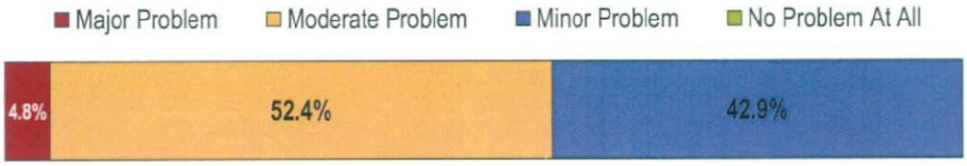
Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Key Informant Input: Chronic Kidney Disease

Key informants taking part in an online survey generally characterized *Chronic Kidney Disease* as a "moderate problem" in the community.

Perceptions of Chronic Kidney Disease as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Potentially Disabling Conditions

About Arthritis, Osteoporosis & Chronic Back Conditions

There are more than 100 types of arthritis. Arthritis commonly occurs with other chronic conditions, such as diabetes, heart disease, and obesity. Interventions to treat the pain and reduce the functional limitations from arthritis are important, and may also enable people with these other chronic conditions to be more physically active. Arthritis affects 1 in 5 adults and continues to be the most common cause of disability. It costs more than $128 billion per year. All of the human and economic costs are projected to increase over time as the population ages. There are interventions that can reduce arthritis pain and functional limitations, but they remain underused. These include: increased physical activity; self-management education; and weight loss among overweight/obese adults.

Osteoporosis is a disease marked by reduced bone strength leading to an increased risk of fractures (broken bones). In the United States, an estimated 5.3 million people age 50 years and older have osteoporosis. Most of these people are women, but about 0.8 million are men. Just over 34 million more people, including 12 million men, have low bone mass, which puts them at increased risk for developing osteoporosis. Half of all women and as many as 1 in 4 men age 50 years and older will have an osteoporosis-related fracture in their lifetime.

Chronic back pain is common, costly, and potentially disabling. About 80% of Americans experience low back pain in their lifetime. It is estimated that each year:

- 15%-20% of the population develop protracted back pain.
- 2-8% have chronic back pain (pain that lasts more than 3 months).
- 3-4% of the population is temporarily disabled due to back pain.
- 1% of the working-age population is disabled completely and permanently as a result of low back pain.

Americans spend at least $50 billion each year on low back pain. Low back pain is the:

- 2nd leading cause of lost work time (after the common cold).
- 3rd most common reason to undergo a surgical procedure.
- 5th most frequent cause of hospitalization.

Arthritis, osteoporosis, and chronic back conditions all have major effects on quality of life, the ability to work, and basic activities of daily living.

- Healthy People 2020 (www.healthypeople.gov)

Arthritis, Osteoporosis, & Chronic Back Conditions

Prevalence of Arthritis/Rheumatism

RELATED ISSUE:

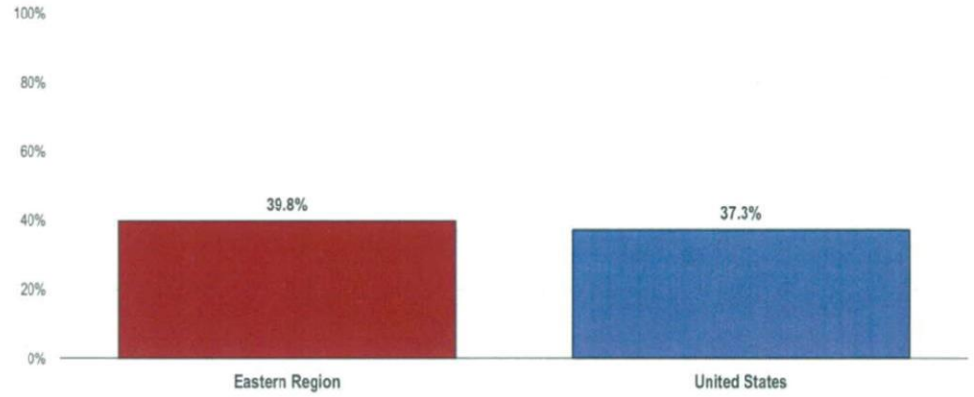
See also *Activity Limitations* in the **General Health Status** section of this report.

A full 4 in 10 Eastern Region adults age 50 and older (39.8%) report suffering from arthritis or rheumatism.

- Similar to the national prevalence.

Prevalence of Arthritis/Rheumatism

(Among Adults Age 50 and Older)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 139]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Reflects respondents age 50 and older.

Prevalence of Osteoporosis

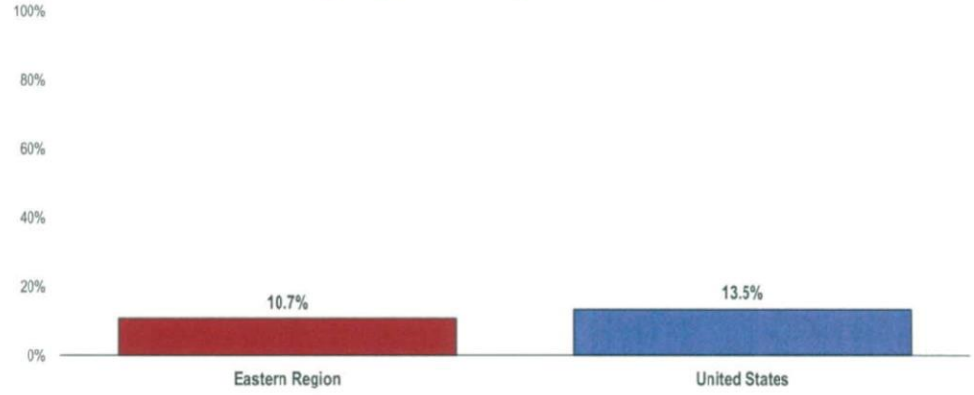
A total of 10.7% of survey respondents age 50 and older have osteoporosis.

- Comparable to that found nationwide.
- Twice the Healthy People 2020 target of 5.3% or lower.

Prevalence of Osteoporosis

(Among Adults Age 50 and Older)

Healthy People 2020 Target = 5.3% or Lower

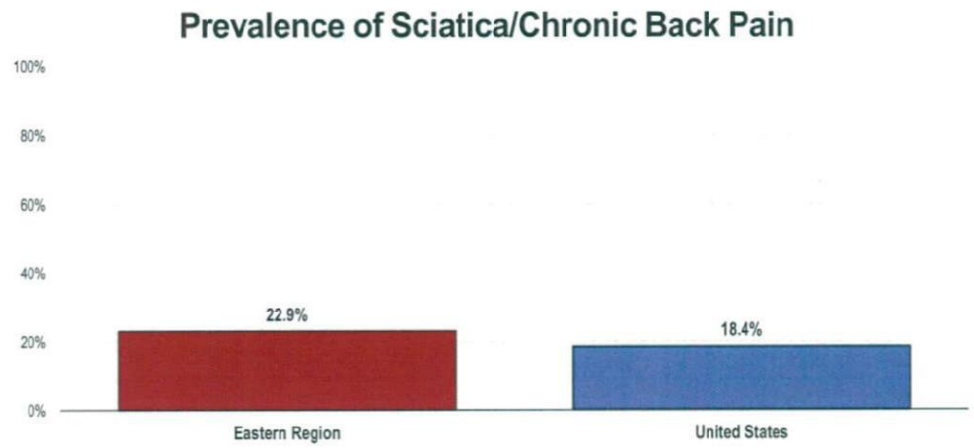


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 140]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
• US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective AOC BC-10]
Notes: • Reflects respondents age 50 and older.

Prevalence of Sciatica/Chronic Back Pain

A total of 22.9% of survey respondents suffer from chronic back pain or sciatica.

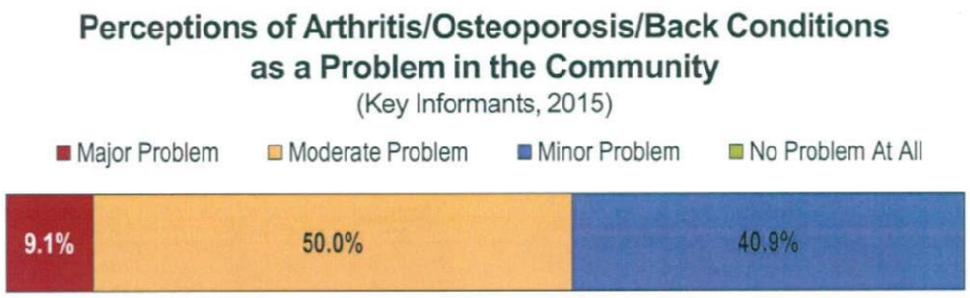
- Worse than the national rate.



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 29]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Key Informant Input: Arthritis, Osteoporosis & Chronic Back Conditions

Half of key informants taking part in an online survey characterized *Arthritis, Osteoporosis & Chronic Back Conditions* as a "moderate problem" in the community.



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Lack of Resources

> *There are not enough accessible resources for treatment, especially back pain. We need more education and treatment options that do not involve narcotics. - Health Provider*

Vision & Hearing Impairment

About Vision

Vision is an essential part of everyday life, influencing how Americans of all ages learn, communicate, work, play, and interact with the world. Yet millions of Americans live with visual impairment, and many more remain at risk for eye disease and preventable eye injury.

The eyes are an important, but often overlooked, part of overall health. Despite the preventable nature of some vision impairments, many people do not receive recommended screenings and exams. A visit to an eye care professional for a comprehensive dilated eye exam can help to detect common vision problems and eye diseases, including diabetic retinopathy, glaucoma, cataract, and age-related macular degeneration.

These common vision problems often have no early warning signs. If a problem is detected, an eye care professional can prescribe corrective eyewear, medicine, or surgery to minimize vision loss and help a person see his or her best.

Healthy vision can help to ensure a healthy and active lifestyle well into a person's later years. Educating and engaging families, communities, and the nation is critical to ensuring that people have the information, resources, and tools needed for good eye health.

- Healthy People 2020 (www.healthypeople.gov)

Vision Trouble

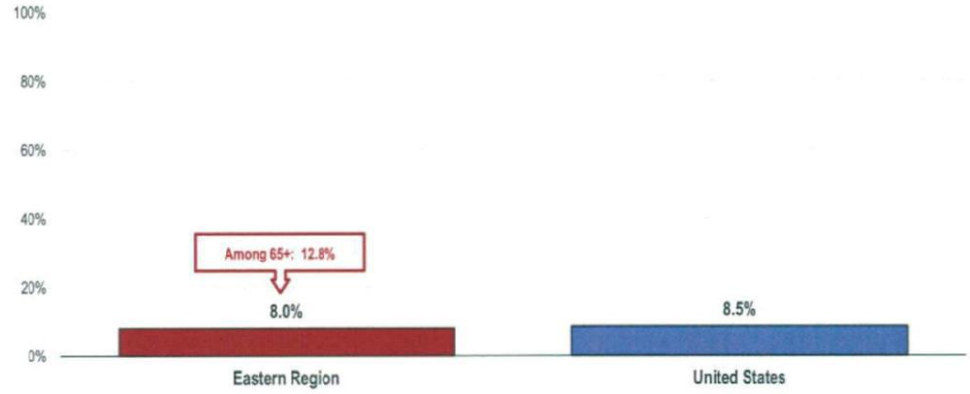
RELATED ISSUE:

See also *Vision Care* in the **Access to Health Services** section of this report.

A total of 8.0% of Eastern Region adults are blind, or have trouble seeing even when wearing corrective lenses.

- Statistically similar to national rate.
- Among Eastern Region adults age 65 and older, 12.8% have vision trouble.

Prevalence of Blindness/Trouble Seeing



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 26]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Hearing Trouble

About Hearing & Other Sensory or Communication Disorders

An impaired ability to communicate with others or maintain good balance can lead many people to feel socially isolated, have unmet health needs, have limited success in school or on the job. Communication and other sensory processes contribute to our overall health and well-being. Protecting these processes is critical, particularly for people whose age, race, ethnicity, gender, occupation, genetic background, or health status places them at increased risk.

Many factors influence the numbers of Americans who are diagnosed and treated for hearing and other sensory or communication disorders, such a social determinants (social and economic standings, age of diagnosis, cost and stigma of wearing a hearing aid, and unhealthy lifestyle choices). In addition, biological causes of hearing loss and other sensory or communication disorders include: genetics; viral or bacterial infections; sensitivity to certain drugs or medications; injury; and aging.

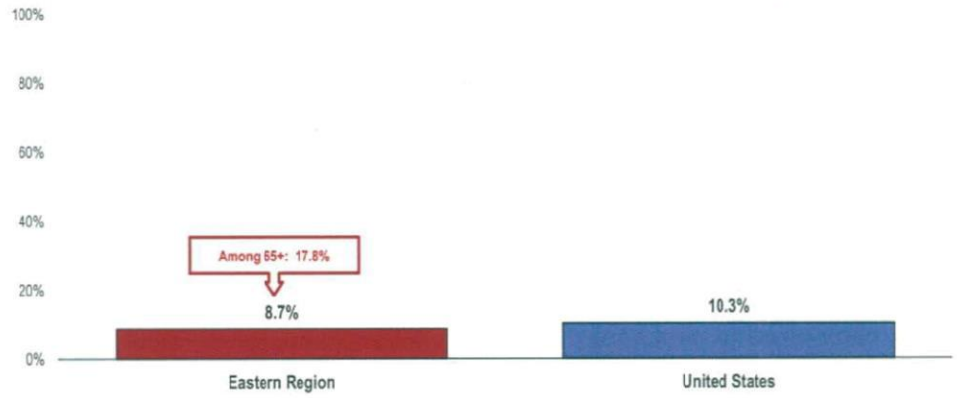
As the nation's population ages and survival rates for medically fragile infants and for people with severe injuries and acquired diseases improve, the prevalence of sensory and communication disorders is expected to rise.

- Healthy People 2020 (www.healthypeople.gov)

In all, 8.7% of Eastern Region adults report being deaf or having difficulty hearing.

- Similar to that found nationwide.
- Among Eastern Region adults age 65 and older, 17.8% have partial or complete hearing loss.

Prevalence of Deafness/Trouble Hearing



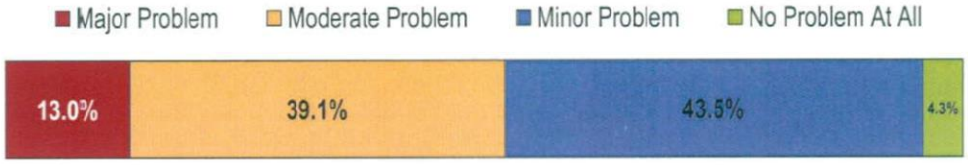
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 27]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Key Informant Input: Vision & Hearing

The largest share of key informants taking part in an online survey characterized *Vision & Hearing* as a "minor problem" in the community.

Perceptions of Hearing and Vision as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Cost & Insurance

> *Vision services are difficult because of expense and little or no coverage through insurance. - Social Services Representative*
>
> *The majority of our population does not have affordable, appropriate, and reliable access and information about these conditions. Translators and translation services, that really work and are appropriate are not in place for our population in need. We see students every day that need vision and hearing services. The information may be there, but their ability to understand and access it is quite limited. Accessible community health educators that speak their languages are desperately needed. - Social Services Representatives*

Infectious Disease

Professional Research Consultants, Inc.

Influenza & Pneumonia Vaccination

About Influenza & Pneumonia

Acute respiratory infections, including pneumonia and influenza, are the 8th leading cause of death in the nation, accounting for 56,000 deaths annually. Pneumonia mortality in children fell by 97% in the last century, but respiratory infectious diseases continue to be leading causes of pediatric hospitalization and outpatient visits in the US. On average, influenza leads to more than 200,000 hospitalizations and 36,000 deaths each year. The 2009 H1N1 influenza pandemic caused an estimated 270,000 hospitalizations and 12,270 deaths (1,270 of which were of people younger than age 18) between April 2009 and March 2010.

- Healthy People 2020 (www.healthypeople.gov)

Flu Vaccinations

FluMist® is a vaccine that is sprayed into the nose to help protect against influenza; it is an alternative to traditional flu shots.

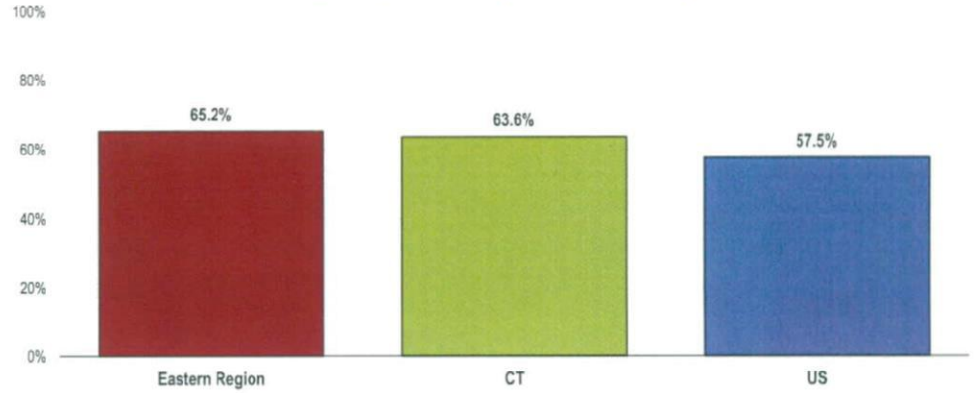
Among the Eastern Region seniors, 65.2% received a flu shot (or FluMist®) within the past year.

- Statistically comparable to the Connecticut finding.
- Statistically comparable to the national finding.
- Fails to satisfy the Healthy People 2020 target (70% or higher).

Older Adults: Have Had a Flu Vaccination in the Past Year

(Among Adults Age 65+)

Healthy People 2020 Target = 70.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 141]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IID-12.12]

Notes:
- Reflects respondents 65 and older.
- Includes FluMist as a form of vaccination.

High-Risk Adults

"High-risk" includes adults who report having been diagnosed with heart disease, diabetes or respiratory disease.

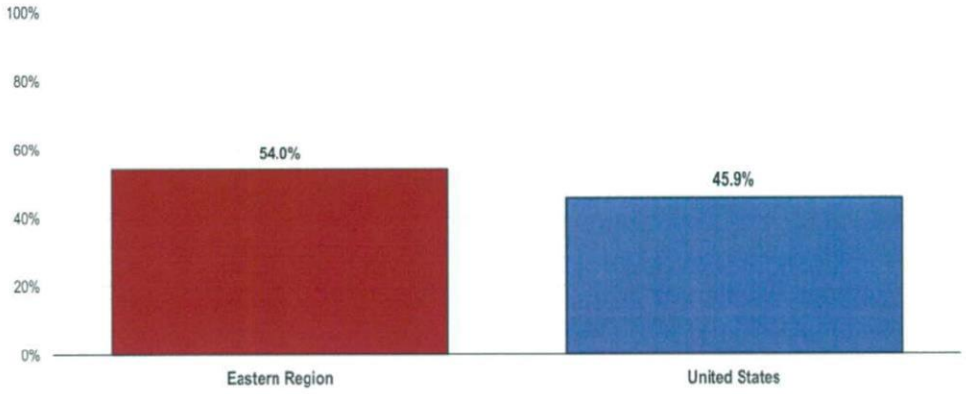
A total of 54.0% of high-risk adults age 18 to 64 received a flu vaccination (flu shot or FluMist®) within the past year.

- Statistically similar to national findings.
- Fails to satisfy the Healthy People 2020 target (70% or higher).

High-Risk Adults: Have Had a Flu Vaccination in the Past Year

(Among High-Risk Adults Age 18-64)

Healthy People 2020 Target = 70.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 142]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IID-12.12]

Notes:
- Reflects high-risk respondents age 18-64.
- "High-Risk" includes adults age 18 to 64 who have been diagnosed with heart disease, diabetes or respiratory disease.
- Includes FluMist as a form of vaccination.

Pneumonia Vaccination

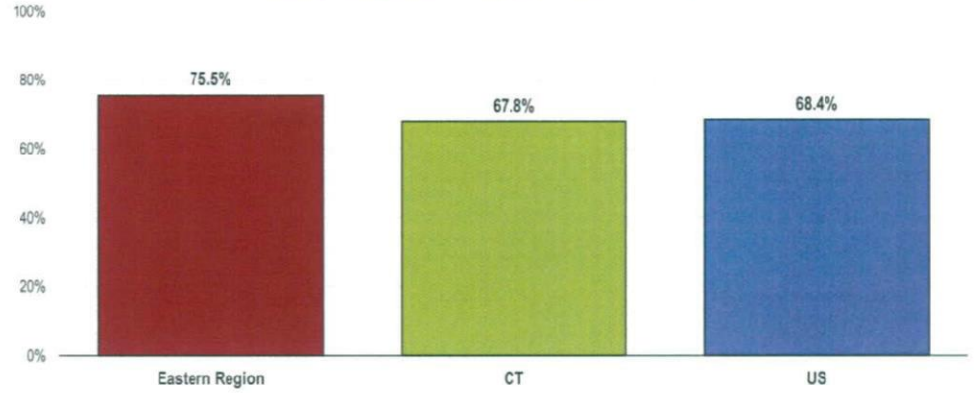
Among adults age 65 and older, 75.5% have received a pneumonia vaccination at some point in their lives.

- Better than the Connecticut finding.
- Statistically similar to the national finding.
- Fails to satisfy the Healthy People 2020 target of 90% or higher.

Older Adults: Have Ever Had a Pneumonia Vaccine

(Among Adults Age 65+)

Healthy People 2020 Target = 90.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 143]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IID-13.1]

Notes:
- Reflects respondents 65 and older.

High-Risk Adults

"High-risk" includes adults who report having been diagnosed with heart disease, diabetes or respiratory disease.

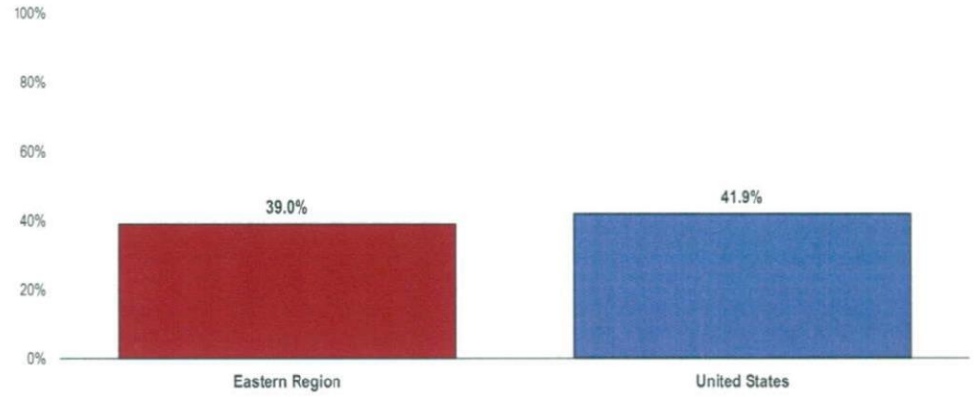
A total of 39.0% of high-risk adults age 18 to 64 have ever received a pneumonia vaccination.

- Statistically similar to the national findings.
- Fails to satisfy the Healthy People 2020 target (60% or higher).

High-Risk Adults: Have Ever Had a Pneumonia Vaccine

(Among High-Risk Adults Age 18-64)

Healthy People 2020 Target = 60.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 144]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective IID-13.2]

Notes:
- Asked of all high-risk respondents under 65.
- "High-Risk" includes adults age 18 to 64 who have been diagnosed with heart disease, diabetes or respiratory disease.

Hepatitis C

Among select towns in the Eastern Region, Norwich experienced the highest case counts for hepatitis C between 2007 and 2011.

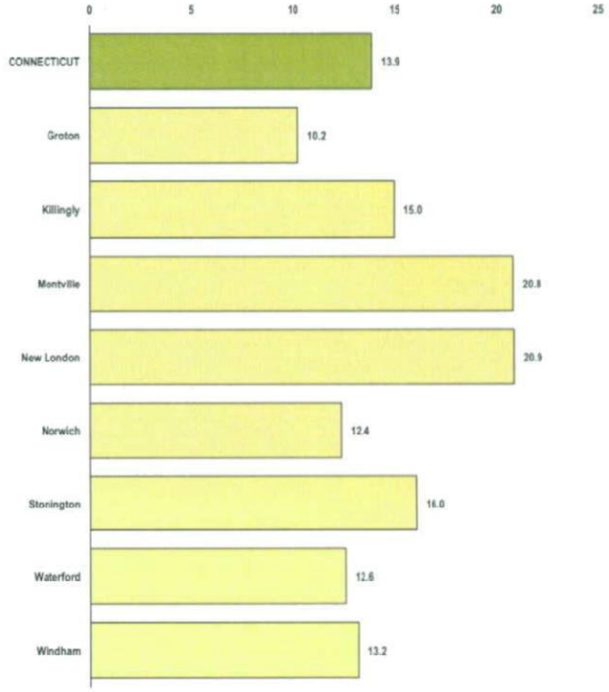
Cases of Acute Hepatitis C
(By Select Towns in the East Region, 2007-2011)

Source: • Connecticut Department of Public Health

Septicemia

From 2006 to 2010, New London and Montville recorded the highest septicemia mortality rates among select towns in the Eastern Region.

Septicemia: Age-Adjusted Mortality
(By Select Towns in the East Region, 2006-2010)



Source: • Connecticut Department of Public Health

Tuberculosis

About Tuberculosis

Viral hepatitis and tuberculosis (TB) can be prevented, yet healthcare systems often do not make the best use of their available resources to support prevention efforts. Because the US healthcare system focuses on treatment of illnesses, rather than health promotion, patients do not always receive information about prevention and healthy lifestyles. This includes advancing effective and evidence-based viral hepatitis and TB prevention priorities and interventions.

- Healthy People 2020 (www.healthypeople.gov)

Among select towns in the Eastern Region, Norwich recorded the highest number of cases of tuberculosis between 2002 and 2011.

Cases of Tuberculosis
(By Select Towns in the East Region, 2002-2011)

Source: • Connecticut Department of Public Health

HIV

About HIV

The HIV epidemic in the United States continues to be a major public health crisis. An estimated 1.1 million Americans are living with HIV, and 1 in 5 people with HIV do not know they have it. HIV continues to spread, leading to about 56,000 new HIV infections each year.

HIV is a preventable disease, and effective HIV prevention interventions have been proven to reduce HIV transmission. People who get tested for HIV and learn that they are infected can make significant behavior changes to improve their health and reduce the risk of transmitting HIV to their sex or drug-using partners. More than 50% of new HIV infections occur as a result of the 21% of people who have HIV but do not know it.

In the era of increasingly effective treatments for HIV, people with HIV are living longer, healthier, and more productive lives. Deaths from HIV infection have greatly declined in the United States since the 1990s. As the number of people living with HIV grows, it will be more important than ever to increase national HIV prevention and healthcare programs.

There are gender, race, and ethnicity disparities in new HIV infections:

- Nearly 75% of new HIV infections occur in men.
- More than half occur in gay and bisexual men, regardless of race or ethnicity.
- 45% of new HIV infections occur in African Americans, 35% in whites, and 17% in Hispanics.

Improving access to quality healthcare for populations disproportionately affected by HIV, such as persons of color and gay and bisexual men, is a fundamental public health strategy for HIV prevention. People getting care for HIV can receive:

- Antiretroviral therapy
- Screening and treatment for other diseases (such as sexually transmitted infections)
- HIV prevention interventions
- Mental health services
- Other health services

As the number of people living with HIV increases and more people become aware of their HIV status, prevention strategies that are targeted specifically for HIV-infected people are becoming more important. Prevention work with people living with HIV focuses on:

- Linking to and staying in treatment.
- Increasing the availability of ongoing HIV prevention interventions.
- Providing prevention services for their partners.

Public perception in the US about the seriousness of the HIV epidemic has declined in recent years. There is evidence that risky behaviors may be increasing among uninfected people, especially gay and bisexual men. Ongoing media and social campaigns for the general public and HIV prevention interventions for uninfected persons who engage in risky behaviors are critical.

- Healthy People 2020 (www.healthypeople.gov)

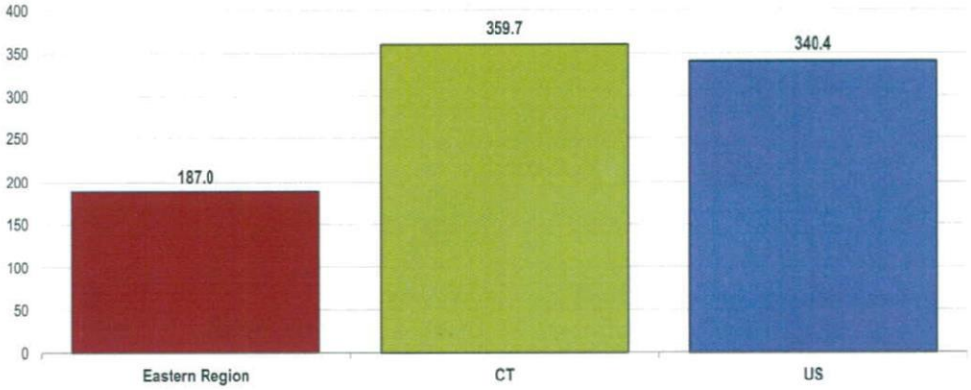
HIV Prevalence

In 2010, there was a prevalence of 187.0 HIV cases per 100,000 population in the Eastern Region.

- Well below the statewide prevalence.
- Well below the national prevalence.

HIV Prevalence

(Prevalence Rate of HIV per 100,000 Population, 2010)



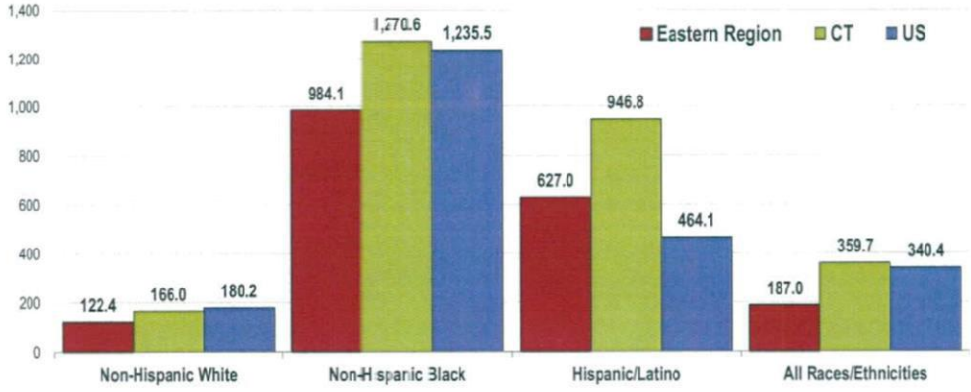
Sources:
- Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: 2010.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator is relevant because HIV is a life-threatening communicable disease that disproportionately affects minority populations and may also indicate the prevalence of unsafe sex practices.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- By race and ethnicity, HIV/AIDS prevalence in the Eastern Region is particularly high among Non-Hispanic Blacks.

HIV Prevalence Rate by Race/Ethnicity

(Prevalence Rate of HIV per 100,000 Population, 2010)

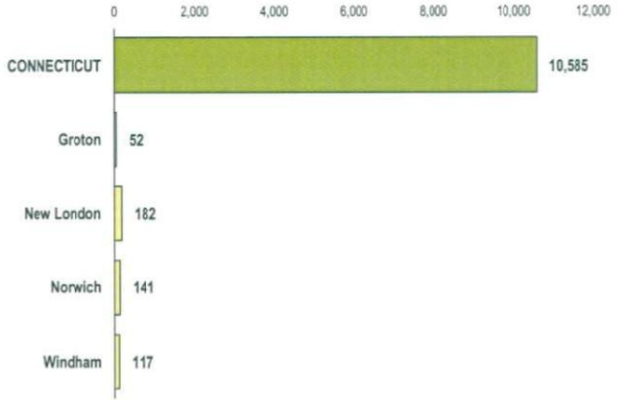


Sources:
- Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: 2010.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator is relevant because HIV is a life-threatening communicable disease that disproportionately affects minority populations and may also indicate the prevalence of unsafe sex practices.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

From 2007 to 2011, there were 182 people in the city of New London living with HIV.

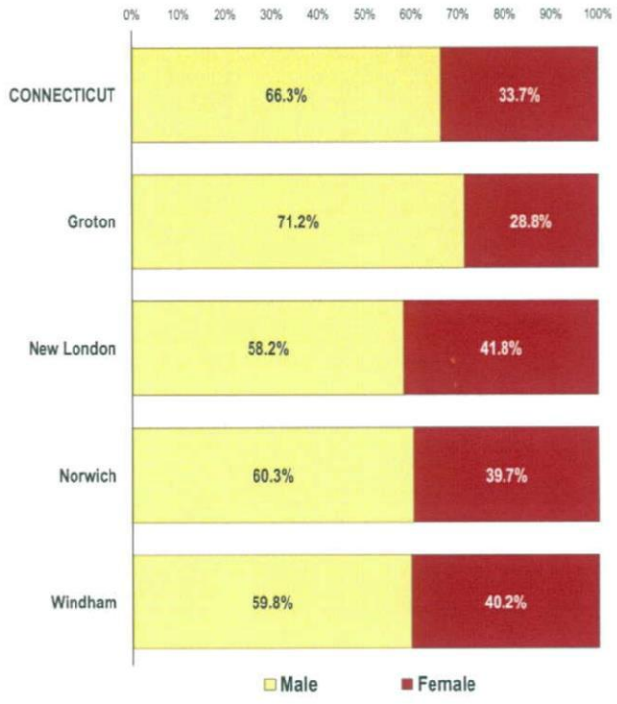
Persons Living With HIV (PLWH)
(By Select Towns in the East Region, 2007-2011)



Source: • Connecticut Department of Public Health

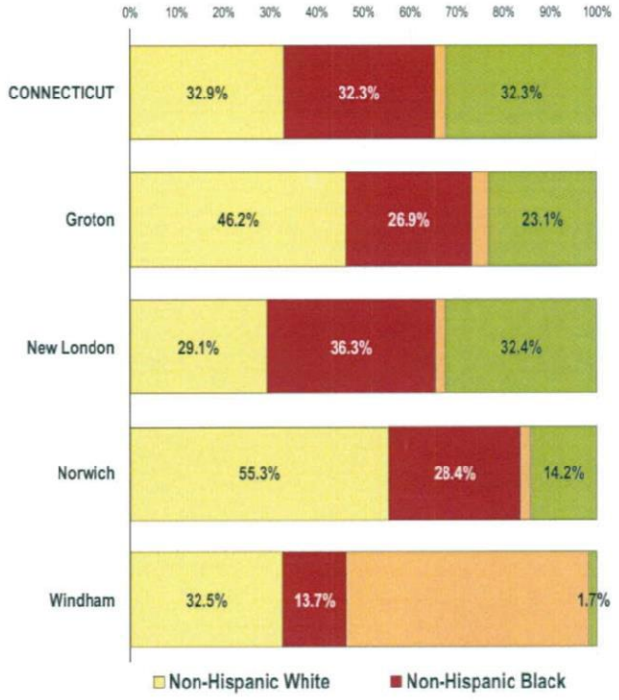
The next three graphs show the distribution of persons in the Eastern Region living with HIV by gender, race/ethnicity, and exposure mode.

PLWH by Gender
(By Select Towns in the East Region, 2011)



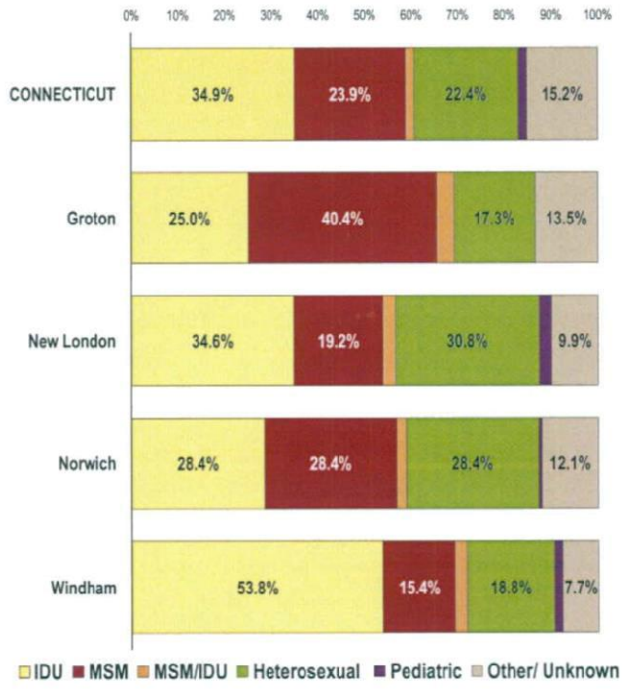
Source: • Connecticut Department of Public Health

PLWH by Race/Ethnicity
(By Select Towns in the East Region, 2011)



Source: • Connecticut Department of Public Health

PLWH by Exposure Mode
(By Select Towns in the East Region, 2011)



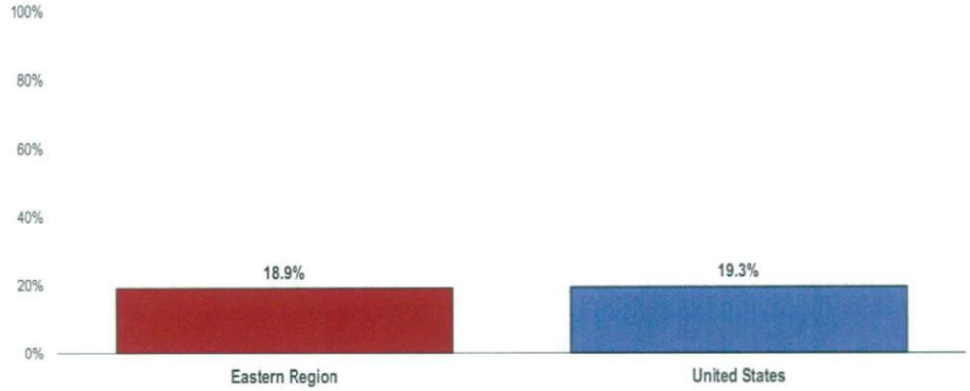
Source: • Connecticut Department of Public Health
Notes: • IDU = Intravenous Drug User
• MSM = Men who have Sex with Men
• Pediatric = includes cases among children, including mother-to-child transmission.

HIV Testing

Among Eastern Region adults age 18-44, 18.9% report that they have been tested for human immunodeficiency virus (HIV) in the past year.

- Statistically similar to the proportion found nationwide.

Tested for HIV in the Past Year
(Among Adults Age 18-44)

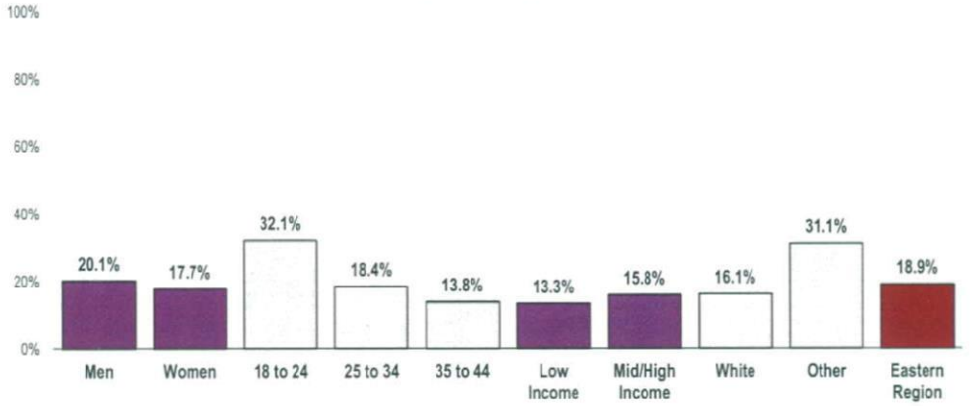


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 145]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Reflects respondents age 18 to 44.

HIV testing is notably lower among:

- Adults ages 25 and older.
- Whites.

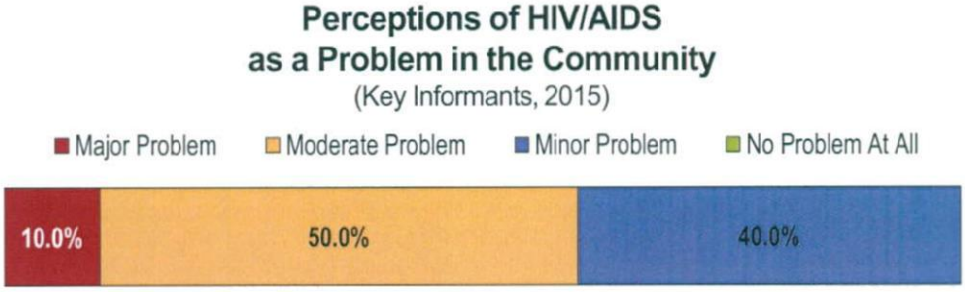
Tested for HIV in the Past Year
(Among Adults Age 18-44)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 145]
Notes: • Reflects respondents age 18 to 44.
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Low Income" includes households with incomes up to 200% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Key Informant Input: HIV/AIDS

Half of key informants taking part in an online survey characterized *HIV/AIDS* as a "moderate problem" in the community.



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Prevalence

> *In our area, we have the highest number of AIDS and HIV cases all concentrated in the area of New London. The reason for why we also have the highest number of cancer rates in the area as well. This can be due to several factors, inaccessibility to forms of protection, lack of education regarding AIDS and the way it's spread, high prostitution rates. - Social Services Representative*

Sexually Transmitted Diseases

About Sexually Transmitted Diseases

STDs refer to more than 25 infectious organisms that are transmitted primarily through sexual activity. Despite their burdens, costs, and complications, and the fact that they are largely preventable, STDs remain a significant public health problem in the United States. This problem is largely unrecognized by the public, policymakers, and health care professionals. STDs cause many harmful, often irreversible, and costly clinical complications, such as: reproductive health problems; fetal and perinatal health problems; cancer; and facilitation of the sexual transmission of HIV infection.

Because many cases of STDs go undiagnosed—and some common viral infections, such as human papillomavirus (HPV) and genital herpes, are not reported to CDC at all—the reported cases of chlamydia, gonorrhea, and syphilis represent only a fraction of the true burden of STDs in the US. Untreated STDs can lead to serious long-term health consequences, especially for adolescent girls and young women. Several factors contribute to the spread of STDs.

Biological Factors. STDs are acquired during unprotected sex with an infected partner. Biological factors that affect the spread of STDs include:

- **Asymptomatic nature of STDs**. The majority of STDs either do not produce any symptoms or signs, or they produce symptoms so mild that they are unnoticed; consequently, many infected persons do not know that they need medical care.
- **Gender disparities**. Women suffer more frequent and more serious STD complications than men do. Among the most serious STD complications are pelvic inflammatory disease, ectopic pregnancy (pregnancy outside of the uterus), infertility, and chronic pelvic pain.
- **Age disparities**. Compared to older adults, sexually active adolescents ages 15 to 19 and young adults ages 20 to 24 are at higher risk for getting STDs.
- **Lag time between infection and complications**. Often, a long interval, sometimes years, occurs between acquiring an STD and recognizing a clinically significant health problem.

Social, Economic and Behavioral Factors. The spread of STDs is directly affected by social, economic, and behavioral factors. Such factors may cause serious obstacles to STD prevention due to their influence on social and sexual networks, access to and provision of care, willingness to seek care, and social norms regarding sex and sexuality. Among certain vulnerable populations, historical experience with segregation and discrimination exacerbates these factors. Social, economic, and behavioral factors that affect the spread of STDs include: racial and ethnic disparities; poverty and marginalization; access to healthcare; substance abuse; sexuality and secrecy (stigma and discomfort discussing sex); and sexual networks (persons "linked" by sequential or concurrent sexual partners).

- Healthy People 2020 (www.healthypeople.gov)

Chlamydia & Gonorrhea

In 2012, the chlamydia incidence rate in the Eastern Region was 220.3 cases per 100,000 population.

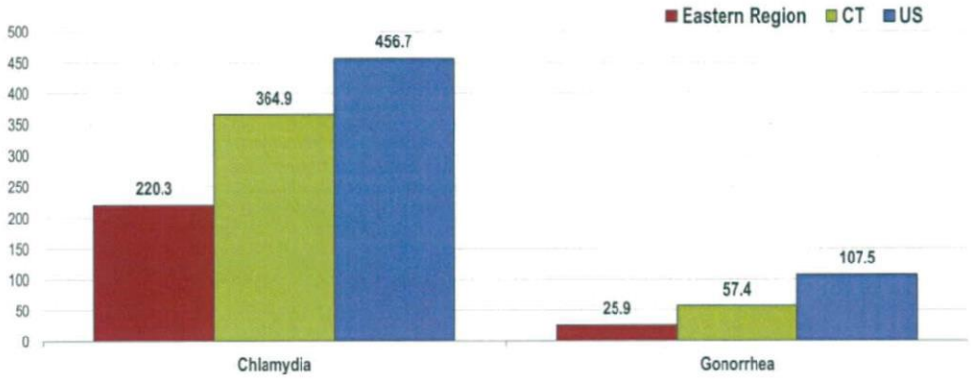
- Lower than the Connecticut incidence rate.
- Lower than the national incidence rate.

The gonorrhea incidence rate in Harford County was 25.9 cases per 100,000 population in 2012.

- Better than the statewide rate.
- Better than the national rate.

Chlamydia & Gonorrhea Incidence

(Incidence Rate per 100,000 Population, 2012)



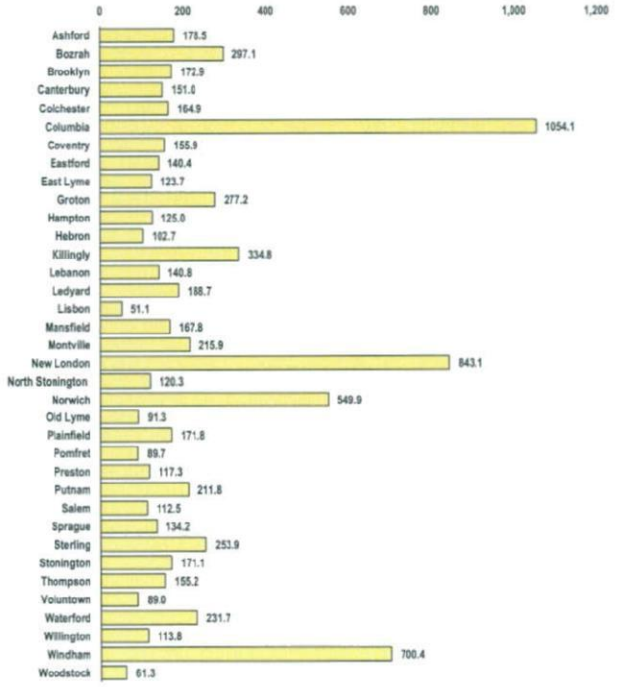
Sources:
- Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: 2012.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator is relevant because it is a measure of poor health status and indicates the prevalence of unsafe sex practices.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

In 2013, the city of Columbia had the highest incidence of chlamydia and gonorrhea per 100,000 population among select towns in the area.

Chlamydia Incidence Rate per 100,000

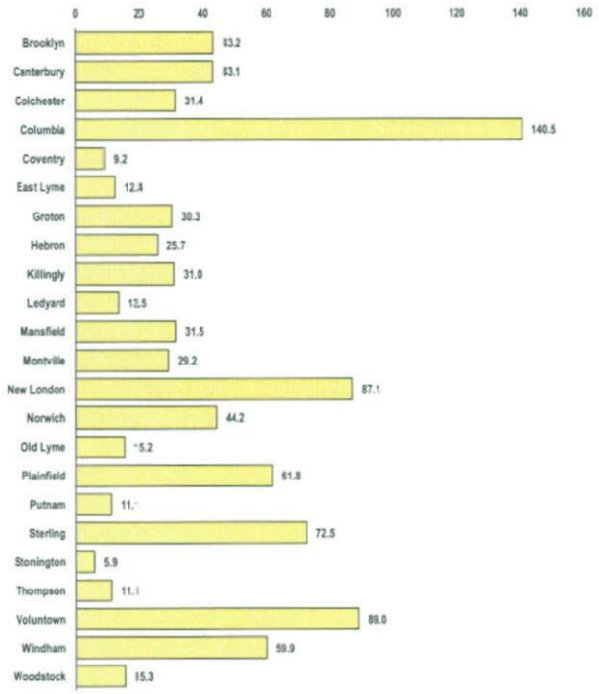
(By Select Towns in the East Region, 2013)



Source:
- Connecticut Department of Public Health

Gonorrhea Incidence Rate per 100,000

(By Select Towns in the East Region, 2013)



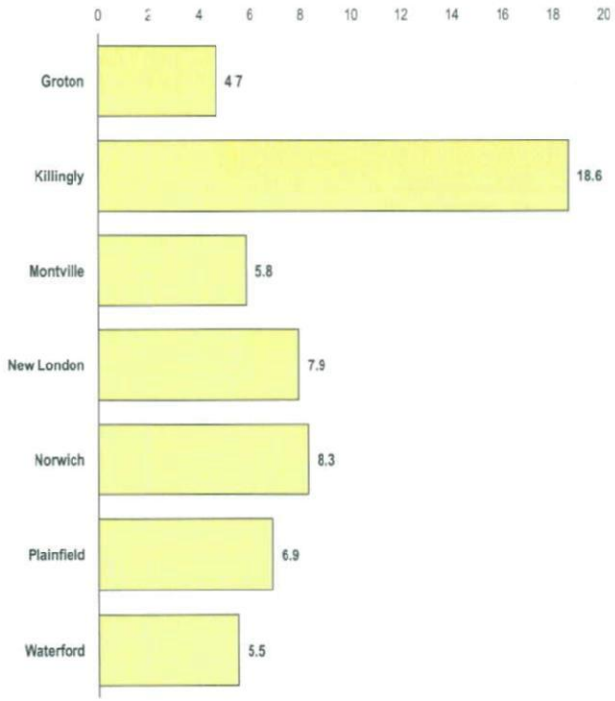
Source: • Connecticut Department of Public Health

Syphilis

Among select towns in the Eastern Region, Killingly experienced the highest incidence of primary/secondary syphilis per 100,000 population in 2013.

Primary & Secondary Syphilis Incidence Rate per 100,000

(By Select Towns in the East Region, 2013)



Source: • Connecticut Department of Public Health

Hepatitis B

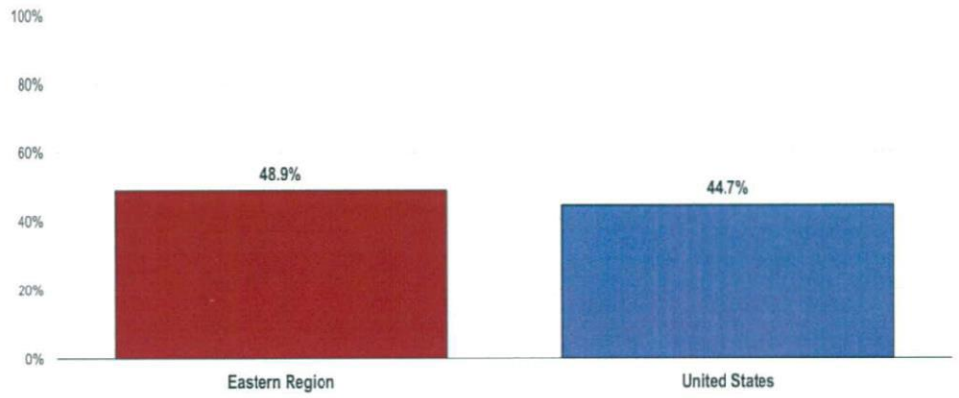
Hepatitis B Vaccination

Based on survey data, nearly one-half of Eastern Region adults (48.9%) report having received the hepatitis B vaccination series.

Respondents were told that, to be vaccinated against hepatitis B, a series of three shots must be administered, usually at least one month between shots. They were then asked if they had completed this vaccination series.

- Higher than is reported nationwide.

Have Completed the Hepatitis B Vaccination Series

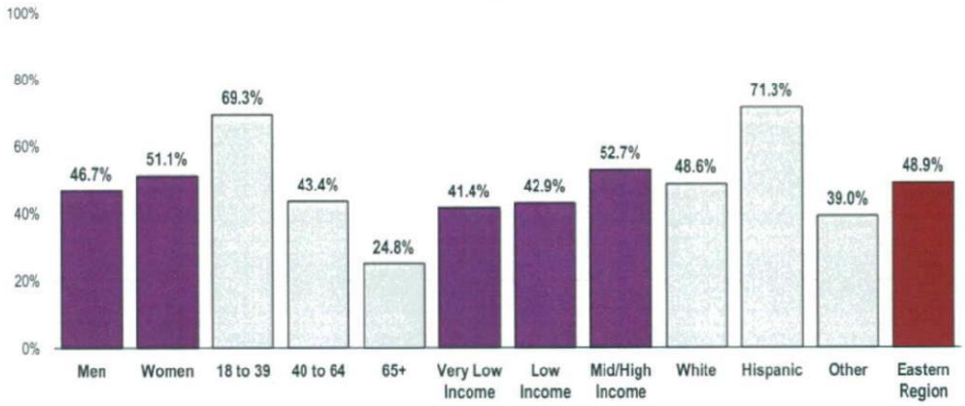


Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 70]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.
- Includes a series of three shots, usually administered at least one month between shots

- Note the negative correlation between age and hepatitis B vaccination.
- Adults in the lower income breakouts are also less likely to have been vaccinated.
- Whites and "Other" adults are less likely than Hispanics to have received the hepatitis B vaccine.

Have Completed the Hepatitis B Vaccination Series
(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 70]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Chronic Hepatitis B Cases

From 2007 to 2011, the city of Norwich had the highest number of cases of chronic hepatitis B and acute hepatitis B among select towns in the Eastern Region.

Cases of Chronic Hepatitis B
(By Select Towns in the East Region, 2007-2011)

Source: • Connecticut Department of Public Health

Cases of Acute Hepatitis B
(By Select Towns in the East Region, 2007-2011)

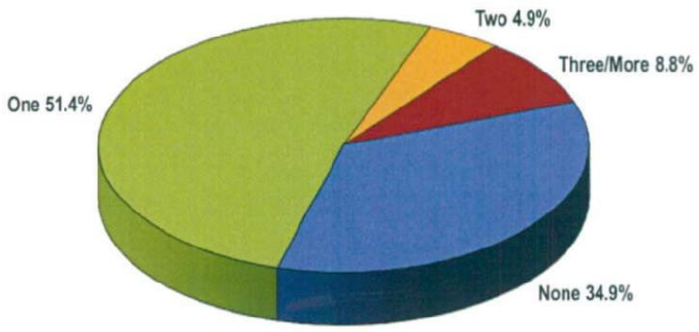
Source: • Connecticut Department of Public Health

Safe Sexual Practices

Sexual Partners

Among unmarried the Eastern Region adults under 65, the vast majority cites having one (51.4%) or no (34.9%) sexual partners in the past 12 months.

Number of Sexual Partners in Past 12 Months
(Among Unmarried Adults Age 18-64; Eastern Region, 2015)

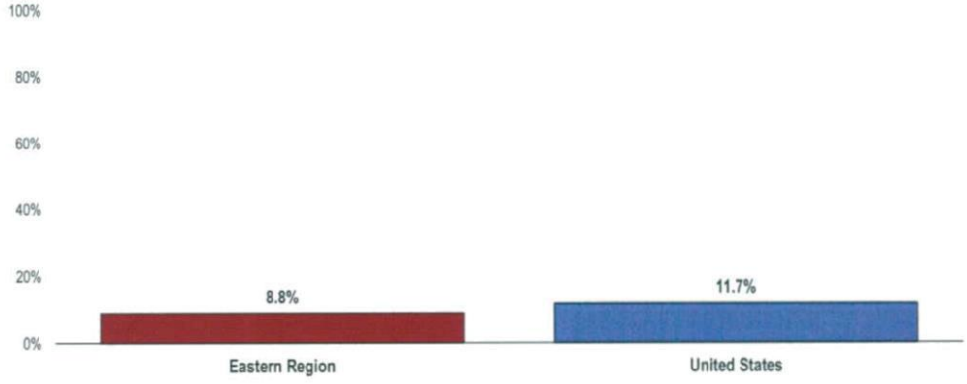


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 86]
Notes: • Asked of all unmarried respondents under the age of 65.

However, 8.8% report three or more sexual partners in the past year.

- Comparable to that reported nationally.

Had Three or More Sexual Partners in the Past Year
(Among Unmarried Adults Age 18-64; Eastern Region, 2015)



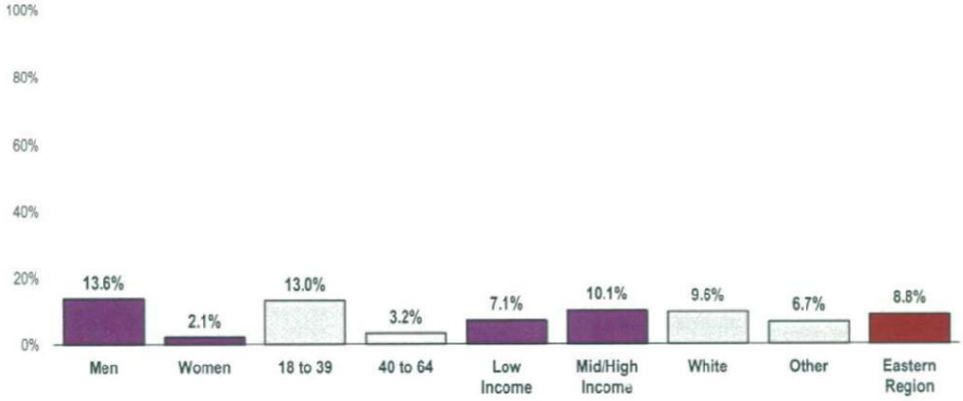
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 86]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all unmarried respondents under the age of 65.

Unmarried respondents (age 18 to 64) more likely to report three or more sexual partners in the past year include:

- Men.
- Residents ages 18 to 39.

Had Three or More Sexual Partners in the Past Year

(Among Unmarried Adults Age 18-64; Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 86]

Notes:
- Asked of all unmarried respondents under the age of 65.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Low Income" includes households with incomes less than 200% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

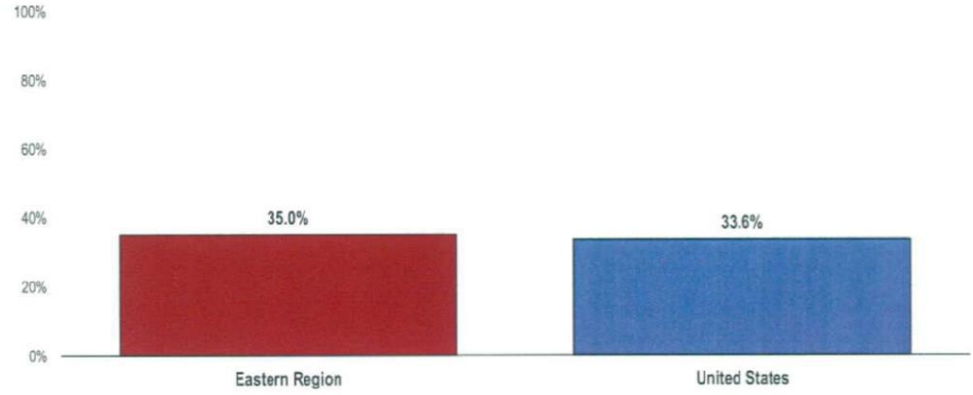
Condom Use

Among Eastern Region adults who are under age 65 and unmarried, 35.0% report that a condom was used during their last sexual intercourse.

- Statistically similar to national findings.

Condom Was Used During Last Sexual Intercourse

(Among Unmarried Adults Age 18-64)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 87]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

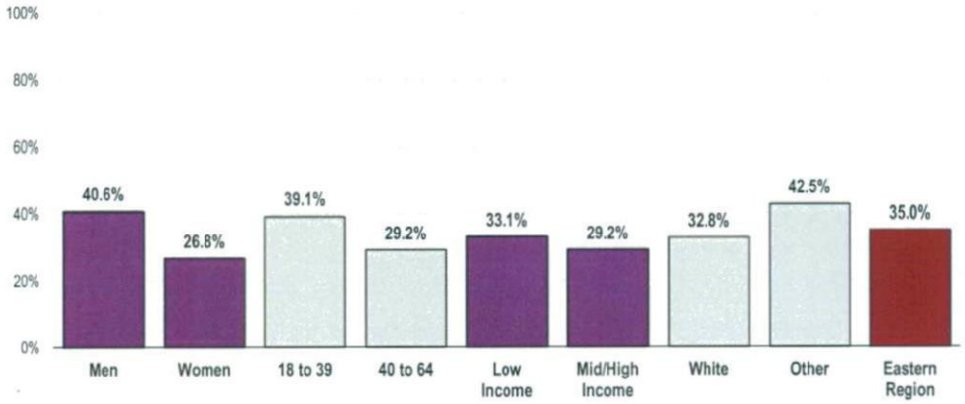
Notes:
- Asked of all unmarried respondents under the age of 65.

Those less likely to report that a condom was used during their last sexual intercourse include:

- Women.
- Residents ages 40 to 64.
- Whites.

Condom Was Used During Last Sexual Intercourse

(Among Unmarried Adults Age 18-64; Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 87]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

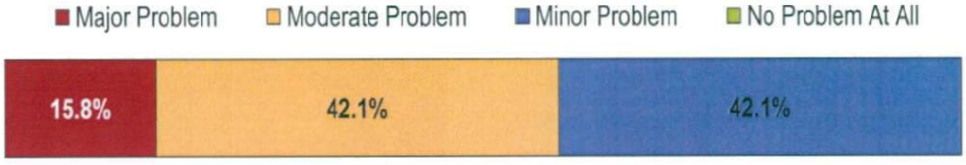
Notes:
- Asked of all unmarried respondents under the age of 65.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Low Income" includes households with incomes less than 200% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Key Informant Input: Sexually Transmitted Diseases

Most key informants taking part in an online survey characterized *Sexually Transmitted Diseases* as a "moderate" or "minor" problem in the community.

Perceptions of Sexually Transmitted Diseases as a Problem in the Community

(Key Informants, 2015)



Sources:
- PRC Online Key Informant Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Access to Contraceptives

> *Even though we have several clinics nearby that have access to contraceptives and other forms of protection, there's lack of knowledge about these resources and how to access them. - Social Services Representative*

Intravenous Drug Use

> *I think there is a strong correlation between STDs and IVDA [intravenous drug use]. - Public Health Expert*

Youth & Risky Sexual Behavior

> *The individuals are getting younger and younger, often finding co-infection with both Chlamydia and gonorrhea. With many parents working long hours, the amount of parental supervision has declined allowing youth more opportunity to engage in risky sexual behaviors. - Public Health Expert*

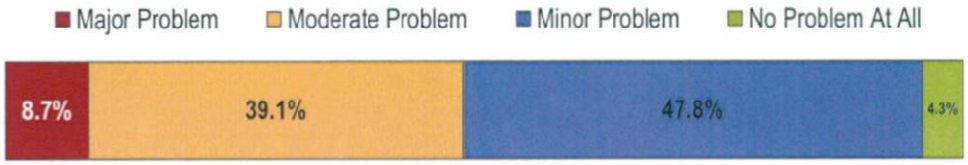
Immunization & Infectious Diseases

Key Informant Input: Immunization & Infectious Diseases

The largest share of key informants taking part in an online survey characterized *Immunization & Infectious Diseases* as a "minor problem" in the community.

Perceptions of Immunization and Infectious Diseases as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Lack of Education

> *Immunization is not understood very well and people with infectious typically are overwhelmed when they are diagnosed and this affects their follow-up. - Health Provider*
>
> *I believe there is a lot of harmful misinformation in the media and on the internet that unfortunately leads to parents making decisions about whether to vaccinate or not. With the adult population, many have ingrained beliefs regarding the influenza immunization, that it somehow makes them sick. It is especially difficult to counter arguments made by celebrities who take up a particular cause without knowing all the facts. With regard to infectious disease, I have seen an increase in the numbers of individuals with co-infection of STI's such as gonorrhea and Chlamydia. I do think that the amount of substance abuse is a big contributing factor in the increase in STI's, as many of the reports come via the STI clinics. There is also a huge surge in HCV in this area, again primarily related to IVDU. - Public Health Expert*

Births

Professional Research Consultants, Inc.

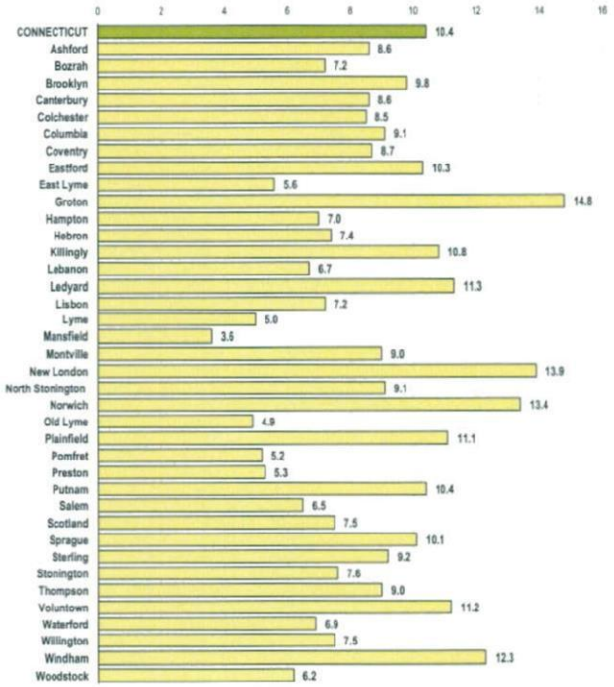
Birth Characteristics

Birth Rate

Among select towns in the Eastern Region, Groton recorded the highest rate of live births per 1,000 population in 2011.

Live Births per 1,000 Population

(By Select Towns in the East Region, 2011)



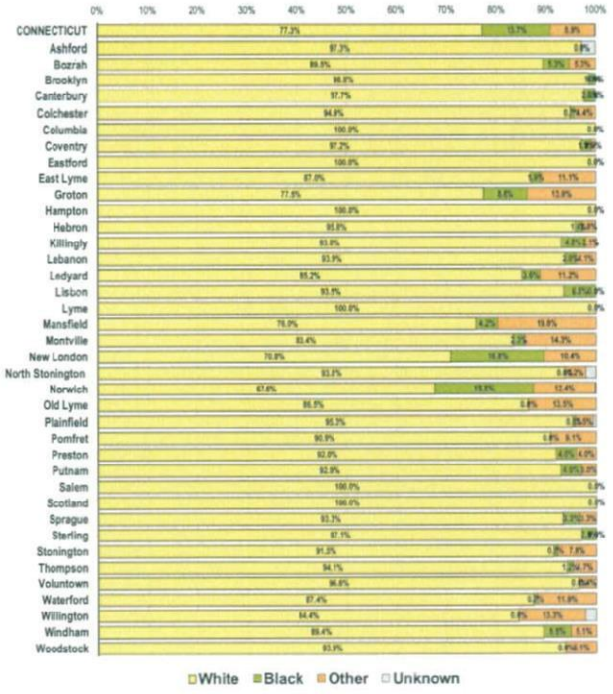
Source: • Connecticut Department of Public Health

Births by Race & Ethnicity

The next two charts segment resident births by race and ethnicity for 2011. Note that relatively high percentages of births among New London and Norwich residents were to Black mothers; near-majorities of those in New London and Windham were to Hispanic mothers.

Resident Births by Race

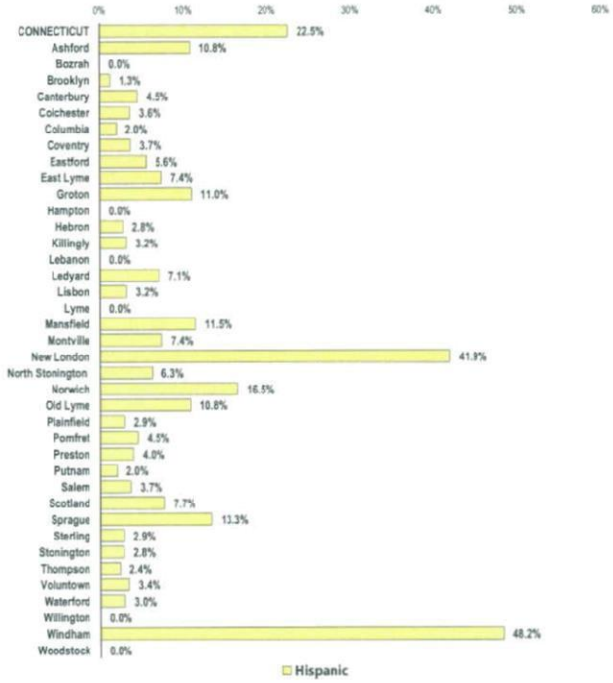
(By Select Towns in the East Region, 2011)



Source: • Connecticut Department of Public Health

Resident Births by Ethnicity

(By Select Towns in the East Region, 2011)



Source: • Connecticut Department of Public Health

Prenatal Care

About Infant & Child Health

Improving the well-being of mothers, infants, and children is an important public health goal for the US. Their well-being determines the health of the next generation and can help predict future public health challenges for families, communities, and the healthcare system. The risk of maternal and infant mortality and pregnancy-related complications can be reduced by increasing access to quality preconception (before pregnancy) and inter-conception (between pregnancies) care. Moreover, healthy birth outcomes and early identification and treatment of health conditions among infants can prevent death or disability and enable children to reach their full potential. Many factors can affect pregnancy and childbirth, including pre-conception health status, age, access to appropriate healthcare, and poverty.

Infant and child health are similarly influenced by socio-demographic factors, such as family income, but are also linked to the physical and mental health of parents and caregivers. There are racial and ethnic disparities in mortality and morbidity for mothers and children, particularly for African Americans. These differences are likely the result of many factors, including social determinants (such as racial and ethnic disparities in infant mortality; family income; educational attainment among household members; and health insurance coverage) and physical determinants (i.e., the health, nutrition, and behaviors of the mother during pregnancy and early childhood).

- Healthy People 2020 (www.healthypeople.gov)

Early and continuous prenatal care is the best assurance of infant health.

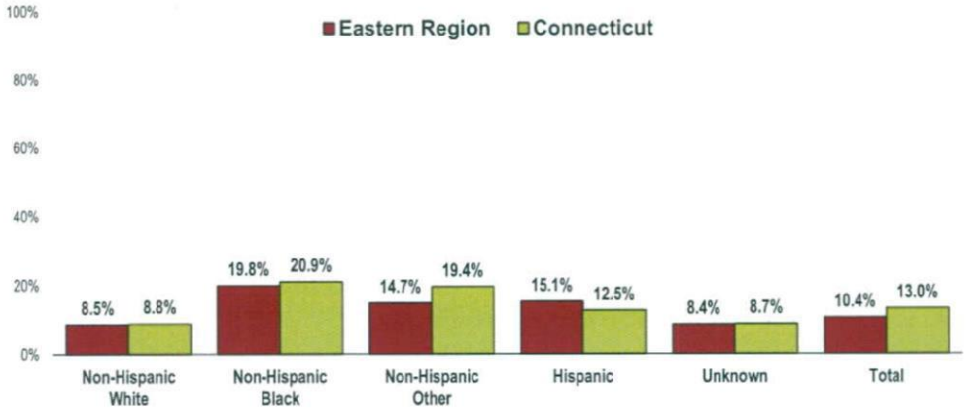
In 2011, 10.4% of all Eastern Region births did not receive prenatal care in the first trimester of pregnancy.

- More favorable than the Connecticut proportion.
- Satisfies the Healthy People 2020 target (22.1% or lower).
- Highest among Non-Hispanic Blacks.

Lack of Prenatal Care in the First Trimester

(By Race; Percentage of Live Births, 2011)

Healthy People 2020 Target = 22.1% or Lower

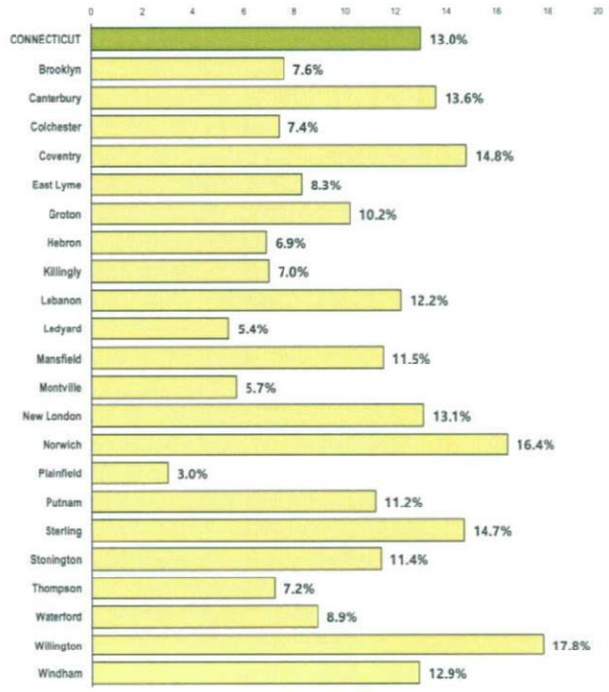


Sources:
- Connecticut Department of Public Health.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective MICH-10.1]

Note:
- This indicator reports the percentage of women who do not obtain prenatal care during their first trimester of pregnancy. This indicator is relevant because engaging in prenatal care decreases the likelihood of maternal and infant health risks. This indicator can also highlight a lack of access to preventive care, a lack of health, knowledge insufficient provider outreach, and/or social barriers preventing utilization of services.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Willington recorded the highest percentage of births with late or no prenatal care in 2011.

Percent of Births With Late or No Prenatal Care
(By Select Towns in the East Region, 2011)



Source: • Connecticut Department of Public Health

Birth Outcomes & Risks

Low-Weight Births

Low birthweight babies, those who weigh less than 2,500 grams (5 pounds, 8 ounces) at birth, are much more prone to illness and neonatal death than are babies of normal birthweight.

Largely a result of receiving poor or inadequate prenatal care, many low-weight births and the consequent health problems are preventable.

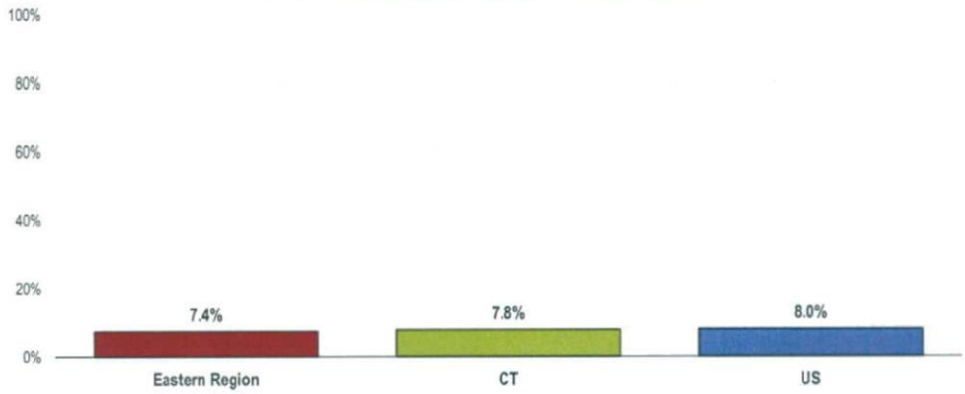
A total of 7.4% of 2011-2013 Eastern Region births were low-weight.

- Better than the Connecticut proportion.
- Better than the national proportion.
- Satisfies the Healthy People 2020 target (7.8% or lower).

Low-Weight Births

(Percent of Live Births, 2011-2013)

Healthy People 2020 Target = 7.8% or Lower



Sources:
- Centers for Disease Control and Prevention, National Vital Statistics System: 2011-13. Accessed using CDC WONDER.
- Retrieved February 2015 from Community Commons at http://www.chna.org.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective MICH-8.1]

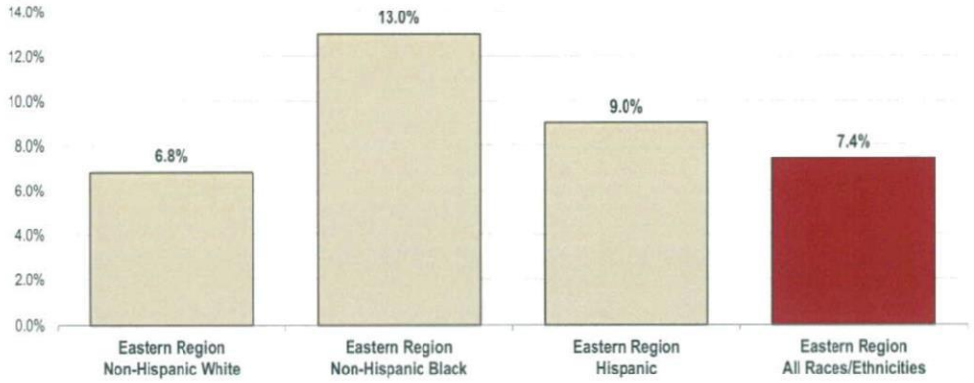
Note:
- This indicator reports the percentage of total births that are low birth weight (Under 2500g). This indicator is relevant because low birth weight infants are at high risk for health problems. This indicator can also highlight the existence of health disparities.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- Low-weight births are more prevalent among Blacks and Hispanics than among Whites in the Eastern Region.

Low-Weight Births

(Percent of Live Births, 2011-2013)

Healthy People 2020 Target = 7.8% or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective MICH-8.1]

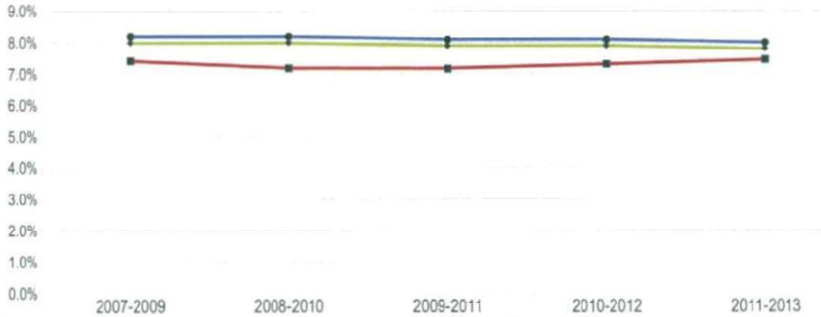
Note:
- This indicator reports the percentage of total births that are low birth weight (Under 2500g). This indicator is relevant because low birth weight infants are at high risk for health problems. This indicator can also highlight the existence of health disparities.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The proportion of low-weight births has remained relatively stable in the Eastern Region; the same can be said for both Connecticut and the US.

Low-Weight Birth Trends

(Percent of Live Births)

Healthy People 2020 Target = 7.8% or Lower



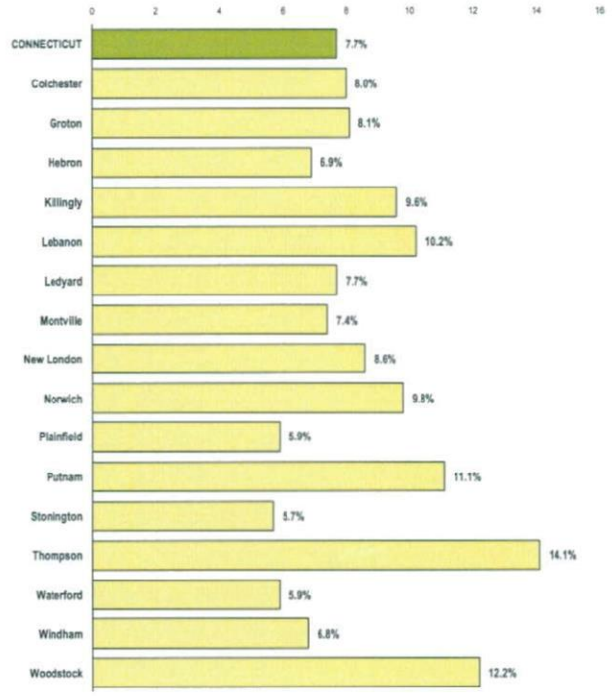
	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	7.4	7.2	7.2	7.3	7.4
Connecticut	8.0	8.0	7.9	7.9	7.8
United States	8.2	8.2	8.1	8.1	8.0

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective MICH-8.1]

Note:
- This indicator reports the percentage of total births that are low birth weight (Under 2500g). This indicator is relevant because low birth weight infants are at high risk for health problems. This indicator can also highlight the existence of health disparities.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

The following graph illustrates the percentage of low-weight births in 2011 in select towns in the area. As shown, Thompson had the highest percentage of low-weight births.

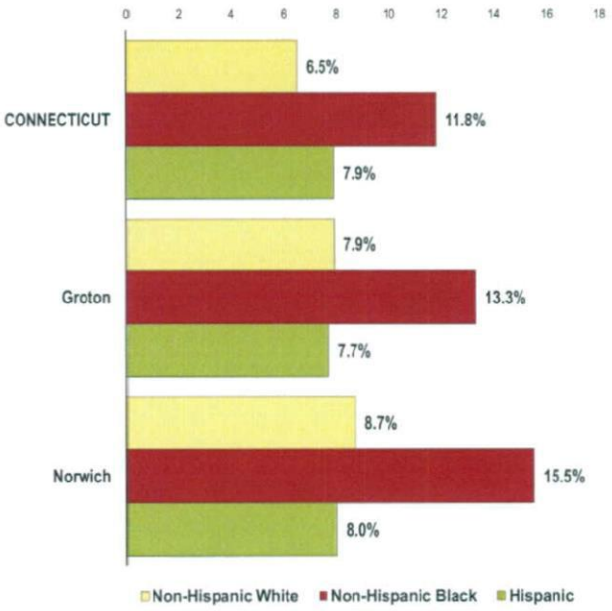
Percent of Births With Low Birthweight
(By Select Towns in the East Region, 2011)



Source: • Connecticut Department of Public Health

Statewide, Blacks experience the highest proportions of low-weight births; the same was true in Groton and Norwich.

Percent of Births With Low Birthweight by Race/Ethnicity
(By Select Towns in the East Region, 2011)



Source: • Connecticut Department of Public Health

Infant Mortality

Infant mortality rates reflect deaths of children less than one year old per 1,000 live births.

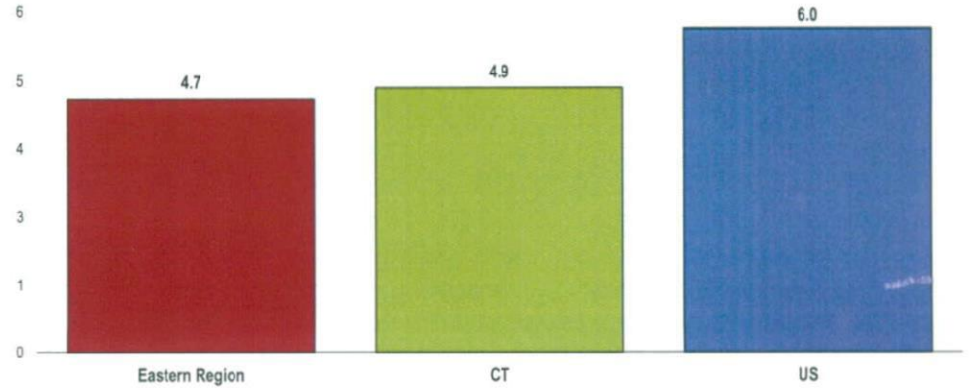
Between 2011 and 2013, there was an annual average of 4.7 infant deaths per 1,000 live births.

- Comparable to the Connecticut rate.
- More favorable than the national rate.
- Satisfies the Healthy People 2020 target of 6.0 per 1,000 live births.

Infant Mortality Rate

(Annual Average Infant Deaths per 1,000 Live Births, 2011-2013)

Healthy People 2020 Target = 6.0 or Lower



Sources:
- Centers for Disease Control and Prevention, National Vital Statistics System: 2006-12. Accessed using CDC WONDER.
- Retrieved February 2015 from Community Commons at http://www.chna.org.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective MICH-1.3]

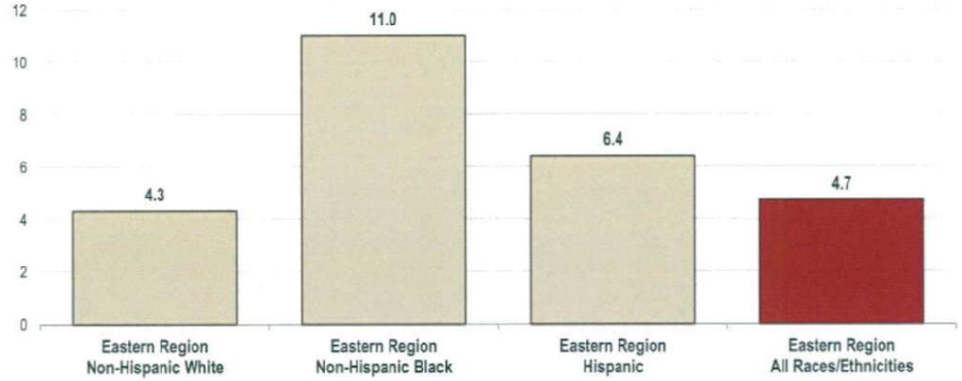
Notes:
- Infant deaths include deaths of children under 1 year old.
- This indicator is relevant because high rates of infant mortality indicate the existence of broader issues pertaining to access to care and maternal and child health.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- The infant mortality rate is notably highest among births to Non-Hispanic Black mothers.

Infant Mortality Rate

(By Race; Annual Average Infant Deaths per 1,000 Live Births, 2011-2013)

Healthy People 2020 Target = 6.0 or Lower



Sources:
- Centers for Disease Control and Prevention, National Vital Statistics System: 2006-12. Accessed using CDC WONDER.
- Retrieved February 2015 from Community Commons at http://www.chna.org.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective MICH-1.3]

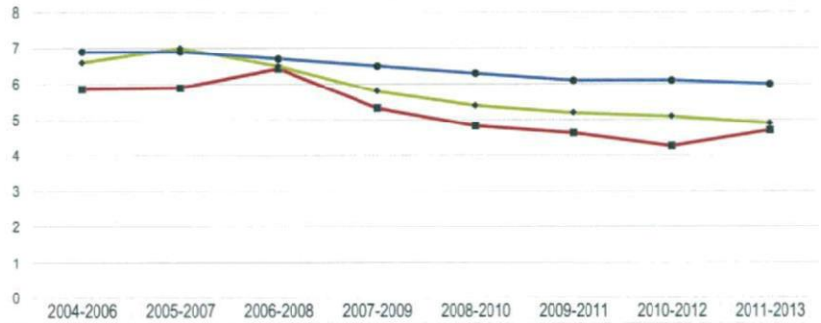
Notes:
- Infant deaths include deaths of children under 1 year old.
- This indicator is relevant because high rates of infant mortality indicate the existence of broader issues pertaining to access to care and maternal and child health.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The infant mortality rate has trended downward in the Eastern Region, echoing the state and national trends.

Infant Mortality Trends

(Annual Average Infant Deaths per 1,000 Live Births)

Healthy People 2020 Target = 6.0 or Lower



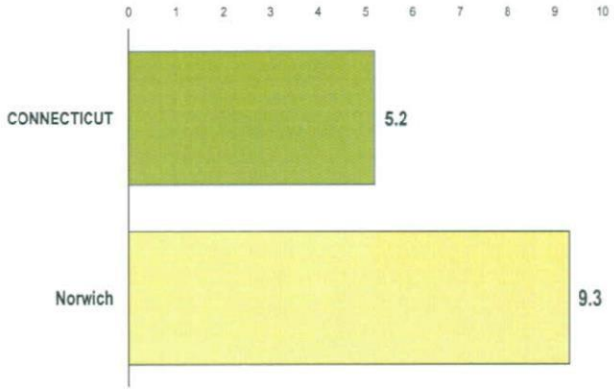
	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	5.9	5.9	6.4	5.3	4.8	4.6	4.3	4.7
Connecticut	6.6	7.0	6.5	5.8	5.4	5.2	5.1	4.9
United States	6.9	6.9	6.7	6.5	6.3	6.1	6.1	6.0

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- Centers for Disease Control and Prevention, National Center for Health Statistics.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective MICH-1.3]

Notes:
- Rates are three-year averages of deaths of children under 1 year old per 1,000 live births.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Note that Norwich exceeded the statewide rate of 5.2 infant deaths per 1,000 live births in 2011. No other town-level data are available.

Infant Deaths per 1,000 Live Births
(By Select Towns in the East Region, 2011)

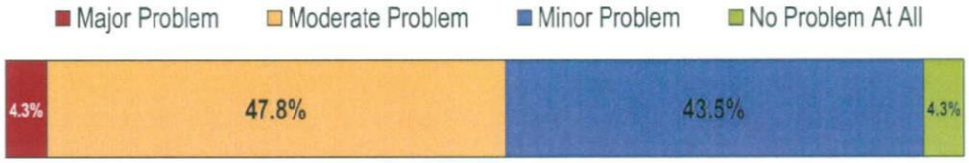


Source: • Connecticut Department of Public Health

Key Informant Input: Infant & Child Health

A plurality of key informants taking part in an online survey characterized *Infant & Child Health* as a "moderate problem" in the community.

Perceptions of Infant and Child Health as a Problem in the Community
(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Barriers & Misconceptions

> *Due to a diverse community, there are many barriers and misconceptions regarding the care required and resources available. - Health Provider*

Family Planning

Births to Teen Mothers

About Teen Births

The negative outcomes associated with unintended pregnancies are compounded for adolescents. Teen mothers:

- Are less likely to graduate from high school or attain a GED by the time they reach age 30.
- Earn an average of approximately $3,500 less per year, when compared with those who delay childbearing.
- Receive nearly twice as much Federal aid for nearly twice as long.

Similarly, early fatherhood is associated with lower educational attainment and lower income. Children of teen parents are more likely to have lower cognitive attainment and exhibit more behavior problems. Sons of teen mothers are more likely to be incarcerated, and daughters are more likely to become adolescent mothers.

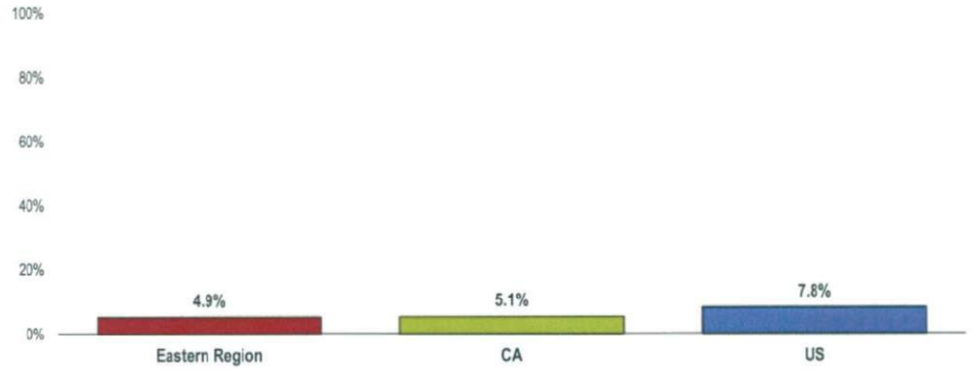
- Healthy People 2020 (www.healthypeople.gov)

Between 2011 and 2013, 4.9% of births in the Eastern Region were to mothers under age 20.

- Similar to the Connecticut proportion.
- Lower than the national proportion.

Births to Teen Mothers

(Births to Women Under 20 as a Percentage of Live Births, 2011-2013)

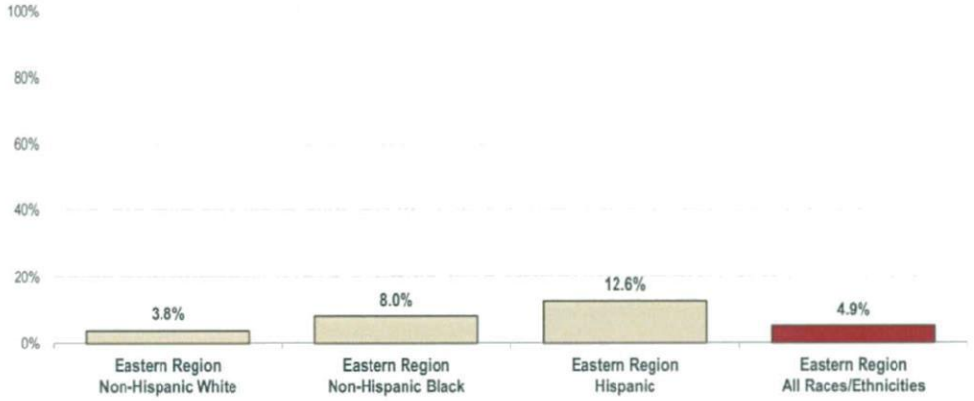


Sources: • Centers for Disease Control and Prevention, National Vital Statistics System.
Note: • Numbers are a percentage of all live births within each population.
• Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- By race and ethnicity, Hispanics/Latinas exhibit the highest percentage of teen births in the Eastern Region, followed by Non-Hispanic Blacks.

Births to Teen Mothers

(Births to Women Under 20 as a Percentage of Live Births, 2011-2013)

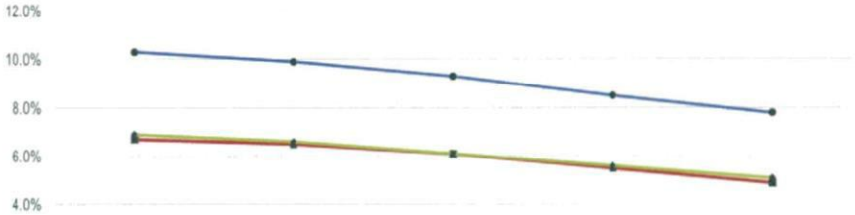


Sources: • Centers for Disease Control and Prevention, National Vital Statistics System: 2006-2012. Accessed using CDC WONDER.
Note: • Numbers are a percentage of all live births within each population.
• Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: This percentage has declined over time in the Eastern Region, mirroring state and national trends.

Teen Birth Trends

(Births to Women Under Age 20 as a Percentage of Life Births)

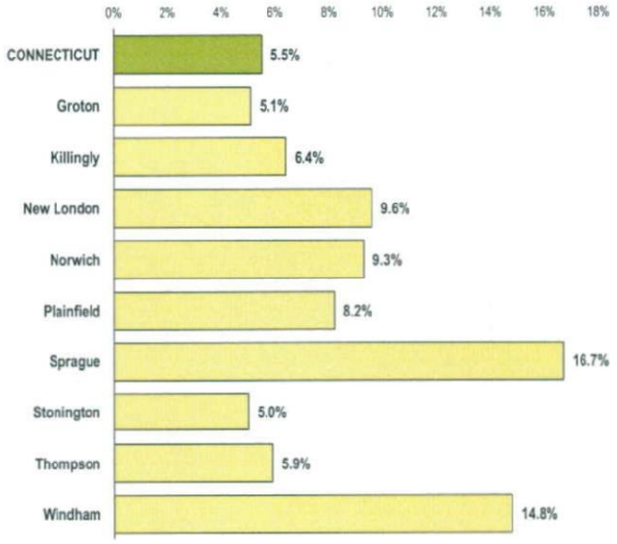


	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	6.7	6.5	6.1	5.5	4.9
Connecticut	6.9	6.6	6.1	5.6	5.1
United States	10.3	9.9	9.3	8.5	7.8

Sources: • Centers for Disease Control and Prevention, National Vital Statistics System: 2006-2012. Accessed using CDC WONDER.
Notes: • This indicator reports the rate of total births to women under the age of 20 per 1,000 female population under 20. This indicator is relevant because in many cases, teen parents have unique social, economic, and health support services. Additionally, high rates of teen pregnancy may indicate the prevalence of unsafe sex practices.
• Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Among select towns, Sprague and Windham recorded the highest percentage of births to teen mothers in 2011.

Percent of Births to Mothers Under Age 20
(By Select Towns in the East Region, 2011)

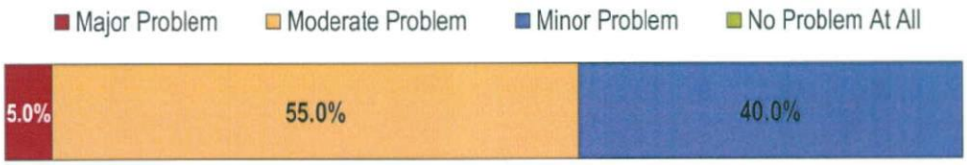


Source: • Connecticut Department of Public Health

Key Informant Input: Family Planning

Key informants taking part in an online survey largely characterized *Family Planning* as a "moderate problem" in the community.

Perceptions of Family Planning as a Problem in the Community
(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Modifiable Health Risks

Professional Research Consultants, Inc.

Actual Causes Of Death

About Contributors to Mortality

A 1999 study (an update to a landmark 1993 study), estimated that as many as 40% of premature deaths in the United States are attributed to behavioral factors. This study found that behavior patterns represent the single-most prominent domain of influence over health prospects in the United States. The daily choices we make with respect to diet, physical activity, and sex; the substance abuse and addictions to which we fall prey; our approach to safety; and our coping strategies in confronting stress are all important determinants of health.

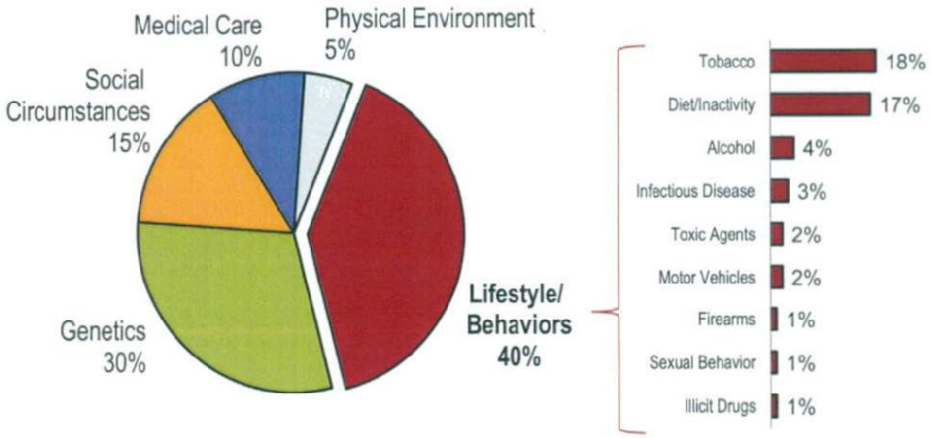
The most prominent contributors to mortality in the United States in 2000 were **tobacco** (an estimated 435,000 deaths), **diet and activity** patterns (400,000), **alcohol** (85,000), **microbial agents** (75,000), **toxic agents** (55,000), **motor vehicles** (43,000), **firearms** (29,000), **sexual behavior** (20,000), and **illicit use of drugs** (17,000). Socioeconomic status and access to medical care are also important contributors, but difficult to quantify independent of the other factors cited. Because the studies reviewed used different approaches to derive estimates, the stated numbers should be viewed as first approximations.

While causes of death are typically described as the diseases or injuries immediately precipitating the end of life, a few important studies have shown that the actual causes of premature death (reflecting underlying risk factors) are often preventable.

These analyses show that smoking remains the leading cause of mortality. However, poor diet and physical inactivity may soon overtake tobacco as the leading cause of death. These findings, along with escalating healthcare costs and aging population, argue persuasively that the need to establish a more preventive orientation in the US healthcare and public health systems has become more urgent.

- Ali H. Mokdad, PhD; James S. Marks, MD, MPH; Donna F. Stroup, PhD, MSc; Julie L. Gerberding, MD, MPH. "Actual Causes of Death in the United States." JAMA, 291(2004):1238-1245.

Factors Contributing to Premature Deaths in the United States



Sources: • "The Case For More Active Policy Attention to Health Promotion" (McGinnis, Williams-Russo, Knickman) Health Affairs. Vol. 32. No. 2. March/April 2002. "Actual Causes of Death in the United States" (Ali H. Mokdad, PhD; James S. Marks, MD, MPH; Donna F. Stroup, PhD, MSc; Julie L. Gerberding, MD, MPH.) JAMA. 291 (2000) 1238-1245.

Leading Causes of Death	Underlying Risk Factors (Actual Causes of Death)	
Cardiovascular Disease	Tobacco use Elevated serum cholesterol High blood pressure	Obesity Diabetes Sedentary lifestyle
Cancer	Tobacco use Improper diet	Alcohol Occupational/environmental exposures
Cerebrovascular Disease	High blood pressure Tobacco use	Elevated serum cholesterol
Accidental Injuries	Safety belt noncompliance Alcohol/substance abuse Reckless driving	Occupational hazards Stress/fatigue
Chronic Lung Disease	Tobacco use	Occupational/environmental exposures

Source: National Center for Health Statistics/US Department of Health and Human Services, Health United States: 1987. DHHS Pub. No. (PHS) 88–1232.

Nutrition

About Healthful Diet & Healthy Weight

Strong science exists supporting the health benefits of eating a healthful diet and maintaining a healthy body weight. Efforts to change diet and weight should address individual behaviors, as well as the policies and environments that support these behaviors in settings such as schools, worksites, healthcare organizations, and communities.

The goal of promoting healthful diets and healthy weight encompasses increasing household food security and eliminating hunger.

Americans with a healthful diet:

- Consume a variety of nutrient-dense foods within and across the food groups, especially whole grains, fruits, vegetables, low-fat or fat-free milk or milk products, and lean meats and other protein sources.
- Limit the intake of saturated and trans-fats, cholesterol, added sugars, sodium (salt), and alcohol.
- Limit caloric intake to meet caloric needs.

Diet and body weight are related to health status. Good nutrition is important to the growth and development of children. A healthful diet also helps Americans reduce their risks for many health conditions, including: overweight and obesity; malnutrition; iron-deficiency anemia; heart disease; high blood pressure; dyslipidemia (poor lipid profiles); type 2 diabetes; osteoporosis; oral disease; constipation; diverticular disease; and some cancers.

Diet reflects the variety of foods and beverages consumed over time and in settings such as worksites, schools, restaurants, and the home. Interventions to support a healthier diet can help ensure that:

- Individuals have the knowledge and skills to make healthier choices.
- Healthier options are available and affordable.

Social Determinants of Diet. Demographic characteristics of those with a more healthful diet vary with the nutrient or food studied. However, most Americans need to improve some aspect of their diet.

Social factors thought to influence diet include:

- Knowledge and attitudes
- Skills
- Social support
- Societal and cultural norms
- Food and agricultural policies
- Food assistance programs
- Economic price systems

Physical Determinants of Diet. Access to and availability of healthier foods can help people follow healthful diets. For example, better access to retail venues that sell healthier options may have a positive impact on a person's diet; these venues may be less available in low-income or rural neighborhoods.

The places where people eat appear to influence their diet. For example, foods eaten away from home often have more calories and are of lower nutritional quality than foods prepared at home.

Marketing also influences people's—particularly children's—food choices.

- Healthy People 2020 (www.healthypeople.gov)

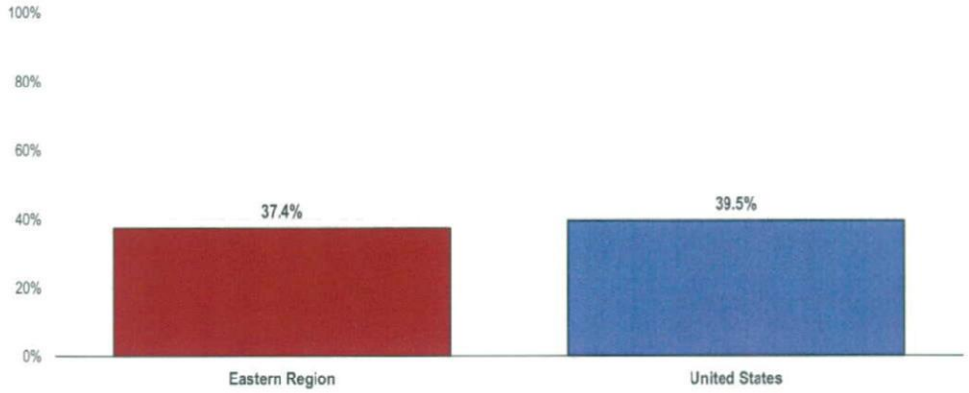
Daily Recommendation of Fruits/Vegetables

A total of 37.4% of Eastern Region adults report eating five or more servings of fruits and/or vegetables per day.

To measure fruit and vegetable consumption, survey respondents were asked multiple questions, specifically about the foods and drinks they consumed on the day prior to the interview.

- Statistically similar to national findings.

Consume Five or More Servings of Fruits/Vegetables Per Day

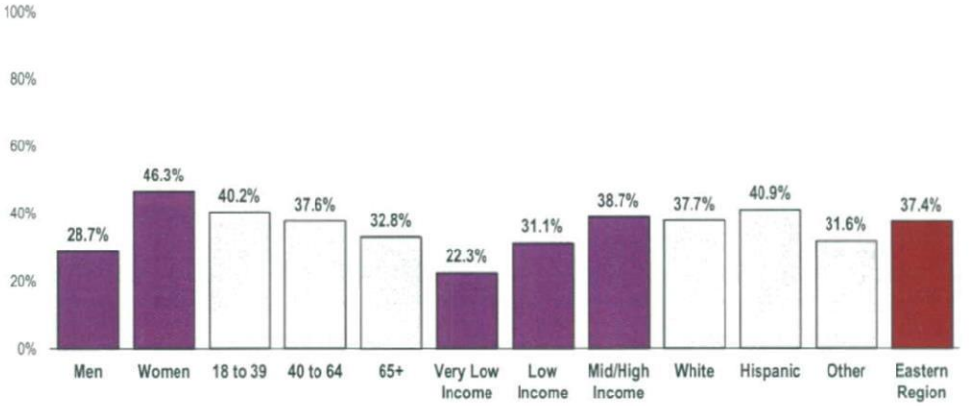


Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 146]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.
- For this issue, respondents were asked to recall their food intake on the previous day.

- Area men are less likely to get the recommended servings of daily fruits/vegetables, as are lower-income adults (positive correlation with income).

Consume Five or More Servings of Fruits/Vegetables Per Day
(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 146]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100--199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Access to Fresh Produce

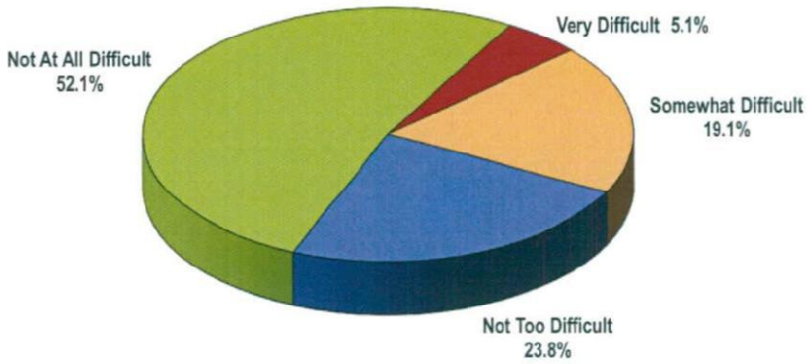
Difficulty Accessing Fresh Produce

While most report little or no difficulty, 24.2% of Eastern Region adults report that it is "very" or "somewhat" difficult for them to access affordable, fresh fruits and vegetables.

Respondents were asked:

"How difficult is it for you to buy fresh produce like fruits and vegetables at a price you can afford? Would you say: Very Difficult, Somewhat Difficult, Not Too Difficult, or Not At All Difficult?"

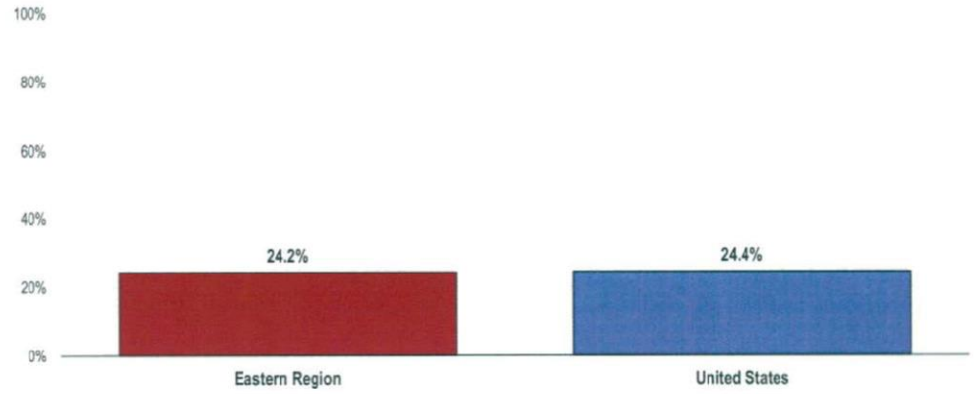
Level of Difficulty Finding Fresh Produce at an Affordable Price
(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 91]
Notes: • Asked of all respondents.

- Comparable to national findings.

Find It "Very" or "Somewhat" Difficult to Buy Affordable Fresh Produce



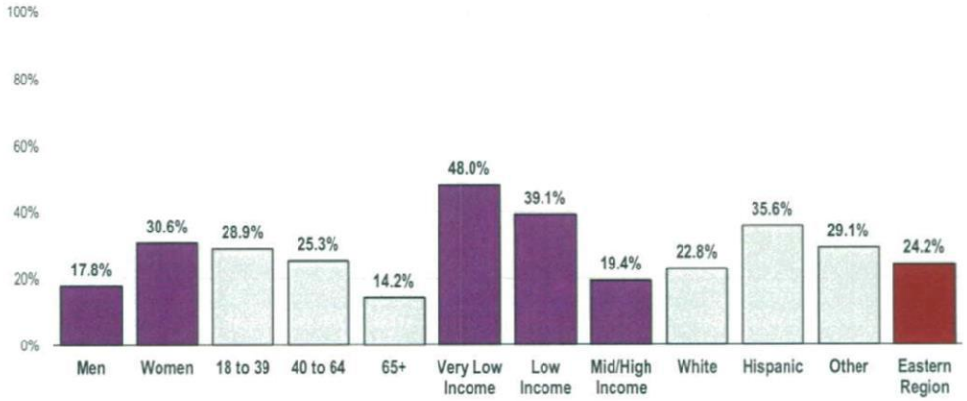
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 91]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Those more likely to report difficulty getting fresh fruits and vegetables include:

- Women.
- Those younger than 65 (negative correlation with age).
- Lower-income residents (negative correlation with income).
- Hispanics and "Other" residents.

Find It "Very" or "Somewhat" Difficult to Buy Affordable Fresh Produce

(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 91]
Notes: • Asked of all respondents.
• Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Low Food Access (Food Deserts)

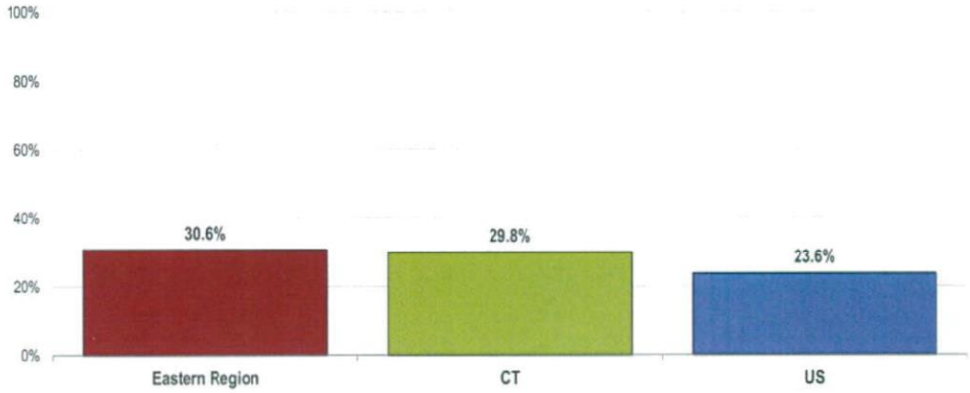
A food desert is defined as an area where a significant number or share of residents is far from a supermarket, where "far" is more than 1 mile in urban areas and more than 10 miles in rural areas.

US Department of Agriculture data show that 30.6% of the Eastern Region population have low food access or live in a "food desert," meaning that they do not live near a supermarket or large grocery store.

- Similar to statewide findings.
- Less favorable than national findings.

Population With Low Food Access

(Percent of Population That Is Far From a Supermarket or Large Grocery Store, 2010)

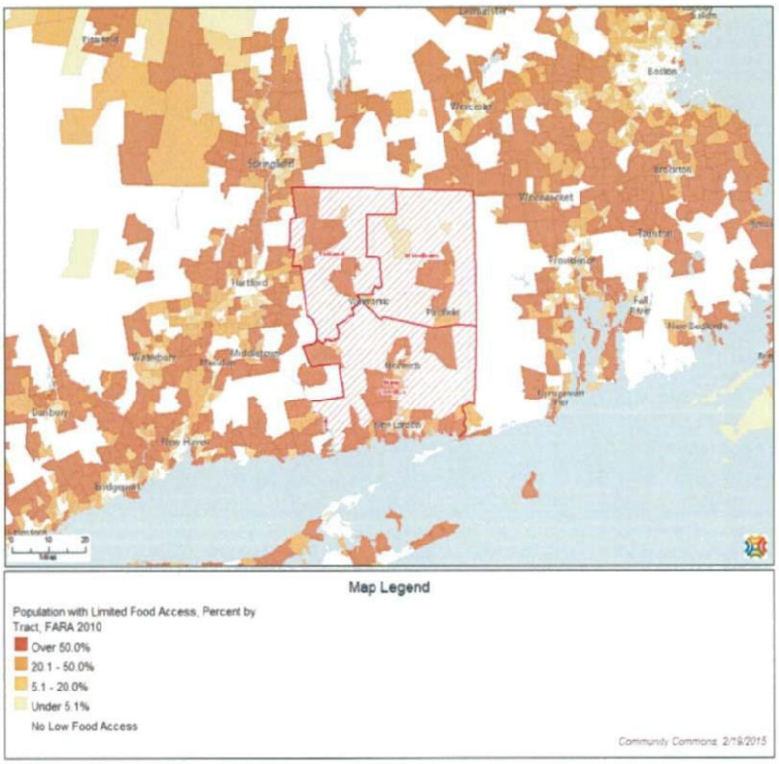


Sources:
- US Department of Agriculture, Economic Research Service, USDA - Food Access Research Atlas (FARA): 2010.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator reports the percentage of the population living in census tracts designated as food deserts. A food desert is defined as low-income areas where a significant number or share of residents is far from a supermarket, where "far" is more than 1 mile in urban areas and more than 10 miles in rural areas. This indicator is relevant because it highlights populations and geographies facing food insecurity.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- The following map provides an illustration of food deserts by census tract.

Population With Limited Food Access, Percent by Tract, FARA 2010



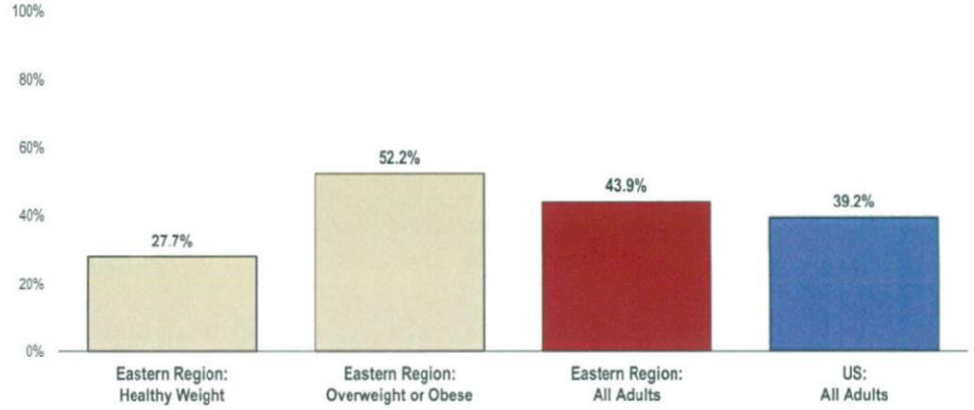
Health Advice About Diet & Nutrition

A total of 43.9% of survey respondents acknowledge that a physician counseled them about diet and nutrition in the past year.

- Better than national findings.
- Note: Among overweight/obese respondents, 52.2% report receiving diet/nutrition advice (meaning that nearly one-half did not).

Have Received Advice About Diet and Nutrition in the Past Year From a Physician, Nurse, or Other Health Professional

(By Weight Classification)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 18]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.

Physical Activity

About Physical Activity

Regular physical activity can improve the health and quality of life of Americans of all ages, regardless of the presence of a chronic disease or disability. Among adults and older adults, physical activity can lower the risk of: early death; coronary heart disease; stroke; high blood pressure; type 2 diabetes; breast and colon cancer; falls; and depression. Among children and adolescents, physical activity can: improve bone health; improve cardiorespiratory and muscular fitness; decrease levels of body fat; and reduce symptoms of depression. For people who are inactive, even small increases in physical activity are associated with health benefits.

Personal, social, economic, and environmental factors all play a role in physical activity levels among youth, adults, and older adults. Understanding the barriers to and facilitators of physical activity is important to ensure the effectiveness of interventions and other actions to improve levels of physical activity.

Factors **positively** associated with adult physical activity include: postsecondary education; higher income; enjoyment of exercise; expectation of benefits; belief in ability to exercise (self-efficacy); history of activity in adulthood; social support from peers, family, or spouse; access to and satisfaction with facilities; enjoyable scenery; and safe neighborhoods.

Factors **negatively** associated with adult physical activity include: advancing age; low income; lack of time; low motivation; rural residency; perception of great effort needed for exercise; overweight or obesity; perception of poor health; and being disabled. Older adults may have additional factors that keep them from being physically active, including lack of social support, lack of transportation to facilities, fear of injury, and cost of programs.

Among children ages 4 to 12, the following factors have a positive association with physical activity: gender (boys); belief in ability to be active (self-efficacy); and parental support.

Among adolescents ages 13 to 18, the following factors have a positive association with physical activity: parental education; gender (boys); personal goals; physical education/school sports; belief in ability to be active (self-efficacy); and support of friends and family.

Environmental influences positively associated with physical activity among children and adolescents include:

- Presence of sidewalks
- Having a destination/walking to a particular place
- Access to public transportation
- Low traffic density
- Access to neighborhood or school play area and/or recreational equipment

People with disabilities may be less likely to participate in physical activity due to physical, emotional, and psychological barriers. Barriers may include the inaccessibility of facilities and the lack of staff trained in working with people with disabilities.

- Healthy People 2020 (www.healthypeople.gov)

Leisure-Time Physical Activity

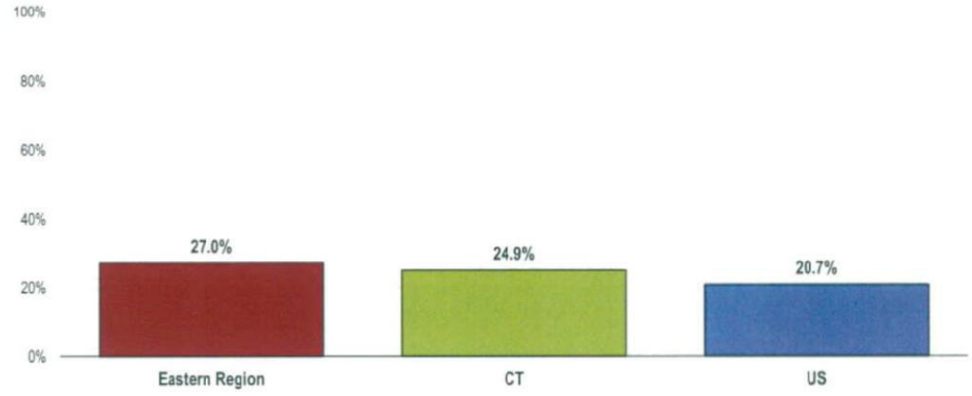
Leisure-time physical activity includes any physical activities or exercises (such as running, calisthenics, golf, gardening, walking, etc.) which take place outside of one's line of work.

A total of 27.0% of Eastern Region adults report no leisure-time physical activity in the past month.

- Similar to statewide findings.
- Less favorable than national findings.
- Satisfies the Healthy People 2020 target (32.6% or lower).

No Leisure-Time Physical Activity in the Past Month

Healthy People 2020 Target = 32.6% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 92]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective PA-1]

Notes:
- Asked of all respondents.

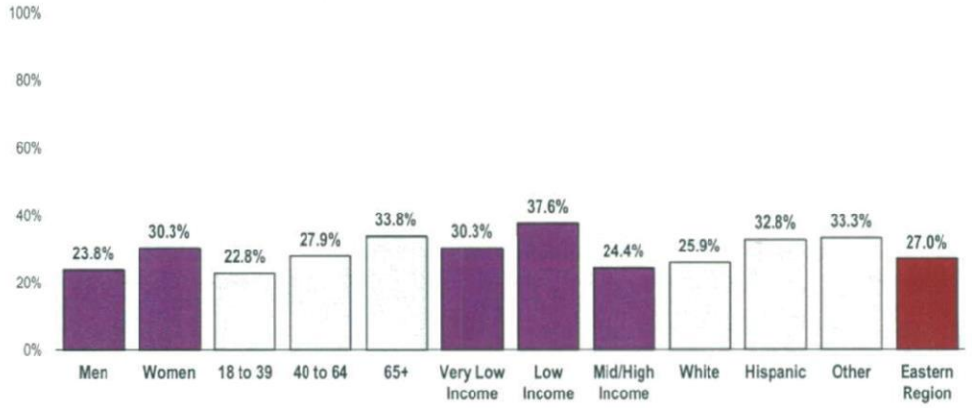
Lack of leisure-time physical activity in the area is higher among:

- Women.
- Adults age 40 and older.
- Residents living just above poverty.

No Leisure-Time Physical Activity in the Past Month

(Eastern Region, 2015)

Healthy People 2020 Target = 32.6% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 92]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective PA-1]

Notes:
- Asked of all respondents.
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- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Activity Levels

Recommended Levels of Physical Activity

Adults (age 18–64) should do 2 hours and 30 minutes a week of moderate-intensity, or 1 hour and 15 minutes (75 minutes) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic physical activity. Aerobic activity should be performed in episodes of at least 10 minutes, preferably spread throughout the week.

Additional health benefits are provided by increasing to 5 hours (300 minutes) a week of moderate-intensity aerobic physical activity, or 2 hours and 30 minutes a week of vigorous-intensity physical activity, or an equivalent combination of both.

Older adults (age 65 and older) should follow the adult guidelines. If this is not possible due to limiting chronic conditions, older adults should be as physically active as their abilities allow. They should avoid inactivity. Older adults should do exercises that maintain or improve balance if they are at risk of falling.

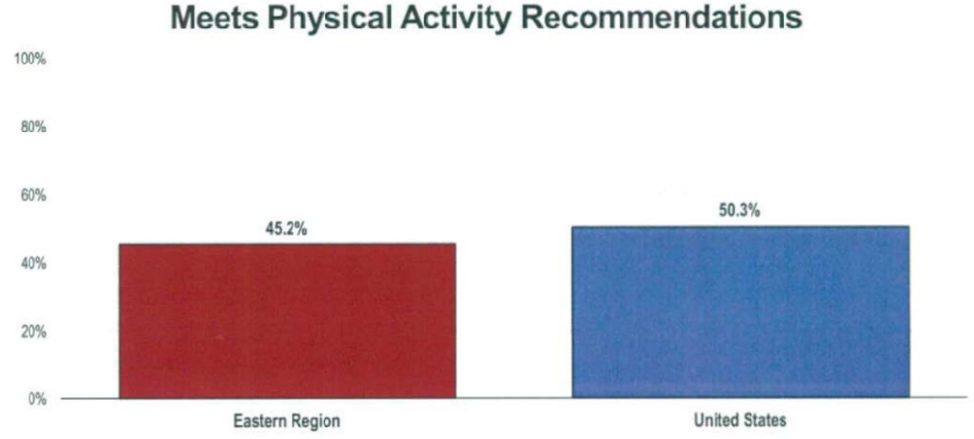
For all individuals, some activity is better than none. Physical activity is safe for almost everyone, and the health benefits of physical activity far outweigh the risks.

- 2008 Physical Activity Guidelines for Americans, U.S. Department of Health and Human Services. www.health.gov/PAGuidelines

Recommended Levels of Physical Activity

A total of 45.2% of Eastern Region adults participate in regular, sustained moderate or vigorous physical activity (meeting physical activity recommendations).

- Less favorable than national findings.



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 147]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

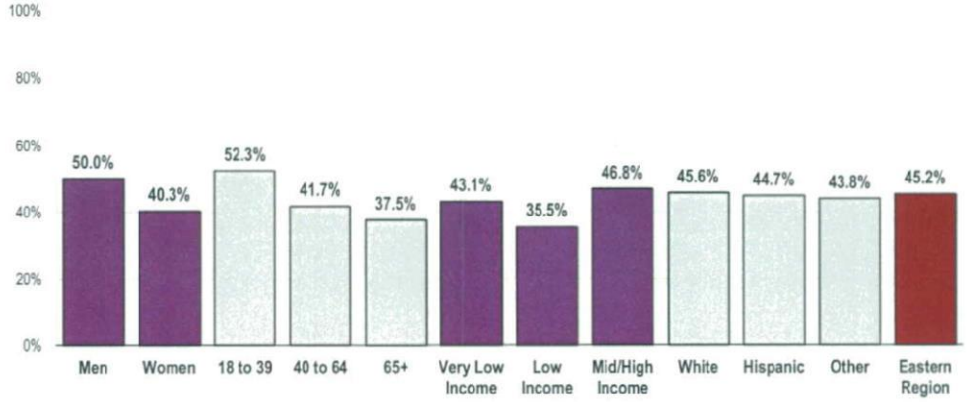
Notes:
- Asked of all respondents.
- In this case the term "meets physical activity recommendations" refers to participation in moderate physical activity (exercise that produces only light sweating or a slight to moderate increase in breathing or heart rate) at least 5 times a week for 30 minutes at a time, and/or vigorous physical activity (activities that cause heavy sweating or large increases in breathing or heart rate) at least 3 times a week for 20 minutes at a time.

Those less likely to meet physical activity requirements include:

- Women.
- Adults age 40 and older.
- Those living just above poverty.

Meets Physical Activity Recommendations

(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 147]
Notes: • Asked of all respondents.
• Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
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• In this case the term "meets physical activity recommendations" refers to participation in moderate physical activity (exercise that produces only light sweating or a slight to moderate increase in breathing or heart rate) at least 5 times a week for 30 minutes at a time, and/or vigorous physical activity (activities that cause heavy sweating or large increases in breathing or heart rate) at least 3 times a week for 20 minutes at a time.

Moderate & Vigorous Physical Activity

In the past month:

The individual indicators of moderate and vigorous physical activity are shown here.

A total of 28.5% of adults participated in moderate physical activity (5 times a week, 30 minutes at a time).

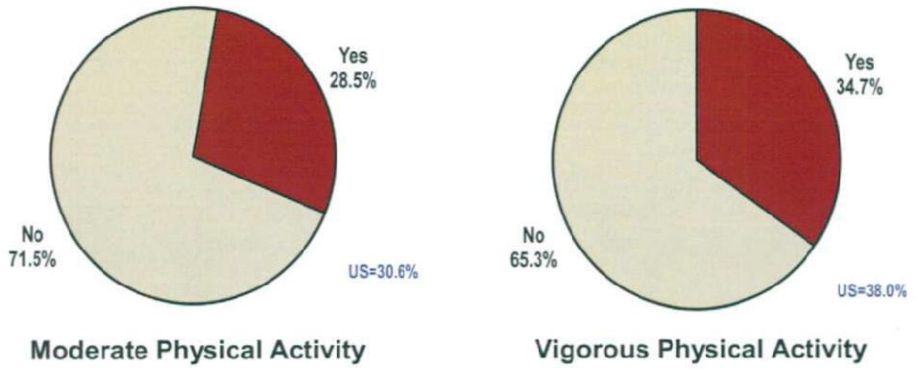
- Comparable to the national level.

A total of 34.7% participated in vigorous physical activity (3 times a week, 20 minutes at a time).

- Comparable to the nationwide figure.

Moderate & Vigorous Physical Activity

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey. Professional Research Consultants, Inc. [Items 148-149]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.
- Moderate Physical Activity: Takes part in exercise that produces only light sweating or a slight to moderate increase in breathing or heart rate at least 5 times per week for at least 30 minutes per time.
- Vigorous Physical Activity: Takes part in activities that cause heavy sweating or large increases in breathing or heart rate at least 3 times per week for at least 20 minutes per time.

Access to Physical Activity

Access to Recreation & Fitness Facilities

In 2012, there were 9.7 recreation/fitness facilities for every 100,000 population in the Eastern Region.

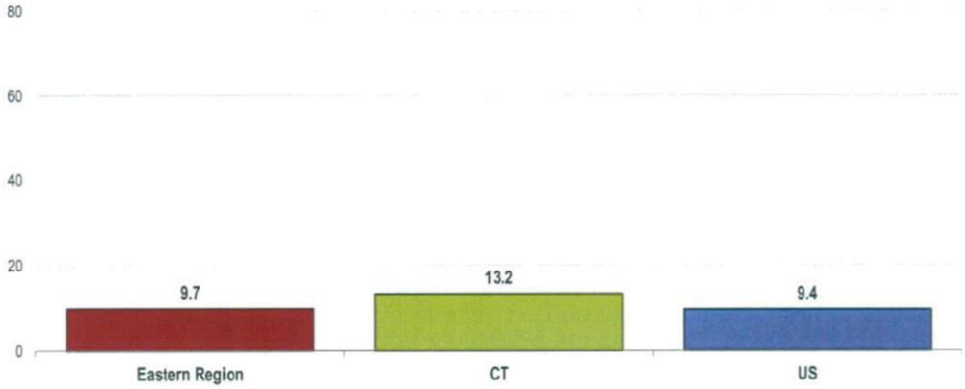
- Lower than what is found statewide.
- Similar to what is found nationally.

Here, recreation/fitness facilities include establishments engaged in operating facilities which offer "exercise and other active physical fitness conditioning or recreational sports activities."

Examples include athletic clubs, gymnasiums, dance centers, tennis clubs, and swimming pools.

Population With Recreation & Fitness Facility Access

(Number of Recreation & Fitness Facilities per 100,000 Population, 2012)



Sources:
- US Census Bureau, County Business Patterns: 2012. Additional data analysis by CARES.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- Recreation and fitness facilities are defined by North American Industry Classification System (NAICS) Code 713940 , which include *Establishments engaged in operating facilities which offer "exercise and other active physical fitness conditioning or recreational sports activities". Examples include athletic clubs, gymnasiums, dance centers, tennis clubs, and swimming pools.* This indicator is relevant because access to recreation and fitness facilities encourages physical activity and other healthy behaviors.

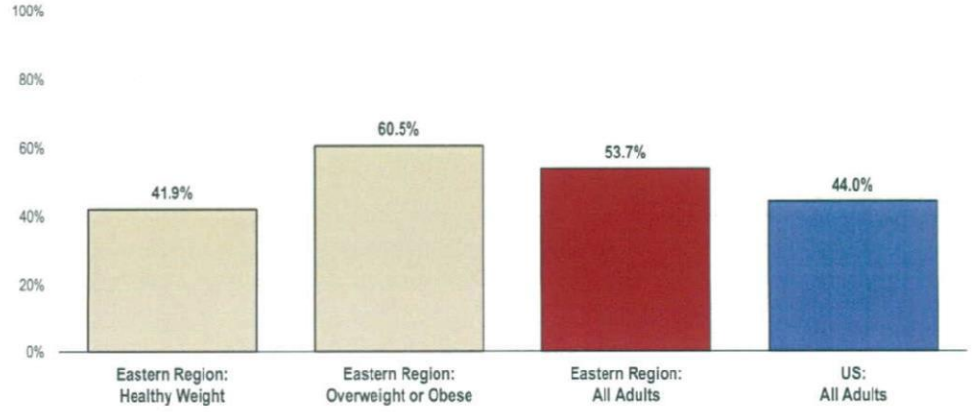
Health Advice About Physical Activity & Exercise

A total of 53.7% of Eastern Region adults report that their physician has asked about or given advice to them about physical activity in the past year.

- Better than the national average.
- Note: 60.5% of overweight/obese Eastern Region respondents say that they have talked with their doctor about physical activity/exercise in the past year.

Have Received Advice About Exercise in the Past Year From a Physician, Nurse, or Other Health Professional

(By Weight Classification)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 19]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

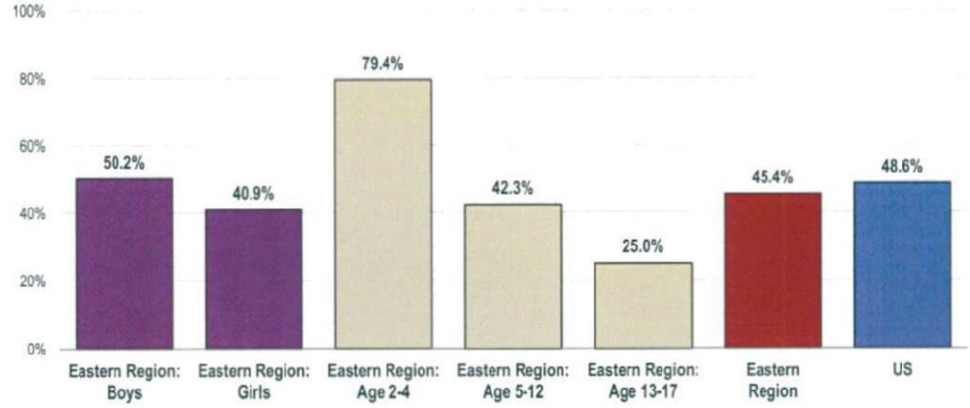
Children's Physical Activity

Among Eastern Region children age 2 to 17, 45.4% are reported to have had 60 minutes of physical activity on <u>each</u> of the seven days preceding the interview (1+ hours per day).

- Similar to the national rate.
- Children age 5 to 17 are much less likely to have had an hour of daily physical activity, as are Eastern Region girls.

Child Is Physically Active for One or More Hours per Day

(Among Children Age 2-17)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 117]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents with children age 2-17 at home.
- Includes children reported to have one or more hours of physical activity on each of the seven days preceding the survey.

Weight Status

About Overweight & Obesity

Because weight is influenced by energy (calories) consumed and expended, interventions to improve weight can support changes in diet or physical activity. They can help change individuals' knowledge and skills, reduce exposure to foods low in nutritional value and high in calories, or increase opportunities for physical activity. Interventions can help prevent unhealthy weight gain or facilitate weight loss among obese people. They can be delivered in multiple settings, including healthcare settings, worksites, or schools.

The social and physical factors affecting diet and physical activity (see Physical Activity topic area) may also have an impact on weight. Obesity is a problem throughout the population. However, among adults, the prevalence is highest for middle-aged people and for non-Hispanic black and Mexican American women. Among children and adolescents, the prevalence of obesity is highest among older and Mexican American children and non-Hispanic black girls. The association of income with obesity varies by age, gender, and race/ethnicity.

- Healthy People 2020 (www.healthypeople.gov)

Body Mass Index (BMI), which describes relative weight for height, is significantly correlated with total body fat content. The BMI should be used to assess overweight and obesity and to monitor changes in body weight. In addition, measurements of body weight alone can be used to determine efficacy of weight loss therapy. BMI is calculated as weight (kg)/height squared (m^2). To estimate BMI using pounds and inches, use: [weight (pounds)/height squared ($inches^2$)] x 703.

In this report, overweight is defined as a BMI of 25.0 to 29.9 kg/m^2 and obesity as a BMI ≥30 kg/m^2. The rationale behind these definitions is based on epidemiological data that show increases in mortality with BMIs above 25 kg/m^2. The increase in mortality, however, tends to be modest until a BMI of 30 kg/m^2 is reached. For persons with a BMI ≥30 kg/m^2, mortality rates from all causes, and especially from cardiovascular disease, are generally increased by 50 to 100 percent above that of persons with BMIs in the range of 20 to 25 kg/m^2.

- Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. National Institutes of Health. National Heart, Lung, and Blood Institute in Cooperation With The National Institute of Diabetes and Digestive and Kidney Diseases. September 1998.

Classification of Overweight and Obesity by BMI	BMI (kg/m^2)
Underweight	<18.5
Normal	18.5 – 24.9
Overweight	25.0 – 29.9
Obese	≥30.0

Source: Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. National Institutes of Health. National Heart, Lung, and Blood Institute in Cooperation With The National Institute of Diabetes and Digestive and Kidney Diseases. September 1998.

Adult Weight Status

Healthy Weight

Based on self-reported heights and weights, 32.0% of Eastern Region adults are at a healthy weight.

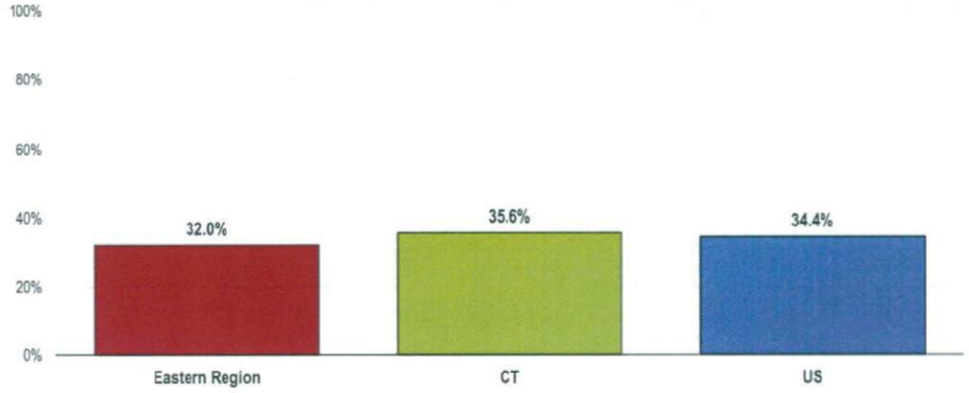
"Healthy weight "means neither underweight, nor overweight (BMI = 18.5-24.9).

- Less favorable than statewide findings.
- Statistically similar to national findings.
- Similar to the Healthy People 2020 target (33.9% or higher).

Healthy Weight

(Percent of Adults With a Body Mass Index Between 18.5 and 24.9)

Healthy People 2020 Target = 33.9% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 151]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective NWS-8]

Notes:
- Based on reported heights and weights, asked of all respondents.
- The definition of healthy weight is having a body mass index (BMI), a ratio of weight to height (kilograms divided by meters squared), between 18.5 and 24.9.

Overweight Status

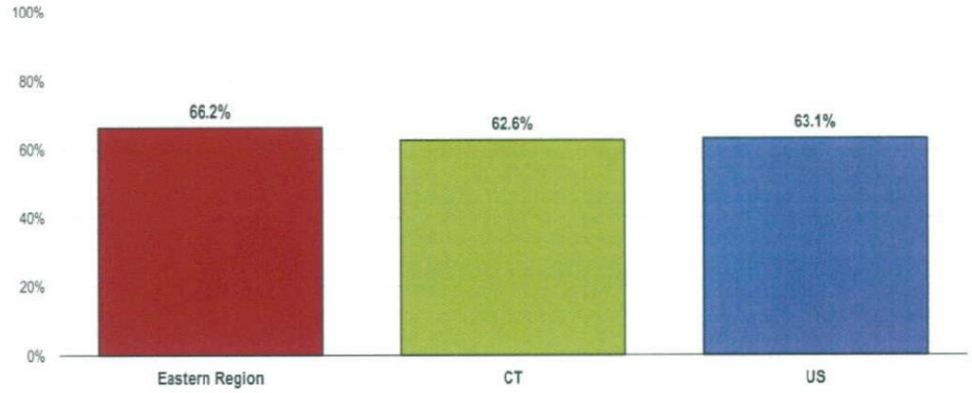
Approximately 2 in 3 Eastern Region adults (66.2%) are overweight.

Here, "overweight" includes those respondents with a BMI value ≥25.

- Less favorable than the Connecticut prevalence.
- Statistically similar to the US overweight prevalence.

Prevalence of Total Overweight

(Percent of Adults With a Body Mass Index of 25.0 or Higher)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 151]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.

Notes:
- Based on reported heights and weights, asked of all respondents.
- The definition of overweight is having a body mass index (BMI), a ratio of weight to height (kilograms divided by meters squared), greater than or equal to 25.0, regardless of gender. The definition for obesity is a BMI greater than or equal to 30.0.

Further, 30.2% of Eastern Region adults are obese.

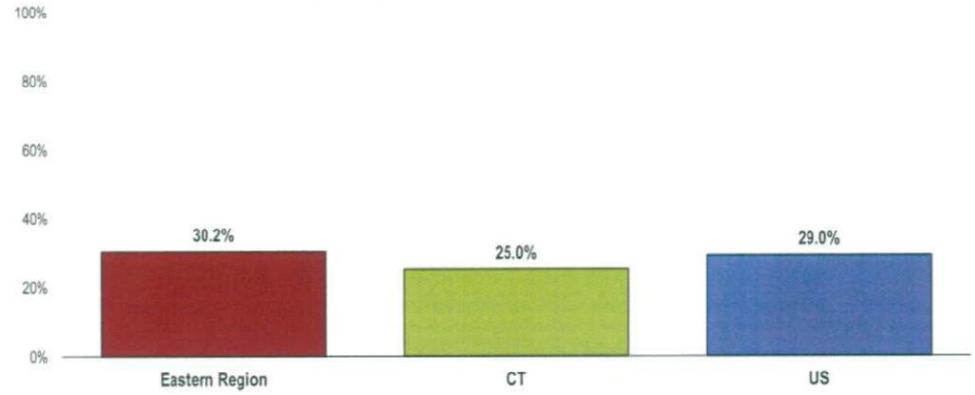
"Obese" (also included in overweight prevalence discussed previously) includes respondents with a BMI value ≥30.

- Less favorable than Connecticut findings.
- Similar to US findings.
- Similar to the Healthy People 2020 target (30.5% or lower).

Prevalence of Obesity

(Percent of Adults With a Body Mass Index of 30.0 or Higher)

Healthy People 2020 Target = 30.5% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 151]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective NWS-9]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.

Notes:
- Based on reported heights and weights, asked of all respondents.
- The definition of obesity is having a body mass index (BMI), a ratio of weight to height (kilograms divided by meters squared), greater than or equal to 30.0, regardless of gender.

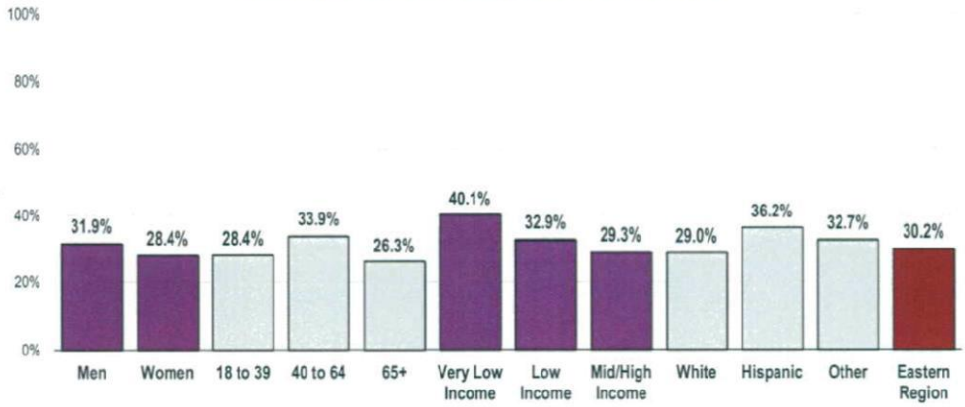
Obesity is notably more prevalent among:

- Adults age 40 to 64.
- Respondents with lower incomes (negative correlation).

Prevalence of Obesity

(Percent of Adults With a BMI of 30.0 or Higher; Eastern Region, 2015)

Healthy People 2020 Target = 30.5% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item151]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective NWS-9]

Notes:
- Based on reported heights and weights, asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.
- The definition of obesity is having a body mass index (BMI), a ratio of weight to height (kilograms divided by meters squared), greater than or equal to 30.0, regardless of gender.

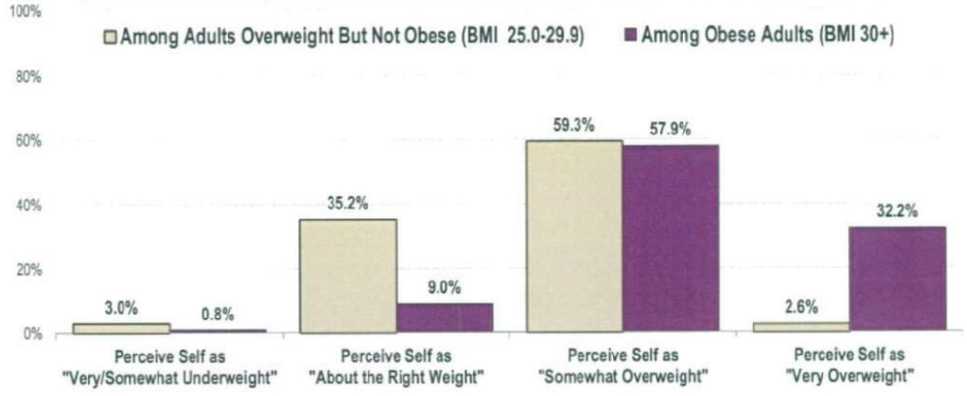
Actual vs. Perceived Body Weight

A total of 9.0% of obese adults and 35.2% of overweight (but not obese) adults feel that their current weight is "about right."

- 59.3% of overweight (but not obese) adults see themselves as "somewhat overweight."
- 32.2% of obese adults see themselves as "very overweight."

Actual vs. Perceived Weight Status

(Among Overweight/Obese Adults Based on BMI; Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 99]
Notes: • BMI is based on reported heights and weights, asked of all respondents.
• The definition of overweight is having a body mass index (BMI), a ratio of weight to height (kilograms divided by meters squared), greater than or equal to 25.0, regardless of gender. The definition for obesity is a BMI greater than or equal to 30.0.

Relationship of Overweight With Other Health Issues

Overweight and obese adults are more likely to report a number of adverse health conditions. Among these are:

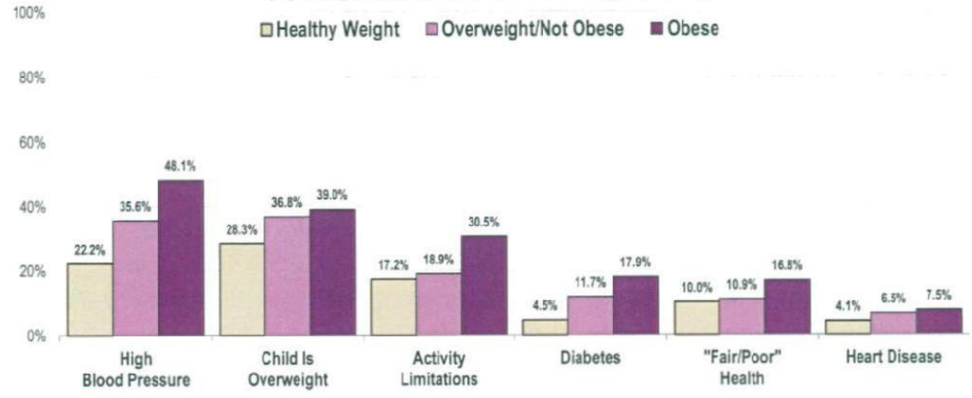
The correlation between overweight and various health issues cannot be disputed.

- Hypertension (high blood pressure).
- Activity limitations.
- Diabetes.
- "Fair/poor" health.
- Heart disease.

Overweight/obese residents are also more likely to have overweight children.

Relationship of Overweight With Other Health Issues

(By Weight Classification; Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 5, 105, 124, 125, 136, 155]
Notes: • Based on reported heights and weights, asked of all respondents.

Weight Management

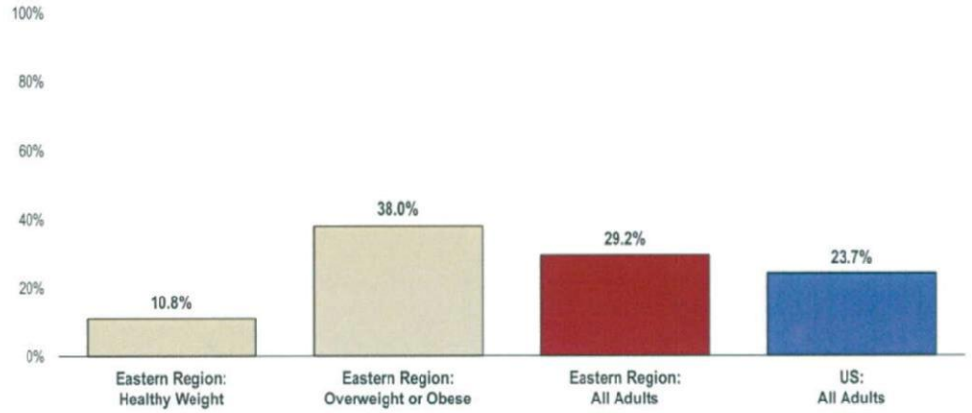
Health Advice

A total of 29.2% of adults have been given advice about their weight by a doctor, nurse, or other health professional in the past year.

- Higher than the national findings.
- Note that 38.0% of overweight/obese adults have been given advice about their weight by a health professional in the past year (while over 6 in 10 have not).

Have Received Advice About Weight in the Past Year From a Physician, Nurse, or Other Health Professional

(By Weight Classification)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 98]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Weight Control

About Maintaining a Healthy Weight

Individuals who are at a healthy weight are less likely to:

- Develop chronic disease risk factors, such as high blood pressure and dyslipidemia.
- Develop chronic diseases, such as type 2 diabetes, heart disease, osteoarthritis, and some cancers.
- Experience complications during pregnancy.
- Die at an earlier age.

All Americans should avoid unhealthy weight gain, and those whose weight is too high may also need to lose weight.

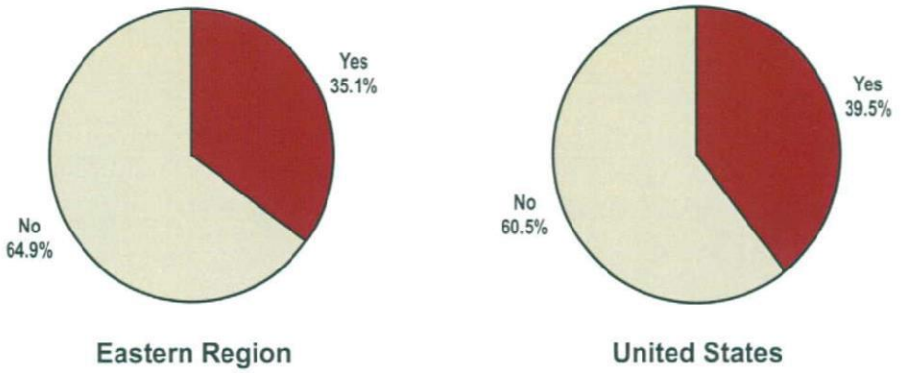
- Healthy People 2020 (www.healthypeople.gov)

A total of 35.1% of Eastern Region adults who are overweight say that they are both modifying their diet and increasing their physical activity to try to lose weight.

- Similar to national findings.

Trying to Lose Weight by Both Modifying Diet and Increasing Physical Activity

(Among Overweight or Obese Respondents)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 152]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Reflects respondents who are overweight or obese based on reported heights and weights.

Childhood Overweight & Obesity

About Weight Status in Children & Teens

In children and teens, body mass index (BMI) is used to assess weight status – underweight, healthy weight, overweight, or obese. After BMI is calculated for children and teens, the BMI number is plotted on the CDC BMI-for-age growth charts (for either girls or boys) to obtain a percentile ranking. Percentiles are the most commonly used indicator to assess the size and growth patterns of individual children in the United States. The percentile indicates the relative position of the child's BMI number among children of the same sex and age.

BMI-for-age weight status categories and the corresponding percentiles are shown below:

- Underweight — <5th percentile
- Healthy Weight — ≥5th and <85th percentile
- Overweight — ≥85th and <95th percentile
- Obese — ≥95th percentile

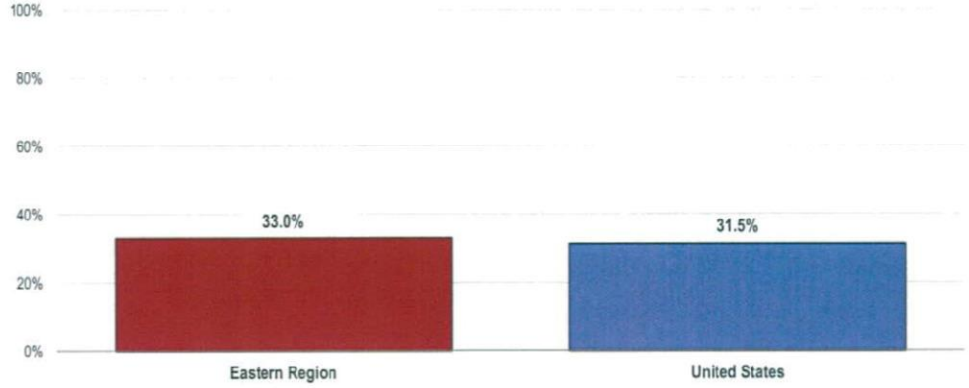
- Centers for Disease Control and Prevention

Based on the heights/weights reported by surveyed parents, 33.0% of Eastern Region children age 5 to 17 are overweight or obese (≥85th percentile).

- Similar to the national findings.

Child Total Overweight Prevalence

(Percent of Children Age 5-17 Who Are Overweight/Obese; BMI in the 85th Percentile or Higher)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 155]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents with children age 5-17 at home.
- Overweight among children is determined by children's Body Mass Index status at or above the 85th percentile of US growth charts by gender and age.

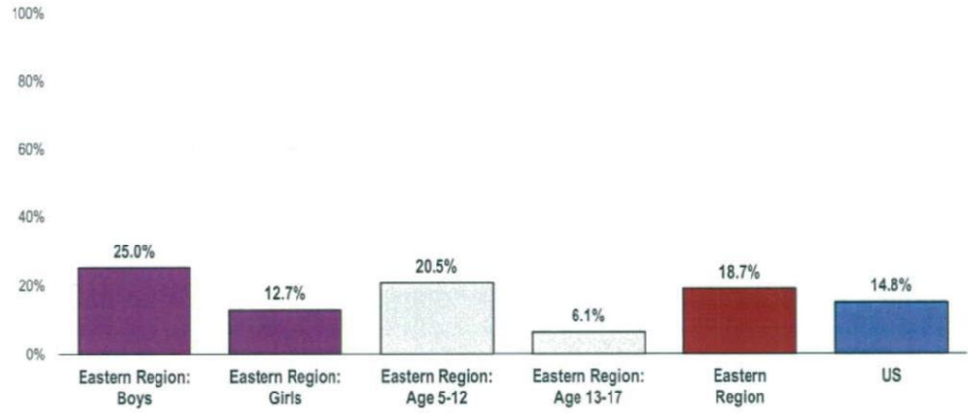
Further, 18.7% of the Eastern Region children age 5 to 17 are obese (≥95th percentile).

- Statistically similar to the national percentage.
- Similar to the Healthy People 2020 target (14.5% or lower for children age 2-19).
- Higher among boys and children age 5 through 12.

Child Obesity Prevalence

(Percent of Children Age 5-17 Who Are Obese; BMI in the 95th Percentile or Higher)

Healthy People 2020 Target = 14.5% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 155]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective NWS-10.4]

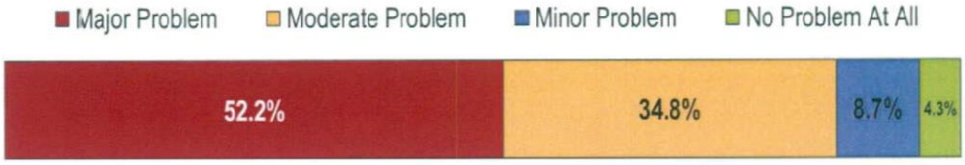
Notes:
- Asked of all respondents with children age 5-17 at home.
- Obesity among children is determined by children's Body Mass Index status equal to or above the 95th percentile of US growth charts by gender and age.

Key Informant Input: Nutrition, Physical Activity & Weight

A majority of key informants taking part in an online survey characterized *Nutrition, Physical Activity & Weight* as a "major problem" in the community.

Perceptions of Nutrition, Physical Activity, and Weight as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Access to Nutritional Services & Healthful Foods

Access to nutritional services as part of a primary care discussion or nutritional services somehow included. Safe and affordable public spaces for youth to find physical activities available. - Social Services Representative

People in Eastern Connecticut need more nutritional counseling and more physical activity to achieve adequate health. - Social Services Representative

People are really ignorant around healthy eating and living. Too much sitting and eating of fast foods. - Community/Business Leader

The majority of our population does not have affordable, appropriate, and reliable access and information about these conditions. Translators and translation services, that really work and are appropriate are not in place for our population in need. We see students every day that suffer from conditions related to poor nutrition, lack of physical activity and weight. Often, their work schedules are irregular and at the mercy of casino schedules. This impacts their day-to-day lives on all levels. The information related to nutrition, activity and weight, may be there, but their ability to understand and access it is quite limited. Accessible community health educators that speak their languages are desperately needed. - Social Services Representatives

Not enough accessible support, especially for those who are uninsured or not yet diagnosed with a disease. - Health Provider

Busy, Stressful Living

Marketing and advertising strategies, availability of junk food and busy schedules of families. - Health Provider

Lifestyles, change in school day structure which does not put emphasis on physical activity, stress placed on children. Demands of work and pace of today's society has taken a toll on overall health well-being of individuals and families. - Social Services Representative

We are a fast-food, tied-to-our-desks-and-couches society. We no longer eat homemade family meals together, nor do we engage in family outdoor time on a regular basis. - Health Provider

Obesity Prevalence

High rates of childhood and adult obesity - poor nutritional habits, high rates of childhood poverty contribute to problem, lack of accessible places for community to exercise safely (walking paths,

community centers etc.) lack of emphasis on exercise at schools, lack of availability of healthy food choices at restaurants (and lack of nutritional information about food choices at restaurants). - Social Services Representative

Obesity, due to percentage of overweight persons in population. - Community/Business Leader

Obesity - Social Services Representative

Access to Physical Activity

Lack of low-cost or no-cost facilities for children and adults to exercise. There are a few parks here and there, but with transportation being a barrier, many folks who live a distance from those areas cannot take advantage of those resources. Schools are so pressured to push academics that any opportunity to add physical activity into the curriculum is quickly quashed. School budgets also impact the quality of foods sold in cafeterias and vending machines. I also think that video games contribute to a lot of the obesity, as kids and adults do not get outside to throw a football or have a game of tag. - Public Health Expert

Schools no longer see the value of recess and PE, therefore those critical pieces of children's' development are eliminated or greatly reduced. - Health Provider

Substance Abuse

About Substance Abuse

Substance abuse has a major impact on individuals, families, and communities. The effects of substance abuse are cumulative, significantly contributing to costly social, physical, mental, and public health problems. These problems include:

- Teenage pregnancy
- Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS)
- Other sexually transmitted diseases (STDs)
- Domestic violence
- Child abuse
- Motor vehicle crashes
- Physical fights
- Crime
- Homicide
- Suicide

Substance abuse refers to a set of related conditions associated with the consumption of mind- and behavior-altering substances that have negative behavioral and health outcomes. Social attitudes and political and legal responses to the consumption of alcohol and illicit drugs make substance abuse one of the most complex public health issues. In addition to the considerable health implications, substance abuse has been a flash-point in the criminal justice system and a major focal point in discussions about social values: people argue over whether substance abuse is a disease with genetic and biological foundations or a matter of personal choice.

Advances in research have led to the development of evidence-based strategies to effectively address substance abuse. Improvements in brain-imaging technologies and the development of medications that assist in treatment have gradually shifted the research community's perspective on substance abuse. There is now a deeper understanding of substance abuse as a disorder that develops in adolescence and, for some individuals, will develop into a chronic illness that will require lifelong monitoring and care.

Improved evaluation of community-level prevention has enhanced researchers' understanding of environmental and social factors that contribute to the initiation and abuse of alcohol and illicit drugs, leading to a more sophisticated understanding of how to implement evidence-based strategies in specific social and cultural settings.

A stronger emphasis on evaluation has expanded evidence-based practices for drug and alcohol treatment. Improvements have focused on the development of better clinical interventions through research and increasing the skills and qualifications of treatment providers.

- Healthy People 2020 (www.healthypeople.gov)

Age-Adjusted Cirrhosis/Liver Disease Deaths

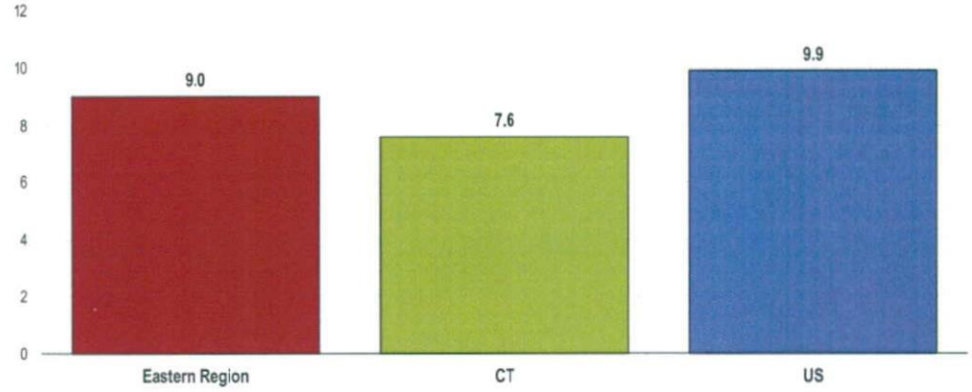
Between 2011 and 2013, there was an annual average age-adjusted cirrhosis/liver disease mortality rate of 9.0 deaths per 100,000 population in the Eastern Region.

- Higher than the statewide rate.
- Lower than the national rate.
- Fails to satisfy the Healthy People 2020 target (8.2 or lower).

Cirrhosis/Liver Disease: Age-Adjusted Mortality

(2011-2013 Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 8.2 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective SA-11]

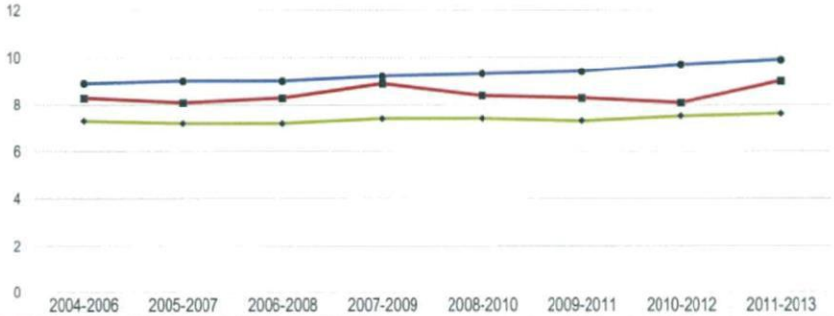
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The mortality rate in the Eastern Region has fluctuated over the past decade, showing no clear trend.

Cirrhosis/Liver Disease: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 8.2 or Lower



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	8.3	8.1	8.3	8.9	8.4	8.3	8.1	9.0
Connecticut	7.3	7.2	7.2	7.4	7.4	7.3	7.5	7.6
United States	8.9	9.0	9.0	9.2	9.3	9.4	9.7	9.9

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective SA-11]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 U.S. Standard Population.
- State and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

High-Risk Alcohol Use

Current Drinking

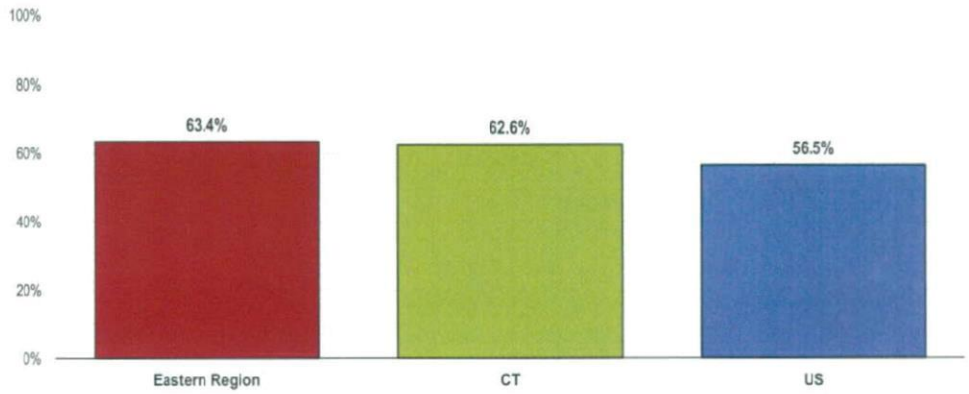
A total of 63.4% of area adults had at least one drink of alcohol in the past month (current drinkers).

"Current drinkers" include survey respondents who had at least one drink of alcohol in the month preceding the interview.

For the purposes of this study, a "drink" is considered one can or bottle of beer, one glass of wine, one can or bottle of wine cooler, one cocktail, or one shot of liquor.

- Similar to the statewide proportion.
- Higher than the national proportion.

Current Drinkers

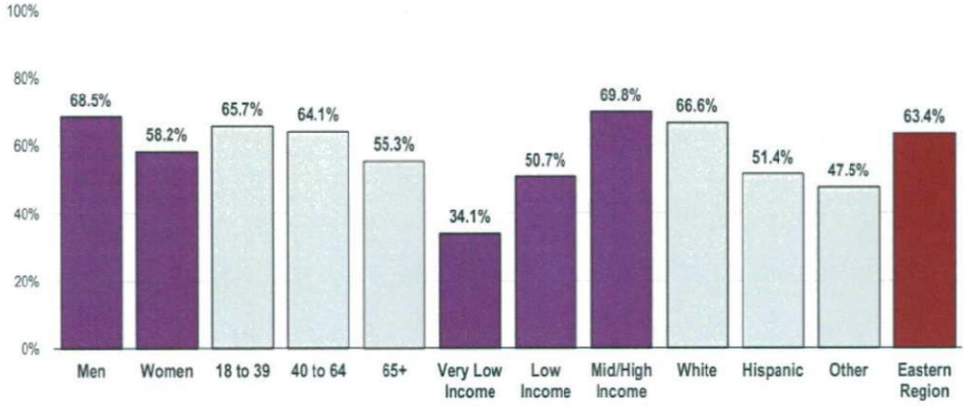


Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 160]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.
- Current drinkers had at least one alcoholic drink in the past month.

- Current drinking is more prevalent among men, adults younger than 65, higher-income residents, and Whites.

Current Drinkers
(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 160]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.
- Current drinkers had at least one alcoholic drink in the past month.

Excessive Drinking

Excessive drinkers" include:

1) Heavy drinkers: men reporting 2+ alcoholic drinks per day or women reporting 1+ alcoholic drinks per day in the month preceding the interview; OR

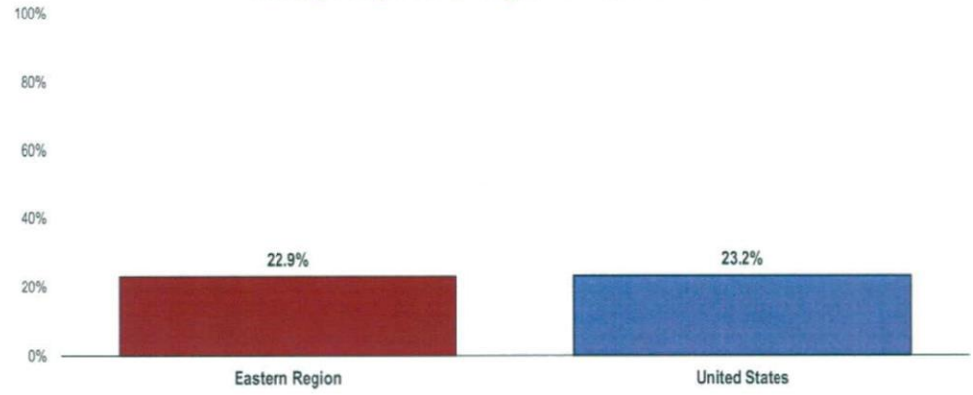
2) Binge drinkers: men reporting 5+ alcoholic drinks on any single occasion or women reporting 4+ alcoholic drinks on any single occasion in the past month.

RELATED ISSUE: See also Stress in the Mental Health & Mental Disorders section of this report.

A total of 22.9% of Eastern Region adults are excessive drinkers (heavy and/or binge drinkers).

- Comparable to national findings.
- Satisfies the Healthy People 2020 target (25.4% or lower).

Excessive Drinkers
Healthy People 2020 Target = 25.4% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 164]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective SA-15]

Notes:
- Asked of all respondents.
- Excessive drinking reflects the number of persons aged 18 years and over who drank more than two drinks per day on average (for men) or more than one drink per day on average (for women) OR who drank 5 or more drinks during a single occasion (for men) or 4 or more drinks during a single occasion (for women) during the past 30 days.

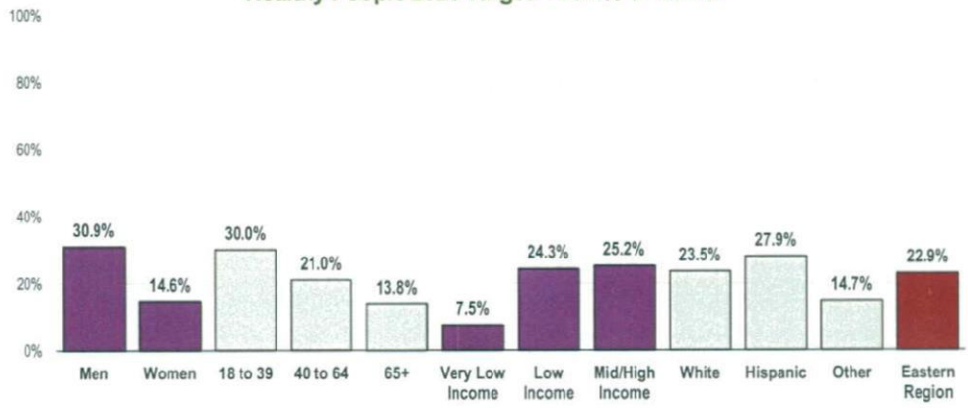
Excessive drinking is more prevalent among:

- Men.
- Young adults (negative correlation with age).
- Residents living above the federal poverty level.
- Whites and Hispanics.

Excessive Drinkers

(Total Area, 2015)

Healthy People 2020 Target = 25.4% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 164]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective SA-15]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "NH White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.
- Excessive drinking reflects the number of persons aged 18 years and over who drank more than two drinks per day on average (for men) or more than one drink per day on average (for women) OR who drank 5 or more drinks during a single occasion (for men) or 4 or more drinks during a single occasion (for women) during the past 30 days.

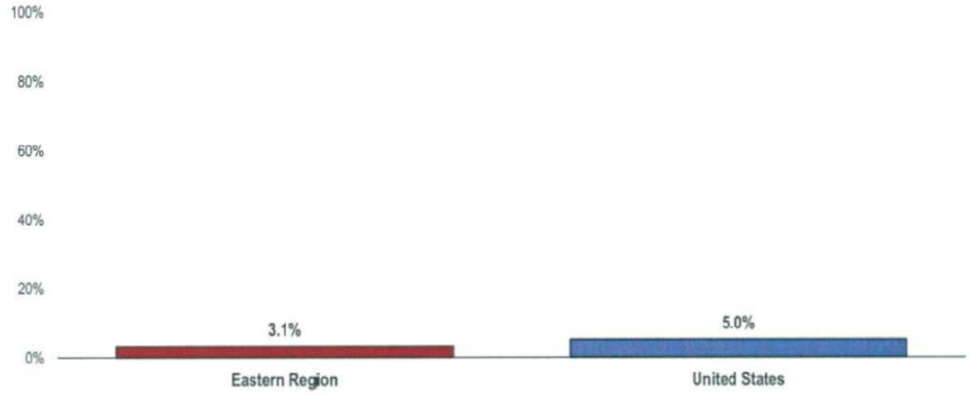
Drinking & Driving

A total of 3.1% of Eastern Region adults acknowledge having driven a vehicle in the past month after they had perhaps too much to drink.

- Lower than the national findings.

Note: As a self-reported measure – and because this indicator reflects potentially illegal behavior – it is reasonable to expect that it might be underreported, and that the actual incidence of drinking and driving in the community is likely higher.

Have Driven in the Past Month After Perhaps Having Too Much to Drink



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 65]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.

Age-Adjusted Drug-Induced Deaths

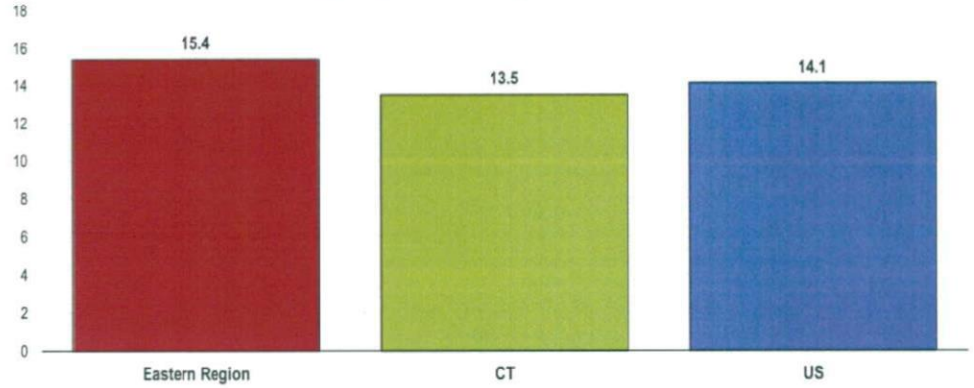
There was an annual average age-adjusted drug-induced mortality rate of 15.4 deaths per 100,000 population in the Eastern Region.

- Worse than the statewide rate.
- Worse than the national rate.
- Fails to satisfy the Healthy People 2020 target (11.3 or lower).

Drug-Induced Deaths: Age-Adjusted Mortality

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 11.3 or Lower



Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective SA-12]

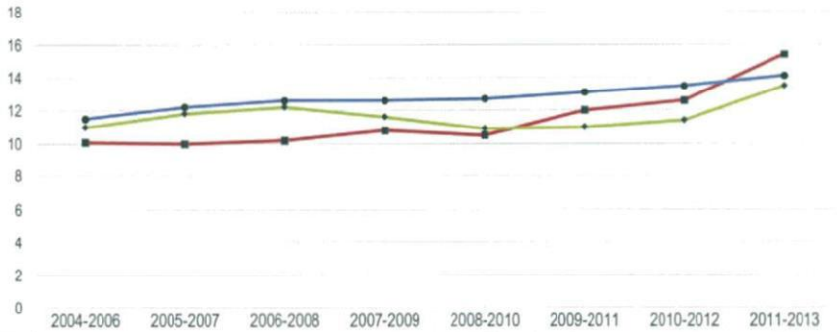
Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- Local, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

- TREND: The mortality rate has increased considerably over time, echoing the state and national trends.

Drug-Induced Deaths: Age-Adjusted Mortality Trends

(Annual Average Deaths per 100,000 Population)

Healthy People 2020 Target = 11.3 or Lower



	2004-2006	2005-2007	2006-2008	2007-2009	2008-2010	2009-2011	2010-2012	2011-2013
Eastern Region	10.1	10.0	10.2	10.8	10.5	12.0	12.6	15.4
Connecticut	11.0	11.8	12.2	11.6	10.9	11.0	11.4	13.5
United States	11.5	12.2	12.6	12.6	12.7	13.1	13.5	14.1

Sources:
- CDC WONDER Online Query System. Centers for Disease Control and Prevention, Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Data extracted February 2015.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective SA-12]

Notes:
- Deaths are coded using the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
- Rates are per 100,000 population, age-adjusted to the 2000 US Standard Population.
- County, state and national data are simple three-year averages.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Illicit Drug Use

A total of 2.4% of Eastern Region adults acknowledge using an illicit drug in the past month.

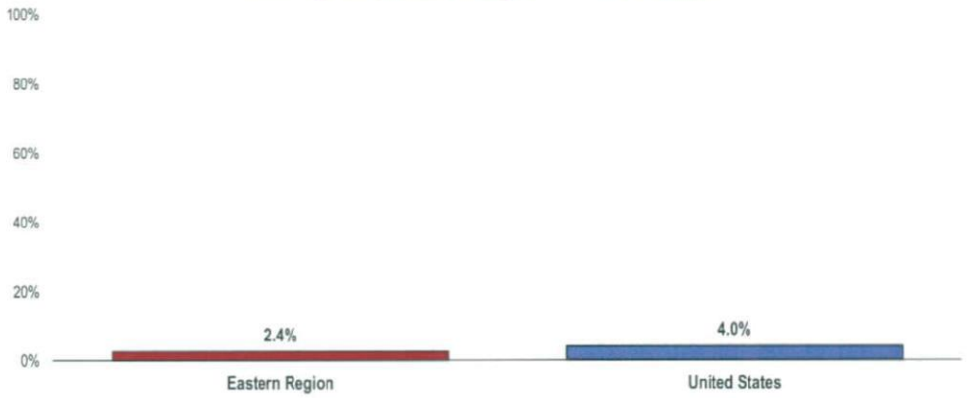
For the purposes of this survey, "illicit drug use" includes use of illegal substances or of prescription drugs taken without a physician's order.

Note: As a self-reported measure – and because this indicator reflects potentially illegal behavior – it is reasonable to expect that it might be underreported, and that actual illicit drug use in the community is likely higher.

- Lower than the proportion found nationally.
- Satisfies the Healthy People 2020 target of 7.1% or lower.

Illicit Drug Use in the Past Month

Healthy People 2020 Target = 7.1% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 66]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective SA-13.3]

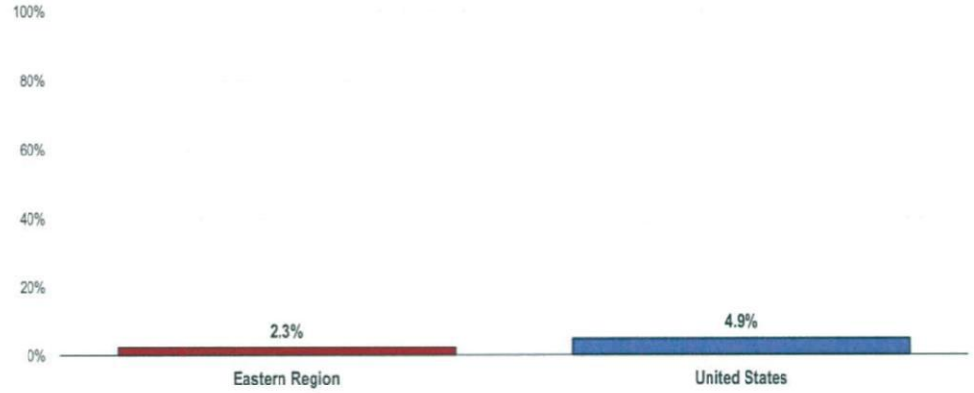
Notes:
- Asked of all respondents.

Alcohol & Drug Treatment

A total of 2.3% of Eastern Region adults report that they have sought professional help for an alcohol or drug problem at some point in their lives.

- Worse than national findings.

Have Ever Sought Professional Help for an Alcohol/Drug-Related Problem



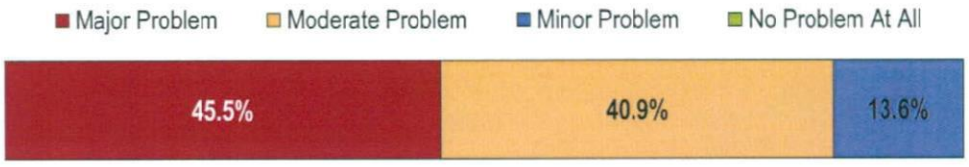
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 67]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Key Informant Input: Substance Abuse

The greatest share of key informants taking part in an online survey characterized *Substance Abuse* as a "major problem" in the community.

Perceptions of Substance Abuse as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Barriers to Treatment

Among those rating this issue as a "major problem," the greatest barriers to accessing substance abuse treatment are viewed as:

Denial

> *Admitting individual has the problem. Cannot think clearly to identify what life would be like without the addiction. Low self-esteem. Fear of walking into facility and who will see them. - Social Services Representative*
>
> *They don't want them until it is too late; ignorance and their addiction make them blind to their problem. - Community/Business Leader*

Stigma

> *Stigma, Cost, waiting lists, lack of availability of both inpatient and outpatient care, including care that people can access while still maintaining employment. - Social Services Representative*
>
> *There are so many stigmas attached to this disease, the most prevalent of which is the feeling that it's their own fault/weakness. - Health Provider*

Prevalence

> *High percentage of arrests for substance abuse. - Community/Business Leader*

Cost & Transportation

> *Transportation, cost, lack of knowledge regarding available resources, denial. - Public Health Expert*

Motivation

> *People need to want treatment, and that treatment needs to be available at exactly the time they seek it out. Therefore jumping through insurance hurdles and finding a provider with open spots can make that difficult, if not impossible. Substance abusers have often burned so many bridges that no one is there to help them navigate the system. - Health Provider*

Lack of Resources

> *Treatment resources for youth ages 13 and older. Also a gap in mid-level treatment. - Health Provider*

Hepatitis C Testing

> *Hepatitis C, we really need access to rapid testing. - Social Services Representative*

Most Problematic Substances

Key informants (who rated this as a "major problem") most often identified alcohol, followed by heroin/other opioids, prescription drugs and marijuana, as the most problematic substances abused in the community (see the following table).

	Most Problematic	Second-Most Problematic	Third-Most Problematic	Total Mentions
Alcohol	**75.0%**	0.0%	12.5%	**7**
Heroin or Other Opioids	12.5%	**50.0%**	12.5%	6
Prescription Medications	12.5%	12.5%	**25.0%**	4
Marijuana	0.0%	12.5%	**25.0%**	3
Cocaine or Crack	0.0%	12.5%	12.5%	2
Methamphetamines or Other Amphetamines	0.0%	12.5%	0.0%	1
Over-The-Counter Medications	0.0%	0.0%	12.5%	1

Tobacco Use

About Tobacco Use

Tobacco use is the single most preventable cause of death and disease in the United States. Scientific knowledge about the health effects of tobacco use has increased greatly since the first Surgeon General's report on tobacco was released in 1964.

Tobacco use causes:

- Cancer
- Heart disease
- Lung diseases (including emphysema, bronchitis, and chronic airway obstruction)
- Premature birth, low birth weight, stillbirth, and infant death

There is no risk-free level of exposure to secondhand smoke. Secondhand smoke causes heart disease and lung cancer in adults and a number of health problems in infants and children, including: severe asthma attacks; respiratory infections; ear infections; and sudden infant death syndrome (SIDS).

Smokeless tobacco causes a number of serious oral health problems, including cancer of the mouth and gums, periodontitis, and tooth loss. Cigar use causes cancer of the larynx, mouth, esophagus, and lung.

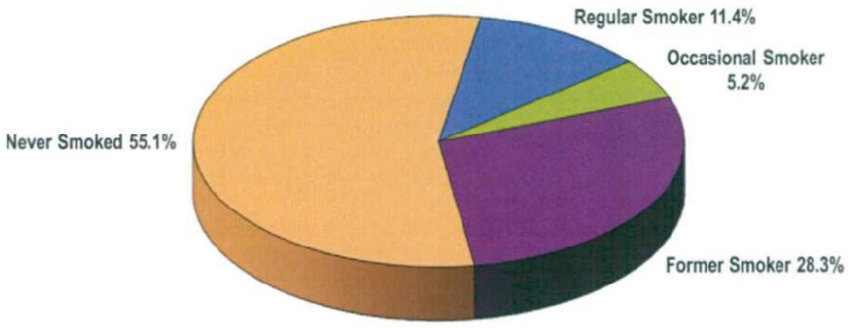
- Healthy People 2020 (www.healthypeople.gov)

Cigarette Smoking

Cigarette Smoking Prevalence

A total of 16.6% of Eastern Region adults currently smoke cigarettes, either regularly (11.4% every day) or occasionally (5.2% on some days).

Cigarette Smoking Prevalence
(Eastern Region, 2015)

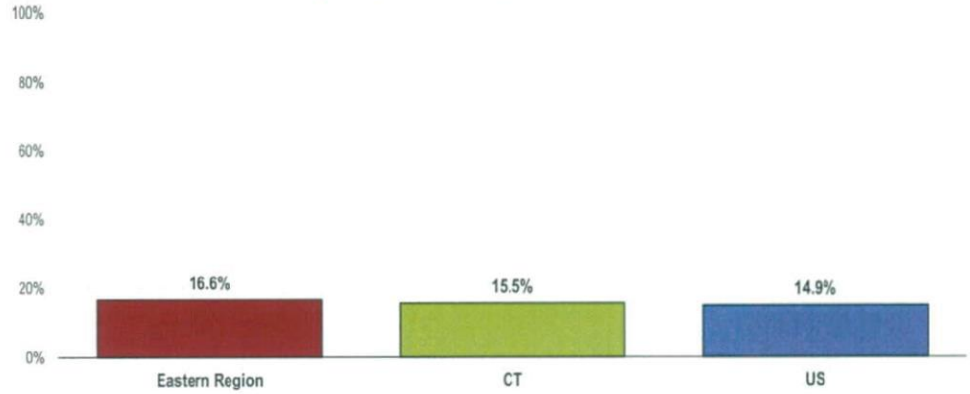


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 156]
Notes: • Asked of all respondents.

- Statistically similar to statewide findings.
- Statistically similar to national findings.
- Fails to satisfy the Healthy People 2020 target (12% or lower).

Current Smokers

Healthy People 2020 Target = 12.0% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 156]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective TU-1.1]

Notes:
- Asked of all respondents.
- Includes regular and occasional smokers (those who smoke cigarettes everyday or on some days).

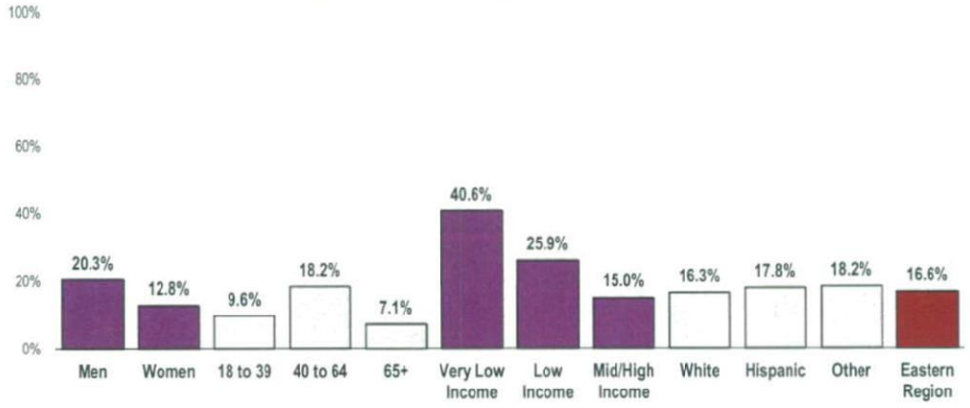
Cigarette smoking is more prevalent among:

- Men.
- Residents age 40 to 64.
- Lower-income residents (strong negative correlation).

Current Smokers

(Eastern Region, 2015)

Healthy People 2020 Target = 12.0% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 156]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective TU-1.1]

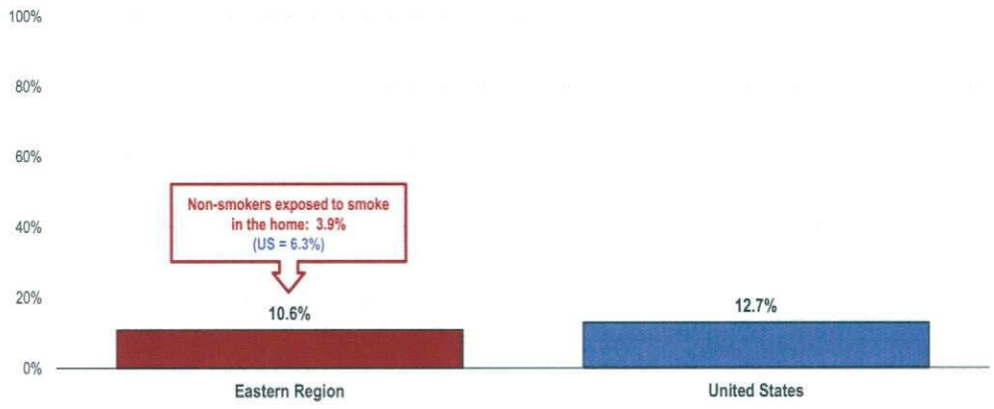
Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; Mid'High Income" includes households with incomes at 200% or more of the federal poverty level.
- Includes regular and occasion smokers (everyday and some days).

Environmental Tobacco Smoke

A total of 10.6% of Eastern Region adults (including smokers and non-smokers) report that a member of their household has smoked cigarettes in the home an average of 4+ times per week over the past month.

- Similar to the national findings.
- Note that 3.9% of the Eastern Region non-smokers are exposed to cigarette smoke at home, more favorable than what is found nationally.

Member of Household Smokes at Home



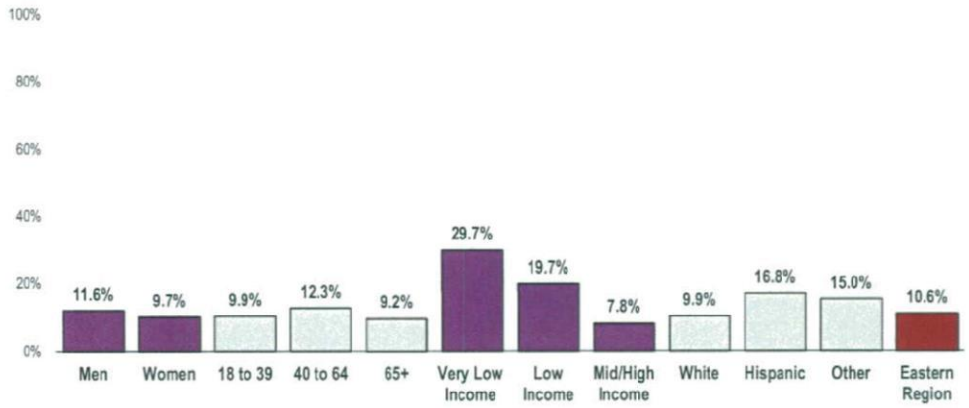
Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 59, 158]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.
- "Smokes at home" refers to someone smoking cigarettes, cigars, or a pipe in the home an average of four or more times per week in the past month.

- Smoking in the home is higher among respondents with lower incomes (strong negative correlation with income).

Member of Household Smokes At Home

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 59]

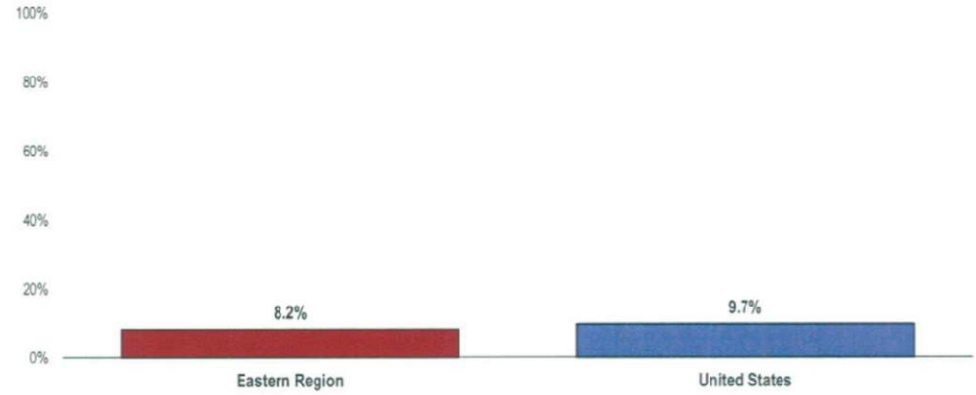
Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.
- "Smokes at home" refers to someone smoking cigarettes, cigars, or a pipe in the home an average of four or more times per week in the past month.

Among households with children, 8.2% have someone who smokes cigarettes in the home.

- Similar to the national findings.

Percentage of Households With Children In Which Someone Smokes in the Home

(Among Households With Children)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 159]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Reflects respondents with children 0 to 17 in the household.
- "Smokes at home" refers to someone smoking cigarettes, cigars, or a pipe in the home an average of four or more times per week in the past month.

Smoking Cessation

About Reducing Tobacco Use

Preventing tobacco use and helping tobacco users quit can improve the health and quality of life for Americans of all ages. People who stop smoking greatly reduce their risk of disease and premature death. Benefits are greater for people who stop at earlier ages, but quitting tobacco use is beneficial at any age.

Many factors influence tobacco use, disease, and mortality. Risk factors include race/ethnicity, age, education, and socioeconomic status. Significant disparities in tobacco use exist geographically; such disparities typically result from differences among states in smoke-free protections, tobacco prices, and program funding for tobacco prevention.

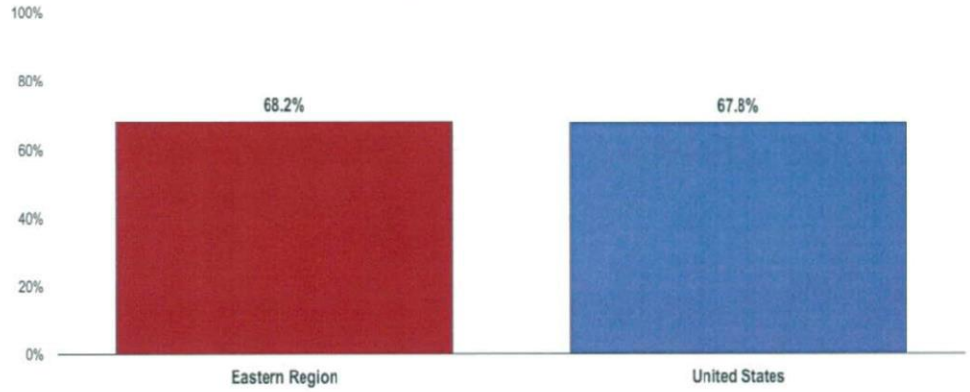
- Healthy People 2020 (www.healthypeople.gov)

Health Advice About Smoking Cessation

A total of 68.2% of smokers say that a doctor, nurse or other health professional has recommended in the past year that they quit smoking.

- Comparable to the national percentage.

Advised by a Healthcare Professional in the Past Year to Quit Smoking
(Among Current Smokers)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 58]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all current smokers.

Smoking Cessation Attempts

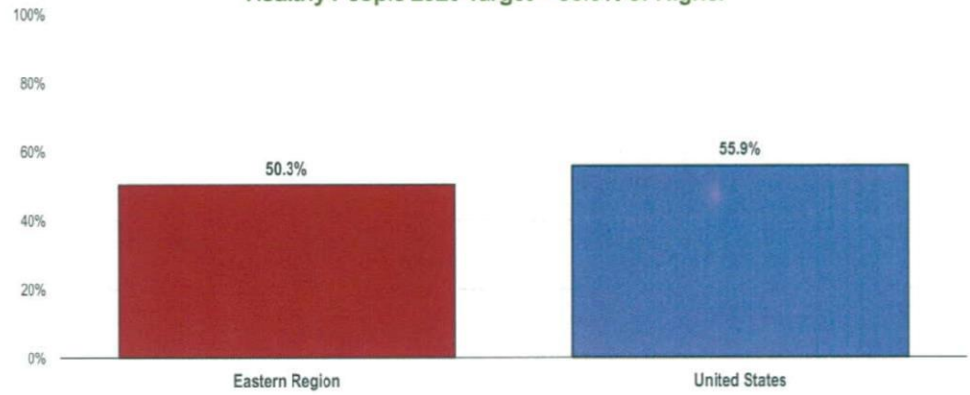
One-half (50.3%) of regular smokers went without smoking for one day or longer in the past year because they were trying to quit smoking.

- Similar to the national percentage.
- Fails to satisfy the Healthy People 2020 target (80% or higher).

Have Stopped Smoking for One Day or Longer in the Past Year in an Attempt to Quit Smoking

(Among Everyday Smokers)

Healthy People 2020 Target = 80.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 57]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective TU-4.1]

Notes:
- Asked of respondents who smoke cigarettes every day.

Other Tobacco Use

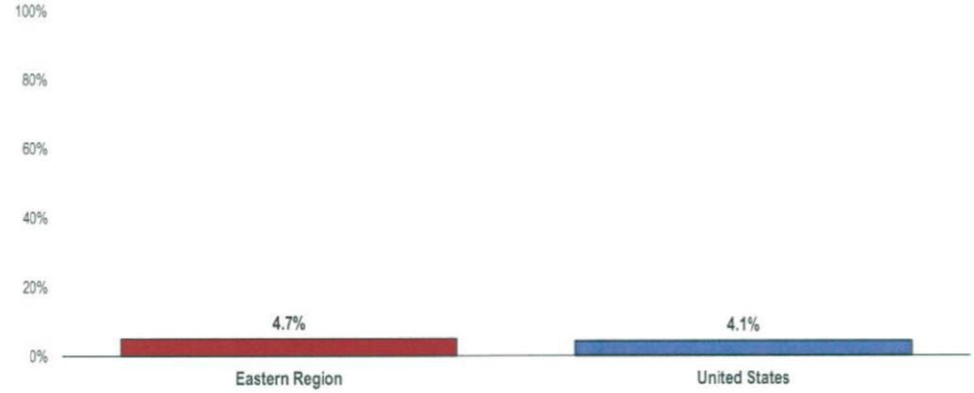
Cigars

A total of 4.7% of Eastern Region adults use cigars every day or on some days.

- Similar to the national percentage.
- Fails to satisfy the Healthy People 2020 target (0.2% or lower).

Use of Cigars

Healthy People 2020 Target = 0.2% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 61]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective TU-1.3]

Notes:
- Asked of all respondents.

Smokeless Tobacco

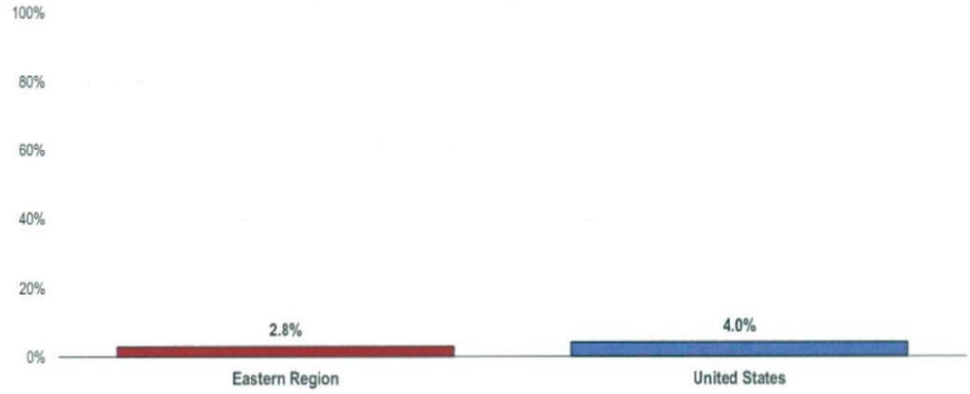
A total of 2.8% of Eastern Region adults use some type of smokeless tobacco every day or on some days.

Examples of smokeless tobacco include chewing tobacco, snuff, or "snus."

- Similar to the national percentage.
- Fails to satisfy the Healthy People 2020 target (0.3% or lower).

Use of Smokeless Tobacco

Healthy People 2020 Target = 0.3% or Lower



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 60]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective TU-1.2]

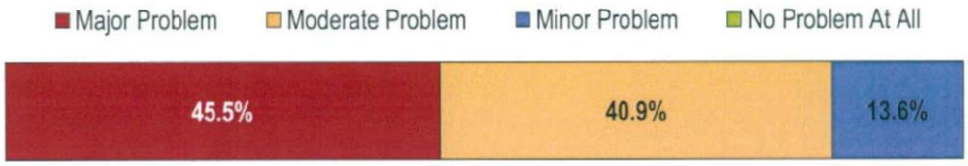
Notes:
- Asked of all respondents.
- Smokeless tobacco includes chewing tobacco or snuff.

Key Informant Input: Tobacco Use

The greatest share of key informants taking part in an online survey characterized *Tobacco Use* as a "major problem" in the community.

Perceptions of Tobacco Use as a Problem in the Community

(Key Informants, 2015)



Sources:
- PRC Online Key Informant Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Prevalence

> *Percentage of smokers seems especially high. Not only a health problem, an economic problem among an impoverished population. - Community/Business Leader*
>
> *Too high of rates. - Health Provider*
>
> *High incidence of tobacco use has been documented; related disease use - high rates of cancer, heart disease, asthma and COPD - there is insufficient attention to this problem and smoking continues to be a concern not only in this community but in the state and country and more creative programming needs to be developed to address it. - Social Services Representative*
>
> *Among some of the towns in which there is a high use of tobacco products in our area are: Jewett City, Griswold, Baltic, New London. - Social Services Representative*
>
> *Despite the rising cost of cigarettes, as well as recent policy, legislative changes, individuals continue with their addiction. There are some who will most likely never quit because they truly enjoy smoking or they just cannot seem to beat their addiction despite multiple attempts. - Public Health Expert*
>
> *Lifestyles, enough education on ramifications and relationship to health/disease. Lifestyle choice. - Social Services Representative*

Youth

> *Too many people still smoking, especially the younger people. - Community/Business Leader*
>
> *It is disheartening to see kids streaming out of NFA, lighting up when they walk down the sidewalk. Smoking is certainly declining, but when parents smoke, kids usually do, too. Smoking is also more prevalent in some of the immigrant communities in our region. It is a very hard habit to quit. - Health Provider*

Access to Healthcare Services

Professional Research Consultants, Inc.

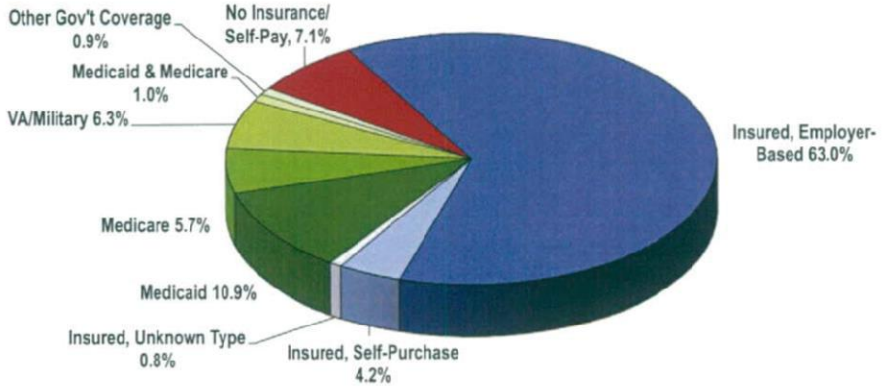
Health Insurance Coverage

Type of Healthcare Coverage

A total of 68.0% of Eastern Region adults age 18 to 64 report having healthcare coverage through private insurance. Another 24.8% report coverage through a government-sponsored program (e.g., Medicaid, Medicare, military benefits).

Survey respondents were asked a series of questions to determine their healthcare insurance coverage, if any, from either private or government-sponsored sources.

Healthcare Insurance Coverage
(Among Adults Age 18-64; Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 165]
Notes: • Reflects respondents age 18 to 64

Lack of Health Insurance Coverage

Among adults age 18 to 64, 7.1% report having no insurance coverage for healthcare expenses.

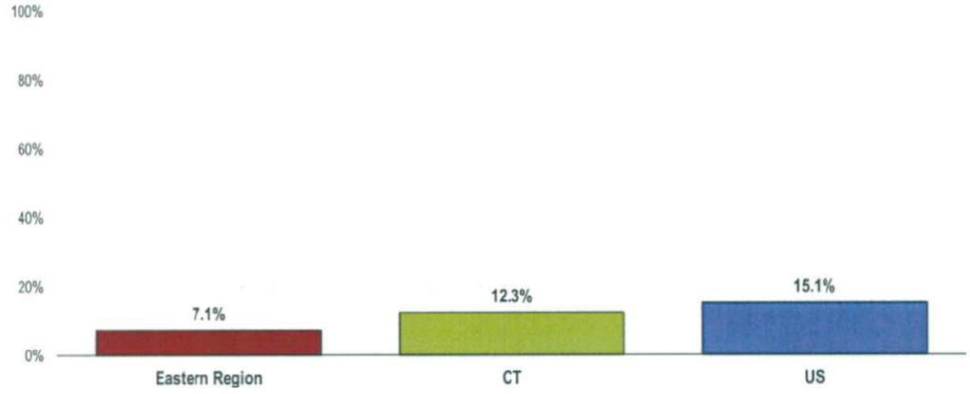
Here, lack of health insurance coverage reflects respondents age 18 to 64 (thus, excluding the Medicare population) who have no type of insurance coverage for healthcare services – neither private insurance nor government-sponsored plans (e.g., Medicaid).

- More favorable than the state finding.
- More favorable than the national finding.
- The Healthy People 2020 target is universal coverage (0% uninsured).

Lack of Healthcare Insurance Coverage

(Among Adults Age 18-64)

Healthy People 2020 Target = 0.0% (Universal Coverage)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 165]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective AHS-1]

Notes:
- Asked of all respondents under the age of 65.

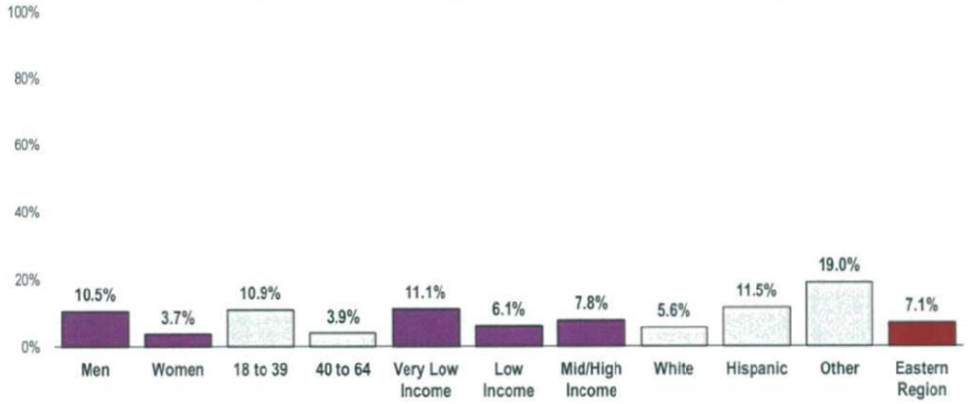
The following population segments are more likely to be without healthcare insurance coverage:

- Men.
- Young adults.
- Hispanics and "Other" residents.

Lack of Healthcare Insurance Coverage

(Among Adults Age 18-64; Eastern Region, 2015)

Healthy People 2020 Target = 0.0% (Universal Coverage)



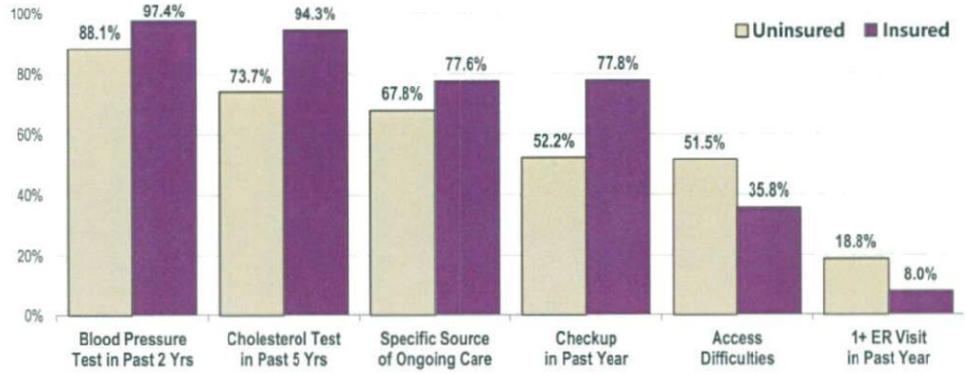
Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 165]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective AHS-1]

Notes:
- Asked of all respondents under the age of 65.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100--199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

- As might be expected, uninsured adults in the Eastern Region are less likely to receive routine care and preventive health screenings, and are more likely to have experienced difficulties accessing healthcare or have multiple ER visits.

Preventive Healthcare

(By Insured Status; Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 17, 23, 45, 48, 166, 169]
Notes: • Asked of all respondents.

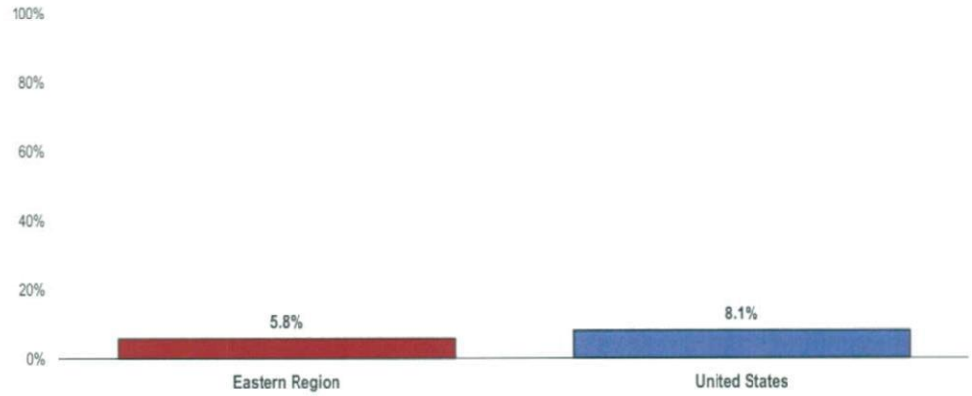
Recent Lack of Coverage

Among currently insured adults in the Eastern Region, 5.8% report that they were without healthcare coverage at some point in the past year.

- Lower than US findings.

Went Without Healthcare Insurance Coverage At Some Point in the Past Year

(Among Insured Adults)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 79]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all insured respondents.

Among insured adults, the following segments are more likely to have gone without healthcare insurance coverage at some point in the past year:

- Adults younger than 65 (negative correlation).
- Lower-income residents (negative correlation).

Went Without Healthcare Insurance Coverage At Some Point in the Past Year

(Among Insured Adults; Eastern Region, 2015)

Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 79]

Notes:
- Asked of all insured respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Difficulties Accessing Healthcare

About Access to Healthcare

Access to comprehensive, quality health care services is important for the achievement of health equity and for increasing the quality of a healthy life for everyone. It impacts: overall physical, social, and mental health status; prevention of disease and disability; detection and treatment of health conditions; quality of life; preventable death; and life expectancy.

Access to health services means the timely use of personal health services to achieve the best health outcomes. It requires three distinct steps: 1) Gaining entry into the health care system; 2) Accessing a health care location where needed services are provided; and 3) Finding a health care provider with whom the patient can communicate and trust.

- Healthy People 2020 (www.healthypeople.gov)

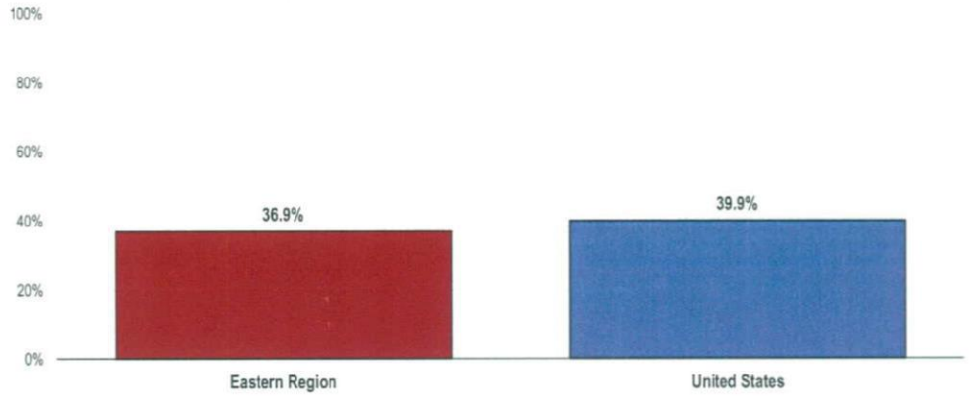
Difficulties Accessing Services

A total of 36.9% of Eastern Region adults report some type of difficulty or delay in obtaining healthcare services in the past year.

This indicator reflects the percentage of the total population experiencing problems accessing healthcare in the past year, regardless of whether they needed or sought care.

- Similar to the national findings.

Experienced Difficulties or Delays of Some Kind in Receiving Needed Healthcare in the Past Year



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 169]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

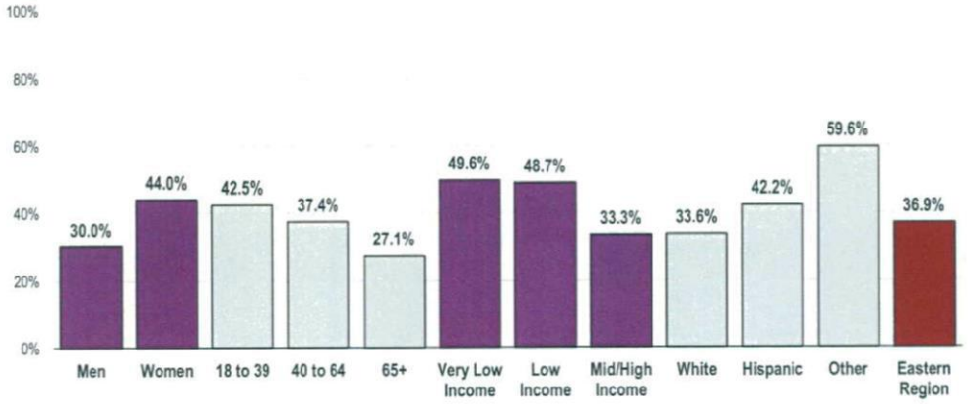
Notes:
- Asked of all respondents.
- Represents the percentage of respondents experiencing one or more barriers to accessing healthcare in the past 12 months.

Note that the following demographic groups more often report difficulties accessing healthcare services:

- Women.
- Adults younger than 65.
- Lower-income residents.
- Residents of "Other" races.

Experienced Difficulties or Delays of Some Kind in Receiving Needed Healthcare in the Past Year

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 169]

Notes:
- Asked of all respondents.
- Represents the percentage of respondents experiencing one or more barriers to accessing healthcare in the past 12 months.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Barriers to Healthcare Access

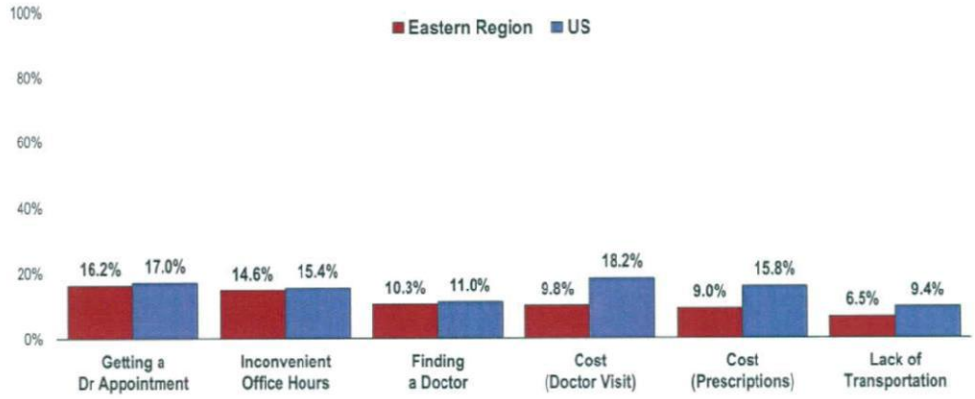
To better understand healthcare access barriers, survey participants were asked whether any of six types of barriers to access prevented them from seeing a physician or obtaining a needed prescription in the past year.

Again, these percentages reflect the total population, regardless of whether medical care was needed or sought.

Of the tested barriers, difficulty getting a doctor's appointment impacted the greatest share of Eastern Region adults (16.2% say that difficulty obtaining a medical appointment prevented them from seeking care in the past year).

- The proportion of Eastern Region adults impacted was statistically comparable to or better than that found nationwide for each of the tested barriers.

Barriers to Access Have Prevented Medical Care in the Past Year



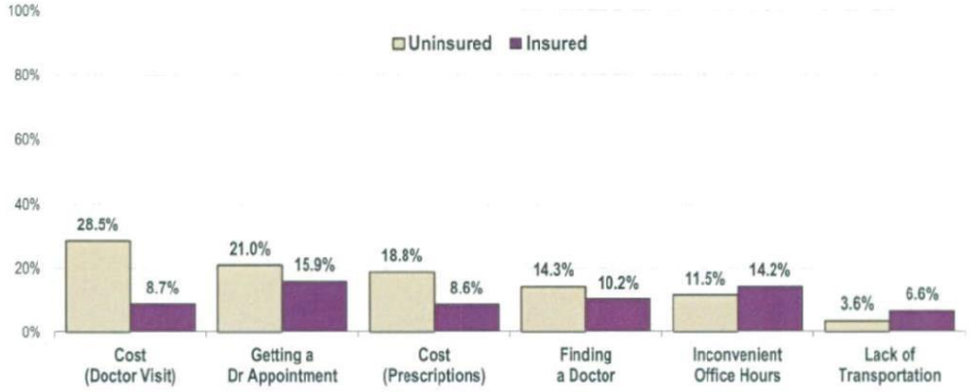
Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 7-12]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

Notes:
- Asked of all respondents.

- As might be expected, the Eastern Region adults without health insurance are more likely to report access barriers when compared to the insured population, particularly those related to cost.

Barriers to Healthcare Access

(By Insured Status; Eastern Region, 2015)



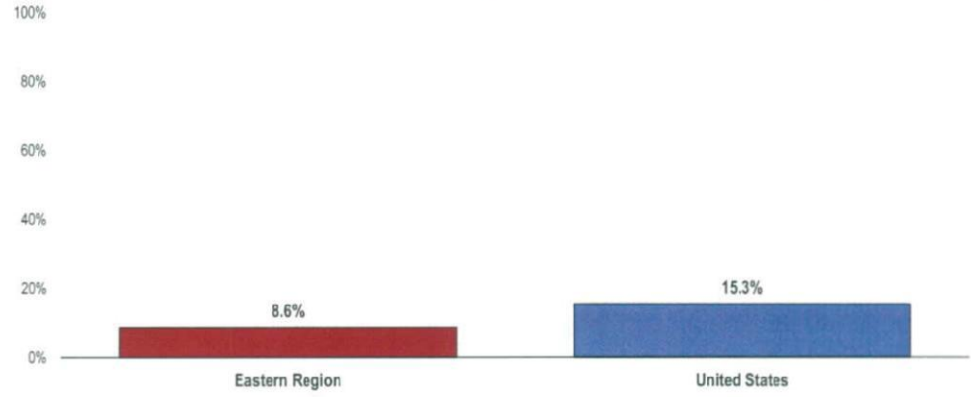
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 7-12]
Notes: • Asked of all respondents.

Prescriptions

Among all the Eastern Region adults, 8.6% skipped or reduced medication doses in the past year in order to stretch a prescription and save money.

- Lower than national findings.

Skipped or Reduced Prescription Doses in Order to Stretch Prescriptions and Save Money



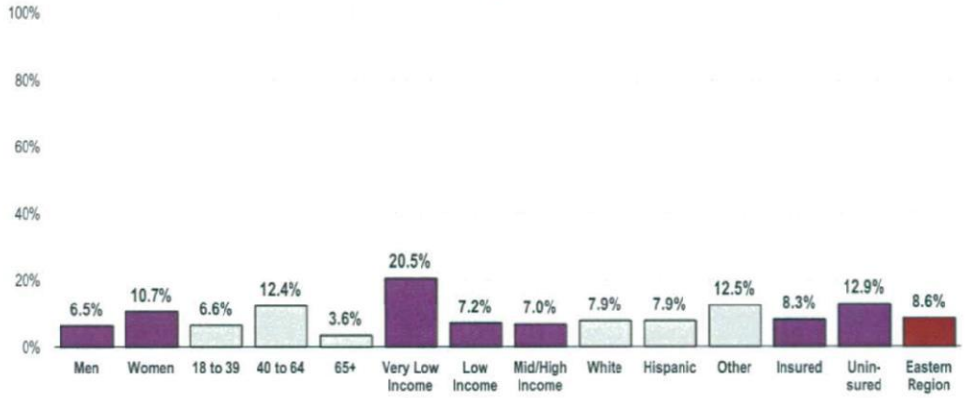
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 13]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Adults more likely to have skipped or reduced their prescription doses include:

- Women.
- Adults ages 40 to 64.
- Respondents with very low incomes (especially).

Skipped or Reduced Prescription Doses in Order to Stretch Prescriptions and Save Money

(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 13]
Notes: • Asked of all respondents.
• Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Accessing Healthcare for Children

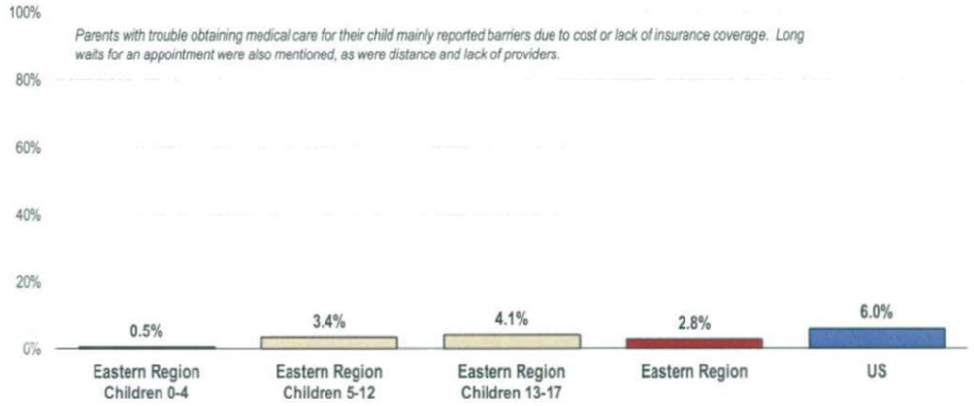
A total of 2.8% of parents say there was a time in the past year when they needed medical care for their child, but were unable to get it.

Surveyed parents were also asked if, within the past year, they experienced any trouble receiving medical care for a randomly-selected child in their household.

- More favorable than national findings.
- Notably higher among parents of children age 5 and older.

Had Trouble Obtaining Medical Care for Child in the Past Year

(Among Parents of Children 0-17)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 111-112]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents with children 0 to 17 in the household.

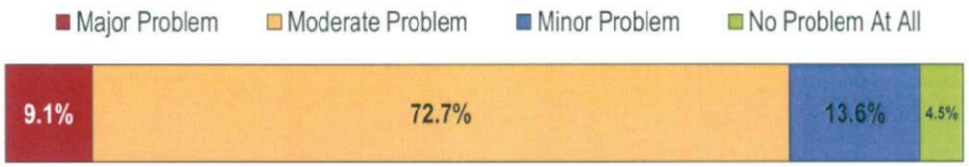
Among the parents experiencing difficulties, the majority cited **cost or a lack of insurance** as the primary reason; others cited long waits for appointments, distance, and lack of providers.

Key Informant Input: Access to Healthcare Services

Key informants taking part in an online survey most often characterized *Access to Healthcare Services* as a "moderate problem" in the community.

Perceptions of Access to Healthcare Services as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Continuity of Care

> *Connection to a medical home to ensure continuity of care, attention to prevention, and adherence to care plans should there be a chronic condition. Also, adequate "intermediate" outpatient care for clients with very complex behavioral and/or substance abuse issues who could stay in the community with the proper intensive outpatient care. Finally, pain management and addiction to pain meds, leading to abuse of illegal drugs, continues to plague our region. - Health Provider*

Health Literacy

> *Health Literacy as defined by the NIH. - Social Services Representatives*

Type of Care Most Difficult to Access

The one key informant who rated this as a "major problem" identified specialty care, mental health, and dental care as the most difficult to access in the community.

	Most Difficult to Access	Second-Most Difficult to Access	Third-Most Difficult to Access	Total Mentions
Specialty Care	**100.0%**	0.0%	0.0%	**1**
Mental Health Care	0.0%	**100.0%**	0.0%	**1**
Dental Care	0.0%	0.0%	**100.0%**	**1**

Primary Care Services

About Primary Care

Improving health care services depends in part on ensuring that people have a usual and ongoing source of care. People with a usual source of care have better health outcomes and fewer disparities and costs. Having a primary care provider (PCP) as the usual source of care is especially important. PCPs can develop meaningful and sustained relationships with patients and provide integrated services while practicing in the context of family and community. Having a usual PCP is associated with:

- Greater patient trust in the provider
- Good patient-provider communication
- Increased likelihood that patients will receive appropriate care

Improving health care services includes increasing access to and use of evidence-based preventive services. Clinical preventive services are services that: **prevent** illness by detecting early warning signs or symptoms before they develop into a disease (primary prevention); or **detect** a disease at an earlier, and often more treatable, stage (secondary prevention).

- Healthy People 2020 (www.healthypeople.gov)

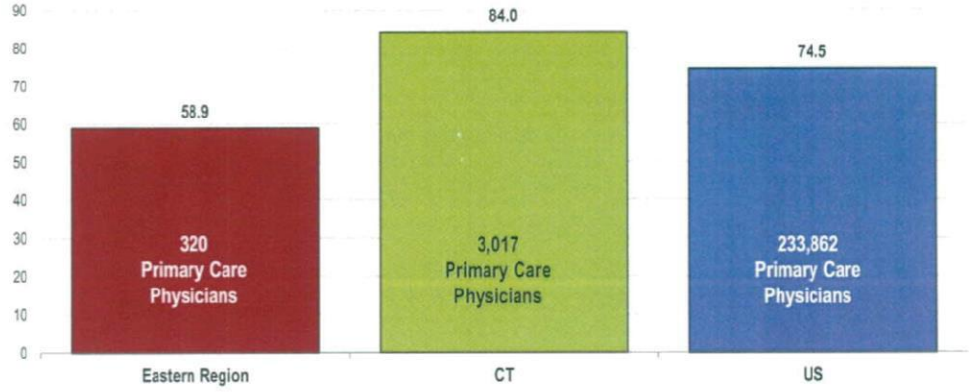
Access to Primary Care

In the Eastern Region in 2012, there were 320 primary care physicians, translating to a rate of 58.9 primary care physicians per 100,000 population.

- Lower than the statewide ratio.
- Lower than the national ratio.

Access to Primary Care

(Number of Primary Care Physicians per 100,000 Population, 2012)



Sources:
- US Department of Health & Human Services, Health Resources and Services Administration, Area Health Resource File: 2012.
- Retrieved February 2015 from Community Commons at http://www.chna.org.

Notes:
- This indicator is relevant because a shortage of health professionals contributes to access and health status issues.
- Here, the "Eastern Region" includes data from all of New London, Tolland & Windham counties.

Specific Source of Ongoing Care

A total of 77.2% of Eastern Region adults were determined to have a specific source of ongoing medical care.

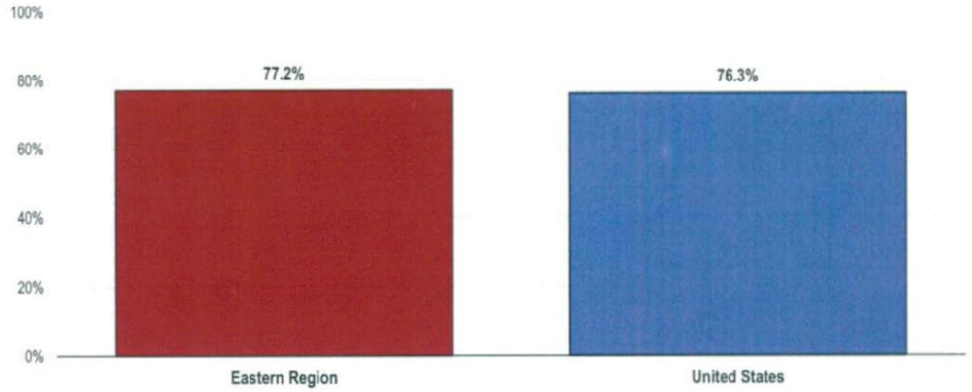
Having a specific source of ongoing care includes having a doctor's office, clinic, urgent care center, walk-in clinic, health center facility, hospital outpatient clinic, HMO or prepaid group, military/VA clinic, or some other kind of place to go if one is sick or needs advice about his or her health. This resource is crucial to the concept of "patient-centered medical homes" (PCMH).

A hospital emergency room is not considered a specific source of ongoing care in this instance.

- Similar to national findings.
- Fails to satisfy the Healthy People 2020 objective (95% or higher).

Have a Specific Source of Ongoing Medical Care

Healthy People 2020 Target = 95.0% or Higher [All Ages]



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 166]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective AHS-5.1]

Notes:
- Asked of all respondents.

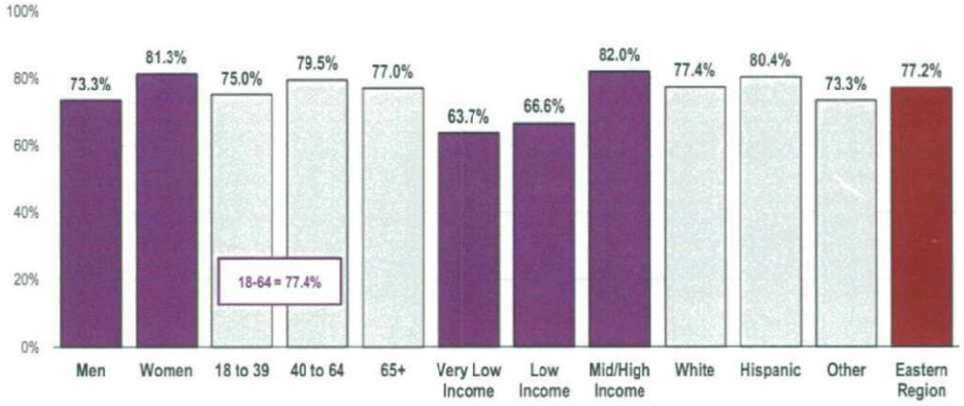
When viewed by demographic characteristics, the following population segments are less likely to have a specific source of care:

- Men.
- Lower-income adults.
- Among adults age 18-64, 77.4% have a specific source for ongoing medical care, similar to the national findings.
  - Fails to satisfy the Healthy People 2020 target for this age group (89.4% or higher).
- Among adults 65+, 77.0% have a specific source for care, similar to the percentage reported among seniors nationally.
  - Fails to satisfy the Healthy People 2020 target of 100% for seniors.

Have a Specific Source of Ongoing Medical Care

(Eastern Region, 2015)

Healthy People 2020 Target = 95.0% or Higher [All Ages]; ≥89.4% [18-64]; 100% [65+]



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 166-168]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objectives AHS-5.1, 5.3, 5.4]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

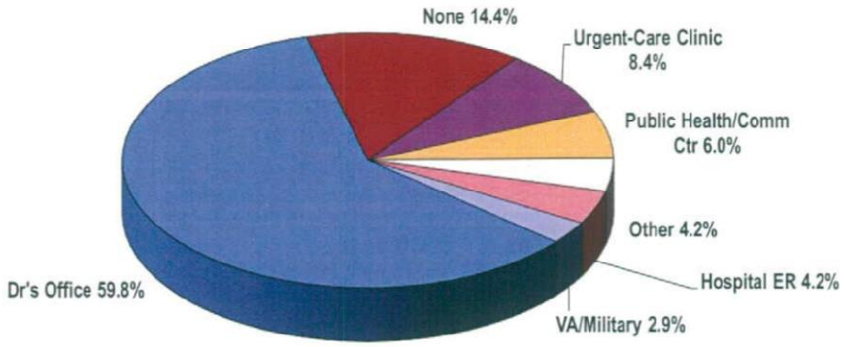
Type of Place Used for Medical Care

When asked where they usually go if they are sick or need advice about their health, the greatest share of respondents (59.8%) identified a particular doctor's office, while 8.4% rely on an urgent-care clinic and 6.0% use a public health or community center.

A total of 4.2% rely on a hospital emergency room, and 2.9% visit a VA/military facility for their healthcare.

Particular Place Utilized for Medical Care

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 15-16]

Notes:
- Asked of all respondents.

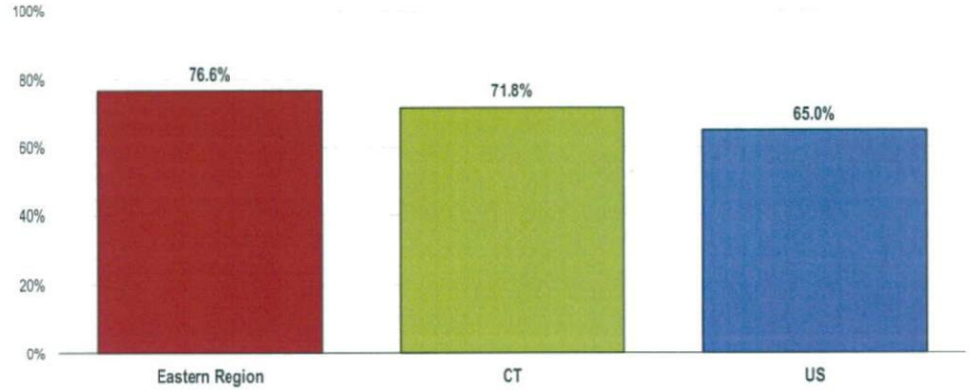
Utilization of Primary Care Services

Adults

Three-fourths of adults (76.6%) visited a physician for a routine checkup in the past year.

- Better than state findings.
- Better than national findings.

Have Visited a Physician for a Checkup in the Past Year



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 17]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2013 Connecticut data.

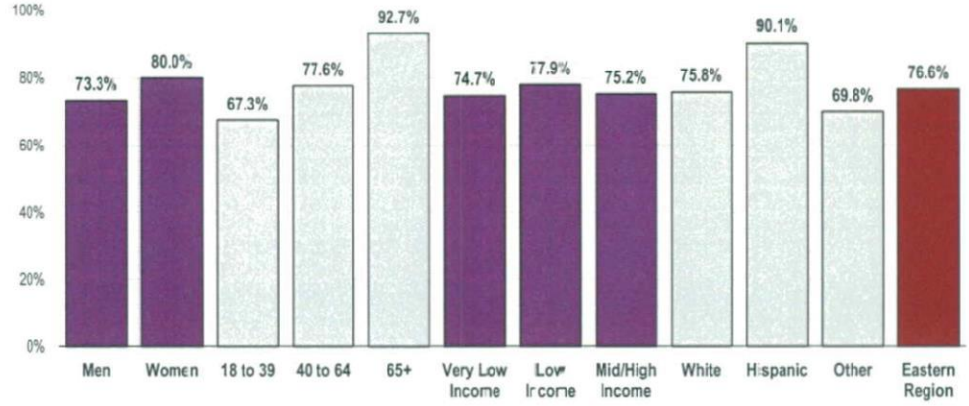
Notes:
- Asked of all respondents.

Those less likely to have received routine care in the past year are:

- Men.
- Adults younger than 40 (note the positive correlation with age).
- White and "Other" residents.

Have Visited a Physician for a Checkup in the Past Year

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 17]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

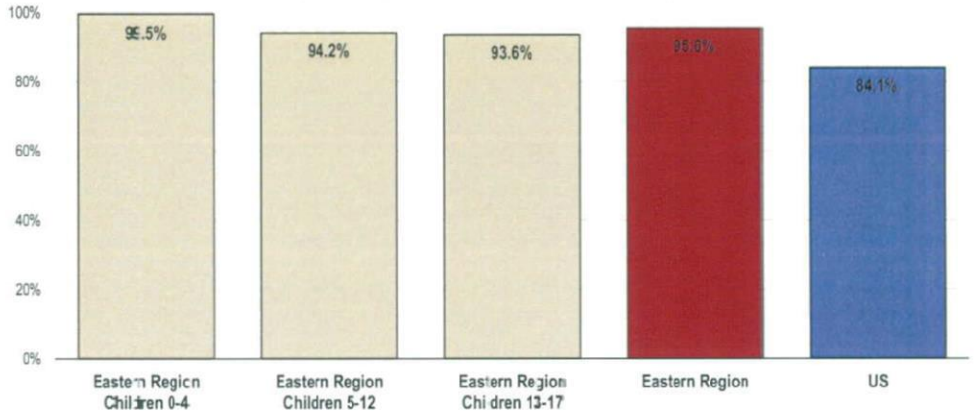
Children

Among surveyed parents, 95.6% report that their child has had a routine checkup in the past year.

- Better than the national findings.
- Note that routine checkups are highest in the Eastern Region among children younger than 5.

Child Has Visited a Physician for a Routine Checkup in the Past Year

(Among Parents of Children 0-17)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 113]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.

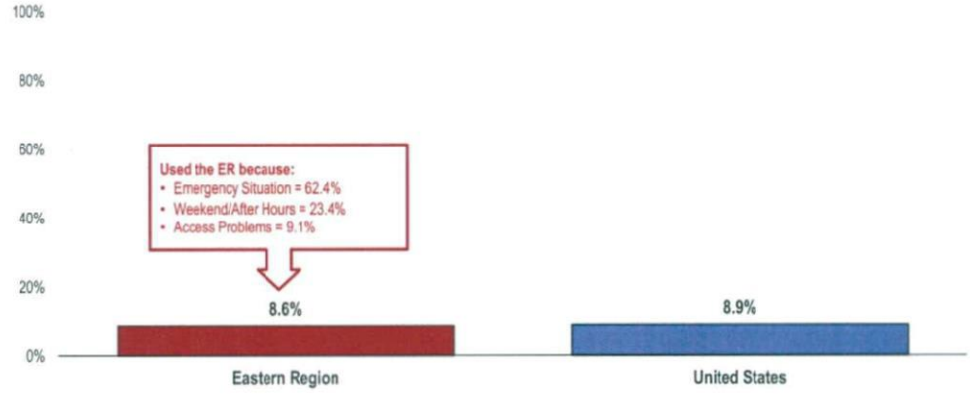
Notes:
- Asked of all respondents with children 0 to 17 in the household.

Emergency Room Utilization

A total of 8.6% of Eastern Region adults have gone to a hospital emergency room more than once in the past year about their own health.

- Similar to the national findings.

Have Used a Hospital Emergency Room More Than Once in the Past Year



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Items 23-24]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

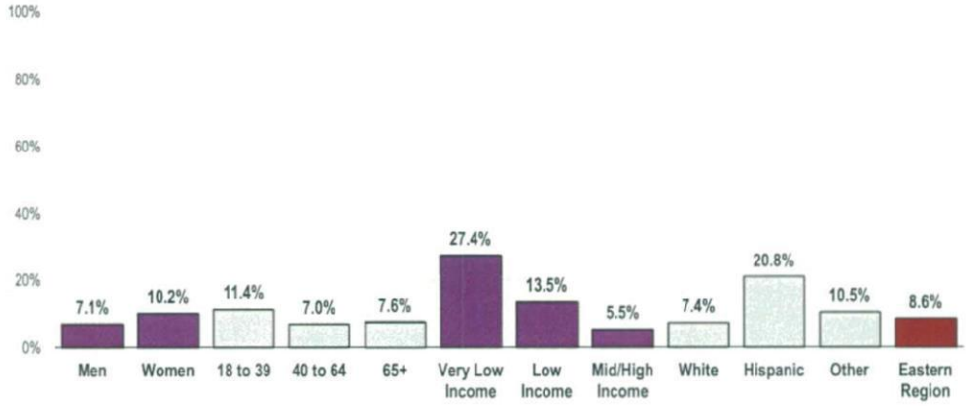
Of those using a hospital ER, 62.4% say this was due to an **emergency or life-threatening situation**, while 23.4% indicated that the visit was during **after-hours or on the weekend**, and 9.1% referenced some type of **access** problem.

Adults more likely to have used an ER more than once in the past year include:

- Lower-income residents (negative correlation with income).
- Hispanics.

Have Used a Hospital Emergency Room More Than Once in the Past Year

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 23]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Oral Health

About Oral Health

Oral health is essential to overall health. Good oral health improves a person's ability to speak, smile, smell, taste, touch, chew, swallow, and make facial expressions to show feelings and emotions. However, oral diseases, from cavities to oral cancer, cause pain and disability for many Americans. Good self-care, such as brushing with fluoride toothpaste, daily flossing, and professional treatment, is key to good oral health. Health behaviors that can lead to poor oral health include: **tobacco use; excessive alcohol use;** and **poor dietary choices.**

The significant improvement in the oral health of Americans over the past 50 years is a public health success story. Most of the gains are a result of effective prevention and treatment efforts. One major success is community water fluoridation, which now benefits about 7 out of 10 Americans who get water through public water systems. However, some Americans do not have access to preventive programs. People who have the least access to preventive services and dental treatment have greater rates of oral diseases. A person's ability to access oral healthcare is associated with factors such as education level, income, race, and ethnicity.

Barriers that can limit a person's use of preventive interventions and treatments include: limited access to and availability of dental services; lack of awareness of the need for care; cost; and fear of dental procedures.

There are also social determinants that affect oral health. In general, people with lower levels of education and income, and people from specific racial/ethnic groups, have higher rates of disease. People with disabilities and other health conditions, like diabetes, are more likely to have poor oral health.

Potential strategies to address these issues include:

- Implementing and evaluating activities that have an impact on health behavior.
- Promoting interventions to reduce tooth decay, such as dental sealants and fluoride use.
- Evaluating and improving methods of monitoring oral diseases and conditions.
- Increasing the capacity of State dental health programs to provide preventive oral health services.
- Increasing the number of community health centers with an oral health component.

- Healthy People 2020 (www.healthypeople.gov)

Dental Care

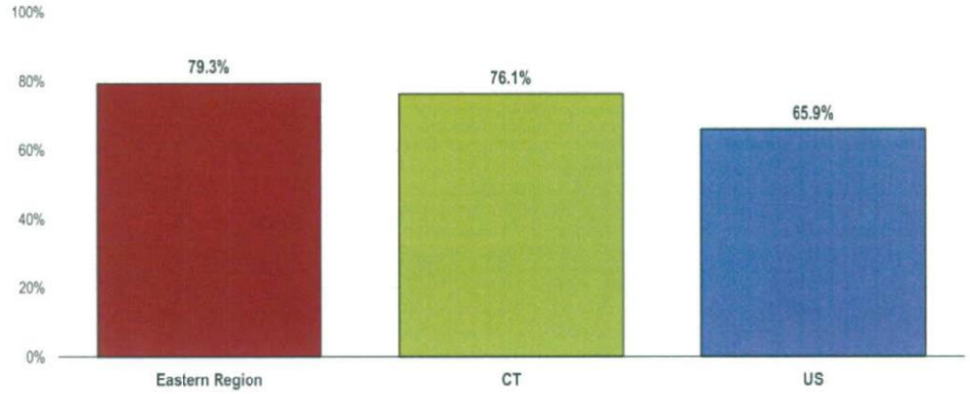
Adults

A total of 79.3% of Eastern Region adults have visited a dentist or dental clinic (for any reason) in the past year.

- Higher than statewide findings.
- Higher than national findings.
- Satisfies the Healthy People 2020 target (49% or higher).

Have Visited a Dentist or Dental Clinic Within the Past Year

Healthy People 2020 Target = 49.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 21]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective OH-7]
- Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia. United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC): 2012 Connecticut data.

Notes:
- Askec of all respondents.

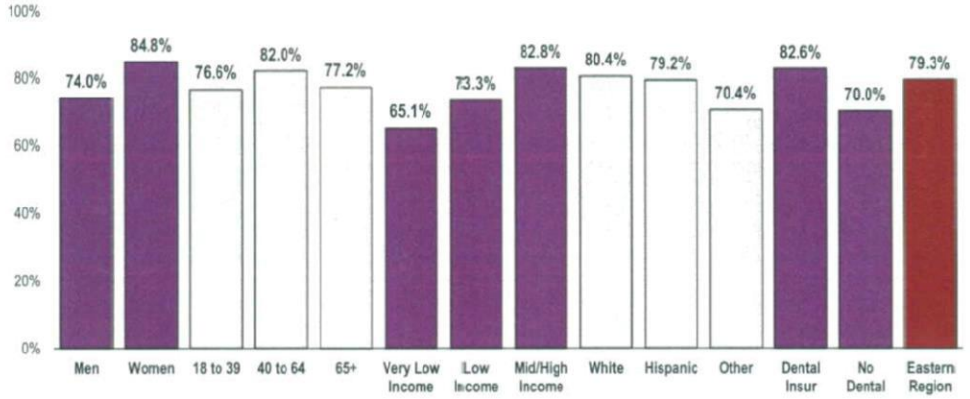
Those less likely to have visited a dentist:

- Men.
- Those in the lower income categories (positive correlation).
- As might be expected, those without dental insurance report lower utilization of oral health services than those with dental coverage.

Have Visited a Dentist or Dental Clinic Within the Past Year

(Eastern Region, 2015)

Healthy People 2020 Target = 49.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 21]
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective OH-7]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
- Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Children

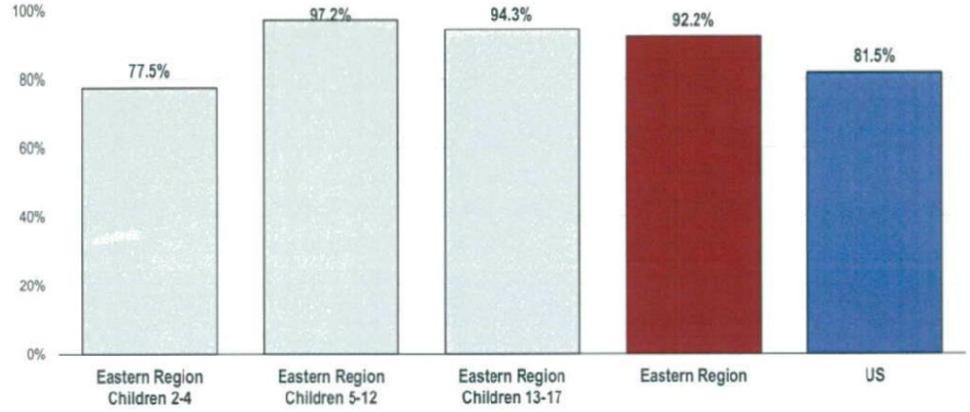
A total of 92.2% of parents report that their child (age 2 to 17) has been to a dentist or dental clinic within the past year.

- More favorable than national findings.
- Satisfies the Healthy People 2020 target (49% or higher).
- Regular dental care is notably lower among children ages 2 to 4.

Child Has Visited a Dentist or Dental Clinic Within the Past Year

(Among Parents of Children Age 2-17)

Healthy People 2020 Target = 49.0% or Higher



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 116]
- 2013 PRC National Health Survey, Professional Research Consultants, Inc.
- US Department of Health and Human Services. Healthy People 2020. December 2010. http://www.healthypeople.gov [Objective OH-7]

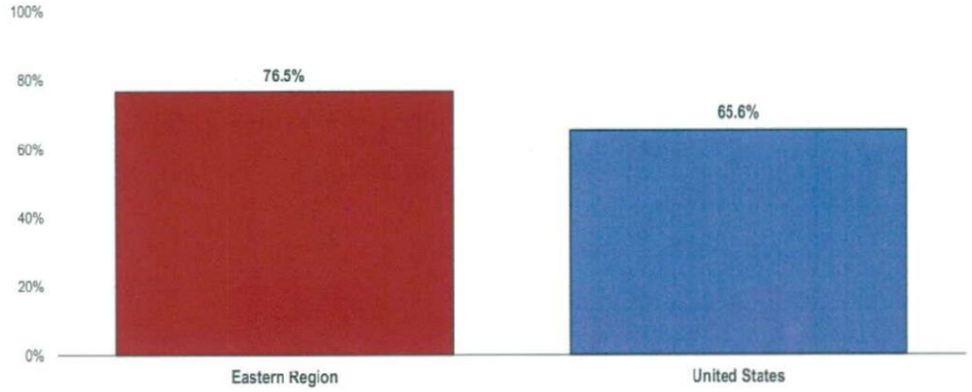
Notes:
- Asked of all respondents with children age 2 through 17.

Dental Insurance

Just over three-fourths of Eastern Region adults (76.5%) have dental insurance that covers all or part of their dental care costs.

- Better than the national finding.

Have Insurance Coverage That Pays All or Part of Dental Care Costs



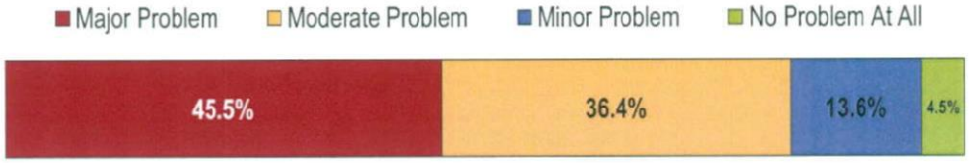
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 22]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Key Informant Input: Oral Health

The largest share of key informants taking part in an online survey characterized *Oral Health* as a "major problem" in the community.

Perceptions of Oral Health as a Problem in the Community

(Key Informants, 2015)



Sources: • PRC Online Key Informant Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Top Concerns

Among those rating this issue as a "major problem," reasons frequently related to the following:

Cost & Insurance

> *The majority of our population does not have affordable, appropriate, and reliable access and information about oral health/dental care. Translators and translation services, that really work and are appropriate are not in place for our population in need. We see students every day that need these services. The information may be there, but their ability to understand and access it is quite limited. Accessible community health educators that speak their languages are desperately needed. - Social Services Representatives*
>
> *Oral health is not covered by many insurances, including Medicare and the Affordable Care Act policies. Commercial coverage is often minimal. Medicaid has probably the best coverage, but people need to understand the value of oral healthcare in relation to overall health to make it a priority. We know that isn't the case. - Health Provider*
>
> *Lack of good insurance to pay for cost. - Community/Business Leader*
>
> *If you take a look around, there are numerous examples of people not taking care of oral hygiene. Problem with insurance coverage or lack of. - Health Provider*

Lack of Providers & Services

> *There are not enough providers that accept Husky D. - Social Services Representative*
>
> *This is a problem that is particularly prevalent in disadvantaged individuals in the community and relates to their nutritional status and access to dental care, particularly for adults who face long waiting lists for routine care and frequently have to travel out of the area to access specialized dental services/oral surgery. - Social Services Representative*
>
> *Beyond general oral health services, low-income people must travel to Hartford to have extensive work on teeth. - Social Services Representative*

Lack of Regular Care

> *The community has major strides in the past eight years to increase access, especially for children. There are still a high percentage of individual adults who do not have regular routine screening and care. - Social Services Representative*

Vision Care

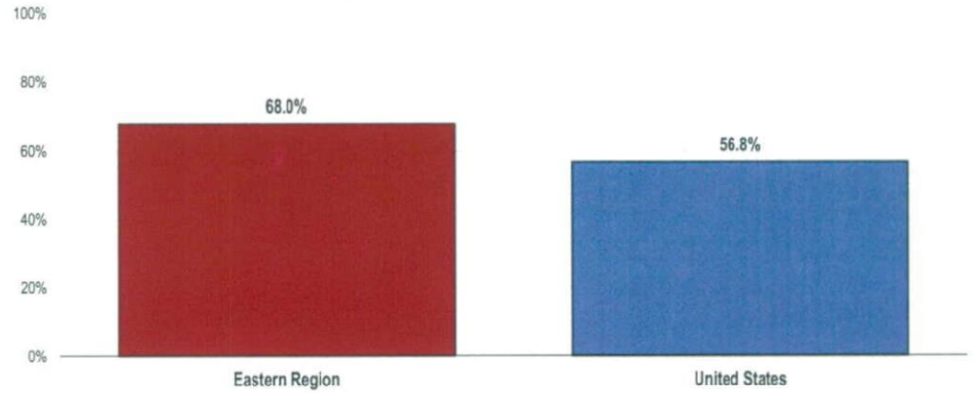
RELATED ISSUE:

See also Vision & Hearing in the **Death, Disease & Chronic Conditions** section of this report.

A total of 68.0% of residents had an eye exam in the past two years during which their pupils were dilated.

- Better than national findings.

Had an Eye Exam in the Past Two Years During Which the Pupils Were Dilated



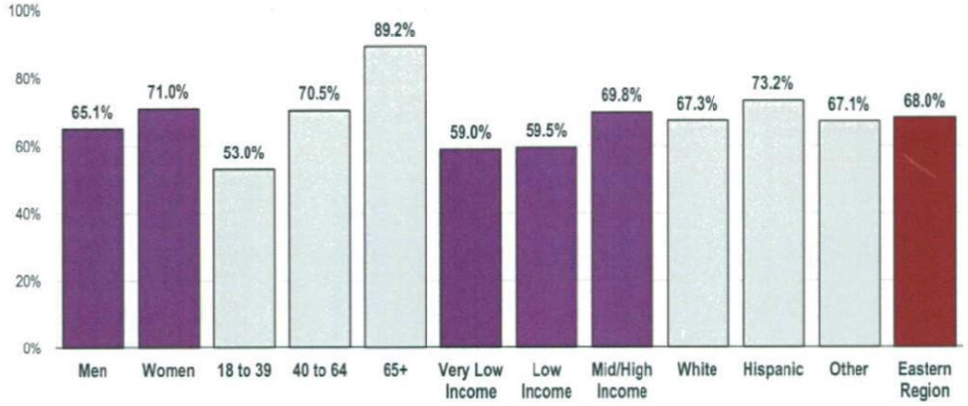
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 20]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

Recent vision care in the Eastern Region is less often reported among:

- Men.
- Younger adults (positive correlation with age).
- Residents with lower incomes.

Had an Eye Exam in the Past Two Years During Which the Pupils Were Dilated

(Eastern Region, 2015)



Sources:
- 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 20]

Notes:
- Asked of all respondents.
- Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
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Local Resources

Professional Research Consultants, Inc.

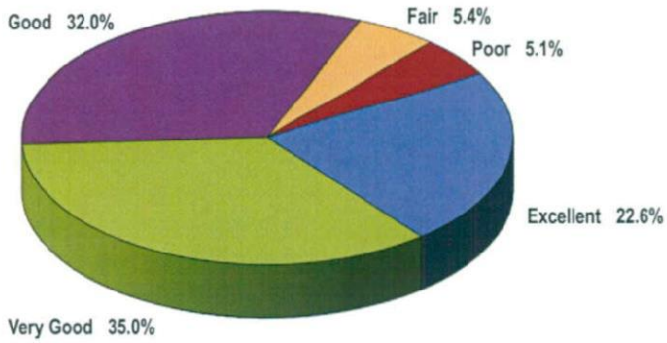
Perceptions of Local Healthcare Services

Over one-half of Eastern Region adults (57.6%) rate the overall healthcare services available in their community as "excellent" or "very good."

- Another 32.0% gave "good" ratings.

Rating of Overall Healthcare Services Available in the Community

(Eastern Region, 2015)

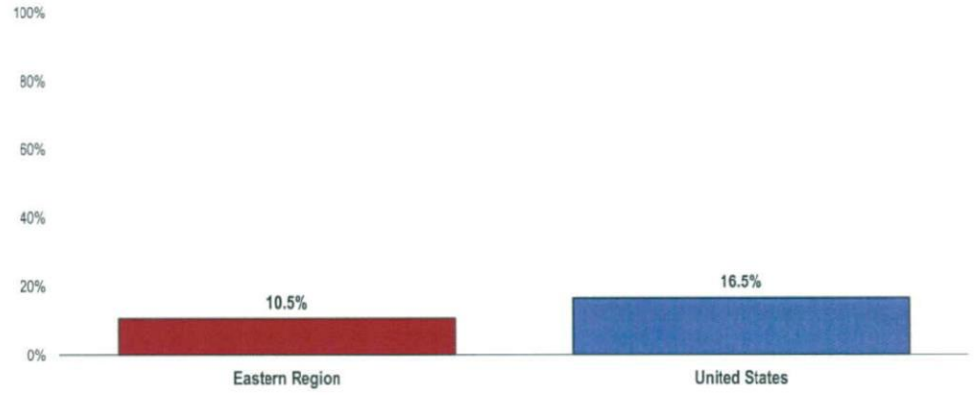


Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 6]
Notes: • Asked of all respondents.

However, 10.5% of residents characterize local healthcare services as "fair" or "poor."

- More favorable than reported nationally.

Perceive Local Healthcare Services as "Fair/Poor"



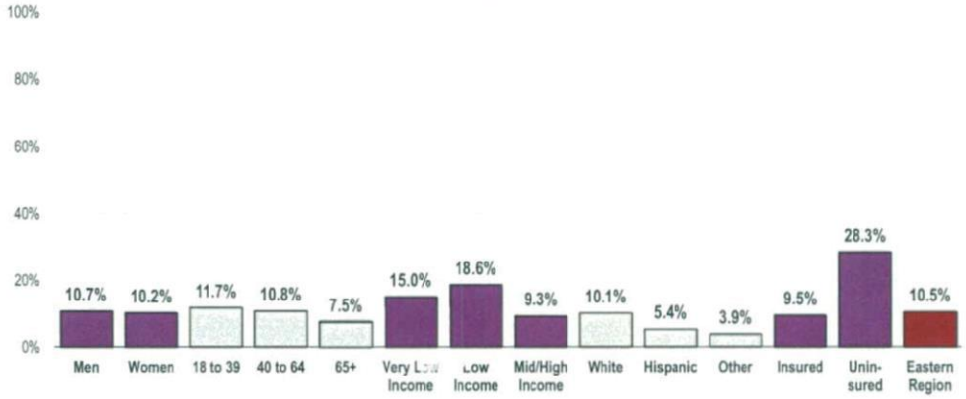
Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 6]
• 2013 PRC National Health Survey, Professional Research Consultants, Inc.
Notes: • Asked of all respondents.

The following residents are more critical of local healthcare services:

- Residents with lower incomes.
- Whites.
- Uninsured adults.

Perceive Local Healthcare Services as "Fair/Poor"

(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 6]

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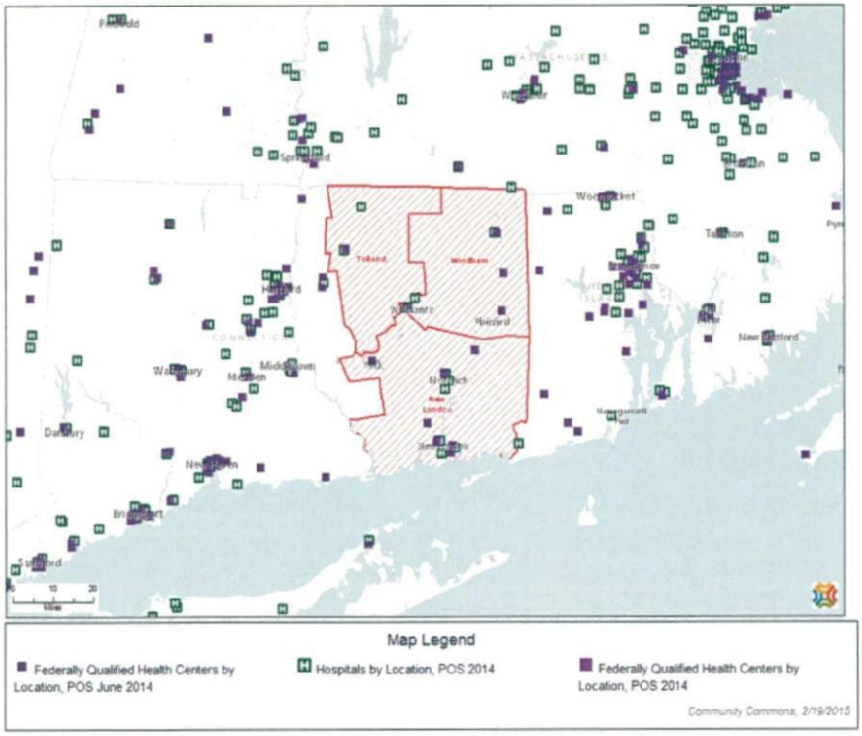
Healthcare Resources & Facilities

Federally Qualified Health Centers (FQHCs)

As of late 2014, there were 10 Federally Qualified Health Centers (FQHCs) within the Eastern Region.

Hospitals & Federally Qualified Health Centers, POS 2014



Awareness of 211 Services

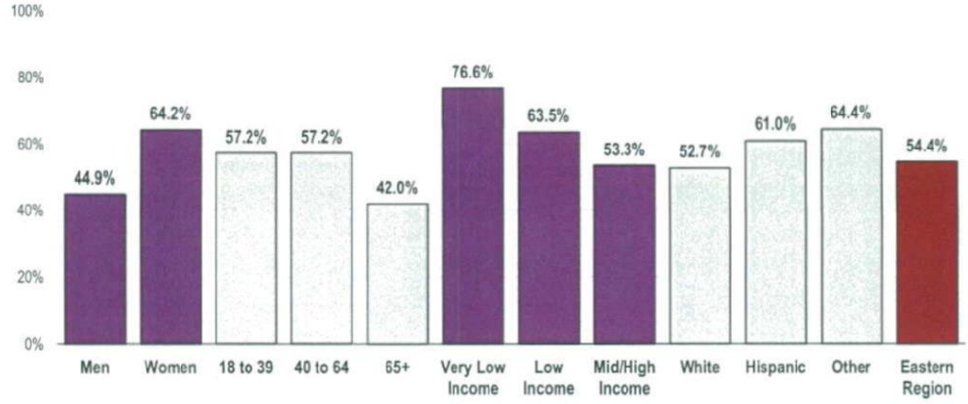
A total of 54.4% of Eastern Region adults expressed awareness of the 211 telephone line that gives access to health and human services information and referrals.

Those less likely to be aware of the 211 program:

- Men.
- Seniors.
- Those with higher incomes (negative correlation with income).
- Whites.

Aware of the Connecticut 211 Program

(Eastern Region, 2015)



Sources: • 2015 PRC Community Health Survey, Professional Research Consultants, Inc. [Item 314]

Notes: • Asked of all respondents.
• Hispanics can be of any race. Other race categories are non-Hispanic categorizations (e.g., "White" reflects non-Hispanic White respondents).
• Income categories reflect respondent's household income as a ratio to the federal poverty level (FPL) for their household size. "Very Low Income" includes households with incomes less than 100% of the federal poverty level; "Low Income" includes households with incomes from 100–199% of the federal poverty level; "Mid/High Income" includes households with incomes at 200% or more of the federal poverty level.

Resources Available to Address the Significant Health Needs

The following represent potential measures and resources (such as programs, organizations, and facilities in the community) available to address the significant health needs identified in this report. This list is not exhaustive, but rather outlines those resources identified in the course of conducting this Community Health Needs Assessment.

Access to Healthcare Services

- Natchaug
- Reliance House
- SEMHA/DMHAS
- Sound Community Services
- UCFS

Cancer

- Backus Cancer Center
- Backus Hospital
- Center For Hospice
- Dana Farber New London
- Eastern Connecticut Hematology and Oncology
- FQHC
- Hospital-Based Services
- L & M Cancer Center
- L & M Hospital

Dementias, Including Alzheimer's Disease

- Alzheimer's Association
- Backus Hospital
- Brief Care Program
- CCCI
- Home Care Organizations
- L & M
- Nursing Homes
- Ross Adult Day Care
- Senior Resources
- SMHA
- UCFS

Diabetes

- Backus Community Education Series
- Backus Diabetes Center
- Backus Hospital
- Community Health Centers
- Diabetes Education at the Hospital
- Generations
- Joslin Diabetes Center
- Lawrence and Memorial Hospital
- UCFS
- UCONN Extension Center
- UNCAS Health District

Hearing & Vision

- Backus Hospital
- Personal Physicians
- UCFS Partners
- Uncas Health District Community Educators

Heart Disease & Stroke

- Achieve/Ledge Light Community Education
- Backus Hospital
- Generations
- Hartford Hospital
- Million Hearts Initiative
- Neurology Associates
- UCFS
- UNCAS Health District

HIV/AIDS

- Alliance for Living
- Backus Hospital AIDS Center
- Lawrence and Memorial AIDS Center

Immunization & Infectious Diseases

- Backus Hospital
- Department of Public Health
- Doctor's Office
- Generations
- Hartford Dispensary
- UCFS

Infant & Child Health

- Backus Hospital
- Clinics

- L & M
- Local Health and DPH Outreach
- UCFS

Mental Health

- ARC of NLC
- Backus Hospital
- Brief Care
- Child and Family Agency
- Child and Family Limited Resources
- Community Health Center
- Community Health Resources
- Generations
- Hospitals
- Madonna Place
- Mental Health Providers
- Natchaug Hospital
- Natchaug Limited Resources
- Norwich Human Services
- Perception Programs
- Private Providers
- Regency Heights
- Reliance House, Inc.
- SCAAD
- School-Based Health Centers
- SECT MHA
- Southeastern Mental Health Authority
- Stonington Institute
- Supportive Housing Programs
- United Community and Family Services
- United Services
- Windham Hospital Emergency Room
- WWBH

Nutrition, Physical Activity & Weight

- Backus Hospital
- Backus/TVCCA Collaborative Nutrition Program
- Community Gardens
- Gyms
- Holistic Health
- Hospitals
- Ice Skating Rink
- Organized Sports
- Pediatrician's Offices
- Pilot Grants
- Primary Care Physicians
- Private Nutritionists
- Public Health
- Schools
- UCFS
- UCONN
- UNCAS Health District Community Educators
- Windham Hospital Diabetes Education
- Windham Recreation Department

Oral Health

- Backus Hospital
- Children's Dental Associates
- Clinics
- Community Health Center
- Dr. Ted Fischer
- FQHC
- Generations
- Private Dentists
- UCFS

Respiratory Diseases

- Backus Hospital
- Community Health Centers
- Lawrence and Memorial Asthma Clinic
- Pulmonary Care and Primary Care Providers
- Pulmonologists
- Putting on Airs Program
- UCFS
- Uncas Health District

Sexually Transmitted Diseases

- Backus Hospital STD Clinic
- Community Health Center
- Generations
- UCFS

Substance Abuse

- Alcoholics Anonymous
- Community Health Services
- Halfway Houses
- Hartford Dispensary
- Local Hospital
- Natchaug Hospital
- Perception House
- Prevention Programs
- Reliance House
- SCADD
- SMHA
- Southeast Mental Health Authority
- Stonington Institute
- UCFS

Windham Hospital

Tobacco Use

Backus Hospital
Cancer Society
Community Health Providers
L & M Hospital
Ledge Light Community Education
Nothing
UCFS
UNCAS Health District
Windham Hospital

EXHIBIT 4

COUNTY HEALTH RANKINGS

The following excerpts are from the County Health Rankings & Roadmaps website (a Robert Wood Johnson Foundation Program) for 2015 taken from the following websites:

New London County:
http://www.countyhealthrankings.org/app/#!/connecticut/2015/rankings/new-london/county/outcomes/overall/snapshot

Windham County:
http://www.countyhealthrankings.org/app/#!/connecticut/2015/rankings/windham/county/outcomes/overall/snapshot

	Connecticut	New London County	Windham County
Health Outcomes (Rank of 8)		5	7
Length of Life (Rank of 8)		5	8
Premature death	5,284	5,452	6,048
Quality of Life (Rank of 8)		5	6
Poor or fair health	11%	11%	12%
Poor physical health days	3.0	3.0	3.4
Poor mental health days	3.1	2.9	3.2
Low birthweight	8.0%	7.3%	7.5%
Health Factors (Rank of 8)		6	8
Health Behaviors (Rank of 8)		7	8
Adult smoking	15%	18%	18%
Adult obesity	24%	26%	30%
Food environment index	7.9	7.9	7.6
Physical inactivity	22%	21%	24%
Access to exercise opportunities	95%	92%	87%
Excessive drinking	19%	19%	17%
Alcohol-impaired driving deaths	34%	37%	31%
Sexually transmitted infections	364	260	206
Teen births	20	20	24

COUNTY HEALTH RANKINGS

	Connecticut	New London County	Windham County
Clinical Care (Rank of 8)		6	8
Uninsured	11%	10%	10%
Primary care physicians	1,190:1	1,594:1	1,867:1
Dentists	1,285:1	1,523:1	2,400:1
Mental health providers	323:1	337:1	426:1
Preventable hospital stays	57	61	65
Diabetic monitoring	85%	83%	86%
Mammography screening	67.1%	69.9%	68.9%
Social & Economic Factors (Rank of 8)		5	7
High school graduation	85%	86%	84%
Some college	67%	63.4%	56.3%
Unemployment	7.8%	7.9%	8.7%
Children in poverty	15%	13%	18%
Income inequality	5.0	4.2	4.5
Children in single-parent households	31%	33%	34%
Social associations	9.3	9.1	9.6
Violent crime	279	385	
Injury deaths	52	54	55
Physical Environment (Rank of 8)		1	5
Air pollution - particulate matter	10.5	10.3	10.4
Drinking water violations	1%	1%	1%
Severe housing problems	18%	15%	16%
Driving alone to work	79%	79%	82%
Long commute - driving alone	31%	27%	39%

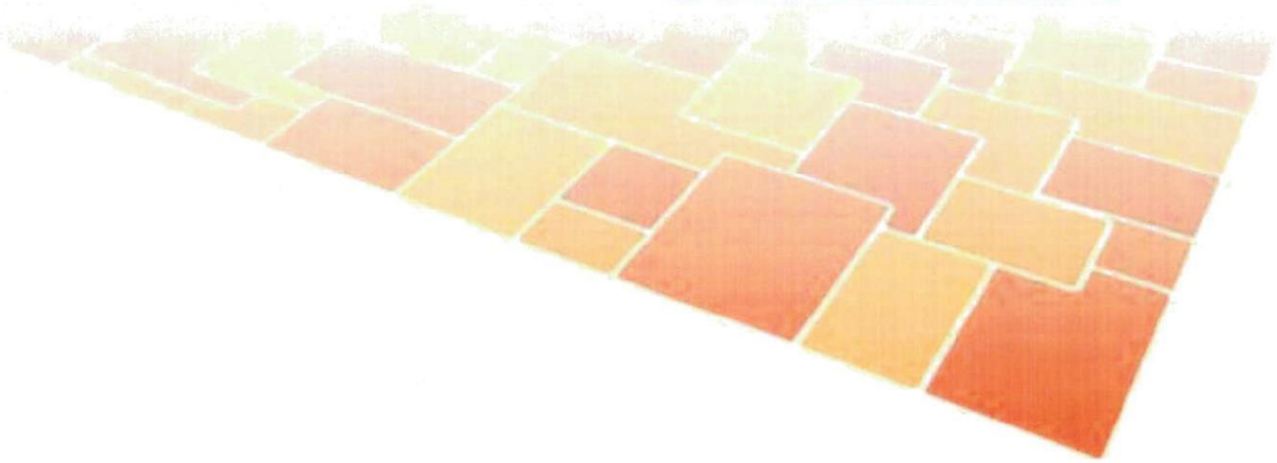
County Health Rankings & Roadmaps

Building a Culture of Health, County by County

A Robert Wood Johnson Foundation program

2015 *County Health Rankings*

Connecticut



A collaboration between the Robert Wood Johnson Foundation and the University of Wisconsin Population Health Institute.

University of Wisconsin Population Health Institute
SCHOOL OF MEDICINE AND PUBLIC HEALTH

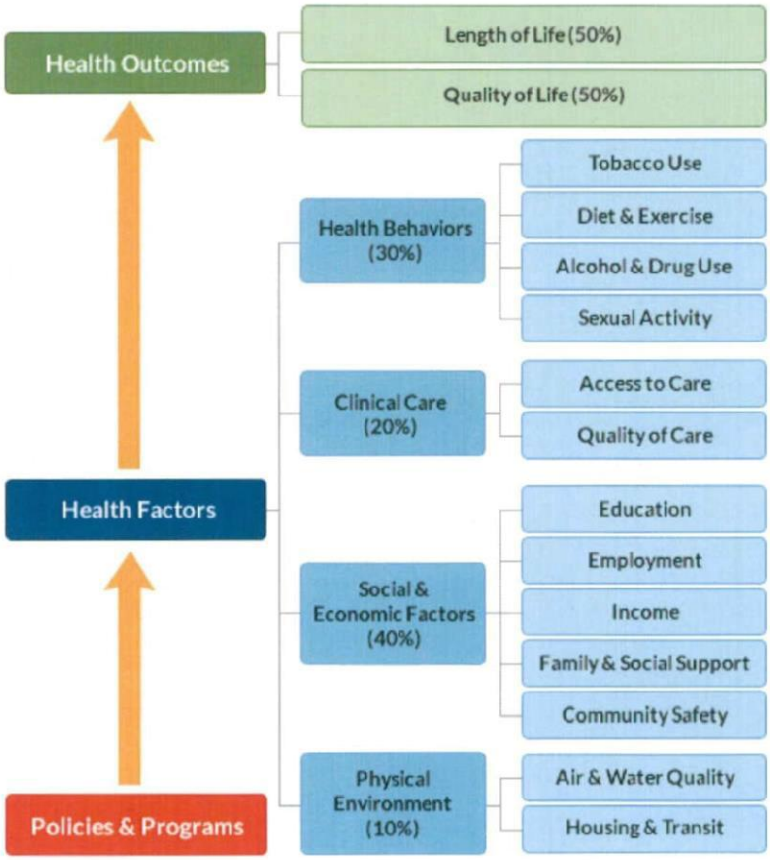
Support provided by
Robert Wood Johnson Foundation

INTRODUCTION

The *County Health Rankings & Roadmaps* program helps communities identify and implement solutions that make it easier for people to be healthy in their homes, schools, workplaces, and neighborhoods. The Robert Wood Johnson Foundation (RWJF) collaborates with the University of Wisconsin Population Health Institute (UWPHI) to bring this program to cities, counties, and states across the nation. Ranking the health of nearly every county in the nation, the *County Health Rankings* illustrate what we know when it comes to what is making people sick or healthy. The *Roadmaps to Health* and *RWJF Culture of Health Prize* show what we can do to create healthier places to live, learn, work, and play.

WHAT ARE THE *COUNTY HEALTH RANKINGS*?

Published online at countyhealthrankings.org, the *Rankings* help counties understand what influences how healthy residents are and how long they will live. The *Rankings* are unique in their ability to measure the current overall health of each county in all 50 states. They also look at a variety of measures that affect the future health of communities, such as high school graduation rates, access to healthy foods, rates of smoking, obesity, and teen births. Communities use the *Rankings* to identify and garner support for local health improvement initiatives among government agencies, healthcare providers, community organizations, business leaders, policy makers, and the public.



MOVING FROM DATA TO ACTION

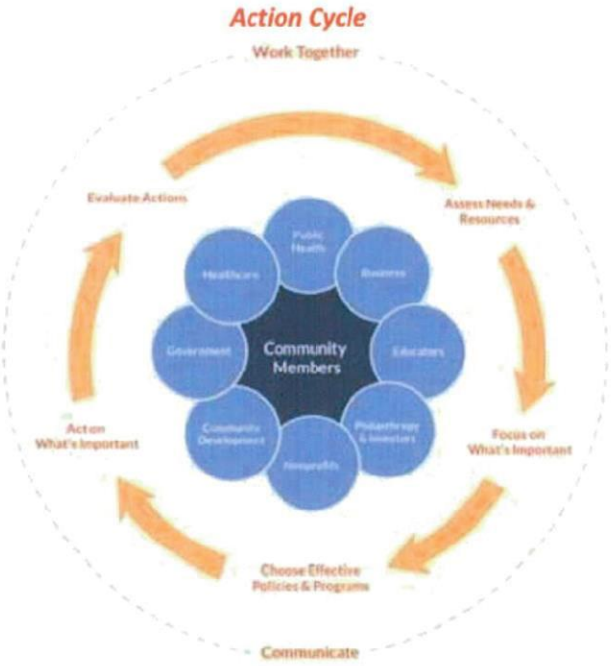
Roadmaps to Health help communities bring people together to look at the many factors that influence health, select strategies that work, and make changes that will have a lasting impact. The *Roadmaps* focus on helping communities move from awareness about their county's ranking to action to improve people's health. The *Roadmaps to Health* Action Center is a one-stop shop of information to help any community member or leader who wants to improve their community's health by addressing factors that we know influence health, such as education, income, and community safety.

Within the Action Center you will find:

- Online step-by-step guidance and tools to move through the Action Cycle
- *What Works for Health* – a searchable database of evidence-informed policies and programs that can improve health

1 www.countyhealthrankings.org/connecticut

- Webinars featuring local community members who share their tips on how to build a healthier community
- Community coaches, located across the nation, who provide customized consultation to local leaders who request guidance in how to accelerate their efforts to improve health. You can contact a coach by activating the Get Help button at countyhealthrankings.org



LEARNING FROM OTHERS

At countyhealthrankings.org, we feature stories from communities across the nation who have used data from the *County Health Rankings* or have engaged in strategies to improve health. The *RWJF Culture of Health Prize* recognizes communities that are creating powerful partnerships and deep commitments to enable everyone in our diverse society to lead healthy lives now and for generations to come. The Prize is awarded annually by RWJF to honor communities that are working to build a Culture of Health by implementing solutions that give everyone the opportunity for a healthy life. In 2015, up to 10 winning communities will each receive a $25,000 cash prize and have their stories shared broadly with the goal of inspiring locally driven change across the nation.

Prize winners are selected based on how well they demonstrate their community's achievement on their journey to a Culture of Health in the following areas:

- Defining health in the broadest possible terms
- Committing to sustainable systems changes and long-term policy-oriented solutions
- Cultivating a shared and deeply held belief in the importance of equal opportunity for health
- Harnessing the collective power of leaders, partners, and community members
- Securing and making the most of resources
- Measuring and sharing progress and results

Visit countyhealthrankings.org or rwjf.org/prize to learn about the work of past Prize winners and the application process.

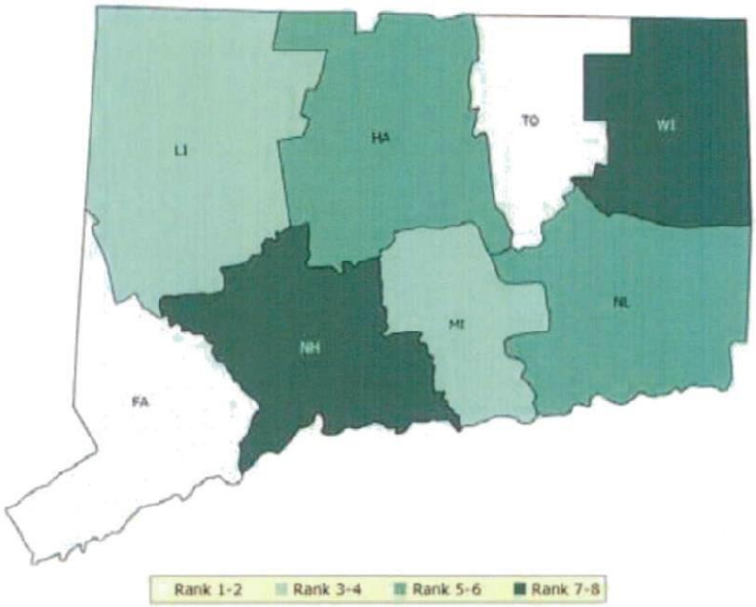
HOW CAN YOU GET INVOLVED?

You might want to contact your local affiliate of United Way Worldwide or the National Association of Counties – their national parent organizations have partnered with us to raise awareness and stimulate action to improve health in their local members' communities. By connecting with other leaders interested in improving health, you can make a difference in your community. In communities large and small, people from all walks of life are taking ownership and action to improve health. Visit countyhealthrankings.org to get ideas and guidance on how you can take action in your community. Working with others, you can improve the health of your community.

HOW DO COUNTIES RANK FOR HEALTH OUTCOMES?

The green map below shows the distribution of Connecticut's **health outcomes**, based on an equal weighting of length and quality of life.

Lighter colors indicate better performance in the respective summary rankings. Detailed information on the underlying measures is available at countyhealthrankings.org.

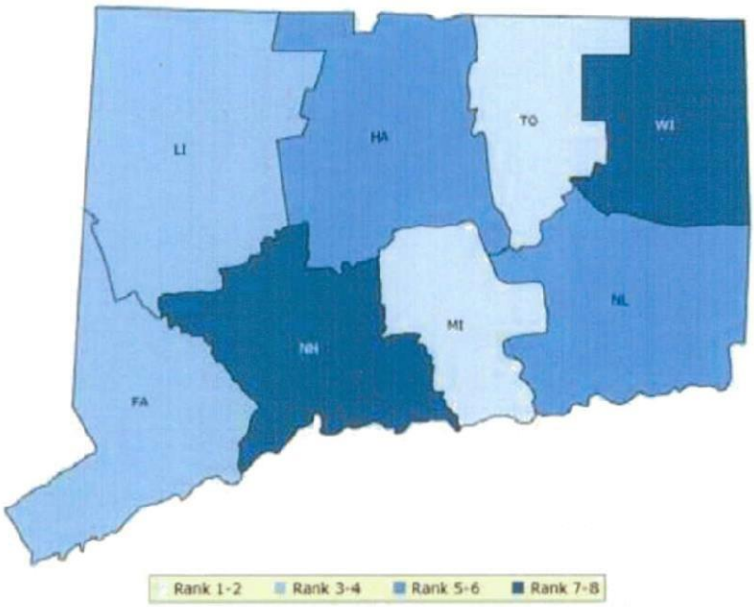


County	Rank	County	Rank	County	Rank	County	Rank
Fairfield	2	Litchfield	4	New Haven	8	Tolland	1
Hartford	6	Middlesex	3	New London	5	Windham	7

HOW DO COUNTIES RANK FOR HEALTH FACTORS?

The blue map displays Connecticut's summary ranks for **health factors**, based on weighted scores for health behaviors, clinical care, social and economic factors, and the physical environment.

Lighter colors indicate better performance in the respective summary rankings. Detailed information on the underlying measures is available at countyhealthrankings.org.



County	Rank	County	Rank	County	Rank	County	Rank
Fairfield	3	Litchfield	4	New Haven	7	Tolland	2
Hartford	5	Middlesex	1	New London	6	Windham	8

2015 *COUNTY HEALTH RANKINGS*: MEASURES AND NATIONAL/STATE RESULTS

Measure	Description	US Median	State Overall	State Minimum	State Maximum
HEALTH OUTCOMES					
Premature death	Years of potential life lost before age 75 per 100,000 population	7681	5284	4371	6048
Poor or fair health	% of adults reporting fair or poor health	17%	11%	9%	12%
Poor physical health days	Average # of physically unhealthy days reported in past 30 days	3.7	3.0	2.6	3.4
Poor mental health days	Average # of mentally unhealthy days reported in past 30 days	3.5	3.1	2.8	3.5
Low birthweight	% of live births with low birthweight (< 2500 grams)	8%	8.0%	6.5%	8.7%
HEALTH FACTORS					
HEALTH BEHAVIORS					
Adult smoking	% of adults who are current smokers	21%	15%	12%	18%
Adult obesity	% of adults that report a BMI ≥ 30	31%	24%	20%	30%
Food environment index	Index of factors that contribute to a healthy food environment, (0-10)	7.3	7.9	7.6	8.7
Physical inactivity	% of adults aged 20 and over reporting no leisure-time physical activity	27%	22%	17%	24%
Access to exercise opportunities	% of population with adequate access to locations for physical activity	65%	95%	87%	96%
Excessive drinking	% of adults reporting binge or heavy drinking	16%	19%	17%	21%
Alcohol-impaired driving deaths	% of driving deaths with alcohol involvement	31%	34%	29%	39%
Sexually transmitted infections	# of newly diagnosed chlamydia cases per 100,000 population	291	364	122	464
Teen births	# of births per 1,000 female population ages 15-19	41	20	6	26
CLINICAL CARE					
Uninsured	% of population under age 65 without health insurance	17%	11%	7%	12%
Primary care physicians	Ratio of population to primary care physicians	2015:1	1190:1	1867:1	1081:1
Dentists	Ratio of population to dentists	2670:1	1285:1	2400:1	1049:1
Mental health providers	Ratio of population to mental health providers	1128:1	323:1	548:1	250:1
Preventable hospital stays	# of hospital stays for ambulatory-care sensitive conditions per 1,000 Medicare enrollees	65.3	57	51	65
Diabetic monitoring	% of diabetic Medicare enrollees ages 65-75 that receive HbA1c monitoring	85%	85%	82%	90%
Mammography screening	% of female Medicare enrollees ages 67-69 that receive mammography screening	61%	67.1%	64.4%	70.2%
SOCIAL AND ECONOMIC FACTORS					
High school graduation	% of ninth-grade cohort that graduates in four years	85%	85%	80%	94%
Some college	% of adults ages 25-44 with some post-secondary education	56%	67.0%	56.3%	73.5%
Unemployment	% of population aged 16 and older unemployed but seeking work	7%	7.8%	6.7%	8.7%
Children in poverty	% of children under age 18 in poverty	24%	15%	7%	18%
Income inequality	Ratio of household income at the 80th percentile to income at the 20th percentile	4.4	5.0	3.8	5.8
Children in single-parent households	% of children that live in a household headed by single parent	31%	31%	22%	37%
Social associations	# of membership associations per 10,000 population	12.6	9.3	6.9	10.8
Violent crime	# of reported violent crime offenses per 100,000 population	199	279	111	406
Injury deaths	# of deaths due to injury per 100,000 population	73.8	52	42	56
PHYSICAL ENVIRONMENT					
Air pollution – particulate matter	Average daily density of fine particulate matter in micrograms per cubic meter (PM2.5)	11.9	10.5	10.3	10.7
Drinking water violations	% of population potentially exposed to water exceeding a violation limit during the past year	1.0%	0%	0%	3%
Severe housing problems	% of households with overcrowding, high housing costs, or lack of kitchen or plumbing facilities	14%	19%	12%	22%
Driving alone to work	% of workforce that drives alone to work	80%	79%	73%	83%
Long commute – driving alone	Among workers who commute in their car alone, % commuting > 30 minutes	29%	31%	27%	42%

2015 COUNTY HEALTH RANKINGS: DATA SOURCES AND YEARS OF DATA

	Measure	Data Source	Years of Data
HEALTH OUTCOMES			
Length of Life	Premature death	National Center for Health Statistics – Mortality files	2010-2012
Quality of Life	Poor or fair health	Behavioral Risk Factor Surveillance System	2006-2012
	Poor physical health days	Behavioral Risk Factor Surveillance System	2006-2012
	Poor mental health days	Behavioral Risk Factor Surveillance System	2006-2012
	Low birthweight	National Center for Health Statistics – Natality files	2006-2012
HEALTH FACTORS			
HEALTH BEHAVIORS			
Tobacco Use	Adult smoking	Behavioral Risk Factor Surveillance System	2006-2012
Diet and Exercise	Adult obesity	CDC Diabetes Interactive Atlas	2011
	Food environment index	USDA Food Environment Atlas, Map the Meal Gap	2012
	Physical inactivity	CDC Diabetes Interactive Atlas	2011
	Access to exercise opportunities	Business Analyst, Delorme map data, ESRI, & US Census Tigerline Files	2010 & 2013
Alcohol and Drug Use	Excessive drinking	Behavioral Risk Factor Surveillance System	2006-2012
	Alcohol-impaired driving deaths	Fatality Analysis Reporting System	2009-2013
Sexual Activity	Sexually transmitted infections	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention	2012
	Teen births	National Center for Health Statistics – Natality files	2006-2012
CLINICAL CARE			
Access to Care	Uninsured	Small Area Health Insurance Estimates	2012
	Primary care physicians	Area Health Resource File/American Medical Association	2012
	Dentists	Area Health Resource File/National Provider Identification file	2013
	Mental health providers	CMS, National Provider Identification file	2014
Quality of Care	Preventable hospital stays	Dartmouth Atlas of Health Care	2012
	Diabetic monitoring	Dartmouth Atlas of Health Care	2012
	Mammography screening	Dartmouth Atlas of Health Care	2012
SOCIAL AND ECONOMIC FACTORS			
Education	High school graduation	data.gov, supplemented w/ National Center for Education Statistics	2011-2012
	Some college	American Community Survey	2009-2013
Employment	Unemployment	Bureau of Labor Statistics	2013
Income	Children in poverty	Small Area Income and Poverty Estimates	2013
	Income inequality	American Community Survey	2009-2013
Family and Social Support	Children in single-parent households	American Community Survey	2009-2013
	Social associations	County Business Patterns	2012
Community Safety	Violent crime	Uniform Crime Reporting – FBI	2010-2012
	Injury deaths	CDC WONDER mortality data	2008-2012
PHYSICAL ENVIRONMENT			
Air and Water Quality	Air pollution – particulate matter [1]	CDC WONDER environmental data	2011
	Drinking water violations	Safe Drinking Water Information System	FY2013-14
Housing and Transit	Severe housing problems	Comprehensive Housing Affordability Strategy (CHAS) data	2007-2011
	Driving alone to work	American Community Survey	2009-2013
	Long commute – driving alone	American Community Survey	2009-2013

[1] Not available for AK and HI.

CREDITS

Report Authors
University of Wisconsin-Madison
School of Medicine and Public Health
Department of Population Health Sciences
Population Health Institute

Bridget Catlin, PhD, MHSA
Amanda Jovaag, MS
Julie Willems Van Dijk, PhD, RN

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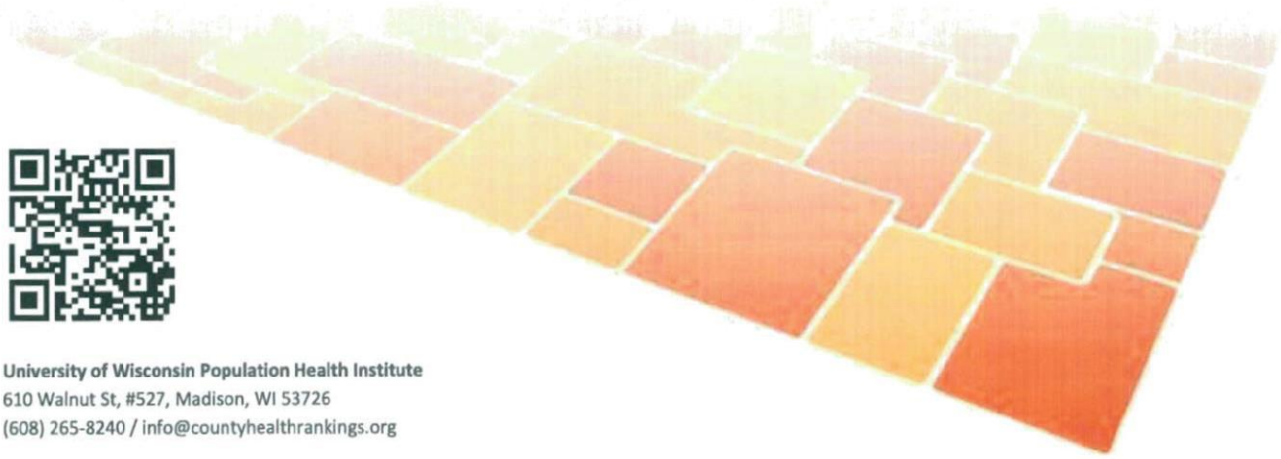
County Health Rankings & Roadmaps
Building a Culture of Health, County by County

countyhealthrankings.org



University of Wisconsin Population Health Institute
610 Walnut St, #527, Madison, WI 53726
(608) 265-8240 / info@countyhealthrankings.org

EXHIBIT 5

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0037

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

The William W. Backus Hospital of Norwich, CT d/b/a The William W. Backus Hospital is hereby licensed to maintain and operate a General Hospital.

The William W. Backus Hospital is located at 326 Washington Street, Norwich, CT 06360.

The maximum number of beds shall not exceed at any time:

20 Bassinets
213 General Hospital Beds

This license expires **March 31, 2016** and may be revoked for cause at any time.
Dated at Hartford, Connecticut, April 1, 2014. RENEWAL.

Satellites:

Backus Infectious Disease & STD Clinic, 107 Lafayette Street, Norwich, CT
Mobile Health Resource Van, 326 Washington Street, Norwich, CT
Pain Management, 112 Lafayette Street, Norwich, CT
Wound Care, 111 Salem Turnpike, Route 82, Norwich, CT
The Backus Emergency Care Center, 582 Norwich Road, Plainfield, CT

Jewel Mullen, MD, MPH, MPA
Commissioner

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0046

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

Hartford Hospital of Hartford, CT d/b/a Hartford Hospital is hereby licensed to maintain and operate a General Hospital.

Hartford Hospital is located at 80 Seymour Street and 200 Retreat Avenue, Hartford, CT 06106.

The maximum number of beds shall not exceed at any time:

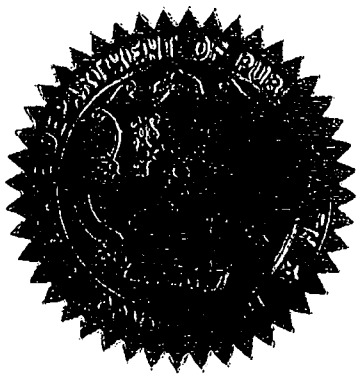
48 Bassinets
819 General Hospital Beds

This license expires **December 31, 2015** and may be revoked for cause at any time.
Dated at Hartford, Connecticut, January 1, 2014.

Satellites:

West Hartford Surgery Center, 65 Memorial Road, Suite 500, West Hartford
Hartford Hospital, 505 Willard Avenue, Bldg. 3, Newington
Duncaster Primary Care Satellite, 40 Loeffler Road, Bloomfield
*Hartford Marathon Medical Tent, Bushnell Park, Hartford, (Finish Line)
*Hartford Marathon Medical Tent, Bushnell Park, Hartford, (East of Carousel)
*Hartford Marathon Medical Tent, Steele Road & Asylum Street, West Hartford

License revised to reflect:
*Added (2) Satellites for Hartford Marathon effective 10/9/14 – 10/13/14



Jewel Mullen, MD, MPH, MPA
Commissioner

EXHIBIT 6

Nader M. Bahadory, DO, DABEM, FACEP

Medical Director
William Backus Hospital
Medical Staff Office
860-889-8331 Extn 6383

Chief of Emergency Services
William Backus Hospital Emergency Department
Plainfield Emergency Care Center
326 Washington Street
Norwich, CT 06360

Education

2014	Physician Leadership Development Institute, Hartford Health Care
2013	Emergency Department Directors Academy thru ACEP (completed phase I and II)
Present	Enrolled in American College of Physician Executives curriculum toward a Certified Physician Executive (CPE) Degree
2009	Physician Leadership Academy Multiple Courses in Physician Performance, Quality Assurance, and Leadership Role
1998	Integrated Residency in Emergency Medicine University of Connecticut, Farmington, CT
1995	Doctor of Osteopathy, University of North Texas Health Science center Fort Worth, Texas
1991	Research Assistant, Marine Biology University of Texas Marine Institute Port Aransas, Texas
1989	Bachelor of Science Texas A&M University Corpus Christi, Texas

Medical License

1997	State of Connecticut (Current)

Certification

1999	Diplomat of American Board of Emergency Medicine Re-certified in 2009
2001	Fellow of American College of Emergency Medicine

Employment

2015	Medical director Backus Hospital/ Chief Emergency Services
2014	Chief of Emergency Services (Norwich and Plainfield Campuses)
2006	Associate Chief Emergency Services William Backus Hospital Norwich CT
2005	Acting Medical Director William Backus Hospital
2004	Assistant director of Emergency Services
1999	Attending Physician William Backus Hospital
1998-1999	Attending Physician, Emergency Department St. Francis Hospital and Medical Center

Nader M. Bahadory, DO, DABEM, FACEP

Experience

1. Medical Director Backus Hospital
2. Chief, two Emergency Departments with annual volume of 78000
3. Planning, development and opening of Backus hospital free standing 24 hr. ED satellite along with its staffing development
4. Physician Safety Officer for Backus Hospital organizational excellence
5. Meditech ED module development and continuous improvement
6. I have managed the Quality Assurance for the Backus Hospital ED since 2004
7. Participated in development of the electronic QA for the ED (Statit and Midas software)
8. I have managed the grievances for this ED since 2005
9. Medical Director for Backus Employee Health Clinic at Foxwoods Casino
10. Chairman, Resuscitative Services at Backus Hospital. Oversee Cardiac arrest and Rapid Response Team for hospital wards and the ICU
11. Developed the Procedural Sedation with addition of Propofol use for deep sedation in the ED
12. Developed the Cardiac Decision Unit in the ED (observation Unit) in operation since 2012
13. Maintain airway management set up including difficult airway plan for the ED
14. Regularly present lecture series for paramedics and nursing
15. Currently working on DNR and end of life living will policy development

Academic Experience

2015	Research published: Virtual cardiac decision unit algorithm improves patient Outcomes and reduces cost. J Am Coll Cardiol. 2015
2013	Oral Board Examiner for American Board of Emergency Medicine
1998-1999	Clinical Instructor of Emergency Medicine University of Connecticut Health Center Department of Emergency Medicine & Traumatology
1999	Developed the ultrasound training section for University of Connecticut Emergency Medicine Residency
1998	Grant from ACEP used to produce an emergency medicine physician educator training video. Video and abstract was presented at New England Society of Emergency Medicine and National SAEM

Awards

1996	Philip A. Stent, MD Award for Excellence in Emergency Medicine
1997	Philip A. Stent Award for second time
1989	Texas A&M University Graduated Magna cum Laude

References

Available Upon Request

Mariane Carna, RN, MSN

Dynamic, Results-Focused Leader Seeking Forward-Thinking Healthcare Executive Role

Specializations in Service Line Development/Achievement, Quality & Service Excellence, Physician Recruitment/Practice Management, Leadership, and Inclusive Management ▪ Proven Ability to Clinically Integrate Multi-System Cardiovascular, Cardiac Surgery, Vascular Surgery, Perioperative Services, Advanced Imaging, Solid Organ Transplant, Neurovascular, Emergency Services, Outpatient Interdisciplinary Practices, Interventional Radiology, Advanced Imaging, Research programs, Clinical Trials, Women's/Children's ▪ Recognized for Establishing Incentive Plans for Physicians, Hospital Clinical Leadership, Nursing and Support Teams to Achieve Programmatic Goals and Align Strategic Healthcare Objectives

KEY AREAS OF EXPERTISE

HEALTHCARE ADMINISTRATION | STRATEGIC ANALYSIS | PHYSICIAN PRACTICE ACQUISITION | BUDGETING | FORECASTING | BUSINESS UNIT DEVELOPMENT | FACILITY MASTER PLANNING | QUALITY CONTROL | CORPORATE CONTRACTING/ LOGISTICS PHYSICIAN RECRUITMENT | INVENTORY MANAGEMENT | COMPLIANCE | SAFETY ASSURANCE | CLINICAL OPERATIONS MANAGEMENT | TEAM BUILDING / TRAINING | STAFF RECRUITMENT | SUSTAINABLE PHYSICIAN EMPLOYMENT | SHARED SERVICES BUDGET MANAGEMENT | BUSINESS PLANNING | CLINICAL TRIALS /RESEARCH | PATIENT RELATIONS | CLINICAL CONSULTING

CAREER HIGHLIGHTS

- Successfully established a Heart & Vascular Service Line by building collaborative governance and a leadership structure with Yale-New Haven Hospital and Yale Medical Group to support goal alignment and goal achievement.
- Demonstrated experience in understanding academic medicine and growing research missions with physician teams.
- Contributed expertise in leading strong, results-driven consulting teams in perioperative and high-margin areas.
- Developed a strategic operations assessment and road map for physician recruitment to establish Centers of Excellence in the areas of Heart Failure, PCI, VAD / Transplant, Electrophysiology, and Cardiac Surgery, and further recruited the Chief of Cardiology, Chief of Cardiothoracic Surgery, and 10 physician recruits within a 4-year period to achieve a 28%cumulative average growth rate in cardiology, cardiac surgery, and vascular surgery.
- Contributed $22+ million to a Heart & Vascular Service Line via growth in wide-ranging specialty areas (e.g. PCI, EP visits, Cardiac CT), and increased operating margin within the same year period (2007 – 2011) by $11+ million.
- Established and co-chaired a quality council responsible for quality outcomes and effectiveness in partnership with national leader, Harlan Krumholz, MD, and ultimately reduced hospital Heart Failure readmission rate from 30% to 10% in less than 1 year by engaging interdisciplinary care teams and establishing a process for accountability.
- Noted for excellence by leading Yale-New Haven Hospital's Cardiovascular Services to achieve highest ranking recognized by *U.S. News & World Report* with a 14 point increase in ranking over a year; additional accomplishments included door-to-balloon results in <90 minutes, certificate from Joint Commission for implant destination VADs, and certificate by Society of Chest Pain Centers for Accredited Chest Pain Center designation.
- Established outpatient comprehensive physician practices with sustained CAGR of 12%.
- Established comprehensive imaging centers with integrated research initiatives with Yale Medical Group.
- Successfully realized double-digit growth performance in the Centers of Excellence as part of the Cardiovascular Service Line supported through inpatient and outpatient growth.
- Successfully engaged operations teams within high margin areas as operating rooms/invasive labs to drive strategic organizational initiatives including but not limited to patient satisfaction in the 90th percentile, exceptional performance in quality/safety, physician collaboration and clinical/administrative alignment.
- Established operations councils and an executive council to ensure shared accountability and alignment of goals to support the service line mission and vision, along with establishing a patient and family advisory council to coordinate the care experience and drive patient satisfaction scores top scores within the organization.
- Honored with "Individual Service Excellence" by senior administration, "Excellence in Leadership" at New York Presbyterian / Weill Cornell, yearly "Team Service Excellence Awards" in the Cardiovascular Service Line, and "Quarterly Patient Satisfaction Awards" for the Cardiac Service Line as evidenced by superior performance.
- Recognized for job excellence with an overall employee satisfaction rate of 95%, and staff turnover of less than 8%.
- Generate improved Business Unit revenue, including doubling revenue within 12 months of hire at 110% to goal- Supported growth and development of clinical consulting team focused on change management and process redesign in perioperative, emergency, inpatient and outpatient services.

PROFESSIONAL SYNOPSIS

HARTFORD HEALTHCARE, HARTFORD, CT — 2015-PRESENT

Vice President – Cardiovascular Service Line

TELETRACKING TECHNOLOGIES, PITTSBURGH, PA — 2012 – 2015

Innovative company providing Real-Time Capacity Management™ to automate a hospital's or health systems' functional operations, and powers live information to an entire enterprise via easy-to-read, graphics-rich digital dashboards to optimize patient care logistics.

Vice President – Consulting Services | Business Unit Leader

- Utilize broad scope of industry knowledge and dynamic healthcare business acumen toward providing forward-thinking direction for the Business Unit while coordinating efforts with product management to ensure market differentiation, collaborating with internal / external stakeholders to provide client sales and services, and ensuring execution and accomplishment of key deliverables established during the sales cycle to maximize the bottom line.
- Spearhead integral support of clients to facilitate change management / process redesign to meet all project goals.
- Generate improved Business Unit revenue, including doubling revenue within 12 months of hire at 110% to goal, as well as further identifying, analyzing, and implementing cost-reducing and profit-generating strategic activities.
- Build and sustain productive relationships with valued partners and ensure cost effective solutions/services.
- Expertly lead execution of new product development for global consulting, including developing product extensions and new product introductions supportive of patient flow and efficiency while managing / tracking NPD processes.
- Serve as key resource facilitating planning for senior management, including proactively leading a top-performing clinical consulting team in providing change management to drive outcomes and interdisciplinary collaboration.

YALE-NEW HAVEN HOSPITAL, NEW HAVEN, CT — 2007 – 2012

1,545-bed delivery network consisting of Yale-New Haven, Bridgeport, and Greenwich Hospitals; 2011's revenue was in excess of $1.4 billion based on 80,000+ discharges and 1.3+ million outpatient visits; Yale-New Haven Hospital is a 966-bed tertiary referral center.

Vice President – Heart & Vascular Service Line | Adult Emergency Department

- Led a Heart & Vascular Service Line, including directing physician recruitment, joint budget planning, and physician practice acquisition in collaboration with the Yale Medical Group / School of Medicine and Yale-New Haven Hospital, as well as managing $100+ million total annual operating expenses and $50+ million shared service budget.
- Cost-effectively directed revenue and expense budget planning processes, and prepared annual operating budgets.
- Strategically steered patient demand and throughput, patient satisfaction, regulatory preparedness, quality improvement, physician satisfaction, employee satisfaction, and business development and integration initiatives.
- Ensured ongoing regulatory compliance with and preparation for all inpatient and outpatient areas, along with creating a synergistic working environment for all teams by promoting innovation across the healthcare system.

NEW YORK – PRESBYTERIAN HOSPITAL | WEILL CORNELL MEDICAL CENTER, NEW YORK, NY — 2002 – 2007

2,369-bed Academic Medical Center; Ranked with Top 10 by U.S. News & World Report; *Composed of two medical centers; Cardiovascular Service Line consists of 40 Intensive Care beds and Telemetry Step-Down beds; Ranked #6 in* U.S. News & World Report.

Service Line Director – Cardiovascular Service Line

- Capitalized on the opportunity to direct 24 / 7 operations for a Cardiovascular Service Line, including facilitating all strategic and operational planning while collaborating with physician leadership to align goals through executive operating councils; ensuring standards met or exceeded requirement of JCAHO, state, federal, regulatory, and reimbursement agencies and promote 24 / 7 readiness; and evaluating practice programs for optimal patient care.
- Drove healthcare success by directing a patient-focused team of 300 professional / non-professional staff (108 beds), including developing and implementing service line staff retention plan to enhance staff and patient satisfaction.
- Coordinated service line development per key patient throughput and volume, and efficiently managed expenses.

Service Line Director (Interim) – Women & Children's

- Played a vital role in directing a team of 515 professional / non-professional staff with an annual operating budget of $35 million, including managing delivery of care in Obstetrics (68 beds / 58 bassinets), Ante-partum, Post-Partum / Newborn Nursery, Labor & Delivery (5,600 annual deliveries), Women's Health Ambulatory Care and Pediatrics (private practice, in-vitro fertilization program, ante-partum testing; 100 beds), Neonatal Intensive Care, Pediatric Critical Care, and General Pediatrics / Research Unit which was instrumental in boosting success.
- Ensured delivery of care was consistent with national standards, city / state / federal regulations, and agency requirements while promoting targeted program planning, service line integration, and leadership development.

EDUCATION, PROFESSIONAL DEVELOPMENT & AFFILIATIONS

Master of Science in Nursing (2006) — University of Phoenix
Bachelor of Science in Nursing (1995) — St. Mary's College NOTRE DAME INDIANA

Critical Care Registered Nurse Certification | Wharton School of Leadership Certificate | BLS Provider | ACLS Provider
Heart Rhythm Society | United Healthcare Consortium | American College of Cardiology | Vascular Study Group of NE
American Association of Critical Care Nurses | Cardiovascular Roundtable Advisory Board | AHA – Connecticut Board

Curriculum Vitae of
Rebecca Durham

EDUCATION:

- Masters of Science in Nursing, University of Connecticut, Storrs, CT 2006
- Bachelors of Science in Nursing, Quinnipiac University, Hamden, CT 2001

CERTIFICATIONS:

- Certification in Critical Care Nursing (CCRN) Certified 2005- 2015
- Certification in Critical Care Nursing (CCRN-K) Certified 2015- present
- Certification in Executive Nursing Practice (CNEP) 2015-present

AWARDS:

- 2007 Recipient of the "Nightingale Award for Excellence in Nursing" awarded by the William W. Backus Hospital
- 2005 Recipient of the "Nursing Master's Student Award" awarded by the University of Connecticut's School of Nursing

EXPERIENCE:

WILLIAM W. BACKUS HOSPITAL, Norwich, CT (4/02-present)
Regional Director of Critical Care Services, August 2013-present
Associate Administrator of Critical Care Services, August 2012- August 2013
Clinical Director: Critical Care Unit/Cardiac Catheterization Lab, August 2008-August 2011
Interim Clinical Director: Critical Care Unit/Cardiac Catheterization Lab January 2008-August 2008
Clinical Director: Progressive Care Unit May 2006-August 2008
Clinical Coordinator: Critical Care Unit May 2005- May 2008
Staff RN: Critical Care Unit April 2002- May 2005

VISITING NURSES ASSOCICATION OF SOUTHEASTERN CONNECTICUT
(Jan 2005-Dec2005)
Per Diem Home Care Nurse

HOSPITAL OF SAINT RAPHEAL'S, New Haven, CT (9/01-4/02)
Staff RN: Coranary Intensive Care Unit

OTHER RELATED EXPERIENCE:

- Graduate of the Center for Frontline Nursing Leadership Academy 2009
- Graduate of the Eastern Connecticut Chamber of Commerce Leadership Program 2010

CURRICULUM VITAE
JOHN ARTHUR FOLEY, M.D., F.A.C.P., F.A.C.C.

Personal Information

Office: Hartford Healthcare Medical Group Cardiology
164 Otrobando Ave
Norwich, Connecticut 06360
(860) 886-0023
email: john.foley@hhchealth.org

Education

B.S. Nursing
Fitchburg State College, Fitchburg, MA
1984

Medical Degree
Albany Medical College, Albany, NY
1992

Current Positions

April 2015-present	Director of Specialty Care Services; East Region (interim) Hartford Healthcare Medical Group
April 2014-present	Director of Cardiovascular Services Hartford Healthcare Medical Group/East Region
July2014-present	Chief of Cardiology William Backus Hospital Norwich, CT
Jan.2014-present	Chief of Cardiology Windham Hospital Windham, CT
Jan. 2012 – present	Director of Heart Failure Services William Backus Hospital
April 2014-present	Norwich, CT Attending Cardiologist Cardiology Associates Norwich, CT
2009-2014	Attending Physician / Clinician Yale University School of Medicine New Haven, CT

Public and Community Service

Feb. 2009 – 2013	Volunteer, Boy Scout Troop 36 Waterford, CT
May 2009 - June 2010	Finance Committee Simmons for Senate US Senate Campaign
Sept. 2004 - Feb. 2009	Den Leader, Cub Scouts Boy Scout Troop 36 Waterford, CT
April 2005 - Dec. 2006	Finance Committee Simmons for Congress US Representative Campaign

Nov. 2002 - 2010	Elected 4th District Representative Representative Town Meeting Waterford, Connecticut
RTM Committees:	Legislative and Administrative Standing Committee Education Subcommittee

Committee Memberships

2014-present	Medical Executive Committee William Backus Hospital
2013–2014	Immediate Past President Connecticut State Medical Society
2012–2013	President Connecticut State Medical Society
2011 – 2012	President-Elect Connecticut State Medical Society
2011 – 2012	President New London County Medical Association
2009 - 2010	President Elect New London County Medical Association
2010 – 2011	Vice President Connecticut State Medical Society
2006 – 2014	Associate Councilor Connecticut State Medical Society
2005 –2014	Trustee, Board of Directors New London County Medical Association
2000 - 2002	Cardiology Task Force William W. Backus Hospital
2000 - 2002	Cardiac Catheterization Lab Committee Cardiology Task Force William W. Backus Hospital
1998	Search Committee for the Dean Graduate School of Nursing University of Massachusetts

1995 – 1996	Chief Resident Committee Graduate Medical Education University of Massachusetts Medical Center
1995 - 1996	Residency Selection Committee University of Massachusetts Medical Center
1991 - 1992	Chair, Honor Code Committee Albany Medical College
1988 - 1991	Honor Code Committee Albany Medical College

Academic Appointments

Aug. 2009- 2014	Attending Physician / Clinician Yale University School of Medicine
July 1996 - June 1999	Fellow, Division of Cardiology University of Massachusetts Medical Center
	Associate Faculty Graduate School of Nursing University of Massachusetts Medical Center
July 1995 – June 1999	Clinical Rotation Coordinator Graduate School of Nursing University of Massachusetts Medical Center
July 1992 – June 1999	Instructor of Medicine University of Massachusetts Medical School

Post-Doctoral Training

July 1996 - June 1999	Clinical Fellow, Cardiovascular Medicine University of Massachusetts Medical Center Worcester, Massachusetts
July 1995 -June 1996	Chief Medical Resident University of Massachusetts Medical Center Worcester, Massachusetts
July 1993 - June1995	Medical Resident University of Massachusetts Medical Center Worcester, Massachusetts
July 1992 – June 1993	Medical Intern

University of Massachusetts Medical Center
Worcester, Massachusetts

Work Experience

Nov. 1997 – June 1999	North East Connecticut Cardiology Associates Putnam, Connecticut (Provided weekend coverage for practice of three cardiologists)
June 1987 – June 1988	Clinical Nurse Manager, Coronary Care Stepdown Unit Saint Vincent Hospital Worcester, Massachusetts
May 1987 – June 1988	Clinical Coordinator of Cardiac Rehabilitation Services Saint Vincent Hospital Worcester, Massachusetts
July 1984 – May 1987	Registered Nurse, Medical Intensive Care Unit Saint Vincent Hospital Worcester, Massachusetts

Licensure

July 1997	Connecticut - current

Professional Society Memberships

Jan 2014-present	American Association for Physician Leadership
Nov 2012- present	American College of Physicians Fellowship
July 2001 - present	Heart Failure Society of America
July 1998 - present	American College of Cardiology 2001 Fellowship
July 1999 - present	Connecticut State Medical Society
July 1999 - present	New London County Medical Association
Sept. 1988 - present	American Medical Association

Research

2007- 2011	Principal Investigator William W. Backus Hospital Site Aristotle Trial
2004 - 2007	Principal Investigator William W. Backus Hospital Site EVEREST(Efficacy of Vasopressin Antagonism in Heart Failure: Outcome Study With Tolvaptan)

2003 - 2006	Principal Investigator William W. Backus Hospital Site OPTIMIZE-HF (Organized Program to Initiate Life-saving Treatment in Hospitalized Patients With Heart Failure)
2003 - 2005	Principal Investigator William W. Backus Hospital Site CATCH(The Complication After Thrombocytopenia Caused by Heparin)
2002 - 2005	Principal Investigator William W. Backus Hospital Site ADHERE (Acute Decompensated Heart Failure National Registry)
2002 - 2005	Principal Investigator William W. Backus Hospital Site CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes with Early Implementation of the ACC/AHA Guidelines: the CRUSADE National Quality Improvement Initiative)
2001	Principal Investigator William W. Backus Hospital Site CARDINAL/COMPLY Trial (Complement and Reduction of Infarct Size After Angioplasty or Lytics; Complement Inhibition in Myocardial Infarction Treated with Thrombolytics)

Bibliography

Foley JA, Becker RC. Recognition, Evaluation and Management of Hypotension and Cardiogenic Shock. In: Cardiovascular Medicine/ Practice and Management. Oxford University Press. 2001

Foley JA, "Domestic Violence: A Challenge for Healthcare." (Commentary) Forum, 1997; (Governor's Commission on Domestic Violence Newsletter) Volume 4, Number 3.

Foley JA, Becker RC. "Calcium Channel Antagonists in the Modern Era of Thrombolysis: Benefit or Detriment?" (Editorial) Cardiovascular Drugs Ther 1996; 10:4:403-407.

Nasraway SA, Foley JA, Sottile FD, Black RM. "Postoperative Fall in the Anion Gap in High Risk Surgical Patients." (Abstract) Chest 1990; 53S.12.

DANIEL E. LOHR, CPA

PROFESSIONAL EXPERIENCE

HARTFORD HEALTHCARE, Hartford, CT` 2013-Present
Regional Vice President, Finance

THE WILLIAM W. BACKUS HOSPITAL, Norwich, CT 1993-2013
Senior Vice President & Chief Financial Officer

Management of the financial operations of a 200 bed, 1300 employee acute care hospital. Responsibilities include board and regulatory agency reporting and operating responsibility with direct oversight for management information systems, materials management, medical records, business office and patient registration. Other corporate responsibilities include investment/foundation oversight, development of for-profit joint ventures and physician practice activities.

ERNST & YOUNG, Hartford, CT 1974-1992
Partner 1987-1992

Coordinated services to hospitals, healthcare systems, small entrepreneurial companies and multi-national organizations. Facilitated merger and acquisition activities, financing transactions and systems conversions.

EDUCATION

University of New Haven, MBA, 1999

Ohio University, BBA, summa cum laude, 1973

Ernst & Young Partners' Executive Development Program, 1991
Northwestern University, J.L. Kellogg Graduate School of Management

Stuart K Markowitz, MD, FACR

Education

Yale University and University of Pennsylvania: Visiting Fellowships in Gastrointestinal Radiology	July-October 1985
Hartford Hospital: Diagnostic Radiology Residency	1982-1985
Hartford Hospital: Flexible Internship	1981-1982
University of Health Sciences – The Chicago Medical School Degree: M.D.	1977-1981
University of Pennsylvania – Degree: B.A.	1973-1977

Professional Work Experience

Hartford Hospital: President Senior Vice President, Hartford HealthCare	2013-present
Hartford Hospital: Chief Medical Officer and Vice President	2012-2013
Jefferson Radiology: Radiologist	1985-2011

Administrative and Professional Activities

Board of Directors, VNA Healthcare	2012-2014
Board of Directors, HPA and HPHO, Hartford Hospital	2012-present
Hartford Healthcare Board Quality and Safety Committee	2010-present
Hartford Hospital Board Credentialing and Quality Committee	2010-present
Board of Directors, Hartford Hospital	2010-2011
Vice President, Medical Staff, Hartford Hospital	2010-2011
Chairman, Department of Radiology, Hartford Hospital	1995-2011
Vice Chair, Department of Radiology, Hartford Hospital	1992-1995
Medical Director, Radiology Technology Program, Hartford Hospital	1990-2011
Section Chief, Gastrointestinal Radiology, Hartford Hospital	1985-2011
Section Chief, Emergency Radiology, Hartford Hospital	1992-2007
Full Time Instructor in the Diagnostic Radiology Residency Program at Hartford Hospital	1985-present
Partner, Jefferson Radiology (Jefferson X-Ray Group)	1986-2011

Board of Directors, Jefferson Radiology	1988-2011
President, 937-941 Farmington Avenue Limited Partnership	1991-2011
American College of Radiology Practice Certification Reviewer	1985-1990
Statewide Healthcare Facilities Planning Advisory Body, Department of Public Health, CT	2010-present
Office of Healthcare Access CON Task Force	2009-present
Connecticut State Radiology Society Legislative Committee	2005-2009

Hospital Committee Experience : Medical Staff Council, Executive Committee of the Medical Staff, Joint Conference Committee, Mead Fund Committee, Library Committee, Credentials Committee, Radiation Safety Committee, Radiology Management Committee, Radiology Quality Council, Risk Management Committee, Claims Review Committee, Radiology/IT Steering Committee, Reimbursement Committee, Technology Advisory Group, Endovascular Credentialing Committee, OR Committee, EMR Committee, IS Physician Advisory Committee, Tumor Board

Hartford Hospital CEO Advisory Body	2009-present

Certifications

Medical License – State of Massachusetts	2011
Fellowship in the American College of Radiology: FACR	2009
American Board of Radiology	1985
Medical License – State of Connecticut	1983
National Board of Medical Examiners	1982

Hospital Appointments

Hartford Hospital, Senior Attending Staff – Hartford, Connecticut

Connecticut Children's Medical Center, Attending Staff – Hartford, Connecticut

University of Connecticut Health Center, Assistant Clinical Professor – Farmington, Connecticut

Johnson Memorial Hospital, Attending Staff – Stafford Springs, Connecticut

Windham Hospital, Attending Staff – Willimantic, Connecticut

Day Kimball Hospital, Attending Staff – Putnam, Connecticut

Noble Hospital, Attending Staff – Westfield, Massachusetts

Current Memberships

Society of Chairman of Academic Radiology Departments
American College of Radiology

American Society of Emergency Radiology – Fellow
Radiologic Society of North America
American Roentgen Ray Society
Connecticut State Radiology Society
Society of Breast Imaging – Fellow
American College of Physician Executives

Publications

ZITER FMH, MARKOWITZ SK, ZAMSTEIN J. LARGE RENAL PELVIC DEFECTS CAUSED BY SOUGHED PAPILLA. APPLIED RADIOLOGY, NOV. 1987.

PISTOIA F AND MARKOWITZ S. SPLENIC LYMPHANGIOMATOSIS: CT DIAGNOSIS. AJR 150: 121-22, JANUARY 1988.

MARKOWITZ S AND ZITER F. THE LATERAL CHEST FILM AND PNEUMOPERITONEUM. ANNALS OF EMERGENCY MEDICINE 15:4 APRIL 1986.

JACOBS J AND MARKOWITZ S. CT DIAGNOSIS OF UTERINE LIPOMA. AJR 150:1335-1336, JUNE 1988.

WOLF S AND MARKOWITZ S. SPONTANEOUS GAS FORMATION IN A STERILE RENAL CELL CARCINOMA. UROLOGIC RADIOLOGY 9:222-224, 1988.

PISTOIA F, MARKOWITZ S, SUSSMAN S. CONTRAST MATERIAL IN POSTERIOR VAGINAL FORNIX MIMICKING BLADDER RUPTURE: CT FEATURES. JCAT 13(1):153-155 JAN/FEB 1989.

MILICI L AND MARKOWITZ S. INTRAMURAL GASTRIC PSEUDOCYST: CT DIAGNOSIS. GASTROINTESTINAL RADIOLOGY, VOL 14:113-114, 1989.

TREEM WR, MARKOWITZ SK, SULLIVAN BM, HYAMS JS. DEFECOGRAPHY IN CHILDREN WITH PROLONGED CONSTIPATION. ABSTRACT SUBMITTED AT THE NORTH AMERICAN SOCIETY FOR PEDIATRIC GASTROENTEROLOGY AND NUTRITION, 1990.

MARKOWITZ SK, ZITER FMH. RADIOLOGIC DIAGNOSIS OF BOWEL OBSTRUCTION. IN: BOWEL OBSTRUCTION, CLINICAL DIAGNOSIS AND MANAGEMENT. J. WELCH, ED. SAUNDERS, 1990.

SAWHNEY R, REES JH, MARKOWITZ SK. CLOSTRIDIAL GAS GANGRENE COMPLICATING LEUKEMIA. ABDOMINAL IMAGING 19:45102, 1994.

SCAPPATICCI F AND MARKOWITZ SK. INTRAHEPATIC PSEUDOCYST COMPLICATING ACUTE PANCREATITIS: IMAGING FINDINGS. AJR, 1995; 165:873-4.

MARKOWITZ SK. DELAYED RUPTURE OF THE GALLBLADDER: DIAGNOSIS BY ERCP. SUBMITTED FOR PUBLICATION.

MARKOWITZ SK. BILIARY OBSTRUCTION DUE TO DUODENAL DIVERTICULUM: DIAGNOSIS BY CT AND ERCP. SUBMITTED FOR PUBLICATION.

MARKOWITZ SK. LONG TERM ALIMENTATION: COMPARISON OF INTRAVENOUS AND NASOENTERIC ALIMENTATION. WORK IN

PROGRESS.

ALLMENDINGER N, HALLISEY MJ, MARKOWITZ SK, ET AL. BALLOON DILATION OF ESOPHAGEAL STRICTURES IN CHILDREN. J. OF PEDIATRIC SURGERY, VOL 31, NO 3, P334-6, MARCH 1996.

CIRAULO DL, NIKKANEN HE, PALTER M, MARKOWITZ S, ET AL. CLINICAL ANALYSIS OF THE UTILITY OF REPEAT COMPUTED TOMOGRAPHIC SCAN BEFORE DISCHARGE IN BLUNT HEPATIC INJURY. JOURNAL OF TRAUMA 41(5):821-824, NOVEMBER 1996.

MARKOWITZ SK, KIRECZYK W. RADIOLOGIC EVALUATION OF DIVERTICULAR DISEASE OF THE SMALL AND LARGE INTESTINES. IN DIVERTICULAR DISEASE: MANAGEMENT OF THE DIFFICULT SURGICAL CASE. J. WELCH, ED. WILLIAMS AND WILKINS, 1997.

Recognitions Awards

Best Doctors in Hartford, Hartford Magazine	2004-2012
Best Doctors in Connecticut, Connecticut Magazine	2010-2014

Current Work Contact Information

Stuart K Markowitz, MD, FACR
President
Hartford Hospital
80 Seymour Street
Hartford, CT 06102

860-545-2349
Stuart.Markowitz@hhchealth.org

ROBERT D SIDMAN, MD, FACEP, CPE

Business Address:
The William W. Backus Hospital
326 Washington Street
Norwich, CT 06360.
860-823-6369 (direct)

QUALIFICATIONS

Physician executive with 20 years experience in physician management, quality, operations, information technology, systems-based improvement, high reliability, education and finance.

PROFESSIONAL EXPERIENCE

Vice President of Medical Affairs
Hartford HealthCare, East Region (2015-)
Regional Vice President of Medical Affairs of the hospitals in the east region of the system.

Medical Director and CMO
The William W. Backus Hospital, Norwich, CT (2013 - 2014)
Hartford HealthCare, Hartford CT
Medical Director of one of five acute care hospitals comprising Hartford HealthCare.

Medical Director, Physician Services
Backus Hospital, Norwich, CT (2010 – 2014)
Medical director for the multispecialty group of the hospital.

Chief of Emergency Services
The William W. Backus Hospital, Norwich, CT (2005 – 2013)
Responsible for the management of two emergency departments and 30 full time physicians and allied health providers that generates $35 million in revenue and cares for 80K patients a year.

Associate Medical Director – Emergency Department
Rhode Island Hospital, Providence, RI (2003 – 2005)
In conjunction with the medical director, provide management to 100 providers who care for 140K patients annually.

Residency Director – Emergency Medicine
Brown University School of Medicine, Providence, RI (1999 – 2005)
Responsible for the operations, management and education of 48 residents within the scope of the ACGME.

Assistant Residency Director – Emergency Medicine
Brown University School of Medicine, Providence, RI (1995 – 1999)
Assist the program director with most aspects of operations. Specific focus on resident education, staffing, curriculum development, recruitment, mentoring and research.

Attending Physician – University Emergency Medicine Foundation
Rhode Island Hospital, Providence, RI (1994 – 2005)
Provide emergency care in a high volume Level I trauma center (busiest in New England).

EDUCATION

Undergraduate	Colby College, BA Molecular Biology (cum laude) Waterville, ME. 1986
Medical School	Albert Einstein College of Medicine, MD Bronx, NY. 1990
Residency	Emergency Medicine, University Hospital, University of Cincinnati, Cincinnati, OH. 1994
Management	Certified Physician Executive, CPE American College of Physician Executives, Tampa, FL. 2010

PROFESSIONAL LICENSES AND BOARD CERTIFICATION

Diplomat	American Board of Emergency Medicine 1995, 2005
Medical Licensure	Connecticut (active) Massachusetts, Rhode Island, Ohio, Kentucky

PROFESSIONAL MEMBERSHIPS

American College of Physician Executives (ACPE)
American College of Health Care Executives (ACHE)
American College of Emergency Physicians (FACEP)
Connecticut Chapter - American College of Emergency Physicians (CCEP)
Connecticut Hospital Association Physician Executive Group (CHA)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Thompson, Paul Davis	Director of Cardiology, Hartford Hospital Professor of Medicine, University of Connecticut
eRA COMMONS USER NAME (credential, e.g., agency login) Pthomps	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Tufts University, Medford, MA	BS	05/69	Biology
Tufts Medical School, Boston, MA	MD	05/73	Medicine
Tufts New England Medical Center, Boston, MA	IM Resident	07/73-06/75	Internal Medicine
Tufts New England Medical Center, Boston, MA	Cath Fellow	07/75-06/76	Cardiology
Stanford University Medical Center, Stanford, CA	Card Fellow	07/76-06/78	Cardiology

Personal Statement – I am board certified in internal medicine and cardiology and continue to practice outpatient preventive and general cardiology as well as inpatient intensive care cardiology. I was one of 12 cardiologists who write the cardiovascular certification exam for the American Board of Internal Medicine. I have a clinical and research interest in exercise physiology, the cardiovascular problems of endurance athletes, the effects of exercise on lipid metabolism, and how statins affect skeletal muscle. I was the PI of the grant, "Lipoproteins in Active Men: Role of Exercise and Diet" (NIH-RO1HL28467) that examined the mechanisms increasing HDL in endurance athletes and received 11 years of funding. In 1990 I reported that statins increase muscle injury during exercise, and I have continued this research as the PI on the recently completed STOMP study (the Effect of **ST**atins **O**n Skeletal **M**uscle Function and **P**erformance – NIH-RO1081893) as well as the PI of a study examining the effect of coenzyme Q10 on muscle strength in statin myopathic patients (RC1 AT005836). I have authored over 350 scientific articles on topics which include: the effects of exercise training on preventing and treating heart disease, the cardiovascular risks of vigorous exercise, the effects of exercise on lipid metabolism, the effects of statins on skeletal muscle, and genetic factors affecting the exercise response. I am extremely interested in how statins affect skeletal muscle and pleased to serve as a consultant for this proposal. I will use my clinical and research experience to consult on any aspects of this project deemed appropriate by the primary investigators.

Positions and Honors

Positions and Employment

1978-1992 Assistant & Associate Professor of Medicine, Brown University Program in Medicine
1992-1997 Visiting & Full Professor of Medicine, University of Pittsburgh
1997-2008 Director of Preventive Cardiology, Hartford Hospital, Hartford, CT
2007- Director of Cardiology, Hartford Hospital, Hartford, CT
1997- Professor of Medicine, University of Connecticut School of Medicine, Farmington, CT

Other Experience and Professional Memberships

1978- Fellow American College of Cardiology
1979- Fellow American College of Sports Medicine
1998-1999 President, American College of Sports Medicine

Honors

1969- Tufts Student Athlete Award
1980- NIH Preventive Cardiology Academic Award
2003- D.Bruce Dill Historical Lecturer, American College of Sports Medicine
2008- American Board of Internal Medicine, Cardiovascular Exam Question Committee

B. Selected Peer-reviewed Publications (Selected from >350 peer-reviewed publications)

1. Thompson, PD, Nugent AM, Herbert PN: Increases in creatine kinase after exercise in patients treated with HMG-CoA reductase inhibitors. JAMA 264: 2992, 1990. PMID: 2243421.
2. Thompson PD, Zmuda JM, Domalik LJ, Zimet RJ, Staggers J, Guyton JR: Lovastatin increases exercise-induced skeletal muscle injury. Metabolism 46:1206-1210, 1997. PMID: 9322808.
3. Thompson PD, Clarkson P, Karas RH. Statin-associated myopathy. JAMA. 289:1681-90, 2003. PMID: 12672737.
4. Urso ML, Clarkson PM, Hittel D, Hoffman EP, Thompson PD. Changes in Ubiquitin Proteasome Pathway Gene Expression in Skeletal Muscle with Exercise and Statins. Arteriosclerosis, Thrombosis, and Vascular Biology. 25:2560-6, 2005. PMID: 16224050.
5. Marcoff L, Thompson PD. The role of coenzyme Q10 in statin-associated myopathy: a systematic review. J Am Coll Cardiol. 49:2231-7, 2007. PMID: 17560286.
6. Gadarla M, Kearns AK, Thompson PD. Efficacy of rosuvastatin (5 mg and 10 mg) twice a week in patients intolerant to daily statins. Am J Cardiol. 2008;101:1747-8. PMID: 18549851.
7. Fernández AB, Karas RH, Alsheikh-Ali AA, Thompson PD. Statins and interstitial lung disease: a systematic review of the literature and of food and drug administration adverse event reports. Chest. 2008;134:824-30. PMID: 18689579.
8. Krishnan GM, Thompson PD. The effects of statins on skeletal muscle strength and exercise performance. Curr Opin Lipidol. 2010;21:324-8. PMID: 20581676.
9. Shave R, Baggish A, George K, Wood M, Scharhag J, Whyte G, Gaze D, Thompson PD. Exercise-induced cardiac troponin elevation: evidence, mechanisms, and implications. J Am Coll Cardiol. 2010;56:169-76. PMID: 20620736.
10. Venero CV, Venero JV, Wortham DC, Thompson PD. Lipid-lowering efficacy of red yeast rice in a population intolerant to statins. Am J Cardiol. 2010;105:664-6. PMID: 20185013.
11. Ghatak A, Faheem O, Thompson PD. .The genetics of statin-induced myopathy. Atherosclerosis. 210:337-43. 2010. PMID: 20042189.
12. Gupta A, Thompson PD. The relationship of vitamin D deficiency to statin myopathy. Atherosclerosis. 215:23-9, 2011. PMID: 2118502.Thompson PD, Parker B. Statins, Exercise, and Exercise Training. J Am Coll Cardiol. 2013 Apr 10. [Epub ahead of print] PMID: 23583256
13. Parker BA, Capizzi JA, Grimaldi AS, Clarkson PM, Cole SM, Keadle J, Chipkin S, Pescatello LS, Simpson K, White CM, Thompson PD. Effect of statins on skeletal muscle function. Circulation. 2013 Jan 1;127(1):96-103. PMID: 23183941
14. Padala S, Thompson PD. Statins as a possible cause of inflammatory and necrotizing myopathies. Atherosclerosis. 2012 May;222(1):15-21. PMID: 22154355
15. Thompson PD, Parker B. Statins, Exercise, and Exercise Training. J Am Coll Cardiol. 2013 Apr 10. [Epub ahead of print] PMID: 23583256154.
16. Parker BA, Thompson PD. Effect of statins on skeletal muscle: exercise, myopathy, and muscle outcomes. Exerc Sport Sci Rev. 2012 Oct;40(4):188-94. Review. Erratum in: Exerc Sport Sci Rev. 2013 Jan;41(1):71. PMID: 23000957
17. Parker BA, Gregory SM, Lorson L, Polk D, White CM, Thompson PD. A randomized trial of coenzyme Q10 in patients with statin myopathy: Rationale and study design. J Clin Lipidol. 2013 May-Jun;7(3):187-93. PMID: 23725917
18. Grimaldi AS, Parker BA, Capizzi JA, Clarkson PM, Pescatello LS, White MC, Thompson PD. 25(OH) vitamin D is associated with greater muscle strength in healthy men and women. Med Sci Sports Exerc. 2013 Jan;45(1):157-62. PMID: 22895376
19. Reich KA, Chen YW, Thompson PD, Hoffman EP, Clarkson PM. Forty-eight hours of unloading and 24 h of reloading lead to changes in global gene expression patterns related to ubiquitination and oxidative stress in humans. J Appl Physiol. 2010 Nov;109(5):1404-15. PMID: 20798274
20. Parker BA, Augeri AL, Capizzi JA, Ballard KD, Troyanos C, Baggish AL, D'Hemecourt PA, Thompson PD. Effect of statins on creatine kinase levels before and after a marathon run. Am J Cardiol. 2012;109(2):282-7. Epub 2011 Oct 28. PMID: 22036108

C. Ongoing Research Support

ACTIVE

Project #: AMR-01-01-0019 – Amarin Pharmaceuticals PI: PDThompson 3/18/2012- 3/18/2016

REDUCE-IT (Reduction of Cardiovascular Events with EPA – Intervention Trial): A Multi-Center, Prospective, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of AMR101 on Cardiovascular Health and Mortality in Hypertriglyceridemic Patients with Cardiovascular Disease or at High Risk for Cardiovascular Disease.

Project #: R727-CL1119- Regeneron Pharmaceuticals, Inc. PI: PDThompson 1/17/2013-11/20/2014

A Randomized, Double-Blind, Double-Dummy, Active-Controlled Study to Evaluate the Efficacy and Safety of REGN727/SAR236553 in Patients with Primary Hypercholesterolemia Who are Intolerant to Statins

Project #: ETC1002-008- Esperion Therapeutics PI: PDThompson 11/05/2013- 11/05/14

A Randomized, Double-Blind, Parallel Group, Multicenter Study to Evaluate the Efficacy and Safety of ETC-1002, Ezetimibe, and the Combination in Hypercholesterolemic Patients With or Without Statin Intolerance.

RECENTLY COMPLETED

Project #: R44GM085201- NIH PI: Ruaño 5/1/2011- 4/31/2014

SINM IIb: System For DNA-Guided Optimization And Personalization Of Statin Therapy

Project #: 1R01HL098085-01 – NHLBI PI: BParker 3/01/2010 – 4/31/2014

The Effect of High-Dose Atorvastatin on Neuronal Activity and Cognition in Humans
The major goal of this study is to investigate the effects of atorvastatin therapy on neuronal activation and cognition in healthy adults.

Project #: RC1AT005836-01(RFA-OD-09-003) – NIH-NCCAM PI: PDThompson 9/30/2009 - 9/29/2012

Coenzyme Q10 in Statin Myopathy
The major goals of this project are to examine the effects of Coenzyme Q10 supplementation on severity of muscle myopathy in patients with statin-associated myalgia.

Project #: 1 R01 HL081893-01A1 NIH/NHLBI PI: PDThompson 6/1/2007 – 5/31/2011

The Effect of Statins on Skeletal Muscle Function
The major goals of this project are to determine the incidence of statin-induced myalgia and the effects of statins on skeletal muscle strength, endurance, and aerobic exercise performance.

Project #: ETC1002-006- Esperion Therapeutics PI: PDThompson 10/30/2012- 7/31/13

A Placebo-Controlled, Randomized, Double-Blind, Parallel Group, Multicenter Study to Evaluate the Efficacy and Safety of ETC-1002 in Subjects With Hypercholesterolemia and a History of Statin Intolerance.

Project #: BC22140 - Hoffman-La Roche, Inc. PI: PDThompson 4/25/2010- 4/25/2014

Alecardio: Cardiovascular Outcomes Study to Evaluate the Potential of Aleglitazar to Reduce Cardiovascular Risk in Patients with a Recent Acute Coronary Syndrome (ACS) Event and Type 2 Diabetes

CAROLYN M. TRANTALIS, RN, MSN

carolyn.trantalis@hhchealth.org

PROFILE

Enterprise thinking, strategically oriented and innovative leader who is results-focused with a strong record of change leadership and managerial courage.

ACADEMIC PREPARATION

University of Hartford
Hartford, Connecticut
Masters of Science Degree in Nursing Management: May 2005. Focus of study related to public policy with a graduate practicum at the Connecticut Department of Public Health's Licensing Bureau.

Western Connecticut State University
Danbury, Connecticut
Bachelors of Science Degree in Nursing: May 1986

Licensure
State of Connecticut E49594, July 1986

PROFESSIONAL EXPERIENCE

Hartford Healthcare
Windham and Backus Hospitals, East Region
Willimantic and Norwich, Connecticut

June 2015- Present — Regional Vice President of Operations and Clinical Services

Accountable for the integration of clinical services with other regional departments and system service lines to improve culture, engagement, quality, patient safety, customer experience, and High Reliability from the hospital frontlines to community-based ambulatory settings.

- Transition 130 groups from monthly to daily How Hartford Healthcare Works (H3W) performance improvement model
- Implement Windham Hospital transition to Cornerstone Services
- CareConnect: successful testing and implementation of EPIC
- Improve Length of Stay through interdisciplinary rounds and just-in-time data collection
- Improve VTE rates through interdisciplinary process change

August 2013-June 2015 — Regional Vice President of Operations

Responsible for the cultural and operational integration of Backus Hospital into Hartford Healthcare.

- Integration of Backus into HHC
- HHC Thrive – reduce the cost structure
- Regional PRC and OPS Council
- MSK Affiliation (2014) – customers to clinical trials, increase standards; COC accreditation for Windham Hospital
- Regional rollout H3W work groups, H3W leadership behaviors, HRO
- Thrive – 10%
- Develop Windham Hospital transition to Cornerstone Services
- Hand washing
- Teleneurology
- Recruitment

Windham Hospital
Willimantic, Connecticut
A partner in Hartford Healthcare Corporation, Windham Hospital is a 130 bed not-for-profit acute care community hospital that provides comprehensive medical services to a 19 town service area

April 2011- August 2013 Vice President of Operations

Accountable for strategic development ,maintaining a culture of excellence, and overall operations including Process Improvement, Medical Staff Support, Physician Recruitment & Relations, Imaging, Cardiopulmonary, Oncology, Pharmacy, Lab, Physical Medicine, Prenatal Clinic, School-Based Health Clinics, Food & Nutrition, Plant Operations, Safety & Security, and Environmental Services. As an Executive Team member, responsible for the strategic and long-range planning of the organization, allocation of human, material, and financial resources, service excellence, fiscal performance, and quality of clinical practice.

- Recruited primary care, cardiology, OB/GYN, and Rheumatology physicians to meet strategic market needs
- Implemented internal Hospitalist program
- Opened centers for Physical Therapy, Mammography, and Surgical Clinic
- Executed & sustained a culture of staff engagement and performance improvement
- Implemented a unified approach to cancer services obtaining NAPBC accreditation with 100% of breast cancer patients being offered navigation and 100% of new breast cancer cases being prospectively reviewed in multidisciplinary cases conferences.

June 2007-April 2011 Vice President of Patient Care Services

Responsible for strategic development, and overall operations of the Patient Care Division including Nursing, Imaging, Cardiopulmonary, Oncology, Pharmacy, Lab, Physical Medicine, School-Based Health Clinics, and Paramedic Services. As an Executive Team member, responsible for the allocation of human, material, and financial resources, service excellence, fiscal performance, and quality of clinical practice. As Chief Nurse Executive, responsible for setting evidenced-based standards of nursing practice and patient care.

- Recruited and stabilized high performing Nurse Leader Team
- Maintained low RN vacancy rates: 1.5 – 0.75%
- Successful bargaining unit negotiations for Nursing and Support Services
- Outstanding results for 2 consecutive Joint Commission surveys
- Maintained top decile performance in composite CORE Measures
- ED Door to Provider in 30 minutes at greater than 85%
- ED ranked at 99th percentile for Connecticut by Press Ganey
- 2010 no hospital acquired pressure ulcers
- 2010 no hospital acquired central line infections
- Reduced & maintained monthly labor productivity FTE variance from 33 to 13

February 2006-June 2007 Director of Outpatient Services

Accountable for planning, organizing and directing all activities for the Emergency Department, Operating Room, Post Anesthesia Care Unit, Ambulatory Care Unit, Central Processing Department, and Pain Management Clinic

- Directed the completion of the 22 bed Jeffrey P. Ossen Emergency Department
- Revised staffing plans to maintain efficient staffing levels to ensure safe continuity of care while maintaining established budgetary guidelines
- Implemented Empower electronic medical record for the ED
- Instituted OR equipment reprocessing program with significant decrease in operational costs
- Developed strategies for labor efficiencies in OR and Pain Management
- Collaborated with Finance on ED, OR, and ACU coding and charging revisions

Hartford Hospital, Hartford, Connecticut
An 800 bed major teaching hospital providing tertiary care to the city of Hartford and surrounding suburbs.

November 2001-February 2006 Emergency Department Nurse Manager

Responsible for the 24-hour operations of a 60-bed Emergency Department with greater than 80,000 patient visits per year and 200 staff.

- Maintained accreditation as a Level I Trauma, Stroke, and Chest Pain Center
- Developed and implemented Computerized Provider Order Entry and Electronic Medication Administration Record
- Implemented multi-disciplinary trauma rounds
- Obtained Magnet status: voting member of Shared Governance Operations Council, Co-chair of Shared Governance Human Resource Subgroup, and Co-chair of Nurse Manager Leadership Development Committee
- Emergency Department APC and Revenue Enhancement Taskforce: 31% improvement in department revenue generation

July 1986 to November 2001 Staff Nurse - Clinical Leader

- Primary Nurse in an acute care medical/surgical and critical care setting
- Charge Nurse in Level I Trauma Center Emergency Department
- Team Leader for Emergency Department Redesign Project:

PROFESSIONAL ASSOCIATIONS

Committee on Human Resources of the Connecticut Hospital Association Board of Trustees
Sub-committee on Diversity and Cultural Competence- Connecticut Hospital Association
Organization of Nurse Executives- Connecticut : Secretary January 2010 to January 2013
American Organization of Nurse Executives
Sigma Theta Tau, Iota Upsilon-At-Large Chapter
Connecticut Nurses Association
American Nurse Association
Site Preceptor Boston University Masters of Public Health
Site Preceptor University of Hartford Masters of Science in Nursing Management

ACHIEVEMENTS

Recipient of Nightingale Award for Excellence in Nursing 2007
Recognized as Patriotic Employer by National Committee for Employer Support of the Guard and Reserve

REFERENCES

Furnished upon request

David A. Whitehead

Highlights

High-energy hospital administrator with extensive healthcare experience in leading strategic development of health care services to achieve mission accountability. Demonstrated talent for leadership, consensus building and team building, developing rapport and alignment with physicians, clinicians and support staff, with a proven ability to manage large and complex projects. Committed to the use of high reliability science in reducing harm to patients, staff and visitors.

Professional Experience

HARTFORD HEALTHCARE, Hartford, CT — August 2013 - Present

Hartford HealthCare (HHC) *aspires to be the next generation of integrated health systems, marked by strong patient focus, heightened efficiency, consistent quality performance and open, collaborative sharing of best practices. It is dedicated to providing patients with an exceptional, coordinated care experience and a single, high standard of service. A hallmark of HHC's vision is to strengthen access to care close to home for patients by enhancing local healthcare delivery capabilities.*

President, Hartford HealthCare East Region

Leads the integrated health care delivery system for Hartford HealthCare's East Region, comprised of Backus and Windham Hospitals, as well as the ambulatory and integrated services delivered within the region. Responsible for executive oversight of Clinical Lab Partners an independent, full-service clinical laboratory providing a broad range of lab services to private physician practices, nursing homes, hospitals, municipalities, industries and managed care organizations including two primary hospital sites - Hartford Hospital and MidState Medical Center, and 80 patient service centers throughout Connecticut.

Senior Vice President, Business and Ambulatory Network Development

Leads system-wide business development processes through the strategic integration and growth of an ambulatory services network across the full continuum of care.

WINDHAM HOSPITAL, Willimantic, CT — August 2013 - Present

The 130-bed acute care hospital has served 19 communities in Eastern CT for nearly 80 years. With a staff of more than 800 committed to excellence in quality and service for the region, Windham boasts a state-of-the-art Emergency Department that consistently ranks in the highest percentiles of customer satisfaction. The hospital also offers convenient and modern satellite services including two Physical Therapy and Rehabilitation Clinics and a Center for Women's Health offering mammography, bone density and integrative health.

President and Chief Executive Officer (August 2013 – Present)

BACKUS CORPORATION and
THE WILLIAM W. BACKUS HOSPITAL, Norwich, CT — 1999 - Present

The 200-bed, not-for-profit, acute care community Hospital is the primary source of health services for nearly a quarter-million people. Since its founding in 1893, Backus Hospital has continually expanded, providing new programs and services and forming strategic alliances with other healthcare organizations and providers. Backus is the only state-designated trauma center east of the Connecticut River, and it is the only regional facility that can receive, via air medical transport helicopter, patients with severe traumatic injuries.

President and Chief Executive Officer (July 2009 – Present)

Vice President, Strategic Planning (2003 – July 2009)
Lead the full planning spectrum for the Hospital and subsidiary health care service corporations to achieve Board-approved strategic initiatives through capital, clinical, financial, facility and operational business plan development and implementation. Provide leadership oversight for the efforts of the Corporate Communications Division, which implements market development, community health coordination and programming, customer service, Foundation operations, government relations and patient experience efforts.

Philanthropic Development Officer (1999 – 2009)
Lead the Corporation's non-profit Foundation through active fundraising and philanthropic development for the purposes of providing health care resources for the direct benefit of the Hospital and community, and through external affiliations with other providers.

Administrator, CONNCare, Inc. (Backus Health Care, Inc.) (2004 – 2009)
Executive leader for the organization's subsidiary healthcare corporation, which provides occupational health services, a network of urgent/primary care health centers, non-hospital-based joint ventures and affiliations and an affiliated multi-specialty surgical practice.

Vice President, Corporate Communications (1999 – 2003)
Led all corporate communications activities including public relations, marketing communications, development and maintenance of Intranet and Internet web sites, publishing of a monthly health magazine, weekly development of an in-house newsletter and development of all constituency communications.

GANNETT CO., INC. 1989 - 1999
President and Publisher, Norwich (CT) Bulletin
President and Publisher, Marietta (OH) Times; Mid-Ohio Valley Color Printing Inc.
Director of Market Development, Norwich (CT) Bulletin
Director of Human Resources, Norwich (CT) Bulletin

GENERAL DYNAMICS, ELECTRIC BOAT DIVISION 1982 – 1989
Supervisor of Personnel (final position)

Education

University of New Haven, New Haven, CT
Master of Healthcare Administration
Master of Science, Labor Relations

Eastern Connecticut State University, Willimantic, CT
Bachelor of Science, Business Administration

Professional Affiliations

Member, American College of Healthcare Executives	2003 - Present
Member, Society for Healthcare Strategy and Market Development	2003 - Present
Member, Advisory Board – Marketing and Planning Leadership Council	1999 - Present
Delegate, American Hospital Association Regional Policy Board	2013 - Present
Vice Chair, Connecticut Hospital Association	2014 - Present
Treasurer, Connecticut Hospital Association	2011 – 2014
Chair, Connecticut Hospital Association Financial Oversight Committee	2011 - Present
Director, Connecticut Hospital Association	2010 - Present

Member, Connecticut Hospital Association Committee on Government 2000 - Present

Community Leadership

Chair, Chamber of Commerce of Eastern Connecticut
Chair, United Way of Southeastern Connecticut
Chair, Norwich Free Academy Board of Trustees
President, Eastern Connecticut Community Foundation
*Trustee, Chamber of Commerce of Eastern Connecticut
* Director, Eastern Connecticut State University Foundation
Director, Hospice Southeastern Connecticut
Director, Three Rivers Community College Foundation
*Corporator, Chelsea-Groton Savings Bank
*Corporator, Dime Bank
*Corporator, Norwich Free Academy

** denotes current participation*

Recognition

2003 Eastern Connecticut Citizen of the Year
1997 Eastern Connecticut Chamber of Commerce Community Spirit Award
1996 Gannett Spotlight on Service Award
1994 Gannett President's Ring recipient for Publishing Leadership
1993 Newspaper Personnel Relations Association Publications Award: *Pay for Performance – A Manager's Guide to Salary Administration*
1991 and 1992 Gannett President's Ring recipient for Human Resource Leadership

EXHIBIT 7

John Michael Sycip Chua Chiaco

General/Interventional Cardiology, Norwich Cardiac Medicine

Current Training
07/14 – 06/15
Dartmouth Hitchcock Interventional Cardiology Fellowship

Fellowship Training
07/11 – 06/14
University of Hawaii Cardiovascular Disease Fellowship Program
3rd Year Chief Fellow

Residency Training
07/08 – 06/11
Grand Rapids Medical Education and Research Center, Grand Rapids, Michigan (Internal Medicine)
3rd Year Chief Resident

Medical Education
University of the Philippines, Manila
06/01 - 04/06
M.D., 04/06

Undergraduate - Ateneo de Manila University, Katipunan Avenue, Loyola Heights, Quezon City, Philippines
BS Biology
06/97 - 03/01

Examinations
USMLE Step 3 (95%) 01/10
USMLE Step 2 CK (Clinical Knowledge) (92%) 07/07
USMLE Step 2 CS (Clinical Skills) (Pass) 08/07
USMLE Step 1 (93%): 3/07
ABIM Internal Medicine (11/11)
ABIM Cardiovascular Disease (01/15)

Medical School Honors / Awards
- Outstanding Intern in Ophthalmology & Rehabilitation Medicine
- Dr. Gregorio T. Alvior Foundation Best Research Paper (1st Place) - "A Preliminary Determination of the Antimalarial Property of Mimosa pudica..." College of Medicine, UP Manila, March 2002
- Dr. Gregorio T. Alvior Foundation Best Research Paper (2nd Place) - "Correlation of Calcium Intake with 24-hour Urinary Calcium Excretion and First Morning Urinary Calcium-Creatinine Ratios in Filipinos..." College of Medicine, UP Manila, March 2002

Publications
John Michael S Chua Chiaco, Univ of Hawaii, Honolulu, HI; David Fergusson, Honolulu, HI ; Nisha Parikh, Univ of Hawaii, Honolulu, HI. *The Jugular Venous Pressure Revisited.* Cleveland Clinic Journal of Medicine. 2013 Oct; 80 (10); 638-44.

Masayuki Nogi, Univ of Hawaii, Honolulu, HI; David Fergusson, Queen's Medical Center, Honolulu, HI; John Michael S Chua Chiaco, Univ of Hawaii, Honolulu, HI. *Mid-Ventricular Variant Takotsubo Cardiomyopathy Associated with Cannabinoid Hyperemesis Syndrome: A Case Report.* Hawai'I Journal of Medicine & Public Health. 2014 April; 73 (4); 115-118.

John Michael S Chua Chiaco, Univ of Hawaii, Honolulu, HI; Robert Wolf, Sharon-Lise Normand, Harvard Medical

Sch, Boston, MA; Eric Rosenthal, Murray Mittleman, Beth Israel Deaconess Medical Ctr, Boston, MA; Joseph Carrozza Jr., Tufts St. Elizabeth's Medical Ctr, Brighton, MA; Ann Lovett, Dept of Healthcare Policy, Boston, MA; Kalon Ho, Beth Israel Deaconess Medical Ctr, Boston, MA; Nisha Parikh, Univ of Hawaii, Honolulu, HI. *Association Between Coronary Arterial Dominance and Mortality in Patients with Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention*, American Heart Association Scientific Sessions 2012, Los Angeles (manuscript in progress)

Oral Presentations

John Michael S Chua Chiaco, Univ of Hawaii, Honolulu, HI; Robert Wolf, Sharon-Lise Normand, Harvard Medical Sch, Boston, MA; Eric Rosenthal, Murray Mittleman, Beth Israel Deaconess Medical Ctr, Boston, MA; Joseph Carrozza Jr., Tufts St. Elizabeth's Medical Ctr, Brighton, MA; Ann Lovett, Dept of Healthcare Policy, Boston, MA; Kalon Ho, Beth Israel Deaconess Medical Ctr, Boston, MA; Nisha Parikh, Univ of Hawaii, Honolulu, HI. *Association Between Coronary Arterial Dominance and Mortality in Patients with Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention*, American Heart Association Scientific Sessions 2012, Los Angeles

Chua Chiaco, J.. (2010, April). *Radiation-Induced Valvular Disease*. Presentation presented at DeVos Place Convention Center, GRMERC Research Day; Grand Rapids, MI. (2nd place, case presentations)

Chua Chiaco, J.. (2009, April). *A Case of Fully Acquired Lutembacher Syndrome*. Oral Presentation presented at DeVos Place Convention Center, GRMERC Research Day; Grand Rapids, MI.

Abes, F., Alcaraz, J., Aujero, H., Bacalzo, K., Bermejo M., Cabuslay, R. Chua Chiaco, J. DelaSena C., Dumbrique L., Gaddi, A., Gozon, M., Laus, A., Lladoc, T., Malaluan, P., Mejia, O., Murakami, C., Ngalob, Q., Puzon, A., Sali, S., Santos, M., Suarez, A.. (2002, March). *Glycemic Index and Variations in the Blood Glucose Response Curves to Two Varieties of Pinawa, Polished Rice, and Oats in Normal Individuals*. Oral Presentation presented at: Department of Physiology Annual Presentation, University of the Philippines; Metro Manila Manila, Philippines.

Abes, F., Alcaraz, J., Aujero, H., Bacalzo, K., Bermejo M., Cabuslay, R. Chua Chiaco, J. DelaSena C., Dumbrique L., Gaddi, A., Gozon, M., Laus, A., Lladoc, T., Malaluan, P., Mejia, O., Murakami, C., Ngalob, Q., Puzon, A., Sali, S., Santos, M., Suarez, A.. (2002, March). *A Preliminary Determination of Antimalarial Property of Mimosa pudica L. using Plasmodium berghei Mouse Model.*. Oral Presentation presented at: Department of Pharmacology Annual Presentation, University of the Philippines; Metro Manila, Philippines.

Hobbies & Interests

Martial Arts (Aikido, Katori Shinto Ryu, Judo), Wall Climbing, Computer Enthusiast with limited programming and hardware assembly experience, Hiking, Leisurely reading

Language Fluency (Other than English)

Filipino / Tagalog

Other Awards/Accomplishments

- 1st Degree Black Belt (Yudansha) in Aikido (instructor from 1995 – 2000)
- Honorable Mention, Ateneo de Manila University (2001)

CURRICULUM VITAE

FRANCIS J. KIERNAN, M.D.

Address:

Hartford Hospital
Cardiac Laboratory
80 Seymour Street
Hartford, CT 06102-5037
Tel: (860) 972-2975
Fax: (860) 545-3557
Email: francis.kiernan@hhchealth.org

Education:

College:

Bachelor of Science with High Distinction
Worcester Polytechnic Institute
Worcester, Massachusetts (1975)
Salisbury Prize (1975)
Tau Beta Pi (1974)

Medical School:

Doctor of Medicine
University of Connecticut
School of Medicine
Farmington, CT (1979)

Post Doctural Training:

Internship:

Intern in Medicine
Hartford Hospital
Hartford, CT (1979-1980)

Residency:

Resident in Medicine
Hartford Hospital
Hartford, CT (1980-1982)

Fellowship:

Fellow in Cardiology
Hartford Hospital
Hartford, CT (1982-1985)

Board Certification:

National Board of Medical Examiners 7/1/80
American Board of Internal Medicine 9/15/82 (valid indefinitely)

Subspecialty Certification: Cardiovascular Diseases 11/20/85 (valid indefinitely)
Interventional Cardiology 12/2009 (valid through 2019)

Present Position:
Director
Cardiac Laboratory
Hartford Hospital
Hartford, CT

Hospital Appointment:
Senior Staff
Department of Medicine
Hartford Hospital
Hartford, CT

Academic Appointment:
Associate Clinical Professor
Program Director, Interventional Cardiology Fellowship
Department of Medicine
University of Connecticut
School of Medicine
Farmington, CT

Professional Organizations:
American College of Cardiology, Fellow, 1987
Society for Cardiac Angiography and Interventions, Fellow, 1994
American Heart Association, Council on Clinical Cardiology
Hartford County Medical Association, Member, 1987
American Medical Association, Member, 1987

Medical Licensure: State of Connecticut, 1981

Publications:

Articles:

Palek J, Kiernan FJ et al: Effect of Procaine HCL on ATP; Calcium dependent alternation in red cell, shape and deformability. Blood 50: 155,1977.

Keating HJ, Klimek JJ, Levine DS, Kiernan FJ: Effects on aging on the clinical significance of fever in ambulatory adult patients. Journal of the American Geriatrics Society 32: 282,1984.

Kiernan FJ, Kluger J, Regnier J., Rutkowski M., Fieldman A: Epoprostenol sodium (Prostacyclin) infusion in acute myocardial infarction. British Heart Journal 56: 428,1986.

Fram DB, Gillam LD, Aretz TA, Tangco RV, Mitchel JF, Fisher JP, Sanzobrino BW, Kiernan FJ, Niklasson S, Fieldman A., McKay RG: Low Pressure Radiofrequency Balloon Angioplasty: Evaluation in Porcine Peripheral Arteries. JACC 21: 1512-1521. 1993.

Mckay RG, Fram DB, Hirst JA, Kiernan FJ, Primiano CA, Rinaldi MJ, Azrin MA, Mitchel JF, Waters DA: Treatment of Intracoronary Thrombus with Local Urokinase Infusion Using a New, Site-Specific Drug Delivery System: The Dispatch Catheter. Cathet Cardiovasc Diagn 33:181-188. 1994.

Glazier JJ, Bauer HH, Kiernan FJ, Primiano CA, Mitchel JF, Dougherty JE, Waters DD, Mckay RG: Recanalization of Totally Occluded Saphaneous Vein Grafts Using Local delivery with the Dispatch Catheter. Cathet Cardiovasc Diagn 36:326-332. 1995

Waters D, Kiernan F: The Abuse of Cardiovascular Procedures. Connecticut Medicine 61:259-262. 1997

Azar RR, McKay RG, Kiernan FJ, Seecharran B, Feng Y, Fram DB, Wu A, Waters DD: Coronary Angioplasty Induces a Systemic Inflammatory Response. Am J Card 80:1476-1478. 1997.

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Giri S, Thompson PD, Kiernan FJ, Clive J, Fram DB, Mitchel JF, Hirst JA, McKay RG, Waters DD. Clinical and Angiographic Characteristics of Exertion-Related Acute Myocardial Infarction. JAMA 282:1731-1736: 1999.

Mitchel JF, Fram DB, Gillam LD, Waters DD, Kiernan FJ. Enhanced local intracoronary delivery of heparin with the Infiltrator catheter: A comparative study. J Invasive Cardiol. Aug;11(8):463-70.1999.

Azar RR, Waters DD, McKay RF, Giri S, Hirst JA, Mitchel JF, Fram DB, Kiernan FJ. Short-and Medium-Term Outcome Differences in Women and Men After Primary Percutaneous Transluminal Mechanical Revascularization for Acute Myocardial Infarction. AJC 85:675-679. 2000.

Azar RR, Aoun G, Fram DF, Waters DD, Wu AHB, Kiernan FJ. Relation of C-Reactive Protein to Extent and Severity of Coronary Narrowing in Patients with Stable Angina Pectoris or Abnormal Exercise Tests. AJC 86:205-207. 2000.

Giri S, Mitchel JF, Hirst JA, McKay RG, Azar RR, Mennett R, Waters DD, Kiernan FJ. Synergy Between Intracoronary Stenting and Abciximab in Improving Angiographic and Clinical Outcomes of Primary Angioplasty in Acute Myocardial Infarction. AJC 86:269.2000.

Azar RR, Prpic R, Kalon KL, Kiernan FJ, Shubrooks SJ, Baim DS, Popma JJ, Kuntz RE, Cohen DJ. Impact on End-Stage Renal Disease In Clinical and Angiographic Outcomes After Coronary Stenting. AJC 86:485. 2000.

Fram DB, Giri S, Jamil G, Mitchel J, Boden WE, Din S, Kiernan FJ. Suture Closure of the Femoral Arteriotomy Following Invasive Cardiac Procedures: A Detailed Analyisis of Efficacy, Complications, and the Impact of Early Ambulation in 1200 Consecutive, Unselected Cases. Cathet Cardiovasc Interventions 53:163. 2001.

Giri S, Mitchel J. Azar RR, Kiernan FJ, Fram DB, McKay RG, Mennett R, Clive J, Hirst JA. Results of Primary Percutaneous Transluminal Coronary Angioplasty plus Abciximab With or Without Stenting for Acute Myocardial Infarction Completed by Cardiogenic Shock. AJC. 89:126.2002.

Velusamy M, Fisherkeller M, Keenan ME, Kiernan FJ, Fram DB. Spontaneous Coronary Dissection in a young woman precipitated by Retching. J Invasive Cardiol. 14(4):198-201. 2002

Fram DB, Azar RR, Ahlberg AW, Gillam LD, Mitchel JF, Kiernan FJ, Hirst JA, Mather JF, Ficaro E, Cyr G, Heller GV. Duration of Abnormal SPECT Myocardial Perfusion Imaging Following Resolution Of Acute Ischemia: an Angioplasty Model. J Am Coll Cardiol 41(3) 452-9.2003.

Silverman IE, Kiernan FJ, Kelsey AM, Brackoniecki JJ, Kazi FA, Dougherty JE, Boden WE, McKay RG. Initial Experience with a Transcatheter Septal Closure System for Secondary Stroke Prevention In Patients with Interatrial Septal Defects. Conn Med. 67(3):135-44. 2003.

Katsenos MC, Jere C., Kiernan FJ, McKay R, Mangion J, Kudler A, Werner M. Recurrent Cerebral Ischemia and Platypnea-orthdeoxia Syndrome. Am J Geriatr Cardiol. 14(4):210-3.2005.

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Thompson PD, Kiernan F. Prevention of Heart Disease in Female Athletes. Med Sci Sports Exerc. 37(8):1440-3.2005.

Kapetanopoulos A, Peckham G, Kiernan FJ, Clyne C, Kluger J, Migeed MA. Implantation of a Biventricular Pacing and Defibrillator Device via a Persistent Left Superior Vena Cava. J Cardiovasc Med. 7(6):430-3. 2006.

Elkoustaf RA, Mamkin I, Mather JF, Murphy D, Hirst JA, Kiernan FJ, McKay RG. Comparison of Results of Percutaneous Coronary Intervention for non--ST-elevation Acute Myocardial Infarction or Unstable Angina Pectoris in Men versus Women. Am J Cardiol. 98(2): 182-6. 2006.

Mamkin I, Elkoustaf RA, Zhang Q, Mather JF, Kiernan FJ, Mckay RG. Drug-eluting Stent Implantation Results in Effective Treatment of Small Coronary Artery Disease (Desire Small CAD). Connecticut Medicine. 71 (9): 517-22. 2007.

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Mckay RG, Murphy DJ, Cloutier J, Mather JF, Mennett RA, Dada MR, Shar AR, Kiernan FJ. Long-Term Efficacy and Safety of Sirolimus-Eluting vs. Bare-Metal Stents. Connecticut Medicine. 72 (8): 453-63. 2008.

Dada MR, Hirst JA, Kiernan FJ, Smally AJ, Lundbye JB, Thompson PD, McKay RG. Use of Prehospital Electrocardiograms for the Treatment of Patients with ST-Segment Elevation Myocardial Infarction. Connecticut Medicine. 72 (2) 69-72. 2009.

McKay RG, Dada MR, Mather JF, Mennett RR, Murphy DJ, Maloney KW, Hirst JA, Kiernan FJ. Comparison of Outcomes and Safety of "Facilitated" versus Primary Percutaneous Coronary Intervention and Patients with ST-Segment Elevation Myocardial Infarction. American Journal of Cardiology. 103 (3): 316-21. 2009.

Shafi NA, Mckay RG, Kiernan FJ, Silverman IE, Ahlquist M, Silverman IE. Determinants and Clinical Significance of Persistent Residual Shunting in Patients with Percutaneous Patent Foramen Ovale Closure Devices. Int J. Cardiol. 2009.

Jacob JC, Kiernan FJ, Patel N, Rock J, Hammond J, Wemcker D, Lasala AF. SCAD: A Rare Case of Cardiac Arrest in a Young Female. Connecticut Medicine 75 (3) 147-152:2011.

Parker BA, Tschakovsky ME, Augeri AL, Polk DM, Thompson PD, Kiernan FJ. Heterogeneous Vasodilator Pathways Underlie Flow-Mediated Dilation in Men and Women. Am J Physiol Heart Circ Physiol. 2011. 301(3);H1118-H1126. 2011

Azemi, T, Almahasneh F, Elbash F, Cheema M, Divinagracia T, Dougherty J, Kiernan F, Sadiq I. Ultrasound-Assisted Catheter Directed Thrombolytic Therapy for Management of Acute Pulmonary Embolism. Connecticut Medicine 76 (4)197-200. 2012

Margey R, Chamakura S, Siddiqi S, Schilling J, Fram D, Silverman D, Kiernan F. First Experience with Implantation of a Percutaneous Right Ventricular Impella Right Side Percutaneous Support Device has a Bridge to Recovery in Acute Right Ventricular Infarction Complicated by Cardiogenic Shock in the United States. Circ Cardiovasc Interv. 2013. Jun 1; 6(3):e37-8.

Siddiqi, S, Ganga HV, Dhesi P, Azemi T, Chamakura S, Kiernan FJ, Hammond JA, Sadiq IR. Sheath Hemorrhage After Percutaneous Ventricular Assist device Implantion. Connecticut Medicine 78 (4)203-206. 2014

Rizvi AA, Margey R, Kiernan FJ. Patent Foramen Ovale (PFO) Closure to Prevent Recurrent Stroke in a Patient with a Nickel Allergy. Connecticut Medicine 78 (4) 215-219. 2014

Ballard KD, Tschakovsky ME, Zaleski AL, Polk DM, Thompson PD, Kiernan FJ, Parker BA. Redundant Vasodilator Pathways Underlying Radial Artery Flow-Mediated Dilation are Preserved in Healthy Aging. J Aging Res. 2014;2014:876125. Epub 2014 May 21.

Parker MW, Kiernan FJ, Dynamic LVOT Obstruction and Aortic Stenosis in the Same Patient: A Case of Challenging Doppler Hemodynamics. Echocardiography. 2015 Jun; 32(6):1032-2.

EXHIBIT 8

Backus Hospital

A Hartford HealthCare Partner

Percutaneous Coronary Intervention Assessment

September 1, 2015

3d health, inc

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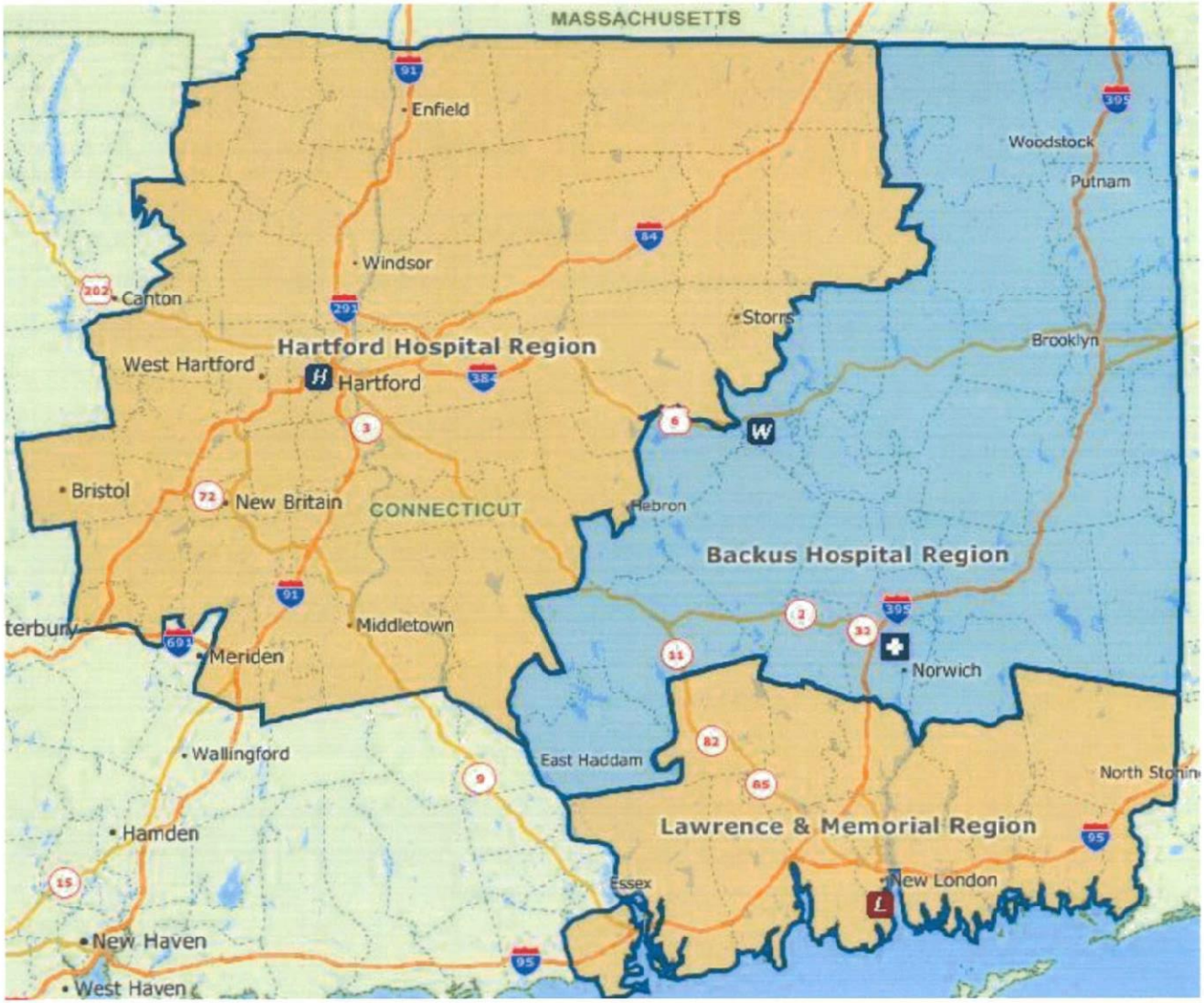
Service Area Definition & Demographics

Defining the Service Area

- In evaluating the potential for Backus to offer a Percutaneous Coronary Intervention ("PCI") program at the Hospital, 3d Health completed an in-depth drive time analysis for all of the towns in Eastern Connecticut.
- Each shaded ZIP code was assigned to the closest potential Connecticut PCI facility. The "Backus Hospital Region" is the defined service area for the analysis.



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Service Area Demographic Estimates

- In order to estimate the current and five-year service area demographics, 3d Health utilized data obtained from The Nielsen Company, the industry leader in estimating demographic data for the past 35 years. In estimating census tract-level demographics, The Nielsen Company's base counts are calculated by utilizing both the 2010 U.S. Census and the annual American Community Survey, also conducted by the U.S. Census Bureau.
- As a point of comparison and to validate The Nielsen Company estimates, 3d Health tested the 2015 Nielsen population for the service area to that of the 2010 U.S. Census as well as the 2014 American Community Survey and found both to have less than one-tenth of a percent variance (the census data from 2010 was lower by 136 residents while the 2014 ACS was higher by 99 residents).
- Upon validating the Nielsen estimates to two other sources of publicly available demographic data, 3d Health decided to utilize The Nielsen Company data in order to have the most current estimates and to best project five-year estimates at the age-gender level.

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The Service Area Includes Over 230,000 Residents

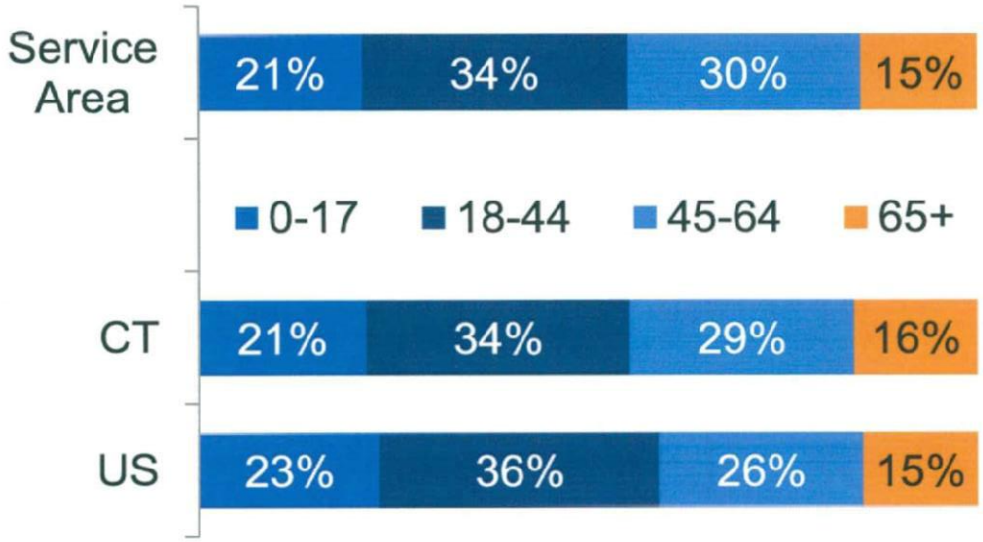
- Over 80% of the service area population lives within 30 minutes of Backus.
- For the remaining 20%, Backus would be the closest potential provider of PCI services in Connecticut.
- Overall, the size of the service area population is expected to remain relatively similar over the next five years.
- That said, the population is forecast to increase 0.2%, or over 800 residents, in the towns around Norwich along State Route 2. These areas account for 40% of the total service area population – or 90,000 residents.

Town / Town Part	2015 Population	2020 Population	Annual Growth
Within 30 Minutes			
Norwich	41,136	41,708	0.3%
Amston	4,271	4,258	(0.1%)
Bozrah	2,911	2,894	(0.1%)
Brooklyn	8,156	8,197	0.1%
Canterbury	5,033	4,965	(0.3%)
Chaplin	2,099	2,036	(0.6%)
Colchester	17,063	17,137	0.1%
Columbia	5,320	5,313	(0.0%)
Franklin	1,969	2,005	0.4%
Griswold-Lisbon	16,272	16,255	(0.0%)
Killingly	18,364	18,089	(0.3%)
Lebanon	7,138	7,075	(0.2%)
Mansfield Center	4,713	4,723	0.0%
Plainfield	14,730	14,700	(0.0%)
Preston	4,708	4,662	(0.2%)
Scotland	157	159	0.3%
Sprague	3,462	3,440	(0.1%)
Sterling	3,081	3,121	0.3%
Voluntown	2,523	2,522	(0.0%)
Windham	26,196	26,266	0.1%
Subtotal	**189,302**	**189,525**	**0.0%**
Outside 30 Minutes			
East Haddam	8,234	8,261	0.1%
Hampton	2,660	2,653	(0.1%)
Pomfret	4,544	4,544	-
Putnam	9,385	9,252	(0.3%)
Thompson	8,650	8,558	(0.2%)
Woodstock	8,644	8,538	(0.2%)
Subtotal	**42,117**	**41,806**	**(0.1%)**
Total Service Area	**231,419**	**231,331**	**(0.0%)**

Note: ZIP Code 06231, Amston, reported separately from the town of Hebron and ZIP Code 06250, Mansfield Center, reported separately from the town of Mansfield

Age and Gender Characteristics of the Population

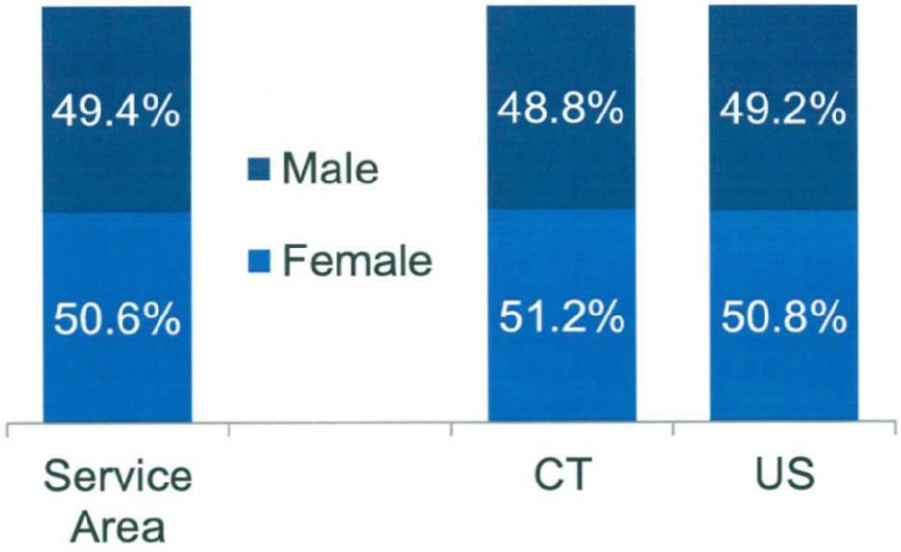
Service Area Age Distribution, 2015



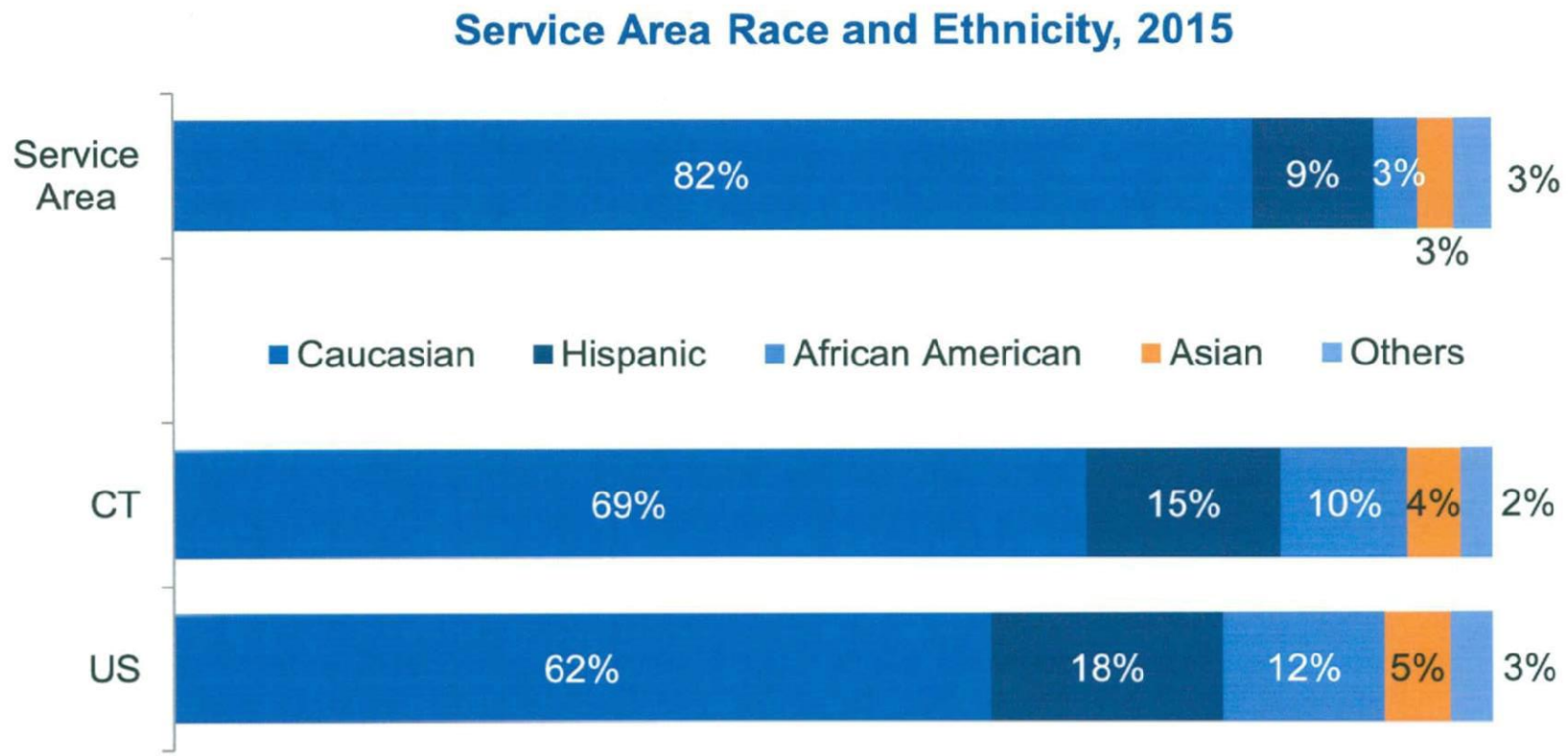
- At 45% of the total population, the service area includes more residents over age 45 than the national average at 41%.

- The gender split within the service area is similar to the state and nation.

Service Area Gender Composition, 2015



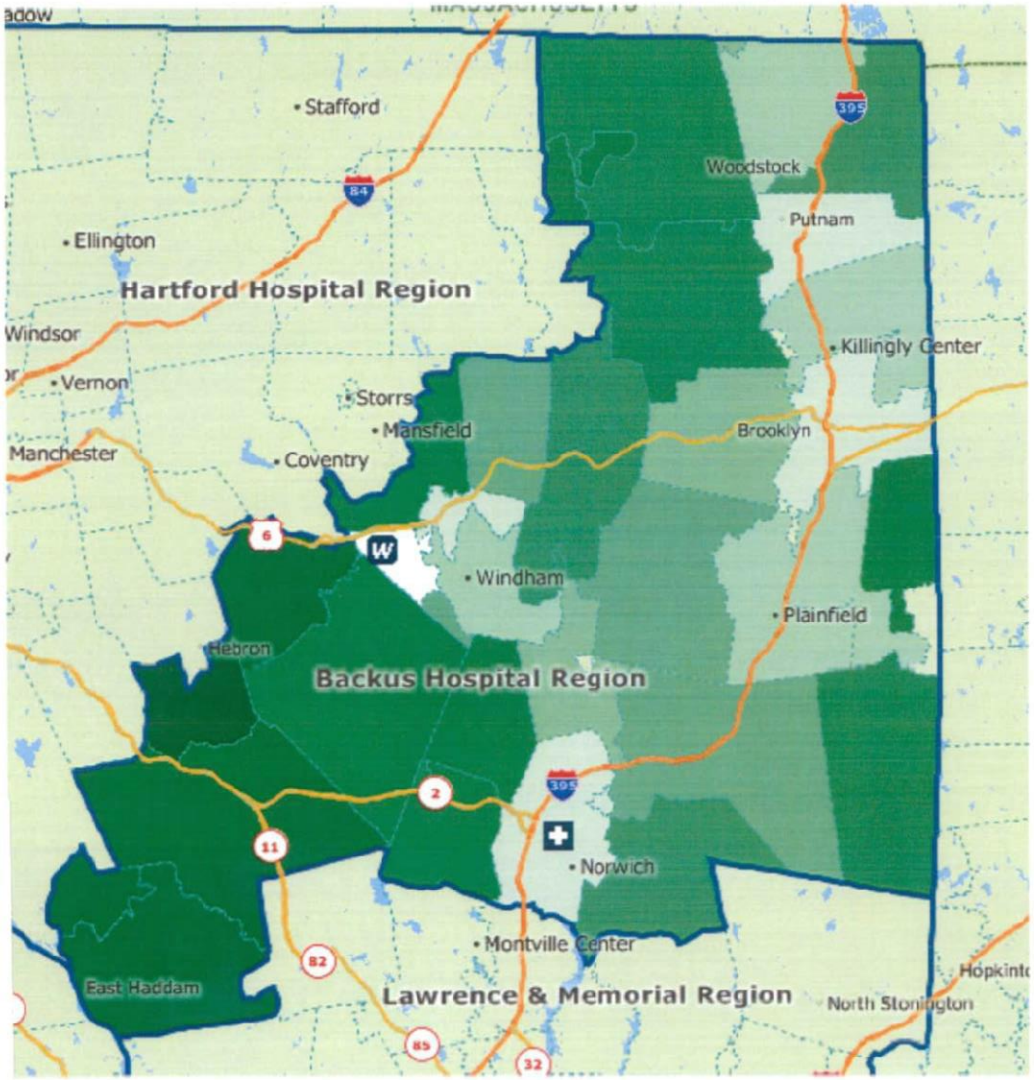
The Service Area Popula ion is Largely Caucasian



- Minority populations make up only 18% of the service area population, compared to 31% in the state and 38% nationally.

Household Income Levels in the Service Area

Median Household Income, 2015



- There are fewer households in the service area with income levels higher than $50,000 (the national median is currently $51,423) compared to Connecticut and the US.
- Median household incomes are higher in the western portion of the service area.

Percent of Households with Income >$50,000	
Service Area	43%
Connecticut	45%
US	51%

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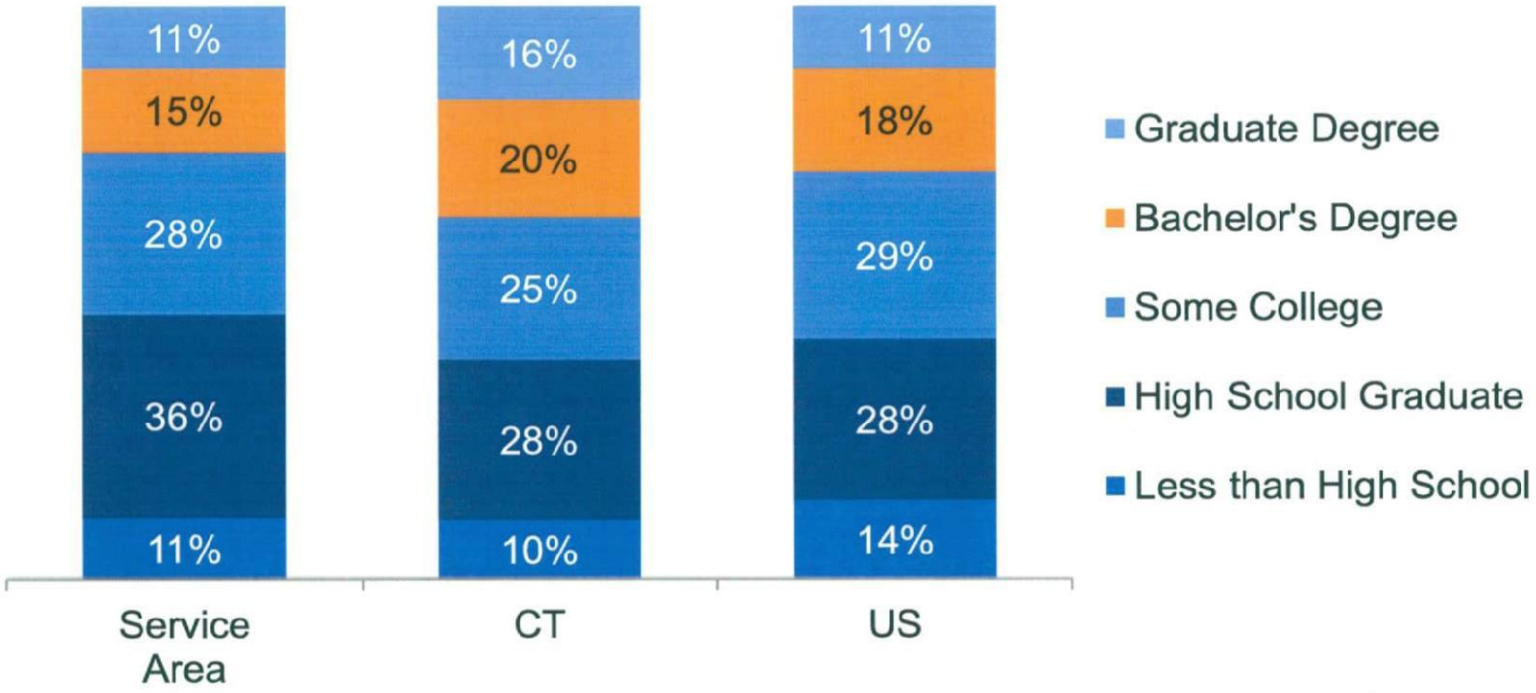
Service Area Educational Levels are Slightly Lower

Educational Attainment Among Residents 25 and Older, 2015



Fewer residents in the service area have completed undergraduate and post-undergraduate degrees – 26% compared to 36% in Connecticut and 29% in the US.

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Market Demand, Volume & Share

Identifying Percutaneous Coronary Intervention Patients

- To complete a PCI volume and market share analysis for the service area, 3d Health analyzed Chime inpatient data for fiscal years 2009 through 2014. 3d Health also collected Massachusetts inpatient data from fiscal year 2012 and extrapolated volumes for FY 2009-11 and FY 2013-14.
- 3d Health also compared certain statistics for the service area and state of Connecticut to data from the National Center for Health Statistics' National Hospital Discharge Survey ("NHDS") for 2010 (the latest available national data).
- To stratify acute coronary syndrome patients, 3d Health used the following "filters" on the inpatient discharge records:
  - Patients were classified by acute myocardial infarction ("MI") type based on ICD-9 diagnosis codes:
    - ✓ STEMI: 410.0x-410.6x, 410.8x-410.9x in any of the first 10 positions
    - ✓ Non-STEMI ("NSTEMI"): 410.7x in any of the first 10 positions
    - ✓ NSTEMI were further classified for initial diagnoses where a Left Bundle Branch Block ("LBBB") was present: 426.2-426.3 in any of the first 10 positions
  - AMI patients were then further segmented based on the intervention performed as detailed by ICD-9 procedure code:
    - ✓ PCI: 00.66, 17.55, 36.06, 36.07, 36.09 in any of the first 10 positions

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Identifying Percutaneous Coronary Intervention Patients

- 3d Health considered any STEMI or acute MI with a new LBBB as a "Primary PCI" case.
- In addition to the CHIME inpatient data, 3d Health utilized Coronary Angioplasty Patient Census Reports from the Connecticut Hospital Association to calculate the percent of total PCI cases that took place in an outpatient setting for 2009 through 2014.
- "Elective PCI" volumes were defined as any PCI that took place in an outpatient setting, plus those performed in an inpatient setting that were not considered a Primary PCI (i.e. NSTEMI or Non-AMI PCI).

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PCI Volumes in the Service Area Have Increased Slightly

PCI Trend within the Service Area

Service Area	FY09	FY10	FY11	FY12	FY13	FY14	Change
Primary PCI							
NSTEMI with New LBBB	2	-	-	4	2	1	(50.0%)
STEMI	100	110	96	98	100	88	(12.0%)
Subtotal, Primary PCI	*102*	*110*	*96*	*102*	*102*	*89*	*(12.7%)*
Elective PCI							
NSTEMI	121	121	109	132	114	115	(5.0%)
Non-AMI	254	271	245	216	197	106	(58.3%)
Outpatient	33	33	38	79	127	204	520.0%
Subtotal, Elective PCI	*408*	*425*	*392*	*427*	*438*	*425*	*4.3%*
Total PCI	**510**	**535**	**488**	**529**	**540**	**514**	**0.9%**

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- Overall, PCI volumes have increased slightly since FY 2009, with a significant shift from the inpatient to the outpatient setting.

Acute MI in he Service Area Has Increased

Acute MI Trend within the Service Area

Service Area	FY09	FY10	FY11	FY12	FY13	FY14	Change
NSTEMI	568	530	558	653	682	747	31.5%
NSTEMI, with New LBBB	8	9	6	17	17	9	12.5%
STEMI	265	237	208	217	214	191	(27.9%)
Total Acute MI	**841**	**776**	**772**	**887**	**913**	**947**	**12.6%**

- Overall, acute MI volumes have increased over 12.6% since FY 2009.
- STEMI volume in the service area dropped sharply between FY 2009 and FY 2011 and remained fairly consistent since then.
- This analysis does not include any potential patients discharged from non-Connecticut and non-Massachusetts hospitals.

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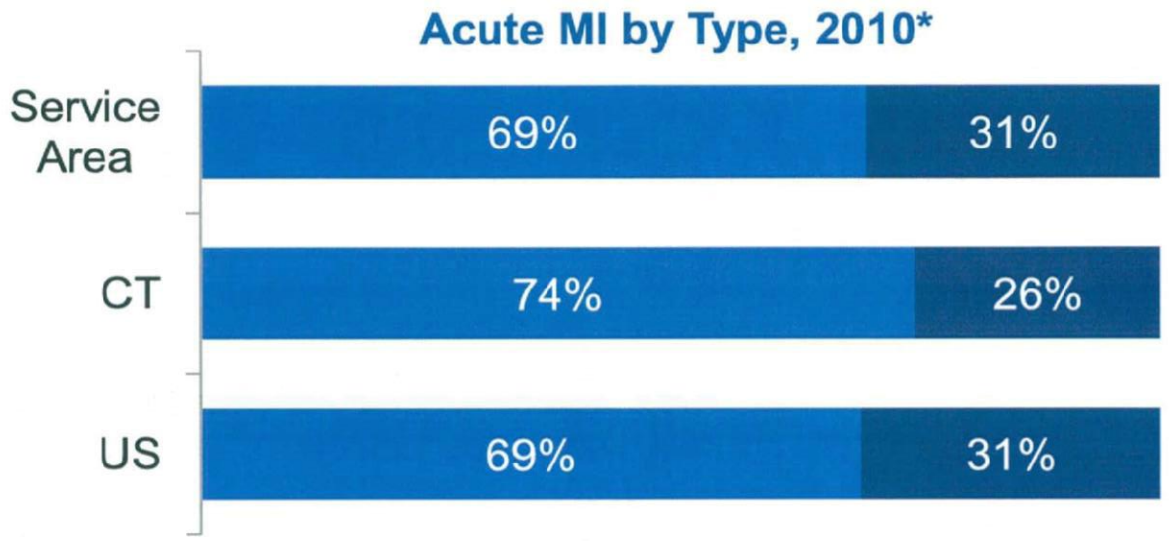
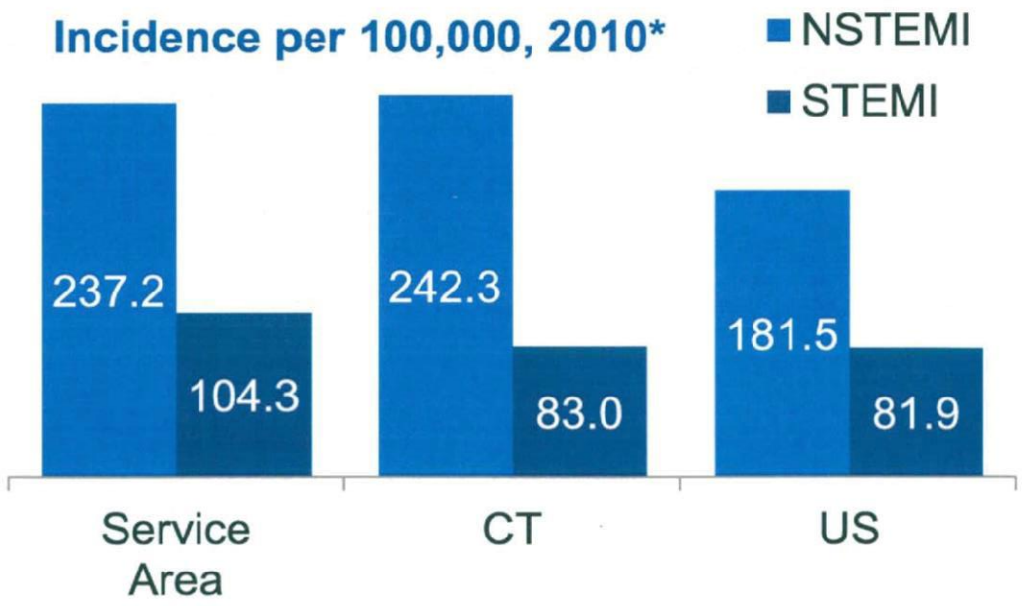
STEMI is More Common in he Service Area

- The STEMI portion of the total acute MI volume in the service area is higher than the Connecticut average, but consistent with the national ratio.
- However, incidence of STEMI per 100,000 population is significantly higher in the service area than in both the state and nation.





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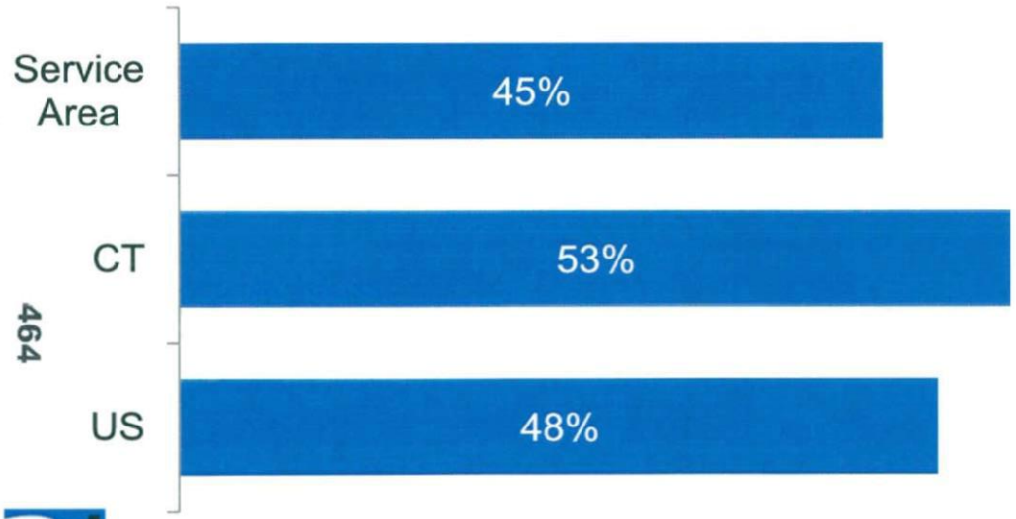
*The latest national data released by the National Center for Health Statistics is from 2010 with no new expected data available until 2016 or later; for consistency purposes, 3d Health compared CT and service area data from FY 2010 to the NHDS data

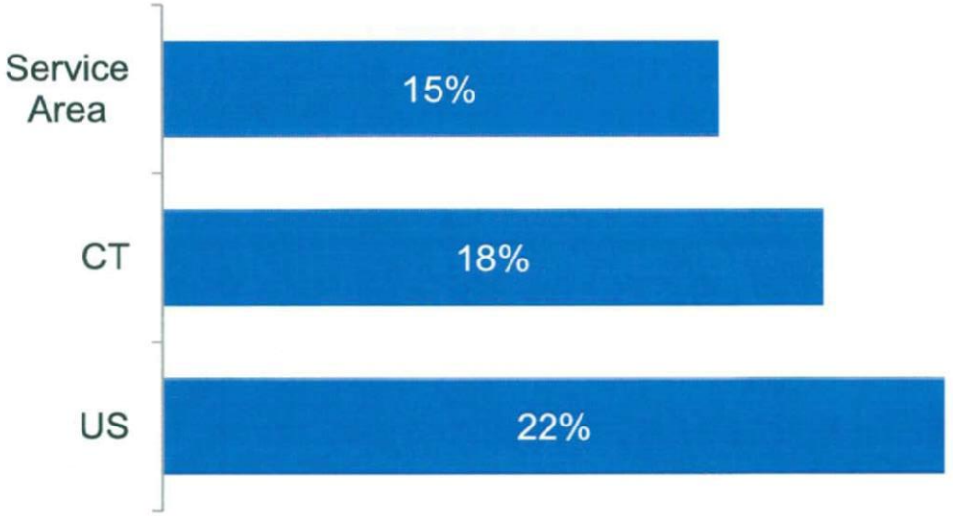
Rate of PCI as an Intervention for AMI Patients

- The rate of Primary PCI as an intervention for patients in the service area is about 18% below the statewide level and 8% below the national level.
- Elective PCI rate of intervention for service area patients is also well below state and national levels at 19% and 41% less, respectively.

Rate of Primary PCI Among STEMI and NSTEMI with New LBBB Patients



Rate of Elective PCI Among NSTEMI Patients



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Service Area Primary PCI by Town

Service Area Primary PCI by Town

Town / Town Part	FY09	FY10	FY11	FY12	FY13	FY14
Within 30 Minutes						
Norwich	18	20	15	17	19	14
Amston	2	2	1	-	1	4
Bozrah	-	3	2	1	2	1
Brooklyn	4	5	7	4	8	5
Canterbury	3	3	1	1	1	1
Chaplin	1	1	2	2	1	1
Colchester	9	7	11	12	1	2
Columbia	-	6	3	3	2	2
Franklin	1	1	-	-	1	1
Griswold-Lisbon	12	7	5	2	8	3
Killingly	11	8	8	9	11	9
Lebanon	1	3	3	3	-	5
Mansfield Center	2	6	-	4	3	3
Plainfield	7	5	9	12	8	9
Preston	1	1	2	2	2	1
Scotland	3	1	-	-	-	1
Sprague	-	1	2	2	1	-
Sterling	1	3	1	1	2	2
Voluntown	-	1	1	1	1	-
Windham	11	13	11	6	12	7
Subtotal	**87**	**97**	**84**	**82**	**84**	**71**
Outside 30 Minutes						
East Haddam	4	2	1	6	4	5
Hampton	-	-	1	3	2	2
Pomfret	2	1	1	1	2	1
Putnam	7	7	7	8	7	8
Thompson	1	1	1	1	1	1
Woodstock	1	2	1	1	2	1
Subtotal	**15**	**13**	**12**	**20**	**18**	**18**
Total Service Area	**102**	**110**	**96**	**102**	**102**	**89**

- Over the past six years, there have been an average of 100 Primary PCI patients from the service area treated at Connecticut or Massachusetts hospitals.
- 84% of this volume originated from towns located within a 30 minute drive time to Backus.
- Larger clusters of Primary PCI cases are strongly correlated with larger population centers. However, incidence rates in general are low for this condition and year-to-year variation in volume by individual town is very common.

Service Area Inpatient Elective PCI by Town

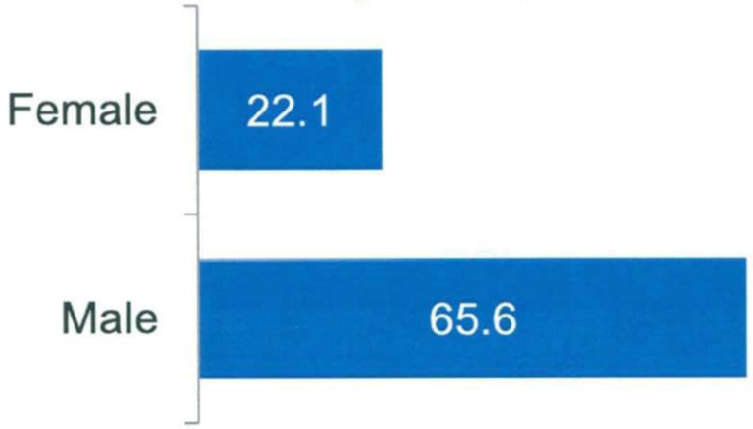
Service Area Inpatient Elective PCI by Town

Town / Town Part	FY09	FY10	FY11	FY12	FY13	FY14
Within 30 Minutes						
Norwich	77	110	72	86	61	41
Amston	4	2	3	-	3	2
Bozrah	11	3	4	2	7	1
Brooklyn	3	7	11	9	10	6
Canterbury	2	7	3	8	9	1
Chaplin	2	1	2	2	3	3
Colchester	26	18	28	17	13	12
Columbia	7	11	5	5	8	3
Franklin	6	3	1	1	5	4
Griswold-Lisbon	39	31	47	34	29	17
Killingly	20	31	25	29	27	23
Lebanon	6	15	6	10	5	9
Mansfield Center	7	7	10	7	4	-
Plainfield	34	25	29	29	28	20
Preston	13	7	9	14	9	5
Scotland	2	1	4	-	2	1
Sprague	6	5	6	3	7	2
Sterling	6	2	2	4	5	5
Voluntown	8	8	5	5	3	3
Windham	37	36	25	26	21	17
Subtotal	**316**	**330**	**297**	**291**	**259**	**175**
Outside 30 Minutes						
East Haddam	12	13	7	8	9	6
Hampton	2	10	4	2	2	2
Pomfret	6	6	8	4	5	5
Putnam	19	17	19	22	18	19
Thompson	12	8	9	11	10	7
Woodstock	9	8	10	10	8	7
Subtotal	**59**	**62**	**57**	**57**	**52**	**46**
Total Service Area	**375**	**392**	**354**	**348**	**311**	**221**

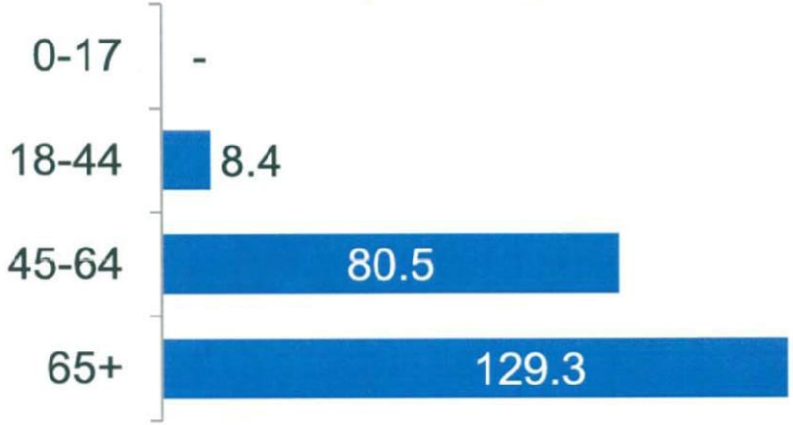
- Similar to Primary PCI volumes, 83% of the service area Inpatient Elective PCI volume treated at Connecticut or Massachusetts hospitals over the past six years originated from towns located within a 30 minute drive time to Backus.
- The number of Elective PCIs performed in an inpatient setting has been steadily decreasing since 2010.

Service Area Incidence of Primary PCI by Cohort

Primary PCI by Gender per 100,000

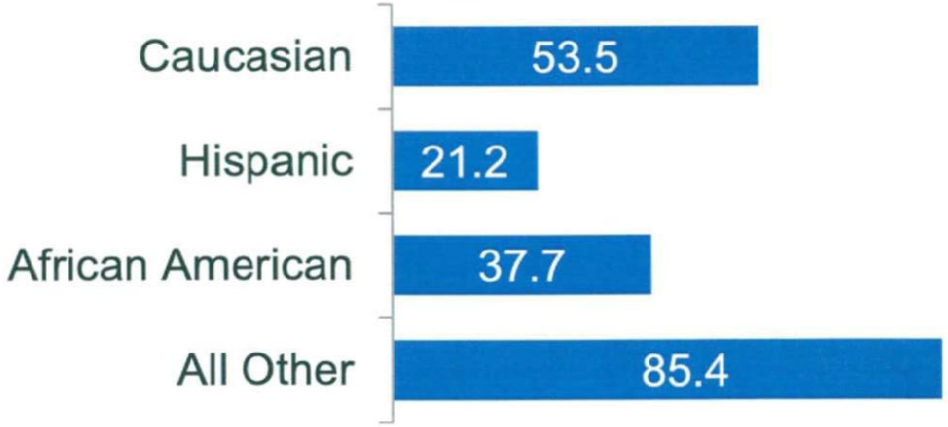


Primary PCI by Age Group per 100,000

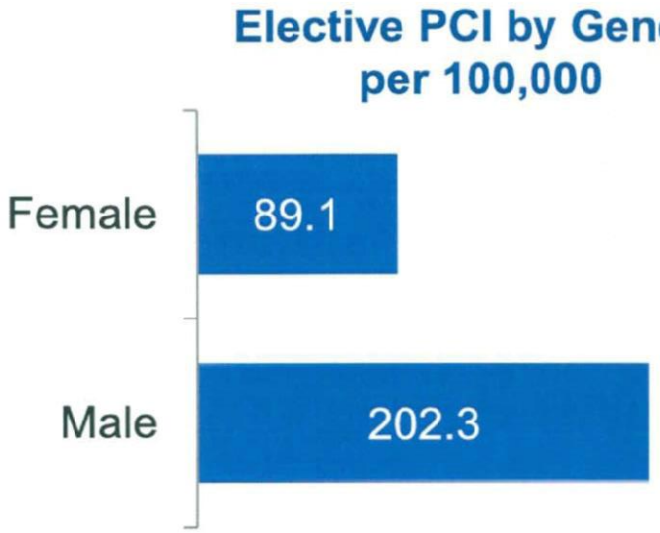


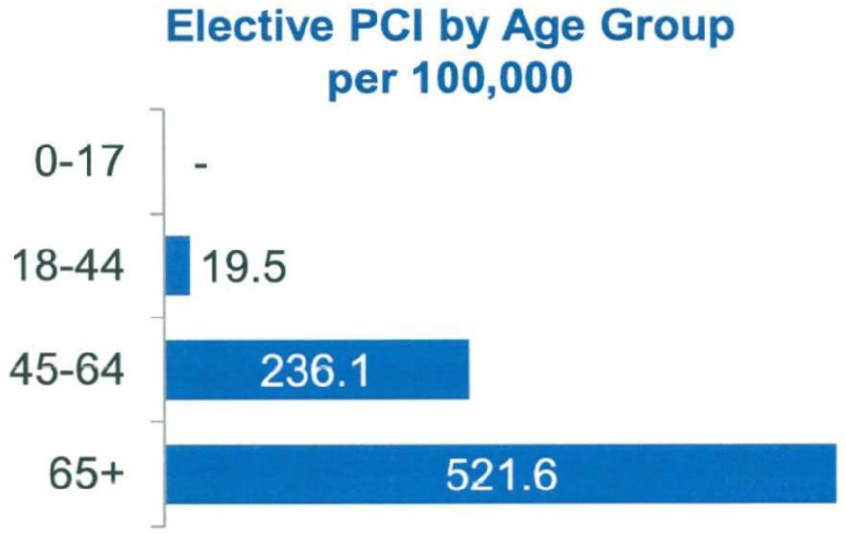
- Incidence of Primary PCI in the service area varies by demographic characteristics. Over the past six years, Primary PCI was much more likely among:
  - Males
  - Older populations
  - Non-Hispanic populations

Primary PCI by Race / Ethnicity per 100,000

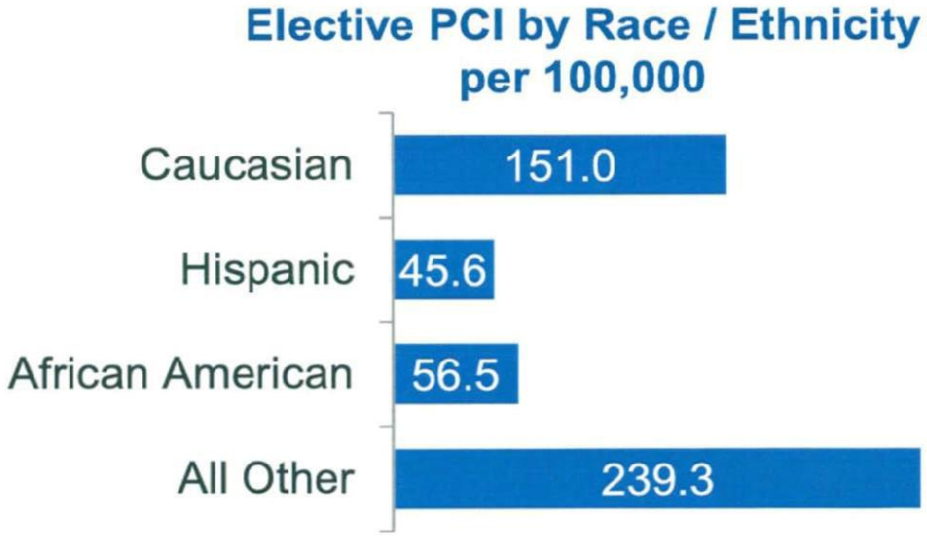


Service Area Incidence of Elective PCI by Cohort





- Incidence of Elective PCI in the service area is consistent with that of Primary PCI – heavily weighted toward Caucasian males that are age 65 or older.



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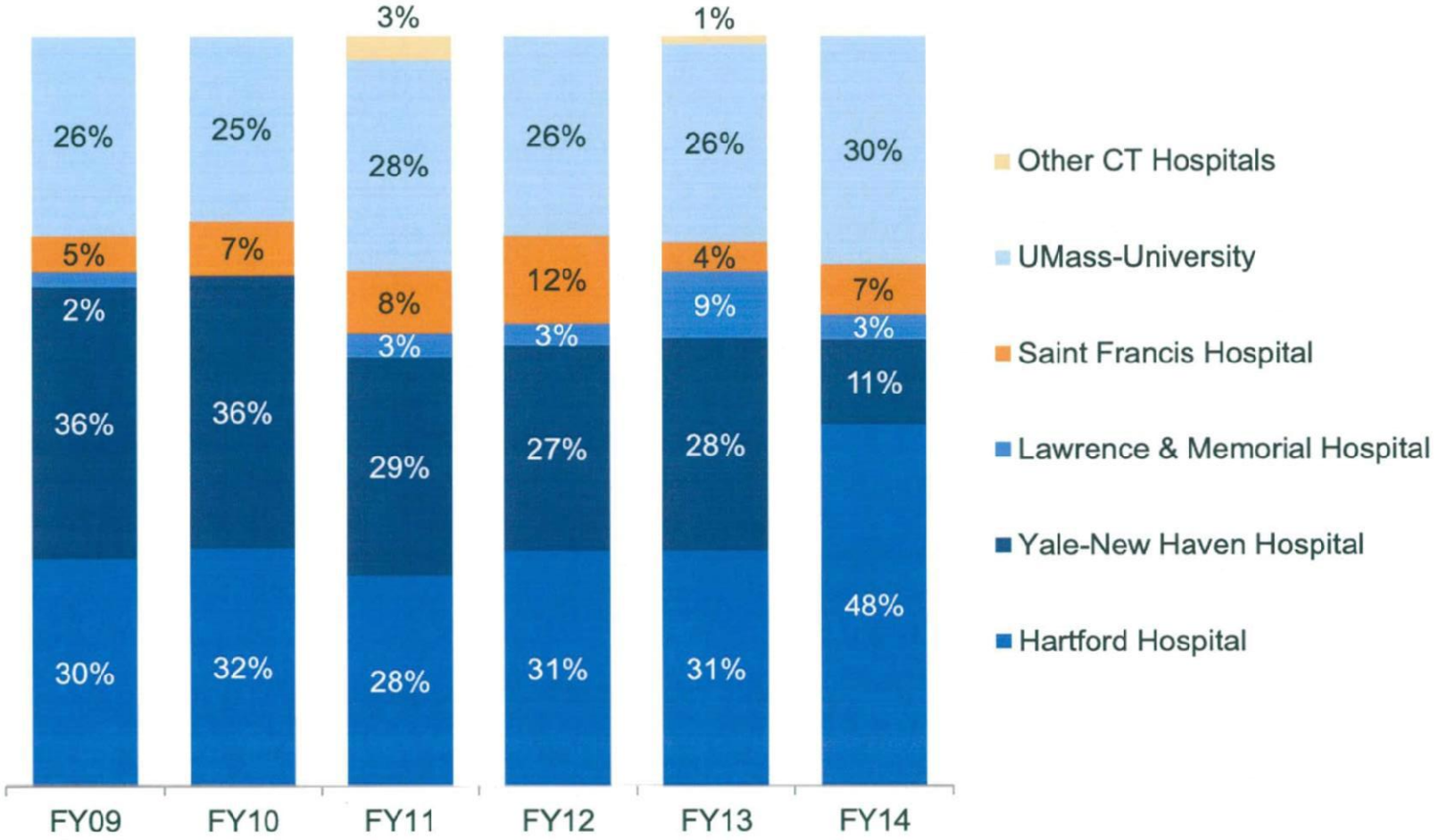
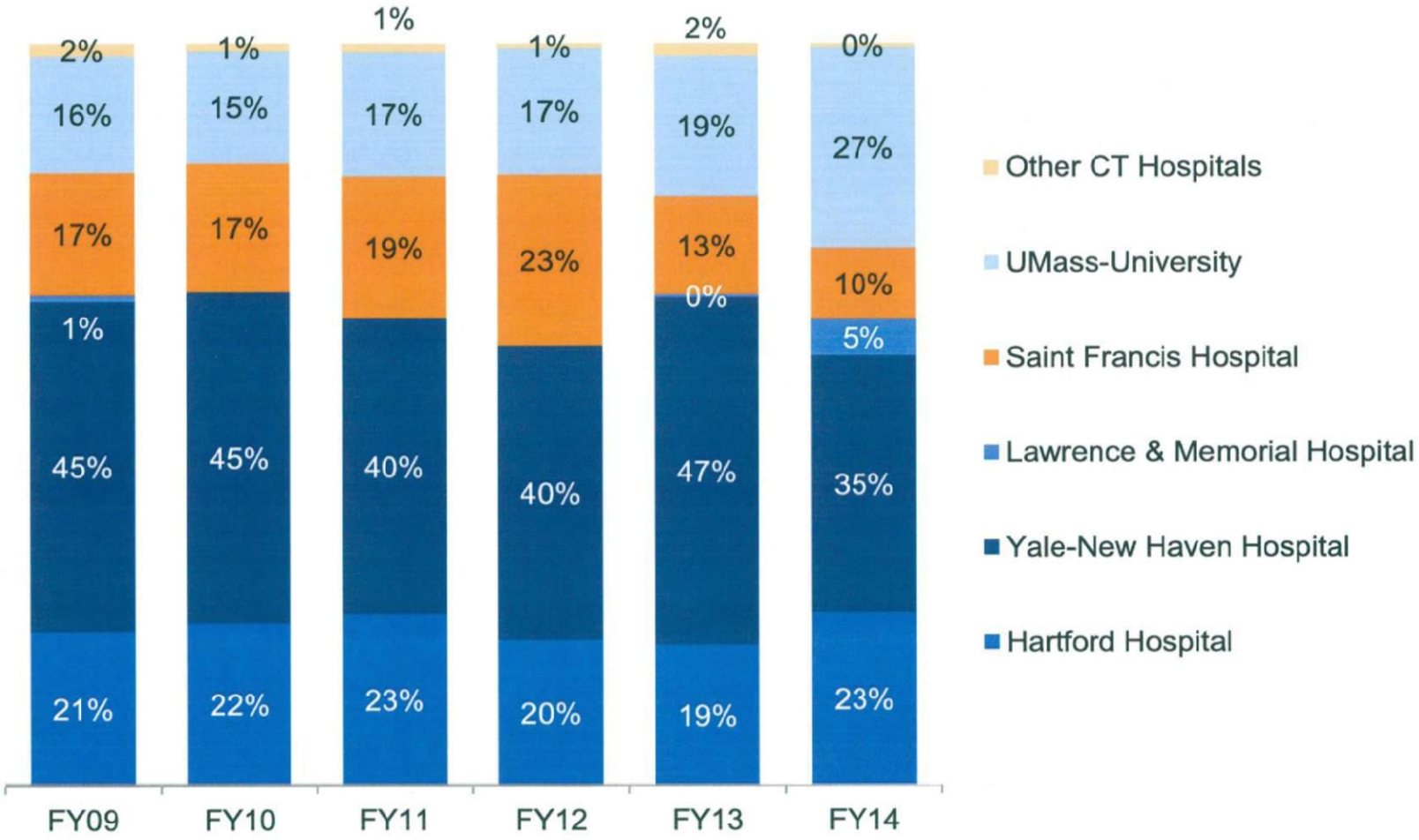
Service Area Primary PCI Market Share Trend



469

- Hartford Hospital currently treats the most Primary PCI patients originating within the service area.

Service Area Elective PCI Market Share Trend



470

- Over half of the service area Elective PCI patients are currently having to travel to either Hartford Hospital or Yale-New Haven Hospital.

Historic Door-to-Balloon Times for Backus Patients

Measuring Primary PCI Times for Backus Patients

Backus provided 3d Health with a number of historic data sets regarding speed of treatment for Primary PCI patients transferred from Backus to other facilities.

Using this data, 3d Health evaluated past performance, with a particular focus on two core time measures:

- Door-to-Balloon Time ("DTB"): Based on current ACC/AHA guidelines[1], optimal treatment time from hospital arrival to balloon inflation is within 90 minutes
- Door-In-Door-Out Time ("DIDO"): Defined as the time between arrival at a non-PCI capable facility to discharge/transfer to a PCI capable facility; current recommendations[2] for DIDO times within 30 minutes

Note: Since STEMI patients must be transferred from Backus to another organization for Primary PCI, a complete DTB time analysis was only available for a subset of these patients where the destination facility was willing and able to share detailed time data with Backus about the post-transfer experience.

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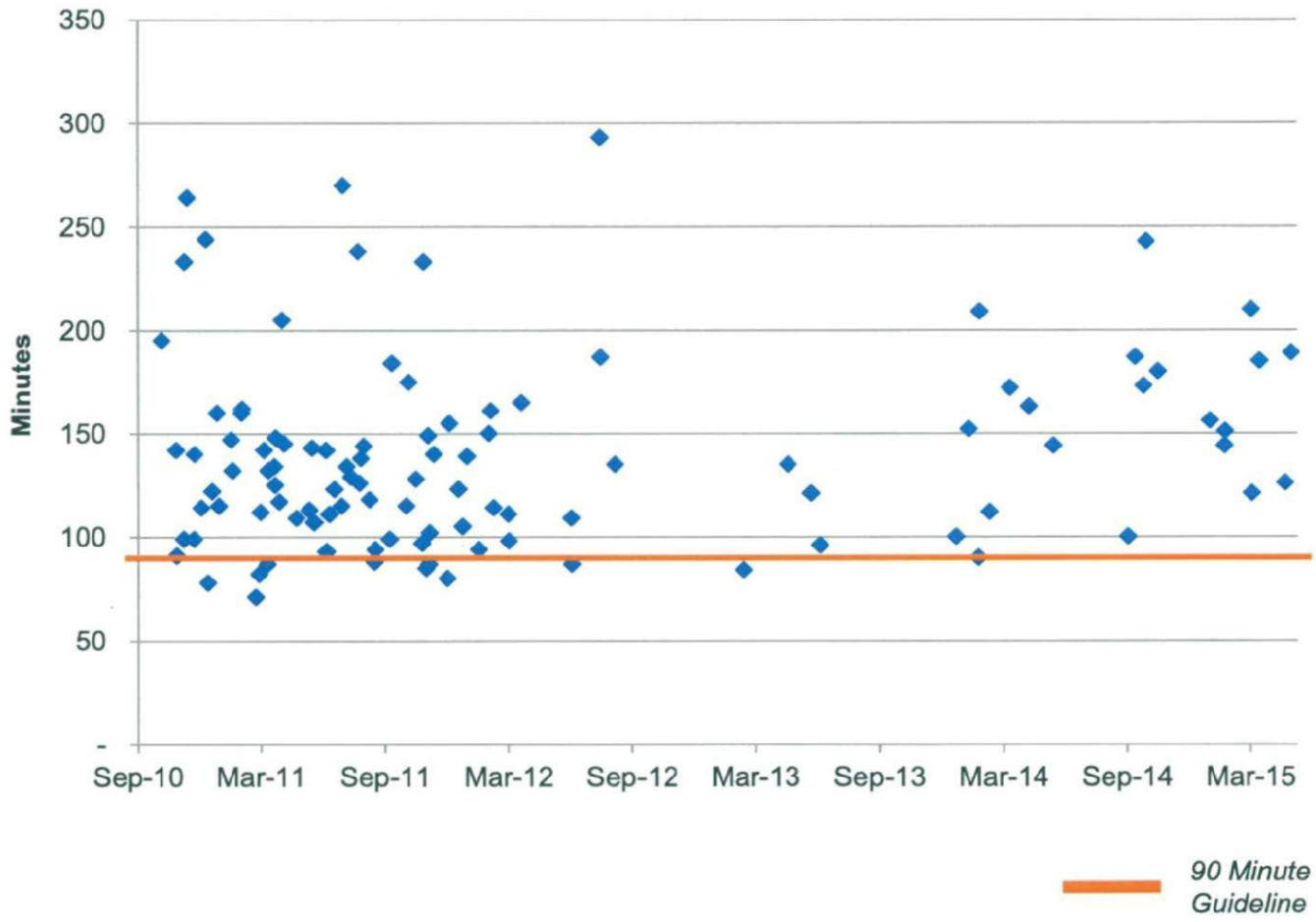
[1]ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction
[2]Wang T, et al. Association of Door-In to Door-Out Time With Reperfusion Delays and Outcomes Among Patients Transferred for Primary Percutaneous Coronary Intervention. JAMA. June 22/29, 2011.

One in Ten Backus AMI Patients Met 90 Minute DTB

- Total DTB times were available for 105 AMI patients that presented at Backus and were transferred to either Hartford Hospital or Yale-New Haven Hospital from FY 2011 to through May 2015.
- The median DTB time was 134 minutes.
- 10% or 11 cases were treated within the recommended 90 minute DTB time.

Door-to-Balloon Times[1], FY 2011 through May 2015



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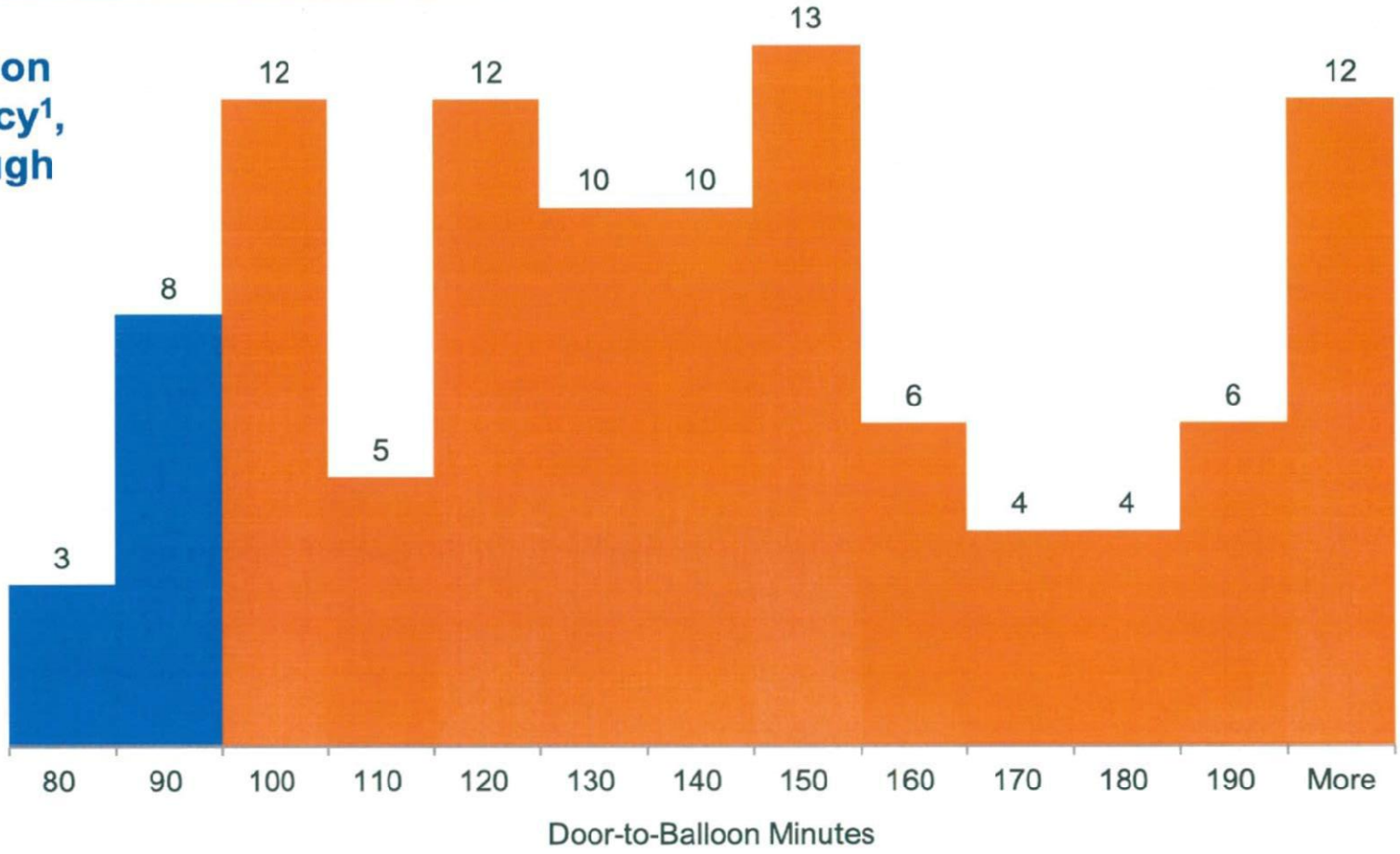
[1]YNHH data only available through June 2012; Hartford Hospital data provided for FY 2012 through May 2015

59% of DTB Times were Between 90 and 150 Minutes

Door-to-Balloon Time Frequency[1], FY 2011 through May 2015



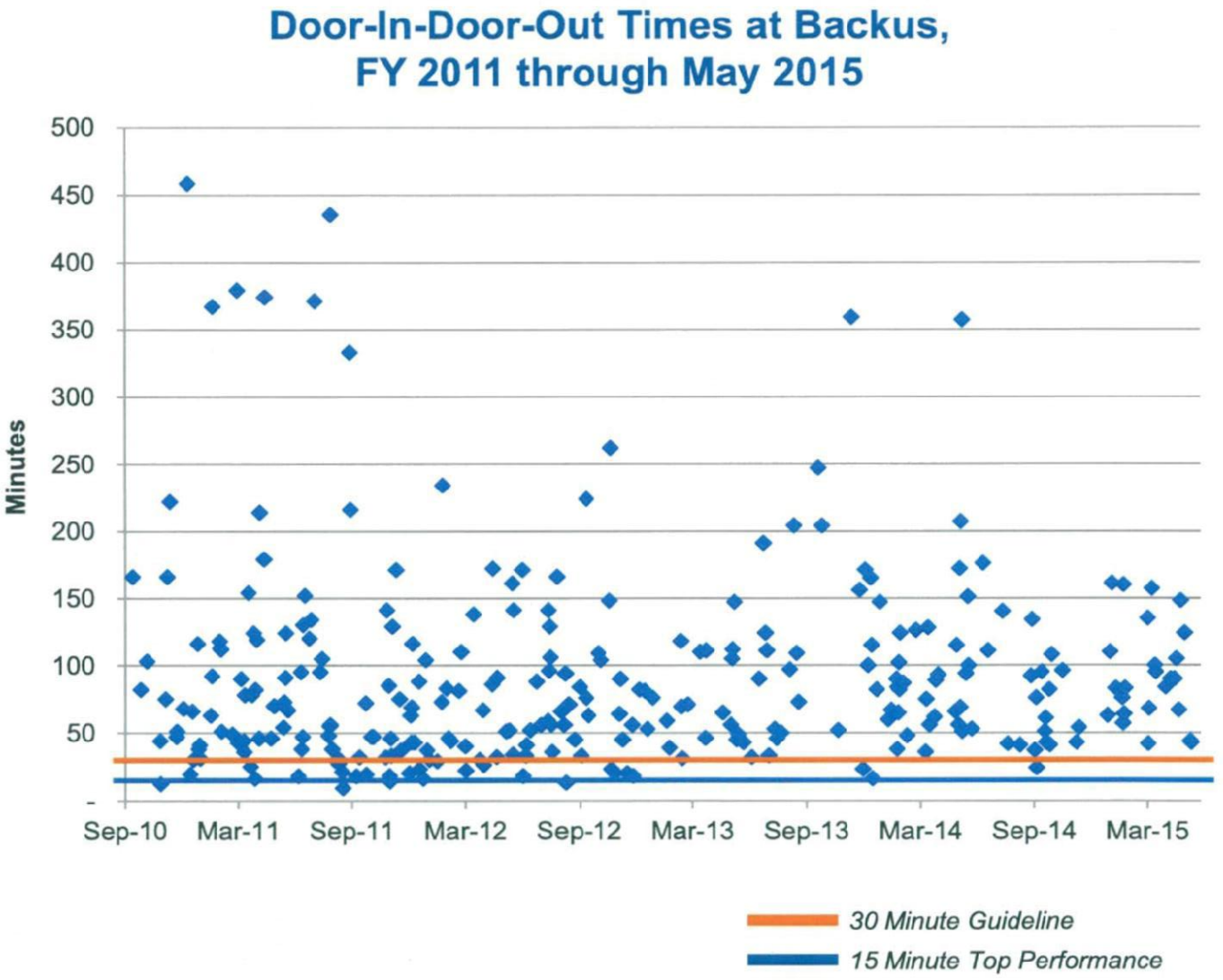
474

- 30% of Backus patients transferred during this timeframe for Primary PCI exceeded 90 minute DTB by an hour or more (150+ minutes).
- Based on Yale-New Haven data from January 2014 through March 2015, the median DTB time was 195 minutes with an average time of 224 minutes.

[1]YNHH data only available through June 2012;
Hartford Hospital data provided for FY 2012 through May 2015

DIDO Times Exceeded Guidelines 89% of the Time

- 3d Health measured DIDO times for 285 STEMI patients presenting at the Backus ED that were transferred to an acute care hospital from FY 2011 through May 2015. During this period, median DIDO at Backus was 73 minutes.
- 11% or 30 cases were treated within the recommended 30 minute DIDO time. Of those, 4 cases had a DIDO time of less than 15 minutes.



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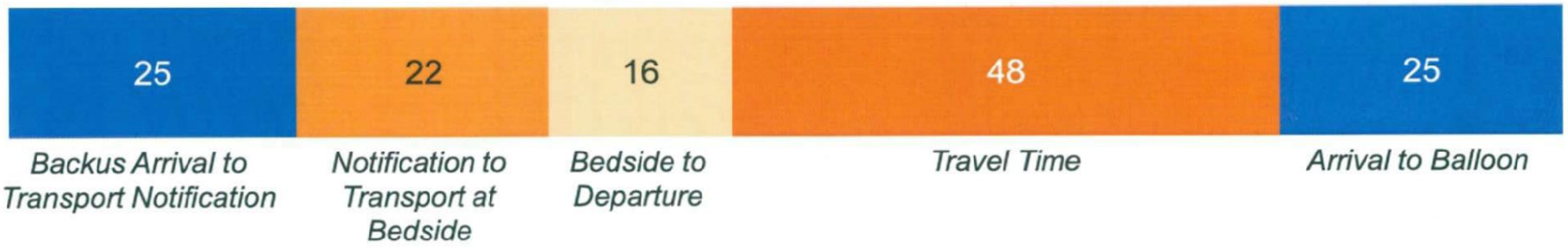
Transport Accounts for Over Half of DTB Minutes

- Backus collected a set of sample time data by detailed Primary PCI segment milestone from YNHH and Hartford Hospital for 105 cases from FY 2011 through May 2015.
- Transport and travel time account for a significant portion of total DTB. Backus' affiliation with Hartford Healthcare has led to an increase in transfers for Primary PCI to Hartford Hospital with a corresponding reduction in travel time. However, total DTB still routinely exceeds the 90 minute guideline and DIDO for this set of data, while slightly lower than Backus' overall median of 73 minutes, also exceeds the 30 minute guideline.

YNHH Median Segment Times in Minutes (n = 79 cases)



Hartford Hospital Median Segment Times in Minutes (n = 26 cases)

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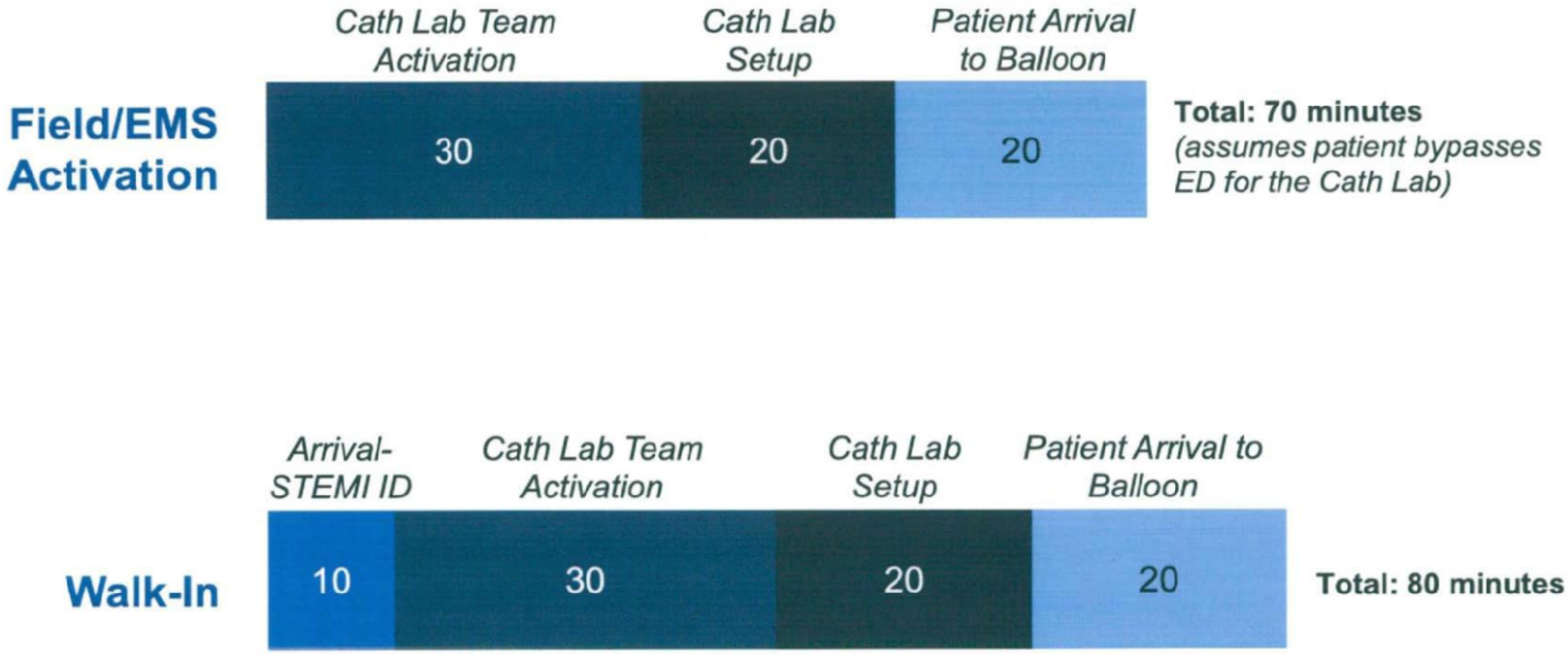
[1]Detailed milestone data for transport notification to departure was not available for Hartford Hospital transfer patients

Achieving Optimal DTB Time for Backus Patients

Backus estimated maximum DTB times of 70 to 80 minutes for a Primary PCI program at the Hospital, depending on the patient mode of arrival:



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Access to PCI Services for Service Area Residents

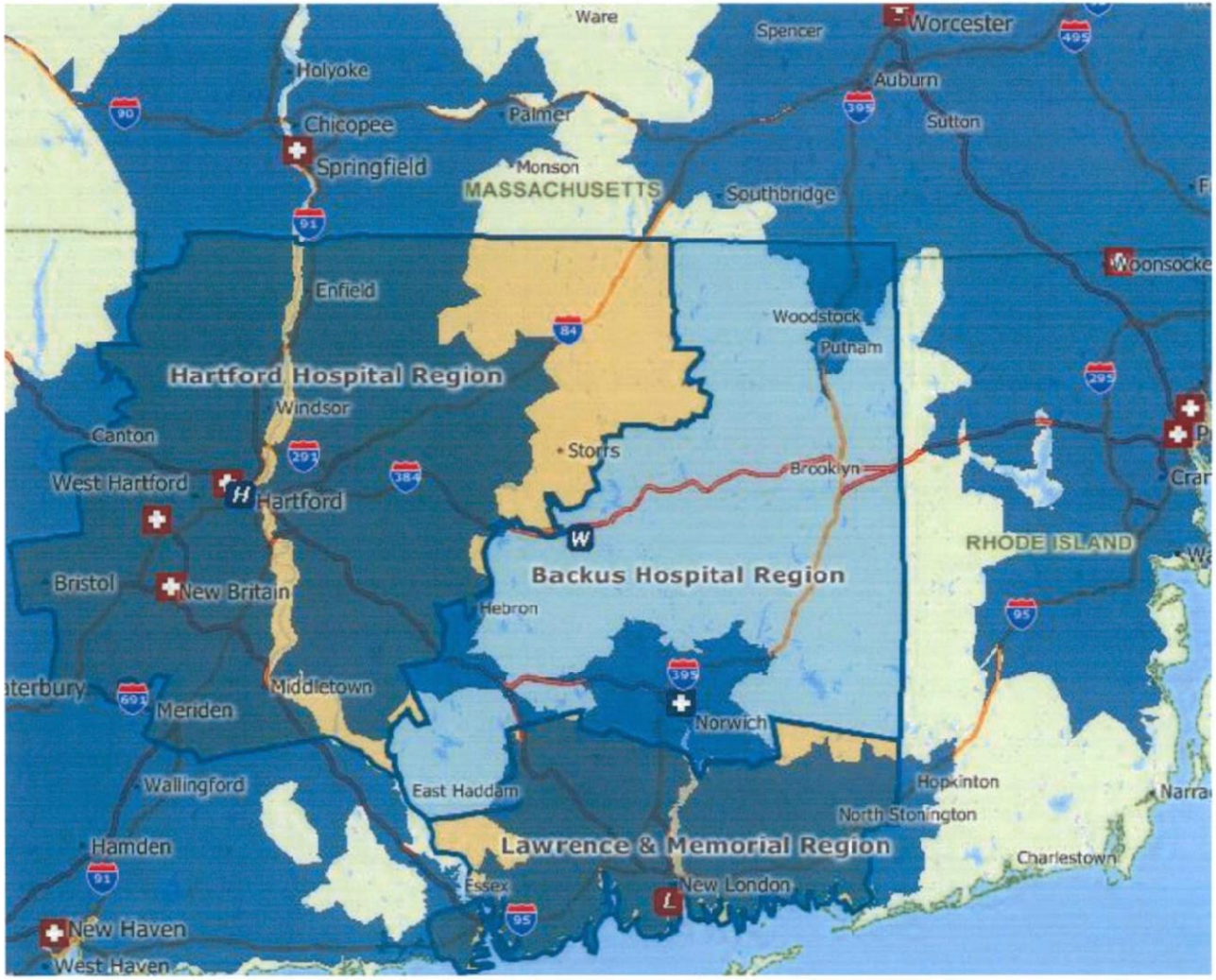
Facilities Providing PCI to the Service Area

FY 2014 Data[1]	Hartford Hospital	Yale-New Haven Hospital	Lawrence & Memorial Hospital	Saint Francis Hospital and Medical Center	UMass Memorial - University
Service Area Cases / Market Share: **Primary PCI**	43 cases / 48% share	10 cases / 11% share	2 cases / 2% share	6 cases / 7% share	27 cases / 30% share
Service Area Cases / Market Share: **Elective PCI**	95 cases / 23% share	141 cases / 35% share	20 cases / 5% share	39 cases / 9% share	110 cases / 25% share
Total Estimated Primary PCI Cases	267 cases	288 cases	97 cases	191 cases	347 cases
Total Estimated Elective PCI Cases	810 cases	1,180 cases	98 cases	664 cases	~753 cases (OP estimated)
Total Coronary Angioplasty (inpatient and outpatient)[2]	1,077 cases	1,468 cases	195 cases	855 cases	~1,100 cases (OP estimated)
Percent of all Hospital's Coronary Angioplasty (Primary + Elective) from the Service Area	12.8%	10.3%	11.3%	5.3%	12.5%

[1]UMass-University data from FY 2012; 33% of all elective estimated to be performed on an outpatient basis
[2]L&M data from OCHA filing
[3]Hartford data obtained directly
[4]YNNH, and St. Francis data per the CHA's Patient Census Report from October 2013 through September 2014

PCI Availability within 30 Minutes

- 146,000 residents – or 63% of the service area population – do not have access to a PCI facility within 30 minutes.
- An additional 18,000 residents in far northeast Connecticut do not have access to a PCI facility within the state within 30 minutes.
- The remaining 67,000 service area residents live within 10 minutes of Backus Hospital.



30 Minute Drive Time, Existing PCI Providers

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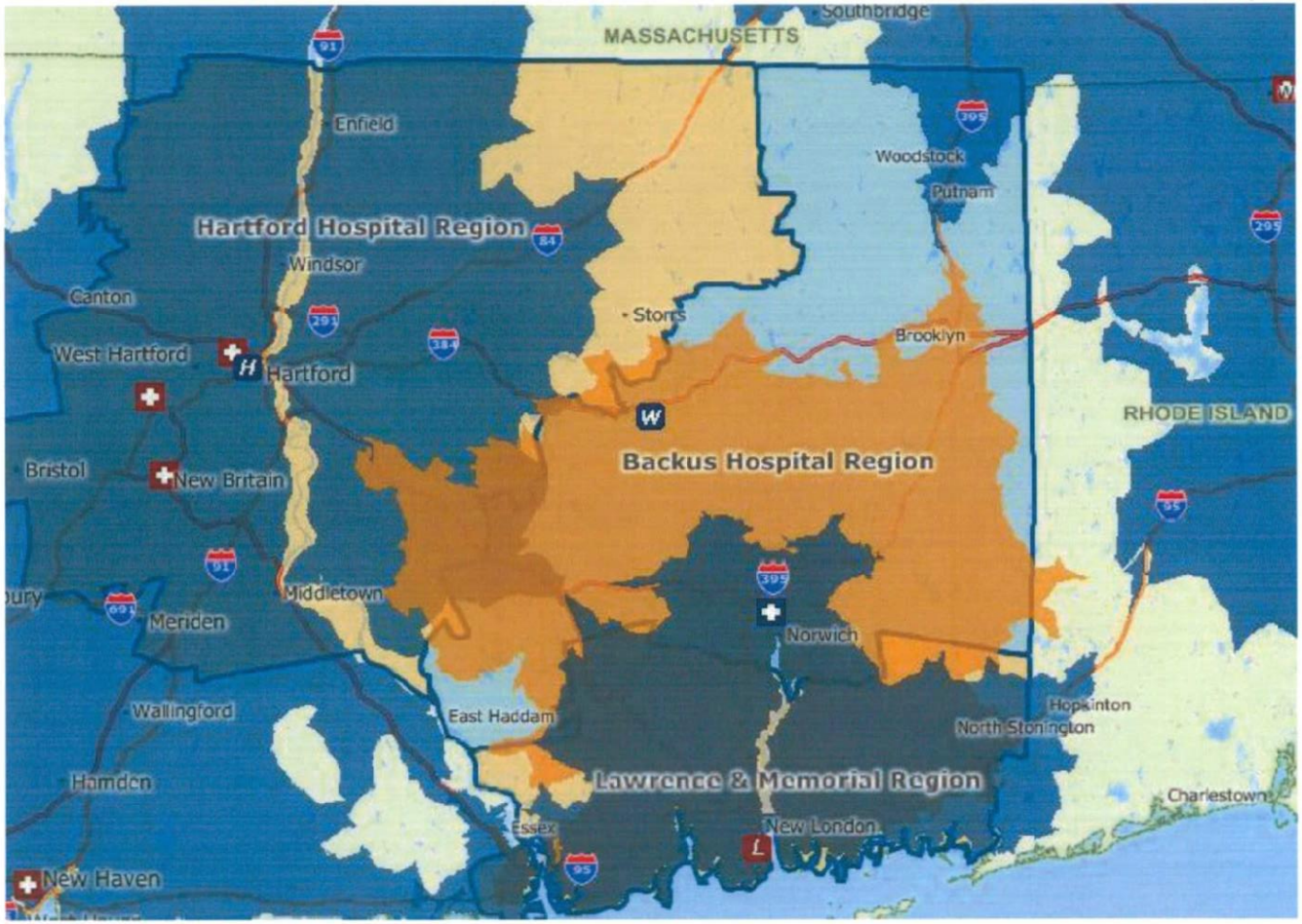
Additional Access with PCI at Backus

- Adding a PCI program at Backus would expand geographic coverage to PCI within 30 minutes to 118,000 service area residents that do not currently have such access.

Service Area Segment	Population
No access within 30 minutes	146,000
Access within 30 minutes if Backus offered	*118,000*
Access within 40-50 minutes if Backus offered	*28,000*
No access to a CT hospital within 30 minutes	18,000
Access today; within 10 minutes of Backus	67,000



	Brooklyn	Plainfield	Windham
Backus	*28 min.*	*17 min.*	*20 min.*
Hartford	*55 min.*	*57 min.*	*43 min.*
L&M	*47 min.*	*36 min.*	*39 min.*

30 Minute Drive Time, Existing PCI Providers

30 Minute Drive Time, Potential Backus Program

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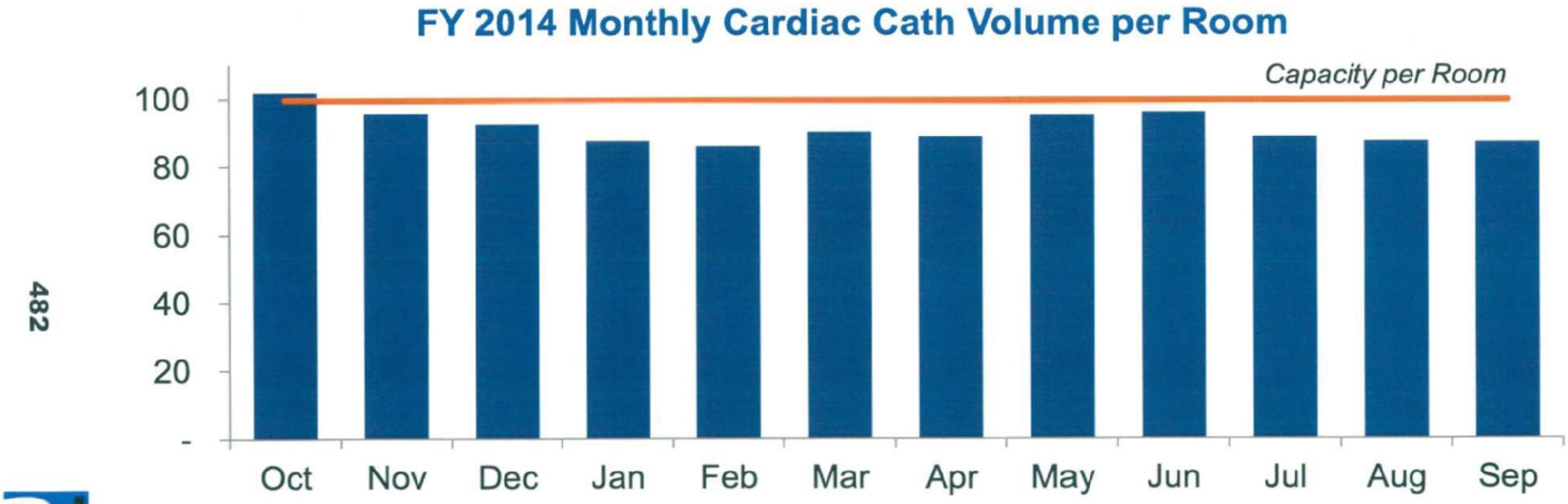
Hartford Hospital Cardiac Cath Lab Capacity

- Hartford Hospital is currently serving more Primary PCI patients from the Backus service area than any other facility. In addition, Primary PCI transfers from Backus to Hartford Hospital are anticipated to continue increasing as a result of Backus' affiliation with Hartford HealthCare.
- 3d Health completed a capacity analysis for Hartford Hospital's cardiac cath labs to understand whether there would be a benefit to that institution if Primary PCI volume was served locally as part of a Backus program, rather than transferred.
- During FY 2014, Hartford Hospital was operating at approximately 92% of capacity.



Projected PCI Volume and Potential Cases at Backus

Estimating Projected PCI Market Volumes

- To estimate future demand for PCI among service area residents, 3d Health prepared market projections based on a set of utilization rates applied to the service area population.
- These utilization rates were calculated by age and gender using PCI volume originating across the state of Connecticut from FY 2009 through FY 2014. These rates also include an estimate for Connecticut patients treated at Massachusetts hospitals based on FY 2012 data.
- In modeling future inpatient Primary and Elective PCI volumes originating from the service area, 3d Health assumed no change in the underlying calculated utilization rates.

Annual Incidence Rate of Inpatient PCI in the State of Connecticut per 100,000 Population (6-Year Rate)

	Primary PCI	
Age Group	Female	Male
0-17	-	-
18-44	4.6	15.9
45-64	32.2	133.4
65+	95.3	192.8

	Elective PCI	
Age Group	Female	Male
0-17	-	-
18-44	6.5	17.2
45-64	74.0	217.6
65+	230.9	538.4

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Estimating Potential Backus Primary PCI Volume

- Since the typical Primary PCI patient presents at a hospital emergency department ("ED"), 3d Health applied Backus and Windham combined FY 2014 ED market share to the projections to estimate the potential for Primary PCI cases at Backus. Market share was calculated for each specific geographic region within the defined service area, based on 30 minute drive time from Backus.
  - For those cases from towns within 30 minutes of Backus, 80% was applied to the total potential Primary PCI volume (the combined market share for Backus and Windham).
  - For those cases from service area towns outside of 30 minutes away from Backus, 11% was applied to total potential volume Primary PCI volume (the combined market share for Backus and Windham).
- An inmigration rate of 5.4% was applied, based on the historic emergency department experience (the combined inmigration rate for Backus and Windham).

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Estimating Potential Backus Elective PCI Volume

- "Complex" Elective PCI cases (those with a history of previous cardiac event or intervention) were removed from the total potential Backus case volume, assuming that these patients would require care at a tertiary institution offering on-site cardiac surgical backup and would not receive their elective angioplasty at Backus.
- Backus Hospital inpatient market share for each town within the defined Backus service area (based on the 10, 10-30, and 30+ drive times) was applied to the remaining potential service area volume (75% of cases originating 10 minutes from Backus, 50% of cases originating 10-30 minutes from Backus, and 25% of cases originating 30+ minutes from Backus).
- An inmigration rate of 3.2% was applied, based on the historic Backus Hospital inpatient experience.
- The number of Elective PCI L&M cases from patients originating from the Backus Service Area was projected based on historic OCHA data and removed from the potential Backus volume under the assumption that these cases would continue to be performed at L&M.

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Lawrence & Memorial Service Area PCI Volume Trends

Service Area	FY13	FY14	FY 15 Annualized	Program Total (FY 15)
Primary PCI	9	2	18	113
Elective PCI, Inpatient	3	5	5	55
Elective PCI, Outpatient	-	15	5	43

- In fiscal year 2015, 28 procedures or 13% of Lawrence & Memorial Hospital's PCI volume were patients originating from within the service area and 18 of the 28 procedures were Primary PCI patients living within 30 minutes of Backus Hospital.
- 18 of the 26 towns within the service area had no PCI patients served by L&M in fiscal year 2015.

Town / Town Part	FY13	FY14	FY 15 Annualized
Within 30 Minutes			
Norwich	9	6	9
Amston	-	-	-
Bozrah	1	1	-
Brooklyn	-	-	-
Canterbury	-	-	1
Chaplin	-	-	-
Colchester	-	1	-
Columbia	-	-	-
Franklin	-	4	1
Griswold-Lisbon	-	3	5
Killingly	-	1	-
Lebanon	-	1	-
Mansfield Center	-	-	-
Plainfield	-	1	3
Preston	2	1	5
Scotland	-	-	-
Sprague	-	-	3
Sterling	-	1	-
Voluntown	-	1	1
Windham	-	1	-
Subtotal	**12**	**22**	**28**
Outside 30 Minutes			
East Haddam	-	-	-
Hampton	-	-	-
Pomfret	-	-	-
Putnam	-	-	-
Thompson	-	-	-
Woodstock	-	-	-
Subtotal	**-**	**-**	**-**
Total Service Area	**12**	**22**	**28**
Program Total	**135**	**195**	**211**
% from Service Area	*9%*	*11%*	*13%*

Service Area PCI Forecasts

- Given expected demographic changes and aging of the population, service area PCI volumes are expected to increase 24% by FY 2020 over FY 2009 estimates (to 634 cases from 512).

	Estimated Historical						Future Projections					
	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20
Primary PCI Market Estimate	**104**	**111**	**107**	**105**	**109**	**111**	**113**	**114**	**115**	**117**	**118**	**120**
Chime Reported Primary PCI	*75*	*83*	*69*	*75*	*75*	*62*						
Est. Massachusetts Primary PCI Cases[1]	*27*	*27*	*27*	*27*	*27*	*27*						
Unmet Need / Other Outmigration	*2*	*1*	*11*	*3*	*7*	*22*						
Elective PCI Market Estimate	**408**	**425**	**426**	**443**	**465**	**474**	**480**	**486**	**493**	**500**	**507**	**514**
Chime Reported Elective PCI	*315*	*332*	*294*	*288*	*251*	*161*						
Est. Massachusetts Elective PCI Cases[1]	*60*	*60*	*60*	*60*	*60*	*60*						
Outpatient Elective PCI Cases	*33*	*33*	*38*	*79*	*127*	*204*						
Unmet Need / Other Outmigration	*-*	*-*	*34*	*15*	*27*	*49*						
Total PCI Market Estimate	**512**	**537**	**533**	**547**	**574**	**586**	**593**	**601**	**608**	**616**	**625**	**634**

[1]Based on FY 2012 Massachusetts data

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Potential Backus Primary PCI Volume

Since the typical Primary PCI patient presents at a hospital emergency department ("ED"), 3d Health applied Backus and Windham combined FY 2014 ED market share to the projections to estimate the potential for Primary PCI cases at Backus.

	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Total Expected Primary PCI Service Area Cases	**114**	**115**	**117**	**118**	**120**
Service Area Volume Originating Within 30 Minutes of Backus	92	93	94	95	96
Service Area Volume Originating Outside 30 Minutes of Backus	23	23	23	23	24
Potential Backus Cases					
Cases from Towns Within 30 Minutes of Backus: 80% HHC East Region ED market share	73	74	75	75	76
Cases from Service Area Towns Outside 30 Minutes: 11% HHC East Region ED market share	2	2	2	2	2
Potential Service Area Cases	75	76	77	77	78
Inmigration			*5.4%*		
Total Potential Primary PCI Cases	**79**	**80**	**81**	**81**	**82**

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Potential Backus Elective & Total PCI Volume Projections

	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Total Service Area Elective PCI, Inpatient & Outpatient	**486**	**493**	**500**	**507**	**514**
% Complex Elective PCI	*39.5%*	*38.8%*	*38.1%*	*37.5%*	*36.9%*
Service Area Non-Complex Elective PCI	**295**	**302**	**309**	**317**	**324**
Service Area Volume Originating Within:					
10 Minutes of Backus	56	58	59	61	62
10-30 Minutes of Backus	180	184	189	193	198
More than 30 Minutes from Backus	58	60	61	63	64
Potential Backus Elective Cases from Towns Within:					
10 Minutes of Backus: 75% HHC East Region IP market share	42	43	45	46	47
10-30 Minutes of Backus: 50% HHC East Region IP market share	89	92	94	96	99
More than 30 Minutes from Backus: 25% Estimated Market Share	15	15	15	16	16
Potential Service Area Cases	146	150	154	158	162
Inmigration			*3.2%*		
Total Potential Elective PCI Cases	**151**	**155**	**159**	**163**	**167**
Total Potential Primary PCI Cases	79	80	81	81	82
Less: Expected L&M Elective Service Area Cases	(14)	(15)	(15)	(15)	(16)
Primary & Elective Projected Cases	***216***	***220***	***225***	***229***	***233***

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EXHIBIT 9

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines

Developed in Collaboration With the American College of Emergency Physicians and Society for Cardiovascular Angiography and Interventions

WRITING COMMITTEE MEMBERS*
Patrick T. O'Gara, MD, FACC, FAHA, *Chair*†;
Frederick G. Kushner, MD, FACC, FAHA, FSCAI, *Vice Chair**†; Deborah D. Ascheim, MD, FACC†;
Donald E. Casey, Jr, MD, MPH, MBA, FACP, FAHA‡; Mina K. Chung, MD, FACC, FAHA*†;
James A. de Lemos, MD, FACC†; Steven M. Ettinger, MD, FACC*§;
James C. Fang, MD, FACC, FAHA†; Francis M. Fesmire, MD, FACEP*‖¶;
Barry A. Franklin, PhD, FAHA†; Christopher B. Granger, MD, FACC, FAHA*†;
Harlan M. Krumholz, MD, SM, FACC, FAHA*†; Jane A. Linderbaum, MS, CNP-BC†;
David A. Morrow, MD, MPH, FACC, FAHA*†; L. Kristin Newby, MD, MHS, FACC, FAHA*†;
Joseph P. Ornato, MD, FACC, FAHA, FACP, FACEP*†; Narith Ou, PharmD†;
Martha J. Radford, MD, FACC, FAHA†; Jacqueline E. Tamis-Holland, MD, FACC†;
Carl L. Tommaso, MD, FACC, FAHA, FSCAI#; Cynthia M. Tracy, MD, FACC, FAHA†;
Y. Joseph Woo, MD, FACC, FAHA†; David X. Zhao, MD, FACC*†

ACCF/AHA TASK FORCE MEMBERS
Jeffrey L. Anderson, MD, FACC, FAHA, *Chair*;
Alice K. Jacobs, MD, FACC, FAHA, *Immediate Past Chair*;
Jonathan L. Halperin, MD, FACC, FAHA, *Chair-Elect*; Nancy M. Albert, PhD, CCNS, CCRN, FAHA;
Ralph G. Brindis, MD, MPH, MACC; Mark A. Creager, MD, FACC, FAHA; David DeMets, PhD;
Robert A. Guyton, MD, FACC, FAHA; Judith S. Hochman, MD, FACC, FAHA;
Richard J. Kovacs, MD, FACC; Frederick G. Kushner, MD, FACC, FAHA**;
E. Magnus Ohman, MD, FACC; William G. Stevenson, MD, FACC, FAHA;
Clyde W. Yancy, MD, FACC, FAHA**

*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry may apply; see Appendix 1 for detailed information. †ACCF/AHA representative. ‡ACP representative. §ACCF/AHA Task Force on Practice Guidelines liaison. ‖ACCF/AHA Task Force on Performance Measures liaison. ¶ACEP representative. #SCAI representative. **Former Task Force member during this writing effort.

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Preamble

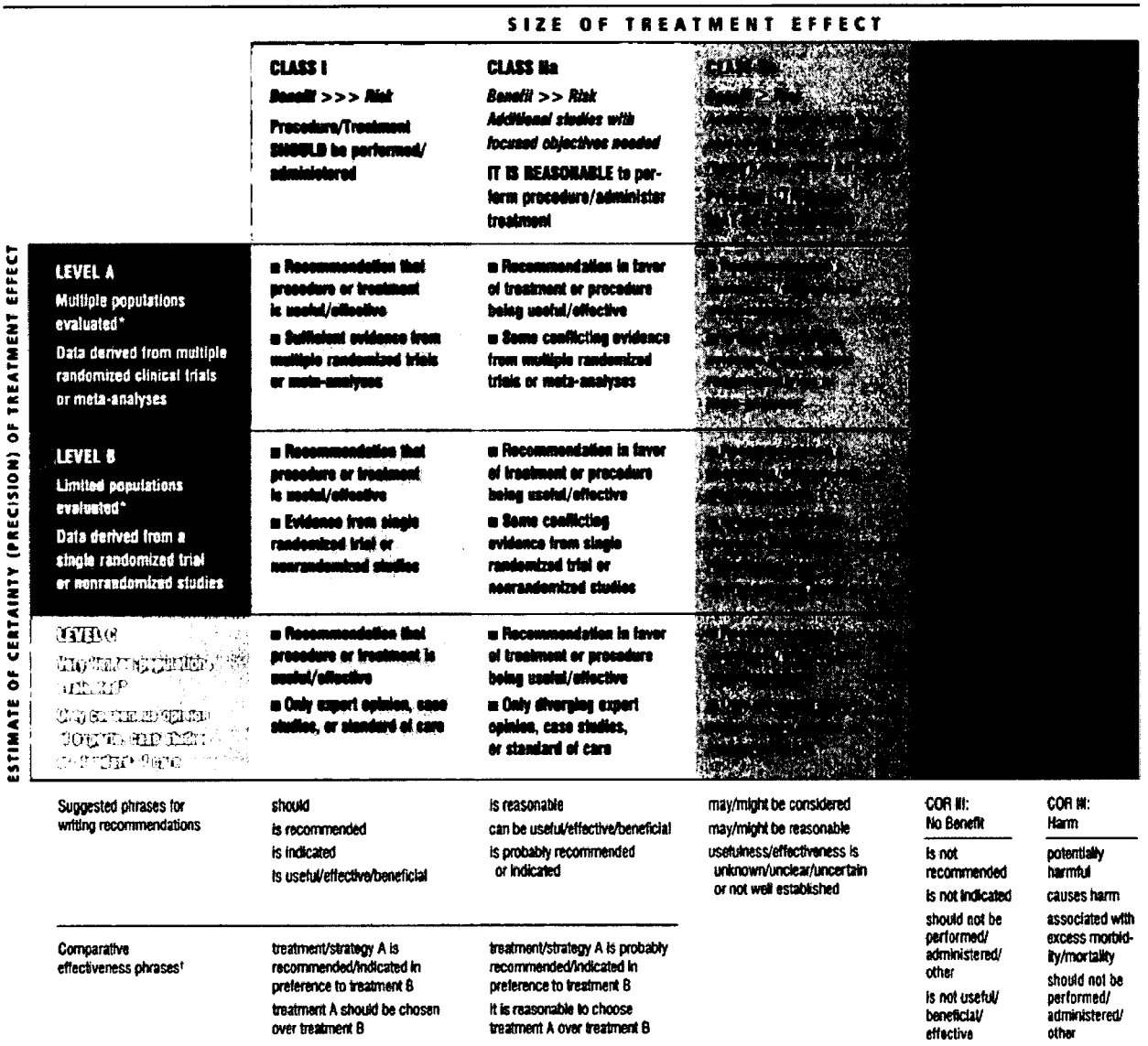
The medical profession should play a central role in evaluating the evidence related to drugs, devices, and procedures for the detection, management, and prevention of disease. When properly applied, expert analysis of available data on the benefits and risks of these therapies and procedures can improve the quality of care, optimize patient outcomes, and favorably affect costs by focusing resources on the most effective strategies. An organized and directed approach to a thorough review of evidence has resulted in the production of clinical practice guidelines that assist physicians in selecting the best management strategy for an individual patient. Moreover, clinical practice guidelines can provide a foundation for other applications, such as performance measures, appropriate use criteria, and both quality improvement and clinical decision support tools.

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have jointly produced guidelines in the area of cardiovascular disease since 1980. The ACCF/AHA Task Force on Practice Guidelines (Task Force), charged with developing, updating, and revising practice guidelines for cardiovascular diseases and procedures, directs and oversees this effort. Writing committees are charged with regularly reviewing and evaluating all available evidence to develop balanced, patient-centric recommendations for clinical practice.

Experts in the subject under consideration are selected by the ACCF and AHA to examine subject-specific data and write guidelines in partnership with representatives from other medical organizations and specialty groups. Writing committees are asked to perform a formal literature review; weigh the strength of evidence for or against particular tests, treatments, or procedures; and include estimates of expected outcomes where such data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that may influence the choice of tests or therapies are considered. When available, information from studies on cost is considered, but data on efficacy and outcomes constitute the primary basis for the recommendations contained herein.

In analyzing the data and developing recommendations and supporting text, the writing committee uses evidence-based methodologies developed by the Task Force.[1] The Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm. The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. The writing committee reviews and ranks evidence supporting

Table 1. Classification of Recommendation and Level of Evidence



ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	SIZE OF TREATMENT EFFECT: CLASS I *Benefit >>> Risk* Procedure/Treatment SHOULD be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* IT IS REASONABLE to perform procedure/administer treatment	CLASS III
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	▪ Recommendation that procedure or treatment is useful/effective ▪ Sufficient evidence from multiple randomized trials or meta-analyses	▪ Recommendation in favor of treatment or procedure being useful/effective ▪ Some conflicting evidence from multiple randomized trials or meta-analyses	
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	▪ Recommendation that procedure or treatment is useful/effective ▪ Evidence from single randomized trial or nonrandomized studies	▪ Recommendation in favor of treatment or procedure being useful/effective ▪ Some conflicting evidence from single randomized trial or nonrandomized studies	
LEVEL C [illegible]	▪ Recommendation that procedure or treatment is useful/effective ▪ Only expert opinion, case studies, or standard of care	▪ Recommendation in favor of treatment or procedure being useful/effective ▪ Only diverging expert opinion, case studies, or standard of care	
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B	

COR III: No Benefit	COR III: Harm
is not recommended	potentially harmful
is not indicated	causes harm
should not be performed/ administered/ other	associated with excess morbidity/mortality
is not useful/ beneficial/ effective	should not be performed/ administered/ other

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

each recommendation with the weight of evidence ranked as LOE A, B, or C according to specific definitions that are included in Table 1. Studies are identified as observational, retrospective, prospective, or randomized where appropriate. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and are ranked as LOE C. When recommendations at LOE C are supported by historical clinical data, appropriate references (including clinical reviews) are cited if available. For issues for which sparse data are available, a survey of current practice among the members of the writing committee is the basis for LOE C recommendations and no references are cited. The schema for COR and LOE is summarized in Table 1, which also provides suggested phrases for writing recommendations within each COR.

A new addition to this methodology is separation of the Class III recommendations to delineate whether the recommendation is determined to be of "no benefit" or is associated with "harm" to the patient. In addition, in view of the increasing number of comparative effectiveness studies, comparator verbs and suggested phrases for writing recommendations for the comparative effectiveness of one treatment or strategy versus another are included for COR I and IIa, LOE A or B only.

In view of the advances in medical therapy across the spectrum of cardiovascular diseases, the Task Force has designated the term *guideline-directed medical therapy*

(GDMT) to represent optimal medical therapy as defined by ACCF/AHA guideline-recommended therapies (primarily Class I). This new term, *GDMT*, will be used throughout subsequent guidelines.

Because the ACCF/AHA practice guidelines address patient populations (and healthcare providers) residing in North America, drugs that are not currently available in North America are discussed in the text without a specific COR. For studies performed in large numbers of subjects outside North America, each writing committee reviews the potential influence of different practice patterns and patient populations on the treatment effect and relevance to the ACCF/AHA target population to determine whether the findings should inform a specific recommendation.

The ACCF/AHA practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the circumstances presented by that patient. As a result, situations may arise for which deviations from these guidelines may be appropriate. Clinical decision making should involve consideration of the quality and availability of expertise in the area where care is provided. When these guidelines are used as the basis for regulatory or payer decisions, the goal should be improvement in quality of care. The Task Force recognizes that situations arise in which additional data are needed to inform patient care more effectively; these areas are identified within each respective guideline when appropriate.

Prescribed courses of treatment in accordance with these recommendations are effective only if followed. Because lack of patient understanding and adherence may adversely affect outcomes, physicians and other healthcare providers should make every effort to engage the patient's active participation in prescribed medical regimens and lifestyles. In addition, patients should be informed of the risks, benefits, and alternatives to a particular treatment and should be involved in shared decision making whenever feasible, particularly for COR IIa and IIb, for which the benefit-to-risk ratio may be lower.

The Task Force makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of relationships with industry and other entities (RWI) among the members of the writing committee. All writing committee members and peer reviewers of the guideline are required to disclose all current healthcare-related relationships, including those existing 1 year before initiation of the writing effort. In December 2009, the ACCF and AHA implemented a new RWI policy that requires the writing committee chair plus a minimum of 50% of the writing committee to have no *relevant* RWI. (Appendix 1 includes the ACCF/AHA definition of *relevance.*) These statements are reviewed by the Task Force and all members during each conference call and/or meeting of the writing committee, and members provide updates as changes occur. All guideline recommendations require a confidential vote by the writing committee and must be approved by a consensus of the voting members. Members may not draft or vote on any text or recommendations pertaining to their RWI. Members who recused themselves from voting are indicated in the list of writing committee members, and specific section recusals are noted in Appendix 1. Authors' and peer reviewers' RWI pertinent to this guideline are disclosed in Appendixes 1 and 2, respectively. In addition, to ensure complete transparency, writing committee members' comprehensive disclosure information—including RWI not pertinent to this document—is available as an online supplement. Comprehensive disclosure information for the Task Force is also available online at http://www.cardiosource.org/ACC/About-ACC/Who-We-Are/Leadership/Guidelines-and-Documents-Task-Forces.aspx. The work of writing committees is supported exclusively by the ACCF and AHA without commercial support. Writing committee members volunteered their time for this activity.

In an effort to maintain relevance at the point of care for practicing physicians, the Task Force continues to oversee an ongoing process improvement initiative. As a result, in response to pilot projects, several changes to these guidelines will be apparent, including limited narrative text, a focus on summary and evidence tables (with references linked to abstracts in PubMed), and more liberal use of summary recommendation tables (with references that support LOE) to serve as a quick reference.

In April 2011, the Institute of Medicine released 2 reports: *Finding What Works in Health Care: Standards for Systematic Reviews* and *Clinical Practice Guidelines We Can Trust.*[2,3] It is noteworthy that the IOM cited ACCF/AHA practice guidelines as being compliant with many of the proposed standards. A thorough review of these reports and of our current methodology is under way, with further enhancements anticipated.

The recommendations in this guideline are considered current until they are superseded by a focused update or the full-text guideline is revised. Guidelines are official policy of both the ACCF and AHA.

Jeffrey L. Anderson, MD, FACC, FAHA
Chair, ACCF/AHA Task Force on Practice Guidelines

1. Introduction

1.1. Methodology and Evidence Review

The recommendations listed in this document are, whenever possible, evidence based. The current document constitutes a full revision and includes an extensive evidence review, which was conducted through November 2010, with additional selected references added through August 2012. Searches were limited to studies conducted in human subjects and reviews and other evidence pertaining to human subjects; all were published in English. Key search words included but were not limited to: *acute coronary syndromes, percutaneous coronary intervention, coronary artery bypass graft, myocardial infarction, ST-elevation myocardial infarction, coronary stent, revascularization, anticoagulant therapy, antiplatelet*

therapy, antithrombotic therapy, glycoprotein IIb/IIIa inhibitor therapy, pharmacotherapy, proton-pump inhibitor, implantable cardioverter-defibrillator therapy, cardiogenic shock, fibrinolytic therapy, thrombolytic therapy, nitrates, mechanical complications, arrhythmia, angina, chronic stable angina, diabetes, chronic kidney disease, mortality, morbidity, elderly, ethics, and contrast nephropathy. Additional searches cross-referenced these topics with the following subtopics: percutaneous coronary intervention, coronary artery bypass graft, cardiac rehabilitation, and secondary prevention. Additionally, the committee reviewed documents related to the subject matter previously published by the ACCF and AHA. References selected and published in this document are representative and not all-inclusive.

To provide clinicians with a comprehensive set of data, whenever deemed appropriate or when published, the absolute risk difference and number needed to treat or harm are provided in the guideline, along with confidence intervals (CI) and data related to the relative treatment effects such as odds ratio (OR), relative risk (RR), hazard ratio (HR), or incidence rate ratio.

The focus of this guideline is the management of patients with ST-elevation myocardial infarction (STEMI). Updates to the 2004 STEMI guideline were published in 2007 and 2009.[4–6] Particular emphasis is placed on advances in reperfusion therapy, organization of regional systems of care, transfer algorithms, evidence-based antithrombotic and medical therapies, and secondary prevention strategies to optimize patient-centered care. By design, the document is narrower in scope than the 2004 STEMI Guideline, in an attempt to provide a more focused tool for practitioners. References related to management guidelines are provided whenever appropriate, including those pertaining to percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), heart failure (HF), cardiac devices, and secondary prevention.

1.2. Organization of the Writing Committee

The writing committee was composed of experts representing cardiovascular medicine, interventional cardiology, electrophysiology, HF, cardiac surgery, emergency medicine, internal medicine, cardiac rehabilitation, nursing, and pharmacy. The American College of Physicians, American College of Emergency Physicians, and Society for Cardiovascular Angiography and Interventions assigned official representatives.

1.3. Document Review and Approval

This document was reviewed by 2 outside reviewers each nominated by the ACCF and the AHA, as well as 2 reviewers each from the American College of Emergency Physicians and Society for Cardiovascular Angiography and Interventions and 22 individual content reviewers (including members from the ACCF Interventional Scientific Council and ACCF Surgeons' Scientific Council). All reviewer RWI information was distributed to the writing committee and is published in this document (Appendix 2).

This document was approved for publication by the governing bodies of the ACCF and the AHA and was endorsed by the American College of Emergency Physicians and Society for Cardiovascular Angiography and Interventions.

2. Background

2.1. Definition and Diagnosis

STEMI is a clinical syndrome defined by characteristic symptoms of myocardial ischemia in association with persistent electrocardiographic (ECG) ST elevation and subsequent release of biomarkers of myocardial necrosis. Diagnostic ST elevation in the absence of left ventricular (LV) hypertrophy or left bundle-branch block (LBBB) is defined by the European Society of Cardiology/ACCF/AHA/World Heart Federation Task Force for the Universal Definition of Myocardial Infarction as new ST elevation at the J point in at least 2 contiguous leads of ≥2 mm (0.2 mV) in men or ≥1.5 mm (0.15 mV) in women in leads V2–V3 and/or of ≥1 mm (0.1 mV) in other contiguous chest leads or the limb leads.[7] The majority of patients will evolve ECG evidence of Q-wave infarction. New or presumably new LBBB has been considered a STEMI equivalent. Most cases of LBBB at time of presentation, however, are "not known to be old" because of prior electrocardiogram (ECG) is not available for comparison. New or presumably new LBBB at presentation occurs infrequently, may interfere with ST-elevation analysis, and should not be considered diagnostic of acute myocardial infarction (MI) in isolation.[8] Criteria for ECG diagnosis of acute STEMI in the setting of LBBB have been proposed (see *Online Data Supplement 1*). Baseline ECG abnormalities other than LBBB (eg, paced rhythm, LV hypertrophy, Brugada syndrome) may obscure interpretation. In addition, ST depression in ≥2 precordial leads (V1–V4) may indicate transmural posterior injury; multilead ST depression with coexistent ST elevation in lead aVR has been described in patients with left main or proximal left anterior descending artery occlusion.[9] Rarely, hyperacute T-wave changes may be observed in the very early phase of STEMI, before the development of ST elevation. Transthoracic echocardiography may provide evidence of focal wall motion abnormalities and facilitate triage in patients with ECG findings that are difficult to interpret. If doubt persists, immediate referral for invasive angiography may be necessary to guide therapy in the appropriate clinical context.[10,11] Cardiac troponin is the preferred biomarker for diagnosis of MI.

2.2. Epidemiology

In 2009, approximately 683 000 patients were discharged from US hospitals with a diagnosis of acute coronary syndrome (ACS). Community incidence rates for STEMI have declined over the past decade, whereas those for non–ST-elevation ACS have increased (Figure 1). At present, STEMI comprises approximately 25% to 40% of MI presentations.[12–15] In-hospital (approximately 5% to 6%) and 1-year (approximately 7% to 18%) mortality rates from STEMI also have decreased significantly in association with a substantial increase in the frequency of care that includes GDMT and interventions ("defect-free" care).[13,15–18] In the United States, important regional differences exist in 30-day acute MI hospital mortality and readmission rates for Medicare beneficiaries ≥65 years of age.[19] Understanding the reasons for

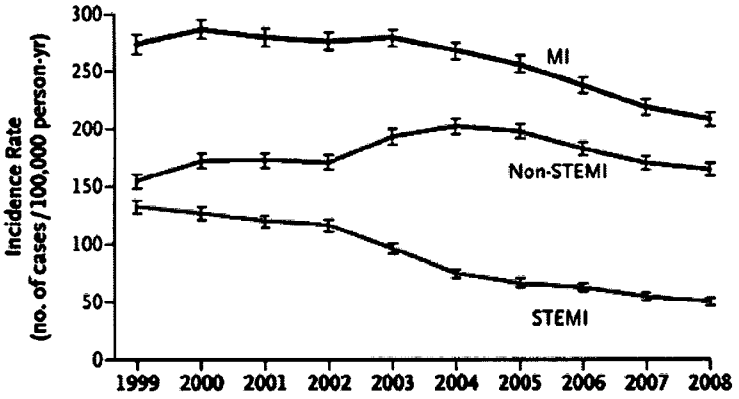


Figure 1. Age- and sex-adjusted incidence rates of acute MI, 1999 to 2008. I bars represent 95% confidence intervals. MI indicates myocardial infarction; STEMI, ST-elevation myocardial infarction. Reprinted with permission from Yeh et al.[14]

such differences may provide opportunities for performance improvement.[20]

Approximately 30% of patients with STEMI are women. Female sex was a strong independent predictor of failure to receive reperfusion therapy among patients who had no contraindications in the CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes with Early Implementation of the ACC/AHA Guidelines) registry.[21] Compared with men, women included in the NCDR (National Cardiovascular Data Registry) ACTION Registry–GWTG (Get With The Guidelines) presented later after symptom onset, had longer door-to-fibrinolysis and door-to-balloon (or device) (D2B) times, and less often received aspirin or beta blockers within 24 hours of presentation. Women further were characterized by a higher risk for bleeding with antithrombotic therapy, which persisted after consideration of age, weight, blood pressure (BP) at presentation, renal function, baseline hematocrit, and other potential confounders.[22]

Nonwhites represented 13.3% of patients with STEMI at hospitals participating in the ACTION Registry–GWTG in quarters 1 and 2 of 2009.[17] Importantly, disparities in the treatment of racial and ethnic minorities appear to be improving over time.[23] In an assessment of the effects of a statewide program for treatment of STEMI, institution of a coordinated regional approach to triage and management was associated with significant improvements in treatment times that were similar for whites and blacks and for women and men.[23] The writing committee endorses the desirability of collecting and using accurate data on patient race and ethnicity to detect disparities, guide quality improvement initiatives, and strengthen ties to the community.[24]

Approximately 23% of patients with STEMI in the United States have diabetes mellitus,[17] and three quarters of all deaths among patients with diabetes mellitus are related to coronary artery disease.[25,26] Diabetes mellitus is associated with higher short- and long-term mortality after STEMI,[27,28] and in patients with diabetes mellitus, both hyperglycemia and hypoglycemia are associated with worse outcomes.[29] Hyperglycemia at presentation in patients who do not have diabetes mellitus by history has been associated with worse hospital outcomes.[30-34] Myocardial tissue perfusion after restoration of epicardial coronary flow was more impaired among patients with diabetes mellitus ("no-reflow").[28,35,36] Management of patients with diabetes mellitus and STEMI should be the same as for patients without diabetes mellitus, with attention to moderate glycemic control.

The elderly comprise a growing segment of the population and present special challenges for diagnosis and management that may lead to disparities in care and delays in treatment. Additional issues to consider include the risks of antithrombotic and interventional therapies and the appropriate boundaries of care within the context of individual comorbidities, frailty, and advanced-care directives. Clinical trials frequently have limited enrollment of older populations.[37] Treatments that are effective in younger populations usually are indicated in the elderly, with the caveat that the elderly more often have absolute or relative contraindications to their use. Impaired renal function associated with aging requires careful attention to drug dosing.[38,39]

In an analysis of 8578 patients with STEMI from 226 US hospitals participating in the CRUSADE quality improvement initiative from September 2004 to December 2006, 7% of eligible patients did not receive reperfusion therapy.[21] The factor most strongly associated with not providing reperfusion therapy in eligible patients was increasing age. Evidence suggests that even the very elderly have reasonable post-MI outcomes when treated aggressively with reperfusion therapy,[40] though individual circumstances vary.

Both the GWTG Quality Improvement Program and the North Carolina Reperfusion of Acute Myocardial Infarction in Carolina Emergency Department's initiative demonstrated that focused quality improvement efforts and programs designed to systematize care across integrated regional centers can lessen disparities and improve the care of elderly patients with STEMI.[23,41]

Numerous studies have highlighted the fact that patients with chronic kidney disease of all stages less frequently receive guideline-recommended interventions than do patients with normal renal function, despite evidence of benefit from most acute treatments.[42-45] In a project that linked the US Renal Data System database with the NRMI (National Registry of Myocardial Infarction)–3, patients on dialysis had longer prehospital delays, were less often recognized as having an acute MI, and less often had ST elevation or LBBB on initial ECG than patients not on dialysis. Only 45% of eligible patients on dialysis received reperfusion therapy, and only 70% received aspirin on admission. The in-hospital

mortality rate was 21.3% among patients on dialysis, compared with 11.7% for patients with end-stage renal failure not on dialysis. At discharge, only 67% of patients on dialysis were prescribed aspirin, and only 57% were prescribed beta blockers. In the GRACE (Global Registry of Acute Coronary Events) registry, the in-hospital mortality rate was approximately 30% among patients with STEMI or LBBB MI with stage 4 or 5 chronic kidney disease. Both fibrinolysis and primary PCI were associated with higher bleeding rates in patients with severely reduced renal function.[46] Progressive renal dysfunction is a strong predictor of bleeding with antithrombotic therapy, a risk that may reflect intrinsic renal dysfunction and/or failure to adjust or avoid antithrombotic medications that are dependent on renal elimination.[22,47]

2.3. Early Risk Assessment

Global risk assessment provides an opportunity to integrate various patient characteristics into a semiquantitative score that can convey an overall estimate of a patient's prognosis; can dictate the acuity, intensity, and location of care; and can provide the patient and family with a more informed sense of potential outcome. Higher risk scores generally imply that higher-intensity treatments may be appropriate within the context of the patient's health status.

Some of the independent predictors of early death from STEMI include age, Killip class, time to reperfusion, cardiac arrest, tachycardia, hypotension, anterior infarct location, prior infarction, diabetes mellitus, smoking status, renal function, and biomarker findings.[48,49] Whereas the Thrombolysis In Myocardial Infarction (TIMI) risk score was developed specifically in patients with STEMI (http://www.mdcalc.com/timi-risk-score-for-stemi), the GRACE model (http://www.outcomes-umassmed.org/grace/acs_risk/acs_risk_content.html) predicts in-hospital and 6-month mortality rate across the spectrum of patients presenting with ACS, including those with ST elevation or ST depression. Risk assessment is a continuous process that should be repeated throughout hospitalization and at time of discharge.

3. Onset of MI

3.1. Patient-Related Delays and Initial Treatment

Patients with STEMI do not seek medical care for approximately 1.5 to 2 hours after symptom onset, and little change in this interval has occurred over the past 10 years.[50,51] Patient delay times are often longer in women, blacks, the elderly, and Medicaid-only recipients and are shorter for Medicare recipients (compared with privately insured patients) and patients who are taken directly to the hospital by emergency medical services (EMS) transport.[52,53] Patients may delay seeking care because their symptoms differ from their preexisting bias that a heart attack should present dramatically with severe, crushing chest pain.[54] Approximately one third of patients with MI experience symptoms other than chest pain.[7] Other reasons for delay in seeking treatment include 1) inappropriate reasoning that symptoms will be self-limited or are not serious[55–57]; 2) attribution of symptoms to other preexisting conditions; 3) fear of embarrassment should symptoms turn out to be a "false alarm"; 4) reluctance to trouble others unless "really sick"[55,57,58]; 5) preconceived stereotypes of who is at risk for a heart attack, an especially common trait among women[59]; 6) lack of knowledge of the importance of rapid action, the benefits of calling EMS or 9-1-1, and the availability of reperfusion therapies[54]; and 7) attempted self-treatment with prescription and/or nonprescription medications.[57] To avoid such delays, healthcare providers should assist patients when possible in making anticipatory plans for timely recognition and response to an acute event. Family members, close friends, or advocates also should be enlisted as reinforcement for rapid action when the patient experiences symptoms of possible STEMI.[60,61] Discussions should include a review of instructions for taking aspirin[62] and nitroglycerin in response to chest pain. Emergency medical dispatchers are trained to instruct patients with possible STEMI symptoms to chew non–enteric-coated aspirin (162 to 325 mg), unless contraindicated, while personnel are en route. If nitroglycerin is prescribed, the patient should be advised to take 1 nitroglycerin dose promptly. If symptoms are unimproved or worsening 5 minutes after 1 dose, the patient should be instructed to call 9-1-1 immediately.

3.2. Mode of Transport to the Hospital

Even though >98% of the US population is covered by 9-1-1 service,[63] patients with STEMI often do not call EMS or 9-1-1 and are not transported to the hospital by ambulance. In a 2011 observational study from the ACTION Registry–GWTG that used data reported from a limited number of predominantly PCI-capable US hospitals, EMS transport was used for only 60% of 37 643 patients with STEMI.[64] Older US surveys reported EMS activation rates of 23% to 53%, with substantial geographic variability.[62,65,66]

Patients with possible ischemic symptoms should be transported to the hospital by ambulance rather than by friends or relatives because 1) 1 in every 300 patients with chest pain transported to the emergency department (ED) by private vehicle suffers cardiac arrest en route[67]; and 2) there is a significant association between arrival at the ED by ambulance and earlier delivery of reperfusion therapy.[64–66,68] In addition, the performance of prehospital ECGs by trained personnel is associated with shorter reperfusion times[69] and lower mortality rates from STEMI. The use of prehospital ECGs, particularly when coupled with communication of STEMI diagnosis and preferential transport to a PCI-capable hospital, has been shown to result in rapid reperfusion times and excellent clinical outcomes.[70–72]

3.3. Patient Education

The AHA and National Institutes of Health "Act in Time to Heart Attack Signs" campaign[73] stresses that patients can increase their chance of surviving STEMI by learning the warning symptoms, filling out a survival plan, and discussing risk reduction with their physician. These materials are available on the National Institutes of Health "Heart Attack" Web page (http://health.nih.gov/topic/HeartAttack/).[74] Healthcare providers should target their educational interventions to patients at increased risk for ACS.[75]

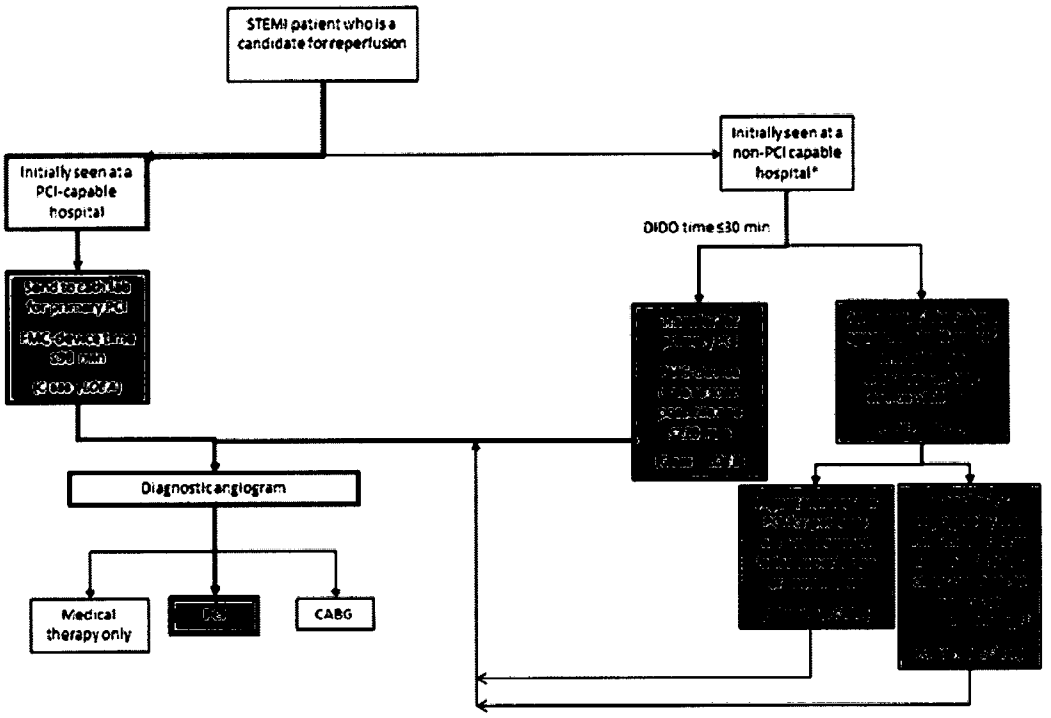


Figure 2. Reperfusion therapy for patients with STEMI. The bold arrows and boxes are the preferred strategies. Performance of PCI is dictated by an anatomically appropriate culprit stenosis. *Patients with cardiogenic shock or severe heart failure initially seen at a non–PCI-capable hospital should be transferred for cardiac catheterization and revascularization as soon as possible, irrespective of time delay from MI onset (*Class I, LOE: B*). †Angiography and revascularization should not be performed within the first 2 to 3 hours after administration of fibrinolytic therapy. CABG indicates coronary artery bypass graft; DIDO, door-in–door-out, FMC, first medical contact; LOE, Level of Evidence; MI, myocardial infarction; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

3.4. Community Preparedness and System Goals for Reperfusion Therapy

3.4.1. Regional Systems of STEMI Care, Reperfusion Therapy, and Time-to-Treatment Goals: Recommendations

See Figure 2.

Class I

1. **All communities should create and maintain a regional system of STEMI care that includes assessment and continuous quality improvement of EMS and hospital-based activities. Performance can be facilitated by participating in programs such as Mission: Lifeline and the D2B Alliance.[71,76–78] (*Level of Evidence: B*)**
2. **Performance of a 12-lead ECG by EMS personnel at the site of first medical contact (FMC) is recommended in patients with symptoms consistent with STEMI.[70–72,79,80] (*Level of Evidence: B*)**
3. **Reperfusion therapy should be administered to all eligible patients with STEMI with symptom onset within the prior 12 hours.[81,82] (*Level of Evidence: A*)**
4. **Primary PCI is the recommended method of reperfusion when it can be performed in a timely fashion by experienced operators.[82–84] (*Level of Evidence: A*)**
5. **EMS transport directly to a PCI-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI, with an ideal FMC-to-device time system goal of 90 minutes or less.*[70–72] (*Level of Evidence: B*)**
6. **Immediate transfer to a PCI-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI who initially arrive at or are transported to a non–PCI-capable hospital, with an FMC-to-device time system goal of 120 minutes or less.*[83–86] (*Level of Evidence: B*)**
7. **In the absence of contraindications, fibrinolytic therapy should be administered to patients with STEMI at non–PCI-capable hospitals when the anticipated FMC-to-device time at a PCI-capable hospital exceeds 120 minutes because of unavoidable delays.[81,87,88] (*Level of Evidence: B*)**
8. **When fibrinolytic therapy is indicated or chosen as the primary reperfusion strategy, it should be administered within 30 minutes of hospital arrival.*[89–93] (*Level of Evidence: B*)**

Class IIa

1. **Reperfusion therapy is reasonable for patients with STEMI and symptom onset within the prior 12 to 24 hours who have clinical and/or ECG evidence of ongoing ischemia. Primary PCI is the preferred strategy in this population.[81,94,95] (*Level of Evidence: B*)**

*The proposed time windows are system goals. For any individual patient, every effort should be made to provide reperfusion therapy as rapidly as possible.

3.4.1.1. Regional Systems of STEMI Care and Goals for Reperfusion Therapy

Any regional medical system must seek to enable rapid recognition and timely reperfusion of patients with STEMI. System delays to reperfusion are correlated with higher rates of mortality and morbidity.[96–100] Although attention to certain performance metrics, such as D2B, door-to-needle, and door-in–door-out times, have catalyzed important institutional quality improvement efforts, broader initiatives at a systems level are required to reduce total ischemic time, the principal determinant of outcome.[101,102] Questions have been raised about the overreliance on primary PCI for reperfusion, especially in the United States, and the unintended consequences that have evolved as familiarity with fibrinolysis has waned.[101] The writing committee reiterates the principle highlighted in the 2004 ACC/AHA STEMI guideline, namely that "the appropriate and timely use of some form of reperfusion therapy is likely more important than the choice of therapy."[4] Greatest emphasis is to be placed on the delivery of reperfusion therapy to the individual patient as rapidly as possible.

Only a minority of US hospitals are capable of performing primary PCI,[103] and any delay in time to reperfusion (D2B) after hospital arrival is associated with a higher adjusted risk of in-hospital mortality in a continuous, nonlinear fashion.[96] Strict time goals for reperfusion may not always be relevant or possible for patients who have an appropriate reason for delay, including initial uncertainty about diagnosis, the need for evaluation and treatment of other life-threatening conditions (eg, acute respiratory failure, cardiac arrest), delays involving informed consent, and long transport times due to geographic distance or adverse weather. To reduce hospital treatment delays, the ACC initiated the D2B Alliance in 2006 to improve door-to-device times in patients with STEMI.[104] The D2B Alliance goal was for participating PCI-capable hospitals to achieve a D2B time of ≤90 minutes for at least 75% of nontransferred patients with STEMI. The Alliance met this goal by 2008.[105] A longitudinal study of hospitals participating in the NCDR CathPCI Registry demonstrated that patients treated in hospitals that had been enrolled in the D2B Alliance for ≥3 months were significantly more likely to have D2B times of ≤90 minutes than patients treated in nonenrolled hospitals.[105]

In a similar manner, the AHA launched "Mission: Lifeline" in 2007 to improve health system readiness and response to STEMI,[106,107] with a focus on the continuum of care from EMS activation to primary PCI. Patients may present directly by private transport to a PCI-capable hospital, in which case all medical care occurs in a single center responsible for optimizing door-to-device times. For patients who call 9-1-1, direct care begins with FMC, defined as the time at which the EMS provider arrives at the patient's side. EMS personnel should be accountable for obtaining a prehospital ECG, making the diagnosis, activating the system, and deciding whether to transport the patient to a PCI-capable or non–PCI-capable hospital. Consideration should be given to the development of local protocols that allow preregistration and direct transport to the catheterization laboratory of a PCI-capable hospital (bypassing the ED) for patients who do not require emergent stabilization upon arrival. Although "false positives" are a concern when EMS personnel and/or emergency physicians are allowed to activate the cardiac catheterization laboratory, the rate of false activations is relatively low (approximately 15%) and is more than balanced by earlier treatment times for the majority of patients for whom notification is appropriate.[108–114] The concept of what constitutes false activation is evolving.[115,116] For patients who arrive at or are transported by EMS to a non–PCI-capable hospital, a decision about whether to transfer immediately to a PCI-capable hospital or to administer fibrinolytic therapy must be made. Each of these scenarios involves coordination of different elements of the system. On the basis of model systems of STEMI care in the United States and Europe,[77,78,117–121] Mission: Lifeline recommends a multifaceted community-wide approach that involves patient education, improvements in EMS and ED care, establishment of networks of STEMI-referral (non–PCI-capable) and STEMI-receiving (PCI-capable) hospitals, and coordinated advocacy efforts to work with payers and policy makers to implement healthcare system redesign. Detailed information about this program can be found on the AHA website.[122]

Several factors should be considered in selecting the type of reperfusion therapy (Figure 2). For patients with STEMI presenting to a PCI-capable hospital, primary PCI should be accomplished within 90 minutes. For patients presenting to a non–PCI-capable hospital, rapid assessment of 1) the time from onset of symptoms, 2) the risk of complications related to STEMI, 3) the risk of bleeding with fibrinolysis, 4) the presence of shock or severe HF, and 5) the time required for transfer to a PCI-capable hospital must be made and a decision about administration of fibrinolytic therapy reached. Even when interhospital transfer times are short, there may be relative advantages to a strategy of immediate fibrinolytic therapy versus any delay to primary PCI for eligible patients who present within the first 1 to 2 hours after symptom onset.[89,101,123,124]

Several trials have suggested a benefit of transferring patients with STEMI from a non–PCI-capable hospital to a PCI-capable hospital for primary PCI,[83,125] but in many instances, transfer times are prolonged and delays may be unavoidable. In the NCDR,[126,127] only 10% of transferred patients were treated within 90 minutes of initial presentation, with a median first door-to-device time of 149 minutes. In many communities, a significant percentage of patients with STEMI who present initially to a non–PCI-capable hospital cannot physically be transferred to a PCI-capable hospital and achieve an FMC-to-device time treatment goal of ≤90 minutes. DANAMI-2 (Danish Multicenter Randomized Study on Thrombolytic Therapy Versus Acute Coronary Angioplasty in Acute Myocardial Infarction) showed that a reperfusion strategy involving the transfer of patients with STEMI from a non–PCI-capable hospital to a PCI-capable hospital for primary PCI was superior to the use of fibrinolysis at the referring hospital, driven primarily by a reduction in the rate of reinfarction in the primary PCI–treated group.[83,85] In this study, the average first door-to-device time delay was approximately 110 minutes.[85] Shorter system delays were associated with a reduced mortality rate for both

fibrinolysis- and primary PCI–treated patients. In an analysis of approximately 19000 propensity score–matched patients with STEMI from NRMI-2, -3, -4, and -5, when delays related to transfer for primary PCI exceeded 120 minutes from FMC, the survival advantage of primary PCI over fibrinolysis was negated. Delays beyond 120 minutes occurred in nearly half the patients in the analysis.[100] Thus, interhospital transfer to a PCI-capable hospital is the recommended triage strategy if primary PCI consistently can be performed within 120 minutes of FMC. Fibrinolytic therapy, in the absence of contraindications to its use, should be administered within 30 minutes of first door arrival when this 120-minute time goal cannot be met. Transfer delays can occur at multiple levels and for varied reasons.[128] Efforts are needed to reduce the time delay between arrival to and transfer from a non–PCI-capable hospital (ie, door-in–door-out). Among a subset of 14821 patients in the NCDR ACTION–GWTG registry, the median door-in–door-out time was 68 minutes (interquartile range, 43 to 120 minutes). A door-in–door-out time ≤30 minutes, achieved in only 11% of patients, was associated with shorter delays to reperfusion and a lower in-hospital mortality rate.[129] Because estimation of treatment times for patients can be inaccurate, the decision to transfer for primary PCI should be based on actual, historical times achieved within the regional system, with quality assurance programs to ensure that such goals are consistently met. A reasonable goal would be that 90% of patients should meet the 120-minute time-to-treatment standard to achieve performance standards.

Several triage and transfer strategies have been tested and are discussed further in Section 5.3. The term *facilitated PCI* was used previously to describe a strategy of full- or half-dose fibrinolysis, with or without administration of a glycoprotein (GP) IIb/IIIa receptor antagonist, with immediate transfer for planned PCI within 90 to 120 minutes. Two large studies failed to show a net clinical benefit with this strategy.[130,131] The term *rescue PCI* refers to the transfer for PCI of patients who demonstrate findings of failed reperfusion with fibrinolysis.[103,130] The term *pharmacoinvasive strategy* refers to the administration of fibrinolytic therapy either in the prehospital setting or at a non–PCI-capable hospital, followed by immediate transfer to a PCI-capable hospital for early coronary angiography and PCI when appropriate. Patients with STEMI who are best suited for immediate interhospital transfer for primary PCI without fibrinolysis are those patients who present with shock or other high-risk features, those with high bleeding risk with fibrinolytic therapy, and those who present >3 to 4 hours after symptom onset and who have short transfer times. Patients best suited for initial fibrinolytic therapy are those with low bleeding risk who present very early after symptom onset (<2 to 3 hours) to a non–PCI-capable hospital and who have longer delay to PCI.

Because patients with STEMI may first present with cardiac arrest, regional systems also should emphasize early access to care (recognition of the problem and bystander activation of EMS), rapid dispatch, bystander cardiopulmonary resuscitation (CPR), defibrillation when indicated, advanced cardiac life support, and an organized approach to postresuscitation care. In addition, family members of patients who have had STEMI or other manifestations of coronary artery disease should be referred to CPR training programs that have a social support component and can familiarize them with the use of automated external defibrillators.

Checklist. Improving Door-to-Device Times

1. Prehospital ECG to diagnose STEMI is used to activate the PCI team while the patient is en route to the hospital.
2. Emergency physicians activate the PCI team.
3. A single call to a central page operator activates the PCI team.
4. Goal is set for the PCI team to arrive in the catheterization laboratory with in 20 minutes after being paged.
5. Timely data feedback and analysis are provided to members of the STEMI care team.

3.4.1.2. Strategies for Shortening Door-to-Device Times

The D2B time interval includes 3 key components: door-to-ECG time, ECG–to–catheterization laboratory time, and laboratory arrival–to–device time.[132] All 3 intervals are dependent on system factors that may vary across institutions.[132]

Public reporting and national initiatives have focused much attention on D2B times[104,133] and the many reasons for system delays.[134] Studies have shown marked differences in the timeliness of primary PCI across hospitals. Focusing on the processes of care at the top-performing institutions, research has revealed characteristics of institutions associated with exemplary performance.[124] Top hospitals have specific cultural attributes that include 1) a commitment to an explicit goal of improving D2B times that is motivated by internal and external pressures, including senior management support; 2) innovative protocols; 3) flexibility in refining standardized protocols; 4) uncompromising individual clinical leaders; 5) collaborative teams; 6) data feedback to monitor progress, identify problems, and successes; and 7) an organizational culture that fosters resilience to challenges or setbacks to improvement efforts.[135] In addition, several key processes are associated strongly with more timely treatment (Checklist). Other studies have indicated that PCI-capable hospitals receiving patients in transfer can reduce their D2B times by coordinating with the referring hospitals and activating their systems while patients are being transported.[78]

Currently, it is estimated that almost 90% of patients presenting to a hospital with PCI capability and without a clinical reason for delay have a D2B time ≤90 minutes.[136] Some innovative programs are achieving much faster times.[137–139] In addition, with improvements in timeliness of care across the country, racial disparities in reperfusion times have been reduced significantly.[140] In an analysis of patients with STEMI reported by hospitals to the Centers for Medicare & Medicaid Services, median D2B times fell from 96 minutes in the year ending December 31, 2005, to 64 minutes in the 3 quarters ending September 30, 2010. This decline was accompanied by an increase in the percentage of patients with D2B times <90 minutes, from 44.2% to 91.4%.[141] Nevertheless, despite substantial improvements in D2B times, evidence that these efforts have translated into reduced mortality rates is lacking. The absence of demonstrated benefit may relate to reduced power to show change in

survival in a population with a relatively low mortality rate, improved early survival of higher-risk patients, and changing STEMI demographics. These findings support the goal of comprehensive efforts to improve all aspects of acute MI care to improve survival rates.

3.5. Prehospital Fibrinolytic Therapy

The time delay from symptom onset to treatment can be shortened by administration of prehospital fibrinolytic therapy by a trained EMS unit either with a physician on board[142–147] or with a hospital-based physician[148–152] in direct contact, especially in rural areas. Multiple randomized controlled trials (RCTs) have demonstrated the safety and feasibility of prehospital fibrinolytic therapy, with decreased treatment times ranging from 30 to 140 minutes.[42,143,145–147,149–151,153] A meta-analysis of 6 higher-quality RCTs revealed an approximately 60-minute reduction in time from symptom onset to delivery of fibrinolytic therapy with prehospital versus hospital-based administration, with a corresponding 17% reduction in risk of all-cause hospital mortality.[154] Analysis of a subgroup of patients enrolled in the CAPTIM (Comparaison de l'Angioplastie Primaire et de la Thrombolyse) trial within 2 hours of symptom onset showed a significantly lower 5-year mortality rate for patients treated with prehospital fibrinolysis than for patients managed with primary PCI (P=0.04).[123,142] These salutary results for early presenters were confirmed in a subsequent analysis of combined data from the CAPTIM and WEST (Which Early ST-Elevation Myocardial Infarction Therapy) trials.[155] Data from the USIC (Unité de Soins Intensifs Coronaires) Registry and the Swedish Registry of Cardiac Intensive Care also suggest that prehospital fibrinolytic therapy may lower STEMI mortality rates.[144,148]

At the present time, however, prehospital fibrinolytic therapy is not used in most communities in the United States. EMS in rural areas, where prehospital fibrinolysis would potentially be of benefit, often have neither the resources to train paramedics nor the funding for necessary equipment. Use of prehospital fibrinolysis is more widespread in some regions of Europe and the United Kingdom. The writing committee endorses the need for further research into the implementation of prehospital strategies to reduce total ischemic time.

3.6. The Relationship Between Sudden Cardiac Death and STEMI

3.6.1. Evaluation and Management of Patients With STEMI and Out-of-Hospital Cardiac Arrest: Recommendations

Class I

1. **Therapeutic hypothermia should be started as soon as possible in comatose patients with STEMI and out-of-hospital cardiac arrest caused by ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT), including patients who undergo primary PCI.[156–158] (*Level of Evidence: B*)**
2. **Immediate angiography and PCI when indicated should be performed in resuscitated out-of-hospital cardiac arrest patients whose initial ECG shows STEMI.[159–174] (*Level of Evidence: B*)**

See *Online Data Supplement 2* for additional data on PCI for cardiac arrest.

Almost 70% of the coronary heart disease deaths annually in the United States occur out of hospital, usually presenting as "sudden death" due to cardiac arrest.[175] Resuscitation is attempted by EMS personnel in approximately 60% of these out-of-hospital cardiac arrest cases; the remaining patients are deceased on arrival of the EMS team.[175–177] Although only 23% of out-of-hospital cardiac arrest cases have a shockable initial rhythm (primarily VF), the majority of neurologically intact survivors come from this subgroup.[175,176] The median rate of survival to hospital discharge with any first recorded rhythm is only 7.9%[175]; the rate of survival in patients who are in VF initially is much higher (median 22%, range 8% to 40%), as documented in 10 US and Canadian regions participating in the National Institutes of Health–sponsored Resuscitation Outcomes Consortium.[176]

Survival from out-of-hospital cardiac arrest is optimal when both CPR and defibrillation are initiated early.[178] Survival from VF specifically is inversely related to the time interval between its onset and termination, with the odds of survival decreasing 7% to 10% for each minute of delay from onset to defibrillation.[178–180] The percentage of patients who are found in VF and the likelihood of survival are higher if the patient's collapse is witnessed, if bystander CPR is performed, and if a monitor/defibrillator can be applied quickly.[181]

Community strategies that improve the delivery of early defibrillation to out-of-hospital cardiac arrest victims include training and equipping first responders (fire and law enforcement), EMS personnel, and paramedics to defibrillate, as well as placing automated external defibrillators in highly populated locations such as airports, commercial aircraft, and gambling casinos ("public access defibrillation").[182–193] The latter strategy has been shown to approximately double the number of neurologically intact out-of-hospital cardiac arrest survivors when laypersons are trained and equipped to provide early CPR and defibrillation with automated external defibrillators, compared with providing CPR alone while awaiting arrival of EMS personnel.[183]

Two RCTs have reported improved rates of neurologically intact survival to hospital discharge when comatose patients with out-of-hospital VF or nonperfusing VT cardiac arrest were cooled to 32°C to 34°C for 12 or 24 hours beginning minutes to hours after the return of spontaneous circulation.[157,158] Additional studies with historical control groups also have shown improved neurological outcomes after therapeutic hypothermia for comatose survivors of VF arrest.[194,195] Accordingly, therapeutic hypothermia should be initiated in patients with STEMI and out-of-hospital cardiac arrest. Cooling should begin before or at the time of cardiac catheterization.

Approximately 5% of patients with STEMI who survive to reach the hospital will experience a cardiac arrest during hospitalization.[196] Reports from high-volume PCI centers indicate that 4% to 11% of patients with STEMI who are

treated with PCI are brought to cardiac catheterization after being resuscitated from out-of-hospital cardiac arrest.[77,197,198] However, the percentage of out-of-hospital cardiac arrest victims whose event is triggered by an acute coronary occlusion is less clear. The majority of out-of-hospital cardiac arrest patients who cannot be resuscitated have significant coronary atherosclerosis.[199] Coronary atherosclerosis is also present in the majority of cardiac arrest victims who survive and undergo coronary angiography.[200] Because of the high prevalence of acute coronary artery occlusions in out-of-hospital cardiac arrest patients who are resuscitated successfully, especially those whose initial rhythm is VF in the setting of STEMI, the AHA 2010 Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care[201] recommend emergency coronary angiography with prompt opening of the infarct artery. Out-of-hospital cardiac arrest victims with initial VF who survive to hospital admission have a rate of survival to hospital discharge of 60% after early PCI.

The AHA issued a policy statement calling for communities to establish regional systems of care for out-of-hospital cardiac arrest.[159] The statement defines 2 different levels of cardiac resuscitation centers and lists the essential elements of such a system. PCI-capable hospitals become ideal candidates to serve as Level I cardiac resuscitation centers that can offer a wide range of services, including timely PCI when indicated, a goal-directed care bundle,[202,203] therapeutic hypothermia,[157,158] frequent or continuous electroencephalographic monitoring, a multidisciplinary team approach, and neuropsychiatric evaluation for survivors. All other participating hospitals should be trained and equipped as Level II cardiac resuscitation centers, which are capable of initiating therapeutic hypothermia and transferring patients for primary postresuscitation care. Ideally, out-of-hospital cardiac arrest outcomes should be measured and compared within a dedicated registry. Lastly, it is important for organizations that collect and publicly report STEMI and PCI data to consider resuscitated out-of-hospital cardiac arrest patients separately from their hospital and individual operator quality "scorecards" because such patients, even with optimal care, have a much higher mortality rate than that of patients with STEMI who have not had a cardiac arrest.[204–206] Public reporting in this instance might have the unintended consequence of reducing appropriate care.[207]

4. Reperfusion at a PCI-Capable Hospital

4.1. Primary PCI

4.1.1. Primary PCI in STEMI: Recommendations

See Table 2 for a summary of recommendations from this section.

Table 2. Primary PCI in STEMI

	COR	LOE	References
Ischemic symptoms <12 h	I	B	82, 208, 209
Ischemic symptoms <12 h and contraindications to fibrinolytic therapy irrespective of time delay from FMC	I	B	210, 211
Cardiogenic shock or acute severe HF irrespective of time delay from MI onset	I	B	212–215
Evidence of ongoing ischemia 12 to 24 h after symptom onset	IIa	B	94, 95
PCI of a noninfarct artery at the time of primary PCI in patients without hemodynamic compromise	III: Harm	B	216–218

COR indicates Class of Recommendation; FMC, first medical contact; HF, heart failure; LOE, Level of Evidence; MI, myocardial infarction; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

Class I

1. **Primary PCI should be performed in patients with STEMI and ischemic symptoms of less than 12 hours' duration.[82,208,209] (*Level of Evidence: A*)**
2. **Primary PCI should be performed in patients with STEMI and ischemic symptoms of less than 12 hours' duration who have contraindications to fibrinolytic therapy, irrespective of the time delay from FMC.[210,211] (*Level of Evidence: B*)**
3. **Primary PCI should be performed in patients with STEMI and cardiogenic shock or acute severe HF, irrespective of time delay from MI onset (Section 9.1.1).[212–215] (*Level of Evidence: B*)**

Class IIa

1. **Primary PCI is reasonable in patients with STEMI if there is clinical and/or ECG evidence of ongoing ischemia between 12 and 24 hours after symptom onset.[94,95] (*Level of Evidence: B*)**

Class III: Harm

1. **PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI who are hemodynamically stable.[216–218] (*Level of Evidence: B*)**

Primary PCI of the infarct artery is preferred to fibrinolytic therapy when time-to-treatment delays are short and the patient presents to a high-volume, well-equipped center with experienced interventional cardiologists and skilled support staff. Compared with fibrinolytic therapy, primary PCI produces higher rates of infarct artery patency, TIMI 3 flow, and access site bleeding and lower rates of recurrent ischemia, reinfarction, emergency repeat revascularization procedures, intracranial hemorrhage (ICH), and death.[82] Early, successful PCI also greatly decreases the complications of STEMI that result from longer ischemic times or unsuccessful fibrinolytic therapy, allowing earlier hospital discharge and resumption of daily activities. Primary PCI has its greatest survival benefit in high-risk patients. PCI outcomes have been shown to be worse with delays to treatment and with low-volume hospitals and operators. Quality metrics for both laboratory and operator performance and considerations with regard to primary PCI at hospitals without on-site cardiac surgery are reviewed in the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, Section 7.[219]

Potential complications of primary PCI include problems with the arterial access site; adverse reactions to volume loading, contrast medium, and antithrombotic medications; technical complications; and reperfusion events. The "no-reflow" phenomenon refers to suboptimal myocardial perfusion despite restoration of epicardial flow in the infarct artery and has been attributed to the combined effects of inflammation, endothelial injury, edema, atheroembolization, vasospasm, and myocyte reperfusion injury.[220] No-reflow is associated with a reduced survival rate. Treatment and prevention strategies have included use of the GP IIb/IIIa antagonist abciximab, vasodilators (nitroprusside, verapamil, adenosine), and inhibitors of various metabolic pathways (nicorandil, pexelizumab), albeit without consistent effect. Manual thrombus aspiration at the time of primary PCI results in improved tissue perfusion and more complete ST resolution[221,222] (Section 4.2), though not all studies have shown positive results.[223]

PCI of a noninfarct artery with TIMI 3 flow at the time of primary PCI in hemodynamically stable patients has been associated with worse clinical outcomes in several studies,[216-218,224] though others have suggested that it may be performed safely.[225-229] Noninfarct artery PCI is not recommended in this context unless multiple complex lesions are seen on angiography and ECG localization of the infarct is ambiguous.[230,231] Clinical stability may be defined broadly as the absence of low output, hypotension, persistent tachycardia, apparent shock, high-grade ventricular or symptomatic supraventricular tachyarrhythmias, and spontaneous recurrent ischemia. In patients with cardiogenic shock due to pump failure, PCI of a severe stenosis in a large noninfarct artery might improve hemodynamic stability and should be considered during the primary procedure (Section 9.1.1). In the majority of patients, delayed PCI can be performed in a noninfarct artery at a later time if indicated by clinical events or the results of noninvasive testing.[218,232,233]

4.2. Aspiration Thrombectomy: Recommendation

Class IIa

1. **Manual aspiration thrombectomy is reasonable for patients undergoing primary PCI.[221,223,234,235] (*Level of Evidence: B*)**

Two RCTs[221,235] and a meta-analysis[234] support the use of manual aspiration thrombectomy during primary PCI to improve microvascular reperfusion and to decrease deaths and adverse cardiac events. However, infarct size was not reduced by manual aspiration thrombectomy in the INFUSE-AMI (Intracoronary Abciximab Infusion and Aspiration Thrombectomy in Patients Undergoing Percutaneous Coronary Intervention for Anterior ST-Segment Elevation Myocardial Infarction) trial of patients with large anterior STEMI.[223] The trial was underpowered to detect differences in clinical outcomes. No clinical benefit for routine rheolytic thrombectomy has been demonstrated in primary PCI.[234,236,237]

4.3. Use of Stents in Primary PCI

4.3.1. Use of Stents in Patients With STEMI: Recommendations

Class I

1. **Placement of a stent (bare-metal stent [BMS] or drug-eluting stent [DES]) is useful in primary PCI for patients with STEMI.[238,239] (*Level of Evidence: A*)**
2. **BMS† should be used in patients with high bleeding risk, inability to comply with 1 year of dual antiplatelet therapy (DAPT), or anticipated invasive or surgical procedures in the next 1 year. (*Level of Evidence: C*)**

Class III: Harm

1. **DES should not be used in primary PCI for patients with STEMI who are unable to tolerate or comply with a prolonged course of DAPT because of the increased risk of stent thrombosis with premature discontinuation of one or both agents.[240-246] (*Level of Evidence: B*)**

Coronary stents are used routinely at the time of primary PCI. Compared with balloon angioplasty, BMS implantation during primary PCI decreases the risk for subsequent target-lesion and target-vessel revascularization and possibly the risk for reinfarction, but is not associated with a reduction in the mortality rate.[238] Compared with BMS, DES implantation decreases restenosis rates and the need for reintervention but does not definitively reduce rates of death or reinfarction. Notably, DES in this setting does not increase the risk of early or late stent thrombosis.[242-245,247,248] Controversy remains as to whether the risk of very late stent thrombosis is higher with first-generation DES than with BMS.[249] The lowest rates of stent thrombosis have been reported with cobalt-chromium everolimus-eluting stents.[250] The greatest challenge in deciding the approach at the time of primary PCI, however, is determining emergently whether the patient is a candidate for a prolonged (ie, 1 year) course of DAPT. DES should be avoided in the presence of financial or social barriers that may limit patient compliance, elevated bleeding risk, the anticipated need for invasive or surgical procedures in the subsequent 1 year, or an independent indication for long-term anticoagulant therapy.

4.4. Adjunctive Antithrombotic Therapy for Primary PCI

See Table 3 for a summary of recommendations from this section and *Online Data Supplement 3* for additional information on antithrombotic therapy.

4.4.1. Antiplatelet Therapy to Support Primary PCI for STEMI: Recommendations

Class I

1. **Aspirin 162 to 325 mg should be given before primary PCI.[251-253] (*Level of Evidence: B*)**

†Balloon angioplasty without stent placement may be used in selected patients.

Table 3. Adjunctive Antithrombotic Therapy to Support Reperfusion With Primary PCI

	COR	LOE	References
Antiplatelet therapy			
Aspirin			
• 162- to 325-mg load before procedure	I	B	251–253
• 81- to 325-mg daily maintenance dose (indefinite)*	I		254, 255, 257
• 81 mg daily is the preferred maintenance dose*	IIa	B	253, 254, 263, 264
$P2Y_{12}$ inhibitors			
Loading doses			
• Clopidogrel: 600 mg as early as possible or at time of PCI	I	B	253, 258, 259
• Prasugrel: 60 mg as early as possible or at time of PCI	I	B	260
• Ticagrelor: 180 mg as early as possible or at time of PCI	I	B	261
Maintenance doses and duration of therapy			
DES placed: Continue therapy for 1 y with:			
• Clopidogrel: 75 mg daily	I	B	260, 262
• Prasugrel: 10 mg daily	I	B	262
• Ticagrelor: 90 mg twice a day*	I	B	261
BMS† placed: Continue therapy for 1 y with:			
• Clopidogrel: 75 mg daily	I	B	260, 262
• Prasugrel: 10 mg daily	I	B	262
• Ticagrelor: 90 mg twice a day*	I	B	261
DES placed:			
• Clopidogrel, prasugrel, or ticagrelor* continued beyond 1 y	IIb	C	N/A
• Patients with STEMI with prior stroke or TIA: prasugrel		B	260
IV GP IIb/IIIa receptor antagonists in conjunction with UFH or bivalirudin in selected patients			
• Abciximab: 0.25-mg/kg IV bolus, then 0.125 mcg/kg/min (maximum 10 mcg/min)	IIa		265–267
• Tirofiban: (high-bolus dose): 25-mcg/kg IV bolus, then 0.15 mcg/kg/min	IIa	B	268, 269
• In patients with CrCl <30 mL/min, reduce infusion by 50%			
• Eptifibatide: (double bolus): 180-mcg/kg IV bolus, then 2 mcg/kg/min; a second 180-mcg/kg bolus is administered 10 min after the first bolus	IIa	B	270
• In patients with CrCl <50 mL/min, reduce infusion by 50%			
• Avoid in patients on hemodialysis			
• Pre–catheterization laboratory administration of IV GP IIb/IIIa receptor antagonist	IIb	B	103, 268, 271–277
• Intracoronary abciximab 0.25-mg/kg bolus	IIb	B	223, 278–284
Anticoagulant therapy			
• UFH:	I	C	N/A
• With GP IIb/IIIa receptor antagonist planned: 50- to 70-U/kg IV bolus to achieve therapeutic ACT‡			
• With no GP IIb/IIIa receptor antagonist planned: 70- to 100-U/kg bolus to achieve therapeutic ACT§	I	C	N/A
• Bivalirudin: 0.75-mg/kg IV bolus, then 1.75-mg/kg/h infusion with or without prior treatment with UFH. An additional bolus of 0.3 mg/kg can be given if needed.	I	B	248
• Reduce infusion to 1 mg/kg/h with estimated CrCl <30 mL/min			
• Preferred over UFH with GP IIb/IIIa receptor antagonist in patients at high risk of bleeding	IIa	B	248
• Fondaparinux: Not recommended as sole anticoagulant for primary PCI		B	304

*The recommended maintenance dose of aspirin to be used with ticagrelor is 81 mg daily.

†Balloon angioplasty without stent placement may be used in selected patients. It might be reasonable to provide $P2Y_{12}$ inhibitor therapy to patients with STEMI undergoing balloon angioplasty alone according to the recommendations listed for BMS. (*LOE: C*)

‡The recommended ACT with planned GP IIb/IIIa receptor antagonist treatment is 200 to 250 s.

§The recommended ACT with no planned GP IIb/IIIa receptor antagonist treatment is 250 to 300 s (HemoTec device) or 300 to 350 s (Hemochron device).

ACT indicates activated clotting time; BMS, bare-metal stent; CrCl, creatinine clearance; COR, Class of Recommendation; DES, drug-eluting stent; GP, glycoprotein; IV, intravenous; LOE, Level of Evidence; N/A, not available; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; TIA, transient ischemic attack; and UFH, unfractionated heparin.

2. **After PCI, aspirin should be continued indefinitely.[254,255,257] (*Level of Evidence: A*)**
3. **A loading dose of a $P2Y_{12}$ receptor inhibitor should be given as early as possible or at time of primary PCI to patients with STEMI. Options include**
   a. **Clopidogrel 600 mg[253,258,259] (*Level of Evidence: B*); or**
   b. **Prasugrel 60 mg[260] (*Level of Evidence: B*); or**
   c. **Ticagrelor 180 mg.[261] (*Level of Evidence: B*)**
4. **$P2Y_{12}$ inhibitor therapy should be given for 1 year to patients with STEMI who receive a stent (BMS or DES) during primary PCI using the following maintenance doses:**
   a. **Clopidogrel 75 mg daily[260,262] (*Level of Evidence: B*); or**
   b. **Prasugrel 10 mg daily[262] (*Level of Evidence: B*); or**
   c. **Ticagrelor 90 mg twice a day.[261]‡ (*Level of Evidence: B*)**

Class IIa

1. **It is reasonable to use 81 mg of aspirin in preference to higher maintenance doses after primary PCI.[253,254,263,264] (*Level of Evidence: B*)**
2. **It is reasonable to begin treatment with an intravenous GP IIb/IIIa receptor antagonist such as abciximab[265–267] (*Level of Evidence: A*), high-bolus-dose tirofiban[268,269] (*Level of Evidence: B*), or double-bolus eptifibatide[270] (*Level of Evidence: B*) at the time of primary PCI (with or without stenting or clopidogrel pretreatment) in selected patients with STEMI who are receiving unfractionated heparin (UFH).**

Class IIb

1. **It may be reasonable to administer intravenous GP IIb/IIIa receptor antagonist in the precatheterization laboratory setting (eg, ambulance, ED) to patients with STEMI for whom primary PCI is intended.[103,268,271–277] (*Level of Evidence: B*)**
2. **It may be reasonable to administer intracoronary abciximab to patients with STEMI undergoing primary PCI.[223,278–284] (*Level of Evidence: B*)**
3. **Continuation of a $P2Y_{12}$ inhibitor beyond 1 year may be considered in patients undergoing DES placement. (*Level of Evidence: C*)**

Class III: Harm

1. **Prasugrel should not be administered to patients with a history of prior stroke or transient ischemic attack.[260] (*Level of Evidence: B*)**

Although the minimum effective aspirin dose in the setting of PCI for STEMI has not been established prospectively, the writing committee recommends that an empiric dose of 325 mg be given as early as possible before PCI and a maintenance dose continued indefinitely thereafter. It is the consensus of the writing committee that the 81-mg maintenance dose is preferred even among patients who receive a stent during primary PCI. This recommendation is based on evidence of an increased risk of bleeding in most studies comparing higher- with lower-dose aspirin,[253,254,263,264] as well as the absence of data from RCTs demonstrating superior efficacy of higher aspirin doses in this setting. However, because the CURRENT-OASIS 7 (Clopidogrel Optimal Loading Dose Usage to Reduce Recurrent Events–Organization to Assess Strategies in Ischemic Syndromes) trial did not report differences in either efficacy or safety in patients with STEMI randomized to 81 mg versus 325 mg of aspirin, the committee did not think that the evidence favoring 81 mg over higher dosages was sufficiently conclusive to merit a Class I recommendation.[253]

Loading doses of $P2Y_{12}$ inhibitors are provided before or at the time of primary PCI. These agents are continued in a maintenance dose for 1 year after PCI with a stent (BMS or DES) in the absence of bleeding. A 600-mg loading dose of clopidogrel is preferred to a 300-mg loading dose, given the more extensive and rapid platelet inhibition achieved with the higher dose, as well as the beneficial effects reported in a CURRENT-OASIS 7 subgroup analysis.[259] The underpowered ARMYDA-6 MI (Antiplatelet Therapy for Reduction of Myocardial Damage During Angioplasty–Myocardial Infarction) study also reported beneficial surrogate outcomes with the higher clopidogrel loading dose.[258]

The antiplatelet response to clopidogrel may vary as a function of patient phenotype (obesity, diabetes mellitus), enteric *ABCB 1* polymorphisms, hepatic *CYP450* enzyme system polymorphisms (predominantly *CYP 2C19*2*), and medications that interfere with clopidogrel biotransformation. Approximately 25% to 30% of patients may harbor a reduced-function *CYP2C19* allele. In TRITON-TIMI 38 (Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel—Thrombolysis In Myocardial Infarction)[285] and 3 cohort studies,[286–288] patients who were carriers of the reduced-function *CYP2C19*2* allele had significantly lower levels of the active metabolite of clopidogrel, diminished platelet inhibition, and increased rates of major adverse cardiovascular events and stent thrombosis.[285] The US Food and Drug Administration has changed clopidogrel's prescribing information to highlight the potential impact of *CYP2C19* genotype on clopidogrel pharmacokinetics and clinical response.[289] Nevertheless, other studies have not confirmed associations between *CYP2C19* polymorphisms and adverse outcomes in clopidogrel-treated patients.[290] Future studies are needed to further clarify the risk associated with these genetic polymorphisms and to develop effective therapeutic strategies for carriers of allelic variants of responsible enzyme systems. Proton-pump inhibitors, most prominently omeprazole, can interfere with clopidogrel metabolism and result in diminished in vitro antiplatelet effect,[291] but it does not appear that this pharmacokinetic effect translates into worse clinical outcomes.[291,292]

Prasugrel, an alternative thienopyridine, achieves greater inhibition of platelet aggregation than clopidogrel. In the TRITON-TIMI 38 trial[260] of prasugrel versus clopidogrel in patients with ACS for whom an invasive strategy was planned, patients with STEMI who were assigned to prasugrel had a lower 30-day rate of the composite primary outcome. This difference persisted to 15 months. In addition, the rate of stent thrombosis

‡The recommended maintenance dose of aspirin to be used with ticagrelor is 81 mg daily.

reported at 30 days was significantly lower with prasugrel.[260,262] The loading dose of clopidogrel in TRITON-TIMI 38, which rarely was administered before coronary angiography and was limited to 300 mg, may have contributed to differences in efficacy and safety between treatment groups.[262]

The benefits of prasugrel relative to clopidogrel in STEMI must be weighed against the increase in the risk of bleeding associated with its use. Prasugrel should not be administered to patients with a history of stroke or transient ischemic attack and was not shown to be beneficial in patients ≥75 years of age or patients who weigh <60 kg.[260] In TRITON-TIMI 38, interaction testing for efficacy and safety showed no significant difference in bleeding risk across the spectrum of ACS. Prasugrel may be best suited for younger patients with diabetes mellitus or large areas of myocardium at risk, who are also at low bleeding risk, have the ability to continue a regimen of DAPT, and have no anticipation of surgery over the subsequent 1 year. The package insert for prasugrel suggests that a lower maintenance dose of 5 mg daily might be considered for patients at high risk of bleeding, though this dose has not been prospectively studied.[293]

Ticagrelor is a reversible, nonthienopyridine $P2Y_{12}$ receptor antagonist that does not require metabolic conversion to active drug. The PLATO (Platelet Inhibition and Patient Outcomes) study compared ticagrelor (180-mg loading dose, 90 mg twice daily thereafter) with clopidogrel (300- or 600-mg loading dose, 75 mg daily thereafter) for the prevention of cardiovascular events in 18 624 patients with ACS, of whom 35% had STEMI.[294] Among the 7544 patients enrolled with ST elevation or LBBB who underwent primary PCI, findings were consistent with the overall trial results. Significant reductions favoring ticagrelor were seen in the primary PCI subgroup for stent thrombosis and total deaths, though there were more strokes and episodes of ICH with ticagrelor.[261] A prespecified subgroup analysis in the PLATO trial showed a significant interaction between treatment effect and geographic region, with an apparently smaller ticagrelor effect in North America than in other areas. Although this interaction could have been due to chance alone,[295] a contribution from higher aspirin doses, as more commonly used in the United States, cannot be excluded. When provided long term with ticagrelor as a component of DAPT, the dose of aspirin should not exceed 100 mg.[293]

Although 1 year of DAPT is recommended after stent implantation during primary PCI for STEMI, earlier discontinuation of a $P2Y_{12}$ inhibitor may be necessary if the risk of morbidity from bleeding outweighs the anticipated benefit of DAPT. Clinical judgment is required, and discussion with the interventional cardiologist is recommended.

DAPT with aspirin and either clopidogrel or prasugrel has increased the risk of ICH in several clinical trials and patient populations (especially in those with prior stroke).[260,296–298] In PLATO, the number of patients with prior stroke was small, limiting the power to detect treatment differences in intracranial bleeding in this subgroup.[299] Until further data become available, it would seem prudent to weigh the possible increased risk of intracranial bleeding when the addition of ticagrelor to aspirin is considered in patients with prior stroke or transient ischemic attack.[300]

Evidence to support the use of intravenous GP IIb/IIIa receptor antagonists in patients with STEMI was established largely before the use of oral DAPT. Although several studies have failed to show benefit with the administration of "upstream" GP IIb/IIIa receptor antagonists before primary PCI in the setting of DAPT with either UFH or bivalirudin anticoagulation,[103,268,271–27] a meta-analysis restricted to the use of abciximab has suggested it may be useful in this setting.[277] The adjunctive use of GP IIb/IIIa agents at the time of PCI can be considered on an individual basis for large thrombus burden or inadequate $P2Y_{12}$ receptor antagonist loading.[265–270,301] For patients receiving bivalirudin as the primary anticoagulant, routine adjunctive use of GP IIb/IIIa inhibitors is not recommended[248] but may be considered as adjunctive or "bail-out" therapy in selected cases.[223,301–303] Studies of intracoronary GP IIb/IIIa administration during primary PCI have shown mixed results for a variety of surrogate and combined clinical endpoints. Use of intracoronary abciximab may be reasonable in select cases.[223,278–284]

4.4.2. Anticoagulant Therapy to Support Primary PCI: Recommendations

Class I

1. **For patients with STEMI undergoing primary PCI, the following supportive anticoagulant regimens are recommended:**
   a. **UFH, with additional boluses administered as needed to maintain therapeutic activated clotting time levels, taking into account whether a GP IIb/IIIa receptor antagonist has been administered (*Level of Evidence: C*); or**
   b. **Bivalirudin with or without prior treatment with UFH.[248] (*Level of Evidence: B*)**

Class IIa

1. **In patients with STEMI undergoing PCI who are at high risk of bleeding, it is reasonable to use bivalirudin monotherapy in preference to the combination of UFH and a GP IIb/IIIa receptor antagonist.[248] (*Level of Evidence: B*)**

Class III: Harm

1. **Fondaparinux should not be used as the sole anticoagulant to support primary PCI because of the risk of catheter thrombosis.[304] (*Level of Evidence: B*)**

Intravenous UFH titrated to an appropriate activated clotting time is a familiar and well-tested strategy for anticoagulant therapy at the time of PCI for STEMI. Enoxaparin and fondaparinux have been studied less extensively in this setting. The ATOLL (Acute STEMI Treated with Primary PCI and IV Enoxaparin or UFH to Lower Ischemic and Bleeding Events at Short- and Long-term Follow-up) trial comparing intravenous enoxaparin with UFH for primary PCI failed to meet its primary, composite endpoint.[305] Fondaparinux has been associated with catheter thrombosis in this setting.[304] On the basis of the findings in the HORIZONS-

Table 4. Indications for Fibrinolytic Therapy When There Is a >120-Minute Delay From FMC to Primary PCI (Figure 2)

	COR	LOE	References
Ischemic symptoms <12 h	I	A	81, 306–311
Evidence of ongoing ischemia 12 to 24 h after symptom onset, and a large area of myocardium at risk or hemodynamic instability	IIa	C	N/A
ST depression except if true posterior (inferobasal) MI suspected or when associated with ST-elevation in lead aVR	III: Harm	B	10, 11, 81, 312, 313

COR indicates Class of Recommendation; FMC, first medical contact; LOE, Level of Evidence; MI, myocardial infarction; N/A, not available; and PCI, percutaneous coronary intervention.

AMI (Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction) trial,[248] the writing committee considers bivalirudin, in combination with oral DAPT, a reasonable anticoagulant alternative for primary PCI in STEMI, regardless of whether pretreatment was given with UFH, especially for patients at higher risk of bleeding and when avoidance of GP IIb/IIIa antagonists is desired. Bivalirudin in this setting may provide a long-term survival benefit related to decreased bleeding but with a higher risk of early stent thrombosis.[248]

5. Reperfusion at a Non–PCI-Capable Hospital

5.1. Fibrinolytic Therapy When There Is an Anticipated Delay to Performing Primary PCI Within 120 Minutes of FMC: Recommendations

See Table 4 for a summary of recommendations from this section.

Class I

1. **In the absence of contraindications, fibrinolytic therapy should be given to patients with STEMI and onset of ischemic symptoms within the previous 12 hours when it is anticipated that primary PCI cannot be performed within 120 minutes of FMC.[81,306–311] (*Level of Evidence: A*)**

Class IIa

1. **In the absence of contraindications and when PCI is not available, fibrinolytic therapy is reasonable for patients with STEMI if there is clinical and/or ECG evidence of ongoing ischemia within 12 to 24 hours of symptom onset and a large area of myocardium at risk or hemodynamic instability. (*Level of Evidence: C*)**

Class III: Harm

1. **Fibrinolytic therapy should not be administered to patients with ST depression except when a true posterior (inferobasal) MI is suspected or when associated with ST elevation in lead aVR.[10,11,81,312,313] (*Level of Evidence: B*)**

5.1.1. Timing of Fibrinolytic Therapy

The benefits of fibrinolytic therapy in patients with ST elevation or bundle-branch block MI are well established, with a time-dependent reduction in both mortality and morbidity rates during the initial 12 hours after symptom onset.[81,306–311,314–320] As noted in Section 3.2, even when interhospital transport times are short, there may be advantages to the immediate delivery of fibrinolytic therapy versus any delay to primary PCI for patients with STEMI and low bleeding risk who present within the first 1 to 2 hours of symptom onset.[123,321] Benefit from fibrinolytic therapy in patients who present >12 hours after symptom onset has not been established,[81,307,309,322,323] although there remains consensus that consideration should be given to administering a fibrinolytic agent in symptomatic patients presenting >12 hours after symptom onset with STEMI and a large area of myocardium at risk or hemodynamic instability if PCI is unavailable.[4,48]

5.1.2. Choice of Fibrinolytic Agent

Table 5 lists currently available fibrinolytic agents.[314,324–326,328,329] Fibrin-specific agents are preferred when available. Adjunctive antiplatelet and/or anticoagulant therapies are indicated, regardless of the choice of fibrinolytic agent.

Table 5. Fibrinolytic Agents

Fibrinolytic Agent	Dose	Fibrin Specificity*	Antigenic	Patency Rate (90-min TIMI 2 or 3 flow)
Fibrin-specific:				
Tenecteplase (TNK-tPA)	Single IV weight-based bolus†	++++	No	85%[328]
Reteplase (rPA)	10 U + 10-U IV boluses given 30 min apart	++	No	84%[314]
Alteplase (tPA)	90-min weight-based infusion‡	++	No	73% to 84%[314, 324, 326]
Non–fibrin-specific:				
Streptokinase§	1.5 million units IV given over 30–60 min	No	Yes‖	60% to 68%[324, 329]

*Strength of fibrin specificity; "++++" is more strong, "++" is less strong.

†30 mg for weight <60 kg; 35 mg for 60–69 kg; 40 mg for 70–79 kg; 45 mg for 80–89 kg; and 50 mg for ≥90 kg.

‡Bolus 15 mg, infusion 0.75 mg/kg for 30 min (maximum 50 mg), then 0.5 mg/kg (maximum 35 mg) over the next 60 min; total dose not to exceed 100 mg.

§Streptokinase is no longer marketed in the United States but is available in other countries.

‖Streptokinase is highly antigenic and absolutely contraindicated within 6 mo of previous exposure because of the potential for serious allergic reaction.

IV indicates intravenous; rPA, reteplase plasminogen activator; TIMI, Thrombolysis In Myocardial Infarction; TNK-tPA, tenecteplase tissue-type plasminogen activator; and tPA, tissue-type plasminogen activator.

Table 6. Contraindications and Cautions for Fibrinolytic Therapy in STEMI*

Absolute contraindications

- Any prior ICH
- Known structural cerebral vascular lesion (eg, arteriovenous malformation)
- Known malignant intracranial neoplasm (primary or metastatic)
- Ischemic stroke within 3 mo
  - EXCEPT acute ischemic stroke within 4.5 h
- Suspected aortic dissection
- Active bleeding or bleeding diathesis (excluding menses)
- Significant closed-head or facial trauma within 3 mo
- Intracranial or intraspinal surgery within 2 mo
- Severe uncontrolled hypertension (unresponsive to emergency therapy)
- For streptokinase, prior treatment within the previous 6 mo

Relative contraindications

- History of chronic, severe, poorly controlled hypertension
- Significant hypertension on presentation (SBP >180 mm Hg or DBP >110 mm Hg)
- History of prior ischemic stroke >3 mo
- Dementia
- Known intracranial pathology not covered in absolute contraindications
- Traumatic or prolonged (>10 min) CPR
- Major surgery (<3 wk)
- Recent (within 2 to 4 wk) internal bleeding
- Noncompressible vascular punctures
- Pregnancy
- Active peptic ulcer
- Oral anticoagulant therapy

*Viewed as advisory for clinical decision making and may not be all-inclusive or definitive.

CPR indicates cardiopulmonary resuscitation; DBP; diastolic blood pressure; ICH, intracranial hemorrhage; SBP, systolic blood pressure; and STEMI, ST-elevation myocardial infarction.

5.1.3. Contraindications and Complications With Fibrinolytic Therapy

Absolute and relative contraindications to fibrinolytic therapy are listed in Table 6. The decision to use fibrinolytic therapy for patients with STEMI is predicated on a risk–benefit analysis that integrates time from onset of symptoms, the clinical and hemodynamic features at presentation, patient comorbidities, risk of bleeding, presence of contraindications, and time delay to PCI (Section 3.2).

5.1.4. Adjunctive Antithrombotic Therapy With Fibrinolysis

See Table 7 for a summary of recommendations from this section.

5.1.4.1. Adjunctive Antiplatelet Therapy With Fibrinolysis: Recommendations

Class I

1. **Aspirin (162- to 325-mg loading dose) and clopidogrel (300-mg loading dose for patients ≤75 years of age, 75-mg dose for patients >75 years of age) should be administered to patients with STEMI who receive fibrinolytic therapy.[308,330,331] (*Level of Evidence: A*)**
2. **Aspirin should be continued indefinitely[308,330,331] (*Level of Evidence: A*) and clopidogrel (75 mg daily) should be continued for at least 14 days[330,331] (*Level of Evidence: A*) and up to 1 year (*Level of Evidence: C*) in patients with STEMI who receive fibrinolytic therapy.**

Class IIa

1. **It is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses after fibrinolytic therapy.[254,257,263,264] (*Level of Evidence: B*)**

The beneficial effects of aspirin and clopidogrel with fibrinolytic therapy are well established.[254,257,263,264] These agents should be given before or with the fibrinolytic.[330] The recommendation that clopidogrel be continued for up to 1 year is extrapolated from the experience with DAPT in patients with non–ST-elevation ACS.[330] The coadministration of other $P2Y_{12}$ antagonists with fibrinolytic therapy has not been prospectively studied.

5.1.4.2. Adjunctive Anticoagulant Therapy With Fibrinolysis: Recommendations

Class I

1. **Patients with STEMI undergoing reperfusion with fibrinolytic therapy should receive anticoagulant therapy for a minimum of 48 hours, and preferably for the duration of the index hospitalization, up to 8 days or until revascularization if performed.[318,332] (*Level of Evidence: A*) Recommended regimens include**
   a. **UFH administered as a weight-adjusted intravenous bolus and infusion to obtain an activated partial thromboplastin time of 1.5 to 2.0 times control, for 48 hours or until revascularization. (*Level of Evidence: C*);**
   b. **Enoxaparin administered according to age, weight, and creatinine clearance, given as an intravenous bolus, followed in 15 minutes by subcutaneous injection for the duration of the index hospitalization, up to 8 days or until revascularization.[332–335] (*Level of Evidence: A*); or**
   c. **Fondaparinux administered with initial intravenous dose, followed in 24 hours by daily subcutaneous injections if the estimated creatinine clearance is greater than 30 mL/min, for the duration of the index hospitalization, up to 8 days or until revascularization.[304] (*Level of Evidence: B*)**

Anticoagulation is recommended in support of fibrin-specific therapy to improve vessel patency and prevent reocclusion.[336] Dosing of UFH is predicated on the activated partial thromboplastin time, and monitoring of platelet counts to avoid the risks of excess bleeding and heparin-induced thrombocytopenia (HIT) is advised.[318,337–339] UFH may be given as an intravenous bolus and infusion for patients receiving streptokinase if they are at high risk for systemic embolization. Enoxaparin is preferred over UFH for anticoagulation extending beyond 48 hours. Caution is advised when enoxaparin is administered to patients

Table 7. Adjunctive Antithrombotic Therapy to Support Reperfusion With Fibrinolytic Therapy

	COR	LOE	References
Antiplatelet therapy			
Aspirin			
• 162- to 325-mg loading dose	I		308, 330, 331
• 81- to 325-mg daily maintenance dose (indefinite)	I		308, 330, 331
• 81 mg daily is the preferred maintenance dose	IIa	B	254, 257, 263, 264
$P2Y_{12}$ receptor inhibitors			
• Clopidogrel:	I		330, 331
• Age ≤75 y: 300-mg loading dose			
• Followed by 75 mg daily for at least 14 d and up to 1 y in absence of bleeding	I		330, 331
		C (up to 1 y)	N/A
• Age >75 y: no loading dose, give 75 mg	I		330, 331
• Followed by 75 mg daily for at least 14 d and up to 1 y in absence of bleeding	I		330, 331
		C (up to 1 y)	N/A
Anticoagulant therapy			
• UFH:	I	C	N/A
• Weight-based IV bolus and infusion adjusted to obtain aPTT of 1.5 to 2.0 times control for 48 h or until revascularization. IV bolus of 60 U/kg (maximum 4000 U) followed by an infusion of 12 U/kg/h (maximum 1000 U) initially, adjusted to maintain aPTT at 1.5 to 2.0 times control (approximately 50 to 70 s) for 48 h or until revascularization.			
• Enoxaparin:	I		332–335
• If age <75 y: 30-mg IV bolus, followed in 15 min by 1 mg/kg subcutaneously every 12 h (maximum 100 mg for the first 2 doses)			
• If age ≥75 y: no bolus, 0.75 mg/kg subcutaneously every 12 h (maximum 75 mg for the first 2 doses)			
• Regardless of age, if CrCl <30 mL/min: 1 mg/kg subcutaneously every 24 h			
• Duration: For the index hospitalization, up to 8 d or until revascularization			
• Fondaparinux:	I	B	304
• Initial dose 2.5 mg IV, then 2.5 mg subcutaneously daily starting the following day, for the index hospitalization up to 8 d or until revascularization			
• Contraindicated if CrCl <30 mL/min			

aPTT indicates activated partial thromboplastin time; COR, Class of Recommendation; CrCl, creatinine clearance; IV, intravenous; LOE, Level of Evidence; N/A, not available; and UFH, unfractionated heparin.

with impaired renal function.[340] Fondaparinux should not be given as the sole anticoagulant to patients referred for PCI and is contraindicated for patients with a creatinine clearance <30 mL/min.[304,341] Bivalirudin may be used for patients treated with a fibrinolytic agent who develop HIT and require continued anticoagulation.[342]

5.2. Assessment of Reperfusion After Fibrinolysis

TIMI 3 flow after fibrinolytic therapy predicts subsequent short- and long-term survival.[343–345] Traditional variables that have been used to assess the angiographic response to fibrinolytic therapy are imprecise[346] and have included an improvement in or relief of chest pain, resolution of ST elevation, and the presence of reperfusion arrhythmias (eg, accelerated idioventricular rhythm). The relatively sudden and complete relief of chest pain coupled with >70% ST resolution (in the index lead showing the greatest degree of elevation on presentation) is highly suggestive of restoration of normal myocardial blood flow. Complete (or near complete) ST-segment resolution at 60 or 90 minutes after fibrinolytic therapy is a useful marker of a patent infarct artery.[347–351] Conversely, partial or absent improvement in the extent of ST elevation is not as accurate in predicting a "closed artery."[349–351] Lack of improvement in ST resolution is associated with worse prognosis.[349,352,353] The combination of <50% ST resolution and the absence of reperfusion arrhythmias at 2 hours after treatment predicts TIMI flow <3 in the infarct artery with a sensitivity of 81%, specificity 88%, positive predictive value 87%, and negative predictive value 83%.[347] Lack of resolution of ST elevation by at least 50% in the worst lead at 60 to 90 minutes should prompt strong consideration of a decision to proceed with immediate coronary angiography and "rescue" PCI.

5.3. Transfer to a PCI-Capable Hospital After Fibrinolytic Therapy

See Figure 2.

5.3.1. Transfer of Patients With STEMI to a PCI-Capable Hospital for Coronary Angiography After Fibrinolytic Therapy: Recommendations

See Table 8 for a summary of recommendations from this section; *Online Data Supplement 4* for additional data on early catheterization and rescue PCI for fibrinolytic failure in the stent era; and *Online Data Supplement 5* for additional

Table 8. Indications for Transfer for Angiography After Fibrinolytic Therapy

	COR	LOE	References
Immediate transfer for cardiogenic shock or severe acute HF irrespective of time delay from MI onset	I	B	354
Urgent transfer for failed reperfusion or reocclusion	IIa	B	346, 355–357
As part of an invasive strategy in stable* patients with PCI between 3 and 24 h after successful fibrinolysis	IIa	B	358–363

*Although individual circumstances will vary, clinical stability is defined by the absence of low output, hypotension, persistent tachycardia, apparent shock, high-grade ventricular or symptomatic supraventricular tachyarrhythmias, and spontaneous recurrent ischemia.

COR indicates Class of Recommendation; HF, heart failure; LOE, Level of Evidence; MI, myocardial infarction; and PCI, percutaneous coronary intervention.

data on early catheterization and PCI after fibrinolysis in the stent era.

Class I

1. **Immediate transfer to a PCI-capable hospital for coronary angiography is recommended for suitable patients with STEMI who develop cardiogenic shock or acute severe HF, irrespective of the time delay from MI onset.[354] (*Level of Evidence: B*)**

Class IIa

1. **Urgent transfer to a PCI-capable hospital for coronary angiography is reasonable for patients with STEMI who demonstrate evidence of failed reperfusion or reocclusion after fibrinolytic therapy.[346,355–357] (Level of Evidence: B)**
2. **Transfer to a PCI-capable hospital for coronary angiography is reasonable for patients with STEMI who have received fibrinolytic therapy even when hemodynamically stable§ and with clinical evidence of successful reperfusion. Angiography can be performed as soon as logistically feasible at the receiving hospital, and ideally within 24 hours, but should not be performed within the first 2 to 3 hours after administration of fibrinolytic therapy.[358–363] (*Level of Evidence: B*)**

5.3.1.1. Transfer for Cardiogenic Shock

The SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) trial[354] demonstrated benefit with coronary angiography and emergency revascularization (with either PCI or CABG) compared with immediate medical stabilization and delayed revascularization in patients with ST-elevation/Q-wave or new LBBB MI and cardiogenic shock (Section 9.1.1). Of note, nearly 50% of patients randomized to the emergency revascularization arm received preprocedural fibrinolytic therapy, and the benefit of emergency revascularization was similar for patients transferred versus those admitted directly to a PCI-capable hospital. For patients with cardiogenic shock, the benefit of emergency revascularization was apparent across a very wide time window, extending up to 54 hours after MI and 18 hours after shock onset.[354] Although PCI should be performed as soon as possible after MI and shock onset, the time window for benefit in this clinical context is more prolonged because of the ongoing "downward ischemic spiral" associated with shock.

5.3.1.2. Transfer for Failure of Fibrinolytic Therapy

Several trials in the stent era and several meta-analyses have examined the role of PCI for fibrinolytic failure[346,355–357,364] (*Online Data Supplement 4*). These studies report a trend toward a lower mortality rate and significantly lower rates of recurrent MI and HF among patients treated with rescue PCI for failed fibrinolysis. For example, in the REACT (Rapid Early Action for Coronary Treatment) study,[355] 427 patients who failed to demonstrate evidence of reperfusion at 90 minutes by ECG criteria were randomized to 1 of 3 treatment arms: rescue PCI, conservative care, or repeat fibrinolytic therapy. The primary endpoint, a composite of death, reinfarction, stroke, or severe HF at 6 months, was significantly lower among patients randomized to rescue PCI than among those randomized to conservative care or repeat fibrinolysis (event-free survival rate: 84.6% versus 70.1% versus 68.7%, P=0.004). The benefit was driven primarily by a reduction in reinfarction; there was no significant survival benefit. Minor bleeding was significantly higher among patients randomized to rescue PCI; however, there were no differences in major bleeding among the 3 groups. Other studies have reported higher rates of periprocedural bleeding and stroke in patients undergoing rescue PCI than in patients treated conservatively.[346,356] The benefit of transferring a patient for PCI of a persistently occluded infarct artery likely would justify these risks if cardiogenic shock, significant hypotension, severe HF, or ECG evidence of an extensive area of myocardial jeopardy (including an anterior infarction or inferior infarction with either right ventricular [RV] involvement or anterior precordial ST depression) is present. In these circumstances, the benefits are greatest if PCI is initiated early after fibrinolytic failure. On the other hand, conservative treatment might be reasonable in a patient with improving symptoms and a limited inferior infarction despite persistence of ST elevation.

5.3.1.3. Transfer for Routine Early Coronary Angiography After Fibrinolytic Therapy

With the introduction of coronary stents and aggressive antiplatelet therapies, there has been renewed interest in immediate and early catheterization after fibrinolytic therapy. The advantage of this approach is that it can be initiated at non–PCI-capable hospitals and affords the healthcare system additional time to arrange a "nonemergency" transfer for angiography and PCI. Routine referral for angiography with the intent to perform PCI is supported indirectly by retrospective analyses from trials of fibrinolytic therapy that suggest that patients treated with PCI during the index hospitalization have a lower risk of recurrent MI and a lower 2-year mortality

§Although individual circumstances will vary, clinical stability is defined by the absence of low output, hypotension, persistent tachycardia, apparent shock, high-grade ventricular or symptomatic supraventricular tachyarrhythmias, and spontaneous recurrent ischemia.

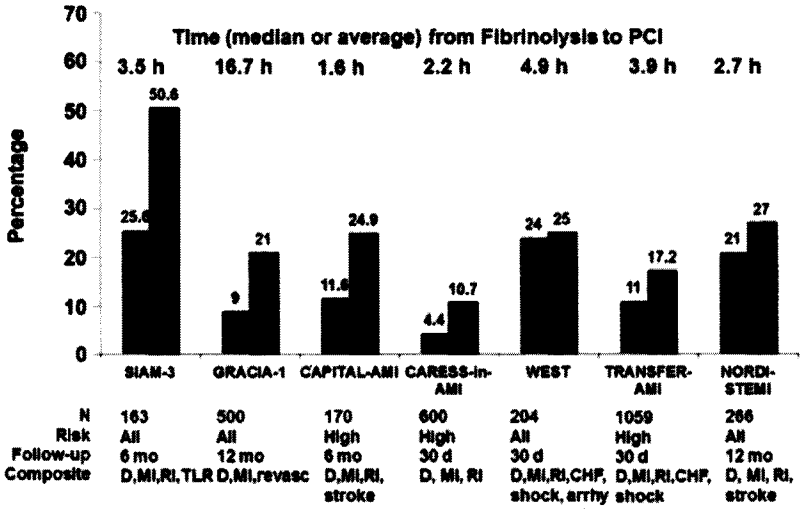


Figure 3. Primary outcome of trials of routine versus ischemia-driven (or delayed) catheterization and PCI after fibrinolytic therapy. The Figure depicts the results of trials comparing routine early catheterization after fibrinolytic therapy with either an ischemia-driven approach or routine delayed catheterization. The y-axis represents the percentage of patients who experienced ≥1 of the clinical trial endpoints. The Figure includes the average (or median) time from fibrinolytic therapy to PCI, the number of patients randomized in each study, the type of patients enrolled in the study (all patients or high-risk patients), the duration of follow-up for the primary endpoint, and the composite primary endpoint for each trial. The darker bars represent patients who underwent routine early catheterization after fibrinolytic therapy. The lighter bars represent patients who underwent either an ischemia-guided or routine delayed catheterization approach. arrhy indicates arrhythmia; CAPITAL-AMI, Combined Angioplasty and Pharmacological Intervention Versus Thrombolysis Alone in Acute Myocardial Infarction; CARESS-in-AMI, Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction; CHF, congestive heart failure; D, death; GRACIA, Grup de Analisis de la Cardiopatia Isquemica Aguda; MI, myocardial infarction; NORDISTEMI, Norwegian study on District treatment of ST-Elevation Myocardial Infarction; PCI, percutaneous coronary intervention; revasc, ischemia-driven revascularization; RI, recurrent ischemia; TLR, target-lesion revascularization; TRANSFER-AMI, Trial of Routine Angioplasty and Stenting after Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction; SIAM-3, Southwest German Interventional Study In Acute Myocardial Infarction; and WEST, Which Early ST-Elevated Myocardial Infarction Therapy.[358,360–362,368–370] Reproduced with permission from Granger.[370a]

rate.[365–367] The results of RCTs evaluating a strategy of routine catheterization after fibrinolysis are limited by small sample sizes or surrogate endpoints and have provided mixed results. Nevertheless, most trials have demonstrated improvement in clinical outcomes in patients transferred for early catheterization, most notably in higher-risk patients[357–362,368–371] (Table 8 and Figure 3). In the GRACIA (Grup de Analisis de la Cardiopatia Isquemica Aguda) study,[362] early catheterization within 6 to 24 hours of successful fibrinolysis in stable patients was compared with an ischemia-guided approach. It resulted in improved outcomes, including a significantly lower rate of death, reinfarction, or ischemia-driven revascularization at 1 year.

The TRANSFER-AMI (Trial of Routine Angioplasty and Stenting after Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction) study[360] was the largest (n=1059) of the RCTs evaluating transfer for coronary angiography and revascularization among high-risk patients and showed a significant reduction in the combined primary endpoint of death, recurrent MI, recurrent ischemia, new or worsening HF, or shock at 30 days with immediate transfer for the angiography group compared with conservative care. The findings from this and other studies indicate that high-risk patients with STEMI appear to benefit from immediate transfer for early catheterization, compared with either an ischemia-guided approach or delayed routine catheterization at 24 hours to 2 weeks.[360,361] The reported benefits relate to a reduction in the incidence of recurrent infarction or ischemia, thus favoring earlier transfer and revascularization when possible.

The NORDISTEMI (Norwegian Study on District Treatment of ST-Elevation Myocardial Infarction) investigators[358] examined the effect of immediate routine transfer for catheterization versus a conservative strategy with either ischemia-guided treatment in the non–PCI-capable hospital or transfer for rescue PCI. Although this study failed to demonstrate a significant difference between the 2 treatment groups in the incidence of the primary composite endpoint of death, recurrent MI, stroke, or new or recurrent ischemia at 1 year, the incidence of death, recurrent MI, or stroke was significantly lower in the immediate-transfer group. Furthermore, the magnitude of reduction in risk was similar to that reported for high-risk patients in the TRANSFER-AMI study (RR: 0.64; 95% CI: 0.47 to 0.87; P=0.004).[360]

In a meta-analysis[359] that included 7 RCTs of early transfer for catheterization, a strategy of routine early catheterization after fibrinolysis was associated with a statistically significant reduction in the incidence of death or MI at 30 days and at 1 year, without an increase in the risk of major bleeding. This meta-analysis was based on a mixture of trials that randomized high-risk patients[360,361,369] and trials that did not mandate the inclusion of high-risk subjects. A meta-regression analysis investigating the relative benefit of an invasive strategy after fibrinolysis according to the baseline risk of the enrolled patients for each trial suggested a larger proportional benefit with early catheterization and PCI in trials enrolling higher-risk patients.[359]

It is important to recognize that the clinical trials that have addressed routine invasive evaluation after initial pharmaco-

logical management used a time window of 0 to 24 hours for the "early invasive" strategy, thus supporting earlier transfer after administration of fibrinolytic therapy even for patients without high-risk features. However, this time window likely was used in the trial designs to create the greatest possible difference in outcome when compared with the control group (rather than an *a priori* expectation that the benefit would be driven entirely in <24 hours). The writing committee believes that there likely will be continued benefit even beyond 24 hours in those patients with a patent but stenotic infarct artery. In stable patients who are not transferred immediately, catheterization can be considered as part of a routine pharmacoinvasive or ischemia-guided approach >24 hours after administration of fibrinolytic therapy. Because of the associated increased bleeding risk, very early (<2 to 3 hours) catheterization after administration of fibrinolytic therapy with intent to perform revascularization should be reserved for patients with evidence of failed fibrinolysis and significant myocardial jeopardy for whom rescue PCI would be appropriate.

6. Delayed Invasive Management

6.1. Coronary Angiography in Patients Who Initially Were Managed With Fibrinolytic Therapy or Who Did Not Receive Reperfusion: Recommendations

See Table 9 for a summary of recommendations from this section.

Class I

1. **Cardiac catheterization and coronary angiography with intent to perform revascularization should be performed after STEMI in patients with any of the following:**
   a. **Cardiogenic shock or acute severe HF that develops after initial presentation[215,354,372,373] (*Level of Evidence: B*);**
   b. **Intermediate- or high-risk findings on predischarge noninvasive ischemia testing[232,233] (*Level of Evidence: B*); or**
   c. **Myocardial ischemia that is spontaneous or provoked by minimal exertion during hospitalization. (*Level of Evidence: C*)**

Table 9. Indications for Coronary Angiography in Patients Who Were Managed With Fibrinolytic Therapy or Who Did Not Receive Reperfusion Therapy

	COR	LOE	References
Cardiogenic shock or acute severe HF that develops after initial presentation	I	B	215, 354, 372, 373
Intermediate- or high-risk findings on predischarge noninvasive ischemia testing	I	B	232, 233
Spontaneous or easily provoked myocardial ischemia	I	C	N/A
Failed reperfusion or reocclusion after fibrinolytic therapy	IIa	B	346, 355–357
Stable* patients after successful fibrinolysis, before discharge and ideally between 3 and 24 h	IIa	B	358–363, 374

*Although individual circumstances will vary, clinical stability is defined by the absence of low output, hypotension, persistent tachycardia, apparent shock, high-grade ventricular or symptomatic supraventricular tachyarrhythmias, and spontaneous recurrent ischemia.

COR indicates Class of Recommendation; HF, heart failure; LOE, Level of Evidence; and N/A, not available.

Class IIa

1. **Coronary angiography with intent to perform revascularization is reasonable for patients with evidence of failed reperfusion or reocclusion after fibrinolytic therapy. Angiography can be performed as soon as logistically feasible.[346,355–357] (*Level of Evidence: B*)**
2. **Coronary angiography is reasonable before hospital discharge in stable§ patients with STEMI after successful fibrinolytic therapy. Angiography can be performed as soon as logistically feasible, and ideally within 24 hours, but should not be performed within the first 2 to 3 hours after administration of fibrinolytic therapy.[358–363,374] (*Level of Evidence: B*)**

The indications for coronary angiography in patients managed with an initial noninvasive strategy are interwoven with the indications for revascularization (Sections 5.3 and 6.2). Survivors of STEMI with indicators of intermediate or high risk and those with recurrent ischemia or mechanical complications should be considered for coronary angiography and revascularization. In addition, when STEMI is suspected to have occurred by a mechanism other than thrombotic occlusion at the site of an atherosclerotic plaque, coronary angiography may be reasonable to provide diagnostic information and to direct specific therapy. Routine referral for angiography of patients after fibrinolytic therapy is discussed in Section 5.3. Coronary angiography in patients with evidence of failed reperfusion or reocclusion should be performed as soon as logistically feasible.[346,355]

6.2. PCI of an Infarct Artery in Patients Who Initially Were Managed With Fibrinolysis or Who Did Not Receive Reperfusion Therapy: Recommendations

See Table 10 for a summary of recommendations from this section.

Class I

1. **PCI of an anatomically significant stenosis in the infarct artery should be performed in patients with suitable anatomy and any of the following:**
   a. **Cardiogenic shock or acute severe HF[354] (*Level of Evidence: B*);**
   b. **Intermediate- or high-risk findings on predischarge noninvasive ischemia testing[232,233] (*Level of Evidence: C*); or**
   c. **Myocardial ischemia that is spontaneous or provoked by minimal exertion during hospitalization. (*Level of Evidence: C*)**

§Although individual circumstances will vary, clinical stability is defined by the absence of low output, hypotension, persistent tachycardia, apparent shock, high-grade ventricular or symptomatic supraventricular tachyarrhythmias, and spontaneous recurrent ischemia.

Table 10. Indications for PCI of an Infarct Artery in Patients Who Were Managed With Fibrinolytic Therapy or Who Did Not Receive Reperfusion Therapy

	COR	LOE	References
Cardiogenic shock or acute severe HF	I	B	354
Intermediate- or high-risk findings on predischarge noninvasive ischemia testing	I	C	232, 233
Spontaneous or easily provoked myocardial ischemia	I	C	N/A
Patients with evidence of failed reperfusion or reocclusion after fibrinolytic therapy (as soon as possible)	IIa	B	344–347
Stable* patients after successful fibrinolysis, ideally between 3 and 24 h	IIa	B	358–363
Stable* patients >24 h after successful fibrinolysis	IIb	B	213, 232, 233, 366, 374–378
Delayed PCI of a totally occluded infarct artery >24 h after STEMI in stable patients	III: No Benefit	B	213, 376

*Although individual circumstances will vary, clinical stability is defined by the absence of low output, hypotension, persistent tachycardia, apparent shock, high-grade ventricular or symptomatic supraventricular tachyarrhythmias, and spontaneous recurrent ischemia.

COR indicates Class of Recommendation; HF, heart failure; LOE, Level of Evidence; N/A, not available; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

Class IIa

1. **Delayed PCI is reasonable in patients with STEMI and evidence of failed reperfusion or reocclusion after fibrinolytic therapy. PCI can be performed as soon as logistically feasible at the receiving hospital.[344–347] (*Level of Evidence: B*)**
2. **Delayed PCI of a significant stenosis in a patent infarct artery is reasonable in stable§ patients with STEMI after fibrinolytic therapy. PCI can be performed as soon as logistically feasible at the receiving hospital, and ideally within 24 hours, but should not be performed within the first 2 to 3 hours after administration of fibrinolytic therapy.[358–363] (*Level of Evidence: B*)**

Class IIb

1. **Delayed PCI of a significant stenosis in a patent infarct artery greater than 24 hours after STEMI may be considered as part of an invasive strategy in stable§ patients.[213,232,233,366,374–378] (*Level of Evidence: B*)**

Class III: No Benefit

1. **Delayed PCI of a totally occluded infarct artery greater than 24 hours after STEMI should not be performed in asymptomatic patients with 1- or 2-vessel disease if they are hemodynamically and electrically stable and do not have evidence of severe ischemia.[213,376] (*Level of Evidence: B*)**

Delayed PCI of the infarct artery is performed in patients treated with an initial noninvasive strategy (ie, with fibrinolysis or without reperfusion therapy) who become unstable because of the development of cardiogenic shock, acute severe HF, or unstable postinfarction angina, provided that invasive management is not considered futile or inappropriate.[215,379] Delayed PCI also encompasses interventions performed for fibrinolytic failure[355,356] or infarct artery reocclusion, as part of an invasive strategy for patients after successful fibrinolysis,[359–361] and for patients who did not receive reperfusion therapy but who did demonstrate significant residual ischemia during hospitalization. The benefits of routine, ie, non–ischemia-driven, PCI of an angiographically significant stenosis in a patent infarct artery >24 hours after STEMI are less well established.[232,233,378] Delayed PCI of a totally occluded infarct artery >24 hours after STEMI should not be undertaken in clinically stable patients without evidence of severe ischemia. In OAT (Occluded Artery Trial), there was no difference in the composite endpoint of death, reinfarction, or class IV HF at a median follow-up of 5.8 years between patients managed with PCI and those treated medically. Reinfarction rates tended to be higher in the PCI group.[380]

§Although individual circumstances will vary, clinical stability is defined by the absence of low output, hypotension, persistent tachycardia, apparent shock, high-grade ventricular or symptomatic supraventricular tachyarrhythmias, and spontaneous recurrent ischemia.

6.3. PCI of a Noninfarct Artery Before Hospital Discharge: Recommendations

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Class I

1. **PCI is indicated in a noninfarct artery at a time separate from primary PCI in patients who have spontaneous symptoms of myocardial ischemia. (*Level of Evidence: C*)**

Class IIa

1. **PCI is reasonable in a noninfarct artery at a time separate from primary PCI in patients with intermediate- or high-risk findings on noninvasive testing.[216,232,233] (*Level of Evidence: B*)**

Multivessel coronary artery disease is present in 40% to 65% of patients presenting with STEMI who undergo primary PCI and is associated with adverse prognosis.[381,382] Studies of staged PCI of noninfarct arteries have been nonrandomized in design and have varied with regard to the timing of PCI and duration of follow-up. These variations have contributed to the disparate findings reported, although there seems to be a clear trend toward lower rates of adverse outcomes when primary PCI is limited to the infarct artery and PCI of a noninfarct artery is undertaken in staged fashion at a later time.[216,224,225,383,384] The largest of these observational studies compared 538 patients undergoing staged multivessel PCI within 60 days of primary PCI with propensity-matched individuals who had culprit-vessel PCI alone.[216] Multivessel PCI was associated with a lower mortality rate at 1 year (1.3% versus 3.3%; P=0.04). A nonsignificant trend toward a lower mortality rate at 1 year was observed in the subset of 258 patients who underwent staged PCI during the initial

Table 11. Adjunctive Antithrombotic Therapy to Support PCI After Fibrinolytic Therapy

	COR	LOE	References
Antiplatelet therapy			
Aspirin			
• 162- to 325-mg loading dose given with fibrinolytic agent (before PCI). (Section 5.1.4.1 and Table 7)	I	A	308, 330, 331
• 81- to 325-mg daily maintenance dose after PCI (indefinite)	I	A	253, 254, 257, 259, 330, 331
• 81 mg daily is the preferred daily maintenance dose	IIa	B	253, 259, 263, 264
$P2Y_{12}$ receptor inhibitors			
Loading doses			
For patients who received a loading dose of clopidogrel with fibrinolytic therapy:			
• Continue clopidogrel 75 mg daily without an additional loading dose	I	C	260, 262, 330, 331
For patients who have not received a loading dose of clopidogrel:			
• If PCI is performed ≤24 h after fibrinolytic therapy: clopidogrel 300-mg loading dose before or at the time of PCI	I	C	N/A
• If PCI is performed >24 h after fibrinolytic therapy: clopidogrel 600-mg loading dose before or at the time of PCI	I	C	N/A
• If PCI is performed >24 h after treatment with a fibrin-specific agent or >48 h after a non–fibrin-specific agent: prasugrel 60 mg at the time of PCI	IIa	B	260, 262
For patients with prior stroke/TIA: prasugrel		B	260
Maintenance doses and duration of therapy			
DES placed: Continue therapy for at least 1 y with:			
• Clopidogrel: 75 mg daily	I	C	260, 262, 330, 331
• Prasugrel: 10 mg daily	IIa	B	260, 262
BMS placed: Continue therapy for at least 30 d and up to 1 y with:*			
• Clopidogrel: 75 mg daily	I	C	330, 331
• Prasugrel: 10 mg daily	IIa	B	260, 262
Anticoagulant therapy			
• Continue UFH through PCI, administering additional IV boluses as needed to maintain therapeutic ACT depending on use of GP IIb/IIIa receptor antagonist†	I	C	N/A
• Continue enoxaparin through PCI:	I	B	332, 390
• No additional drug if last dose was within previous 8 h			
• 0.3-mg/kg IV bolus if last dose was 8 to 12 h earlier			
• Fondaparinux:		C	304
• As sole anticoagulant for PCI			

*Balloon angioplasty without stent placement may be used in selected patients. It might be reasonable to provide $P2Y_{12}$ inhibitor therapy to patients with STEMI undergoing balloon angioplasty after fibrinolysis alone according to the recommendations listed for BMS. (*Level of Evidence: C*)

†The recommended ACT with no planned GP IIb/IIIa receptor antagonist treatment is 250-300 s (HemoTec device) or 300-350 s (Hemochron device).

ACT indicates activated clotting time; BMS, bare-metal stent; COR, Class of Recommendation; DES, drug-eluting stent; GP, glycoprotein; IV, intravenous; LOE, Level of Evidence; N/A, not available; PCI, percutaneous coronary intervention; TIA, transient ischemic attack; and UFH, unfractionated heparin.

hospitalization for STEMI.[216] Although fractional flow reserve is evaluated infrequently in patients with STEMI, at least 1 study suggests that determination of fractional flow reserve may be useful to assess the hemodynamic significance of potential target lesions in noninfarct arteries.[385] The writing committee encourages research into the benefit of PCI of noninfarct arteries in patients with multivessel disease after successful primary PCI (Section 12.6).

6.4. Adjunctive Antithrombotic Therapy to Support Delayed PCI After Fibrinolytic Therapy

See Table 11 for a summary of recommendations from this section.

The selection of adjunctive antiplatelet and anticoagulant therapies for use during PCI after fibrinolytic therapy should take into account the fibrinolytic agent used, the time since its administration, and the antiplatelet and anticoagulant agents already administered. GP IIb/IIIa inhibitors should be used with great caution, if at all, after full-dose fibrinolytic therapy, because this combination is associated with high rates of bleeding and ICH, particularly in the elderly.[386–388,389]

6.4.1. Antiplatelet Therapy to Support PCI After Fibrinolytic Therapy: Recommendations

Class I **516**

1. **After PCI, aspirin should be continued indefinitely.[253,254,257,259,330,331] (*Level of Evidence: A*)**
2. **Clopidogrel should be provided as follows:**
   a. **A 300-mg loading dose should be given before or at the time of PCI to patients who did not receive a previous loading dose and who are undergoing PCI**

within 24 hours of receiving fibrinolytic therapy (*Level of Evidence: C*);

b. A 600-mg loading dose should be given before or at the time of PCI to patients who did not receive a previous loading dose and who are undergoing PCI more than 24 hours after receiving fibrinolytic therapy (*Level of Evidence: C*); and

c. A dose of 75 mg daily should be given after PCI.[260,262,330,331] (*Level of Evidence: C*)

Class IIa

1. After PCI, it is reasonable to use 81 mg of aspirin per day in preference to higher maintenance doses.[253,259,263,264] (*Level of Evidence: B*)
2. Prasugrel, in a 60-mg loading dose, is reasonable once the coronary anatomy is known in patients who did not receive a previous loading dose of clopidogrel at the time of administration of a fibrinolytic agent, but prasugrel should not be given sooner than 24 hours after administration of a fibrin-specific agent or 48 hours after administration of a non–fibrin-specific agent.[260,262] (*Level of Evidence: B*)
3. Prasugrel, in a 10-mg daily maintenance dose, is reasonable after PCI.[260,262] (*Level of Evidence: B*)

Class III: Harm

1. Prasugrel should not be administered to patients with a history of prior stroke or transient ischemic attack.[260] (*Level of Evidence: B*)

Patients with STEMI should receive clopidogrel at the time of administration of a fibrinolytic agent as a routine part of a pharmacological reperfusion strategy (Section 5.1). Clopidogrel then should be continued in uninterrupted fashion through and after PCI. The optimal loading dose of clopidogrel before or at the time of PCI in patients who may not have received it previously with fibrinolytic therapy is not known. In the CLARITY-TIMI 28 (Clopidogrel as Adjunctive Reperfusion Therapy—Thrombolysis In Myocardial Infarction 28) trial,[331] PCI was performed 2 to 8 days after fibrinolysis in about half of the enrolled patients, and open-label clopidogrel (300-mg loading dose, 75-mg maintenance dose) was administered after diagnostic angiography in patients undergoing infarct artery stenting. Treatment with clopidogrel significantly reduced the incidence of cardiovascular death, MI, or stroke (major secondary composite endpoint) after PCI. In addition, there was no significant increase in the rates of TIMI major or minor bleeding with clopidogrel treatment. A subset of patients with STEMI in the TRITON-TIMI 38 trial received fibrinolytic therapy >24 hours (for fibrin-specific agents) or >48 hours (for non–fibrin-specific agents) before PCI. In this subset, the use of prasugrel compared to clopidogrel was associated with a significantly lower rate of the primary composite endpoint of cardiovascular death, nonfatal MI, or nonfatal stroke (HR: 0.65; 95% CI: 0.54 to 0.87; P=0.0017), and a similar rate of TIMI major bleeding unrelated to CABG.[262] Accordingly, prasugrel (60-mg loading dose) may be used as an alternative to clopidogrel in patients with STEMI who undergo delayed PCI after administration of a fibrinolytic agent.

6.4.2. Anticoagulant Therapy to Support PCI After Fibrinolytic Therapy: Recommendations

Class I

1. For patients with STEMI undergoing PCI after receiving fibrinolytic therapy with intravenous UFH, additional boluses of intravenous UFH should be administered as needed to support the procedure, taking into account whether GP IIb/IIIa receptor antagonists have been administered. (*Level of Evidence: C*)
2. For patients with STEMI undergoing PCI after receiving fibrinolytic therapy with enoxaparin, if the last subcutaneous dose was administered within the prior 8 hours, no additional enoxaparin should be given; if the last subcutaneous dose was administered between 8 and 12 hours earlier, enoxaparin 0.3 mg/kg IV should be given.[335,390] (*Level of Evidence: B*)

Class III: Harm

1. Fondaparinux should not be used as the sole anticoagulant to support PCI. An additional anticoagulant with anti-IIa activity should be administered because of the risk of catheter thrombosis.[304] (*Level of Evidence: C*)

Anticoagulation should be continued through emergent or nonurgent PCI procedures performed during the index hospitalization after initial use of fibrinolytic therapy. For patients who received UFH or enoxaparin with fibrinolytic therapy, these agents may be continued uninterrupted through the PCI procedure.[390] Transitioning from enoxaparin to either UFH or bivalirudin is possible, provided the last enoxaparin dose was >12 hours before PCI. Similarly, UFH may be transitioned to bivalirudin for PCI. Fondaparinux does not provide adequate anticoagulation for PCI, and additional intravenous boluses of UFH (or bivalirudin) should be administered.[304]

7. Coronary Artery Bypass Graft Surgery

7.1. CABG in Patients With STEMI: Recommendations

Class I

1. Urgent CABG is indicated in patients with STEMI and coronary anatomy not amenable to PCI who have ongoing or recurrent ischemia, cardiogenic shock, severe HF, or other high-risk features.[391–393] (*Level of Evidence: B*)
2. CABG is recommended in patients with STEMI at time of operative repair of mechanical defects.[394–398] (*Level of Evidence: B*)

Class IIa

1. The use of mechanical circulatory support is reasonable in patients with STEMI who are hemodynamically unstable and require urgent CABG. (*Level of Evidence: C*)

Class IIb

1. **Emergency CABG within 6 hours of symptom onset may be considered in patients with STEMI who do not have cardiogenic shock and are not candidates for PCI or fibrinolytic therapy. (*Level of Evidence: C*)**

CABG has a limited role in the acute phase of STEMI other than for cardiogenic shock, but it may be indicated for failed PCI, for coronary anatomy not amenable to PCI, and at the time of surgical repair of a mechanical defect, such as ventricular septal, papillary muscle, or free-wall rupture. Older case series highlighted a potential excess mortality risk for CABG when performed early after STEMI, which was related to worsening myocardial injury from cardiopulmonary bypass, aortic cross-clamping, and cardioplegic arrest, with hemorrhagic transformation and infarct expansion. However, contemporary modifications to the standard operative approach, such as on-pump beating-heart surgery, off-pump techniques, or adjunctive temporary mechanical circulatory support devices, may lead to improved survival rates after CABG in the acute hospital phase.

7.2. Timing of Urgent CABG in Patients With STEMI in Relation to Use of Antiplatelet Agents: Recommendations

Class I

1. **Aspirin should not be withheld before urgent CABG.[399] (*Level of Evidence: C*)**
2. **Clopidogrel or ticagrelor should be discontinued at least 24 hours before urgent on-pump CABG, if possible.[400–404] (*Level of Evidence: B*)**
3. **Short-acting intravenous GP IIb/IIIa receptor antagonists (eptifibatide, tirofiban) should be discontinued at least 2 to 4 hours before urgent CABG.[405,406] (*Level of Evidence: B*)**
4. **Abciximab should be discontinued at least 12 hours before urgent CABG.[362] (*Level of Evidence: B*)**

Class IIb

1. **Urgent off-pump CABG within 24 hours of clopidogrel or ticagrelor administration might be considered, especially if the benefits of prompt revascularization outweigh the risks of bleeding.[401,407–409] (*Level of Evidence: B*)**
2. **Urgent CABG within 5 days of clopidogrel or ticagrelor administration or within 7 days of prasugrel administration might be considered, especially if the benefits of prompt revascularization outweigh the risks of bleeding. (*Level of Evidence: C*)**

In contrast to previous observations[410–412] of markedly increased rates of major bleeding and mediastinal reexploration after CABG in patients exposed to clopidogrel within 5 to 7 days before CABG, several reports have suggested that it might be reasonable to proceed with urgent surgery within a shorter time frame, especially when the benefits of revascularization outweigh the risks of bleeding, as often may be the case among patients with ACS.[402,404] Shorter delays to urgent surgery may also be possible when off-pump revascularization is planned. Among the 136 patients in CLARITY-TIMI 28 who underwent CABG within 5 days of clopidogrel exposure, there was no difference in the rates of major bleeding through 30 days of follow-up between the clopidogrel and placebo groups (7.5% versus 7.2%, respectively; P=1.00).[331] In a prospective RCT examining the effect of the timing of clopidogrel discontinuation before CABG, 3 groups were studied: clopidogrel continued to the day of surgery, clopidogrel discontinued 3 days before surgery, and clopidogrel discontinued 5 days before surgery. Patients in the continuation group experienced increased rates of bleeding and blood product utilization, but the 3- and 5-day discontinuation groups had comparably low bleeding rates and blood product usage that resembled historical control values.[413] In a retrospective analysis of a nonrandomized subgroup of patients in the PLATO trial, in which several definitions of bleeding were used, no significant differences in CABG-related bleeding were observed between patients allocated ticagrelor and patients who received clopidogrel, and there were no observed differences in the rates of reoperation.[401] In contrast, among the relatively few patients with STEMI in TRITON-TIMI 38 who underwent CABG during the 15-month course of the study, rates of TIMI major or minor bleeding after CABG were significantly higher with prasugrel than with clopidogrel (21.9% versus 4.1%; OR: 6.53; 95% CI: 1.78 to 23.94; P=0.0032).[262] The excess bleeding hazard observed with prasugrel should prompt consideration of an alternative antiplatelet strategy in patients with STEMI who may require urgent CABG during their index hospitalization. The timing of elective CABG in relation to the use of $P2Y_{12}$ receptor antagonists is referenced in Section 4.1 of the 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery.[393]

8. Routine Medical Therapies

See Table 12 for a summary of selected routine medical therapies.

8.1. Beta Blockers: Recommendations

Class I

1. **Oral beta blockers should be initiated in the first 24 hours in patients with STEMI who do not have any of the following: signs of HF, evidence of a low output state, increased risk for cardiogenic shock,‖ or other contraindications to use of oral beta blockers (PR interval more than 0.24 seconds, second- or third-degree heart block, active asthma, or reactive airways disease).[414–416] (*Level of Evidence: B*)**
2. **Beta blockers should be continued during and after hospitalization for all patients with STEMI and with no contraindications to their use.[417,418] (*Level of Evidence: B*)**

‖Risk factors for cardiogenic shock (the greater the number of risk factors present, the higher the risk of developing cardiogenic shock) are age >70 years, systolic BP <120 mm Hg, sinus tachycardia >110 bpm or heart rate <60 bpm, and increased time since onset of symptoms of STEMI.

Table 12. Selected Routine Medical Therapies

Therapy	Indications	Dose/Administration	Avoid/Caution
Beta-Receptor Antagonists	• Oral: All patients without contraindication • IV: Patients with refractory hypertension or ongoing ischemia without contraindication	Individualize: • Metoprolol tartrate 25 to 50 mg every 6 to 12 h orally, then transition over next 2 to 3 d to twice-daily dosing of metoprolol tartrate or to daily metoprolol succinate; titrate to daily dose of 200 mg as tolerated • Carvedilol 6.25 mg twice daily, titrate to 25 mg twice daily as tolerated • Metoprolol tartrate IV 5 mg every 5 min as tolerated up to 3 doses; titrate to heart rate and BP	• Signs of HF • Low output state • Increased risk of cardiogenic shock • Prolonged first-degree or high-grade AV block • Reactive airways disease
ACE Inhibitors	• For patients with anterior infarction, post-MI LV systolic dysfunction (EF ≤0.40) or HF • May be given routinely to all patients without contraindication	Individualize: • Lisinopril 2.5 to 5 mg/d to start; titrate to 10 mg/d or higher as tolerated • Captopril 6.25 to 12.5 mg 3 times/d to start; titrate to 25 to 50 mg 3 times/d as tolerated • Ramipril 2.5 mg twice daily to start; titrate to 5 mg twice daily as tolerated • Trandolapril test dose 0.5 mg; titrate up to 4 mg daily as tolerated	• Hypotension • Renal failure • Hyperkalemia
ARB	• For patients intolerant of ACE inhibitors	• Valsartan 20 mg twice daily to start; titrate to 160 mg twice daily as tolerated	• Hypotension • Renal failure • Hyperkalemia
Statins	• All patients without contraindications	• High-dose atorvastatin 80 mg daily	• Caution with drugs metabolized via *CYP3A4*, fibrates • Monitor for myopathy, hepatic toxicity • Combine with diet and lifestyle therapies • Adjust dose as dictated by targets for LDL cholesterol and non–HDL cholesterol reduction
Nitroglycerin	• Ongoing chest pain • Hypertension and HF	• 0.4 mg sublingual every 5 min up to 3 doses as BP allows • IV dosing to begin at 10 mcg/min; titrate to desired BP effect	• Avoid in suspected RV infarction • Avoid with SBP <90 mm Hg or if SBP >30 mm Hg below baseline • Avoid if recent (24 to 48 h) use of 5′-phosphodiesterase inhibitors
Oxygen	• Clinically significant hypoxemia (oxygen saturation <90%) • HF • Dyspnea	• 2 to 4 L/min via nasal cannula • Increase rate or change to face mask as needed	• Caution with chronic obstructive pulmonary disease and CO_2 retention
Morphine	• Pain • Anxiety • Pulmonary edema	• 4 to 8 mg IV initially, with lower doses in elderly • 2 to 8 mg IV every 5 to 15 min if needed	• Lethargic or moribund patient • Hypotension • Bradycardia • Known hypersensitivity

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; AV, atrioventricular; BP, blood pressure; CO_2, carbon dioxide; EF, ejection fraction; HDL, high-density lipoprotein; HF, heart failure; IV, intravenous; LDL, low-density lipoprotein; LV, left ventricular; MI, myocardial infarction; RV, right ventricular; and SBP, systolic blood pressure.

3. **Patients with initial contraindications to the use of beta blockers in the first 24 hours after STEMI should be reevaluated to determine their subsequent eligibility. (*Level of Evidence: C*)**

Class IIa

1. **It is reasonable to administer intravenous beta blockers at the time of presentation to patients with STEMI and no contraindications to their use who are hypertensive or have ongoing ischemia.[414–416] (*Level of Evidence: B*)**

The efficacy and safety of the early routine use of intravenous beta blockers were examined in COMMIT/CCS-2 (Clopidogrel and Metoprolol in Myocardial Infarction Trial).[414] Early intravenous metoprolol followed by high-dose oral therapy had a neutral effect on the combined endpoint of death, recurrent MI, or cardiac arrest. There were lower rates of recurrent MI and VF in the treated group, outcomes that were balanced by a significantly higher rate of cardiogenic shock with metoprolol, especially on days 0 and 1. The likelihood of developing cardiogenic shock was increased in certain subgroups, including patients with age >70 years,

systolic BP <120 mm Hg, presenting heart rate >110 bpm, or increased time since onset of symptoms of STEMI. The benefit of beta blockers for secondary prevention has been established in numerous trials conducted in the prereperfusion era and appears to be greatest for patients with MI complicated by HF, LV dysfunction, or ventricular arrhythmias.[418] The long-term duration of routine beta-blocker therapy after uncomplicated MI in patients without HF or hypertension has not been prospectively addressed. AHA/ACCF secondary prevention guidelines recommend a 3-year treatment course in this patient subset.[257]

8.2. Renin-Angiotensin-Aldosterone System Inhibitors: Recommendations

Class I

1. **An angiotensin-converting enzyme (ACE) inhibitor should be administered within the first 24 hours to all patients with STEMI with anterior location, HF, or ejection fraction (EF) less than or equal to 0.40, unless contraindicated.[420–423] (Level of Evidence: A)**
2. **An angiotensin receptor blocker (ARB) should be given to patients with STEMI who have indications for but are intolerant of ACE inhibitors.[424,425] (*Level of Evidence: B*)**
3. **An aldosterone antagonist should be given to patients with STEMI and no contraindications who are already receiving an ACE inhibitor and beta blocker and who have an EF less than or equal to 0.40 and either symptomatic HF or diabetes mellitus.[426] (*Level of Evidence: B*)**

Class IIa

1. **ACE inhibitors are reasonable for all patients with STEMI and no contraindications to their use.[427–429] (*Level of Evidence: A*)**

Oral ACE inhibitors reduce fatal and nonfatal major cardiovascular events in patients with STEMI.[360,361,420,422,428–430] Their protective effects have been demonstrated independent of the use of other pharmacotherapies (ie, fibrinolytics, aspirin, and beta blockers). The magnitude of clinical benefit is greatest in high-risk patient subgroups (ie, anterior MI, EF ≤0.40, HF, prior MI, and tachycardia).[431] Demonstration of an early benefit (within the first 24 hours) supports the prompt use of these agents in patients without existing contraindications (hypotension, shock, bilateral renal artery stenosis or history of worsening of renal function with ACE inhibitor/ARB exposure, renal failure, or drug allergy). The role of routine long-term ACE inhibitor therapy in low-risk patients after STEMI who have been revascularized and treated with aggressive lipid-lowering therapies is less certain.[432] ARBs are indicated for ACE inhibitor–intolerant patients. Specifically, valsartan was found to be noninferior to captopril in the VALIANT (Valsartan in Acute Myocardial Infarction) trial.[424]

The EPHESUS (Eplerenone Post-Acute Myocardial Infarction Heart Failure Efficacy and Survival) study established the benefit of an aldosterone antagonist, eplerenone, added to optimal medical therapy in eligible patients (creatinine ≤2.5 mg/dL in men and ≤2.0 mg/dL in women, potassium ≤5.0 mEq/L) 3 to 14 days after STEMI with EF ≤0.40 and either symptomatic HF or diabetes mellitus.[426] A post hoc analysis of the EPHESUS trial suggested a time-dependent treatment effect of eplerenone. Earlier initiation of the drug (<7 days) significantly reduced the rates of all-cause mortality, sudden cardiac death (SCD), and cardiovascular mortality/hospitalization, whereas initiation ≥7 days had no significant effect on outcomes.[433]

8.3. Lipid Management: Recommendations

Class I

1. **High-intensity statin therapy should be initiated or continued in all patients with STEMI and no contraindications to its use.[434–436] (*Level of Evidence: B*)**

Class IIa

1. **It is reasonable to obtain a fasting lipid profile in patients with STEMI, preferably within 24 hours of presentation. (*Level of Evidence: C*)**

Treatment with statins in patients stabilized after an ACS, including STEMI, lowers the risk of coronary heart disease death, recurrent MI, stroke, and the need for coronary revascularization.[437,438] More intensive statin therapy, compared with less intensive therapy, appears to be associated with an additional lowering of nonfatal clinical endpoints.[434,436,439] Among currently available statins, only high-dose atorvastatin (80 mg daily) has been shown to reduce death and ischemic events among patients with ACS.[436,440] Approximately one third of patients in the PROVE-IT TIMI 22 (Pravastatin or Atorvastatin Evaluation and Infection Therapy—Thrombolysis in Myocardial Infarction 22) trial had STEMI.[436] Cardiovascular event rates were not significantly reduced with a tiered strategy of simvastatin (40 mg daily for 1 month followed by 80 mg daily) in the A to Z Trial (Aggrastat to Zocor),[439] and concerns have been raised recently about the safety of high-dose simvastatin (ie, 80 mg daily).[441] Although the benefit of high-intensity statins declines among statin-naïve patients with ACS as a function of decreasing low-density lipoprotein levels,[442] the writing committee recommends the use of statins in all patients with STEMI.[435] Statin therapy after ACS is beneficial even in patients with baseline low-density lipoprotein cholesterol levels <70 mg/dL.[443] Trials of statin therapy in patients with ACS and stable ischemic heart disease have been designed to compare either more intensive versus less intensive statin treatment or active statin versus placebo.[434–440] They have not been designed to compare clinical outcomes as a function of the specific low-density lipoprotein cholesterol level achieved with treatment. Improved compliance with therapy is a strong rationale for timing the initiation of lipid-lowering drug therapy before discharge after STEMI. Longer-term lipid management after STEMI, including indications for targeting triglycerides and non–high-density lipoprotein cholesterol, are addressed in the

"AHA/ACC Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Vascular Disease: 2011 Update."[257]

8.4. Nitrates

Although nitroglycerin can ameliorate symptoms and signs of myocardial ischemia by reducing LV preload and increasing coronary blood flow, it generally does not attenuate the myocardial injury associated with epicardial coronary artery occlusion unless vasospasm plays a significant role. Intravenous nitroglycerin may be useful to treat patients with STEMI and hypertension or HF. Nitrates should not be given to patients with hypotension, marked bradycardia or tachycardia, RV infarction, or 5'phosphodiesterase inhibitor use within the previous 24 to 48 hours.[444] There is no role for the routine use of oral nitrates in the convalescent phase of STEMI.

8.5. Calcium Channel Blockers

An overview of 28 RCTs involving 19000 patients demonstrated no beneficial effect on infarct size or the rate of reinfarction when calcium channel blocker therapy was initiated during either the acute or convalescent phase of STEMI.[445] Calcium channel blockers may be useful, however, to relieve ischemia, lower BP, or control the ventricular response rate to atrial fibrillation (AF) in patients who are intolerant of beta blockers. Caution is advised in patients with LV systolic dysfunction. The use of the immediate-release nifedipine is contraindicated in patients with STEMI because of hypotension and reflex sympathetic activation with tachycardia.[446]

8.6. Oxygen

Few data exist to support or refute the value of the routine use of oxygen in the acute phase of STEMI, and more research is needed. A pooled Cochrane analysis of 3 trials showed a 3-fold higher risk of death for patients with confirmed acute MI treated with oxygen than for patients with acute MI managed on room air. Oxygen therapy is appropriate for patients who are hypoxemic (oxygen saturation <90%) and may have a salutary placebo effect in others. Supplementary oxygen may, however, increase coronary vascular resistance.[447] Oxygen should be administered with caution to patients with chronic obstructive pulmonary disease and carbon dioxide retention.

8.7. Analgesics: Morphine, Nonsteroidal Anti-Inflammatory Drugs, and Cyclooxygenase II Inhibitors

In the absence of a history of hypersensitivity, morphine sulfate is the drug of choice for pain relief in patients with STEMI, especially those whose course is complicated by acute pulmonary edema. It can alleviate the work of breathing, reduce anxiety, and favorably affect ventricular loading conditions. The dose of morphine sulfate needed to achieve adequate pain control will vary depending on patient age, body size, BP, and heart rate. Naloxone can be administered in doses of 0.1 to 0.2 mg IV every 15 minutes when indicated to reverse the narcotic effects of morphine, and atropine 0.5 to 1.5 mg IV may be administered to counter excessive morphine-related bradycardia.

Epidemiological studies and retrospective analyses of RCTs have suggested that nonsteroidal anti-inflammatory drugs and selective cyclooxygenase II enzyme (COX-2) inhibitors may be associated with an increased risk of death, reinfarction, cardiac rupture, hypertension, renal insufficiency, and HF.[448–451] Nonsteroidal anti-inflammatory drugs and COX-2 inhibitors are contraindicated in patients with STEMI. They should not be initiated in the acute phase and should be discontinued in patients using them before hospitalization.

9. Complications After STEMI

9.1. Cardiogenic Shock

9.1.1. Treatment of Cardiogenic Shock: Recommendations

Class I

1. **Emergency revascularization with either PCI or CABG is recommended in suitable patients with cardiogenic shock due to pump failure after STEMI irrespective of the time delay from MI onset.[212,379,452] (*Level of Evidence: B*)**
2. **In the absence of contraindications, fibrinolytic therapy should be administered to patients with STEMI and cardiogenic shock who are unsuitable candidates for either PCI or CABG.[81,453,454] (*Level of Evidence: B*)**

Class IIa

1. **The use of intra-aortic balloon pump (IABP) coun-terpulsation can be useful for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy.[455–459] (*Level of Evidence: B*)**

Class IIb

1. **Alternative LV assist devices for circulatory support may be considered in patients with refractory cardiogenic shock. (*Level of Evidence: C*)**

Cardiogenic shock in patients with STEMI may be caused by extensive LV infarction or by mechanical complications, including papillary muscle rupture, ventricular septal rupture, free-wall rupture with tamponade, and RV infarction. The onset of cardiogenic shock due to mechanical complications after STEMI is bimodal; most cases occur within 24 hours. For those with pump failure, 15% of cases occur at time of presentation, and 85% develop during hospitalization. Revascularization with timely PCI or CABG is the preferred reperfusion strategy for patients with STEMI and shock due to pump failure, irrespective of the time delay. Shock or severe HF is perhaps the only clinical scenario in which acute revascularization of significant stenoses in noninfarct arteries can be justified. In the SHOCK trial, mortality rates at 6 and 1 year were significantly lower in patients allocated to emergency revascularization than in patients who received immediate medical stabilization.[212,354] Nearly two thirds of the patients in the medical stabilization group received

fibrinolytic therapy, and 25% underwent delayed revascularization. IABP support was used in 86% of both groups. Although the trial did not show benefit with emergency revascularization for the prespecified age group >75 years, the small number of patients in the trial did not allow for firm conclusions to be drawn about management. Elderly patients offered emergency revascularization in the nonrandomized SHOCK registry had a substantial adjusted survival benefit with emergency revascularization compared with delayed or no revascularization.[460] Similar findings in favor of early revascularization for selected elderly patients were reported from 2 additional registries.[461,462] Although age alone is not a contraindication to emergency revascularization in this setting, individual judgment based on comorbidities, functional status, and patient directives is necessary in the elderly. Triage and immediate transfer to a PCI-capable facility with on-site cardiac surgical backup are indicated for patients with STEMI complicated by shock. Fibrinolytic therapy is reserved for patients without contraindications within 24 hours of MI for whom revascularization is considered not feasible for technical, anatomic, or patient-related issues. The need for hemodynamic support with inotropic therapy, IABP, or both should be assessed on an individual basis. Observational data on the usefulness of IABP in this setting are conflicting. A meta-analysis supports IABP therapy as an adjunct to fibrinolysis but not to primary PCI.[458] Compared with IABP, LV assist devices may provide superior hemodynamic support and serve as more effective bridges to recovery or transplantation, though experience with their use in this setting is limited.[463,464] Medical support with inotropes and vasopressor agents should be individualized and guided by invasive hemodynamic monitoring. Use of dopamine in this setting may be associated with excess hazard.[465]

9.2. Severe HF

The development of HF after STEMI is an indication for angiography with intent to proceed with revascularization if not previously performed. LV myocardium may be ischemic, stunned, hibernating, or irrevocably injured, and viability assessment may be needed depending on the timing of revascularization. Ischemic (functional) mitral regurgitation due to LV remodeling may coexist, progress over time, and require surgical attention depending on its severity. Medical treatment is based on the use of diuretics, vasodilators, and inotropic agents when required. Inhibitors of the renin-angiotensin-aldosterone system should be provided as tolerated, and the indications for beta-blocker therapy should be evaluated continuously throughout the hospital course.

9.3. RV Infarction

RV infarction complicates the course of approximately one third of patients with inferior STEMI, is most often due to proximal occlusion of the right coronary artery, and is associated with a higher mortality risk. Evidence of RV involvement should be sought in all patients with inferior STEMI. The clinical triad of hypotension, clear lung fields, and elevated jugular venous pressure is characteristic. Demonstration of 1-mm ST elevation in lead V1 and in right precordial lead V_4R is the most sensitive ECG marker of RV injury.[466] Transthoracic echocardiography can be helpful in patients with initially nondiagnostic findings.[467] Treatment includes maintenance of RV preload, reduction of RV afterload, inotropic support if needed, and immediate reperfusion.[468,469] Nitrates and diuretics should be avoided. Restoration of atrioventricular (AV) synchrony or cardioversion from AF may be needed.

9.4. Mechanical Complications

9.4.1. Diagnosis

Mechanical complications after STEMI have a bimodal, temporal distribution: Most occur in the first 24 hours, and the remainder present within the first week. The presence of a new systolic murmur indicates the possibility of either ventricle septal rupture or mitral regurgitation. Diagnosis usually can be established with transthoracic echocardiography. Surgical consultation should be obtained when a mechanical defect is suspected. Prompt repair (with or without CABG) is indicated in most cases. IABP can provide temporary circulatory support.

9.4.2. Mitral Regurgitation

Mitral regurgitation after STEMI occurs via 1 of 2 mechanisms: papillary muscle rupture or postinfarction LV remodeling with displacement of the papillary muscles, leaflet tethering, and annular dilatation. Acute rupture affects the posteromedial papillary muscle more often than anterolateral papillary muscle because of its singular blood supply.[470,471] Acute severe mitral regurgitation is characterized by pulmonary edema and/or shock; a systolic murmur may not always be appreciated. Suitable patients with papillary muscle rupture should be considered for urgent surgery while temporary stabilization with medical therapy and IABP is attempted. Mitral valve replacement rather than repair usually is required in this setting. Although emergency mitral valve replacement is associated with a relatively high mortality rate (20%), survival and ventricular function are improved with surgery compared with medical therapy alone. Delay to operation appears to increase the risk of further myocardial injury, organ failure, and death.[472] Five-year survival rates after surgery average 60% to 70%.[397,473–476]

With ischemic (functional) mitral regurgitation, treatment is focused on timely reperfusion, diuretics, and afterload reduction. The severity of mitral regurgitation may improve in some patients with aggressive medical treatment, PCI, or both. The rate of long-term survival after STEMI declines as a function of residual mitral regurgitation severity. If surgery is required during the index hospitalization because of ongoing ischemia or HF, mitral valve repair with a downsized annuloplasty ring usually is performed, though valve replacement may be preferred in many cases. In this regard, management of ischemic mitral regurgitation differs importantly from that of myxomatous mitral regurgitation.

9.4.3. Ventricular Septal Rupture

Ventricular septal rupture usually is heralded by a loud systolic murmur and HF or shock, depending on the size of the defect and the degree of RV and LV dysfunction. Data from the GUSTO-1 (The Global Use of Strategies to Open Occluded Coronary Arteries) trial and the SHOCK registry

indicate that ventricular septal rupture occurs most often within the first 24 hours in patients with STEMI treated with fibrinolytic therapy.[477,478] Emergency surgical repair is necessary, even in hemodynamically stable patients,[479–481] because the rupture site can expand abruptly, resulting in sudden hemodynamic collapse in previously stable patients.[481] Temporizing medical treatment consists of inotropic and vasodilator agents, with IABP when needed. The surgical mortality rate remains high, especially among patients with shock, ranging from 20% to 87% in reported series.[395,477–480,482,483] Mortality risk is higher for patients with inferior-basal defects than for those with anterior-apical defects. Percutaneous closure is a less invasive option that might allow for initial hemodynamic stabilization, but experience with this approach is limited, and residual shunts are common. Further technical developments and prospective trials are required to identify patients best suited for transcatheter closure.

9.4.4. LV Free-Wall Rupture

Free-wall rupture is characterized by recurrent chest pain and ST-T-wave changes, with rapid progression to hemodynamic collapse, electromechanical dissociation, and death.[484] It is observed most frequently in patients with first MI, anterior infarction, the elderly, and women. Other risk factors include hypertension during the acute phase of STEMI, lack of antecedent angina or prior MI, absence of collateral blood flow, Q waves on ECG, use of corticosteroids or nonsteroidal anti-inflammatory drugs, and administration of fibrinolytic therapy >14 hours after symptom onset.[485,486] Pseudoaneurysm formation with contained rupture and tamponade can be recognized with transthoracic echocardiography, and emergency surgery should be considered. Most case series of patients reaching the operating room for management of this complication are of small size, with mortality rates approaching 60%.[396,487]

9.4.5. LV Aneurysm

Ventricular aneurysm formation after STEMI occurs in <5% of patients and is more frequent in those with anterior infarction. Incidence rates have declined with timely reperfusion. Surgery for LV aneurysm after STEMI is rarely needed but may be considered for treatment of HF, ventricular arrhythmias not amenable to drugs or radiofrequency ablation, or recurrent thromboembolism despite appropriate anticoagulant therapy.

9.5. Electrical Complications During the Hospital Phase of STEMI

9.5.1. Ventricular Arrhythmias

Ventricular arrhythmias are common early after onset of STEMI, and not all require intervention. Out-of-hospital cardiac arrest with STEMI is most often due to lethal ventricular arrhythmias, including sustained VT and VF (Section 3.6.1). The mechanisms for these arrhythmias are multifactorial and include ongoing ischemia, hemodynamic and electrolyte abnormalities, reentry, and enhanced automaticity. As many as 10% of hospitalized patients receiving fibrinolytic therapy in the GUSTO-I trial had sustained VT/VF complicating their course.[488] An analysis of patients referred for primary PCI in the APEX-AMI (Assessment of Pexelizumab in Acute Myocardial Infarction) trial reported a lower incidence of sustained VT/VF (5.7%); 90% of cases occurred within 48 hours of presentation.[489] Compared with patients without VT/VF, 90-day mortality risk was 2-fold higher for patients with early VT/VF (ie, before the completion of primary PCI) and 5-fold higher for patients with late VT/VF (ie, after primary PCI). Several factors were associated with the occurrence of both early and late VT/VF, including HF, hypotension, tachycardia, shock, and TIMI flow grade. Treatment consists of immediate defibrillation or cardioversion for VF or pulseless sustained VT, respectively, and antiarrhythmic drug therapy in accordance with the 2010 Advanced Cardiac Life Support guidelines for sustained VT with a pulse.[490] Prevention of VT/VF is directed to correction of electrolyte and acid/base abnormalities, optimization of myocardial perfusion, eradication of ongoing ischemia, and treatment of associated complications such as HF or shock. Early (within 24 hours of presentation) administration of beta blockers has been associated with a reduction in the incidence of VF[414,489] and is recommended for all patients without contraindications (Section 8.1). The prophylactic use of lidocaine is not recommended. Premature ventricular complexes, nonsustained VT not associated with hemodynamic compromise, and accelerated idioventricular rhythms that emerge after reperfusion are not indicative of increased SCD risk and do not require specific therapy in the acute phase of STEMI.

9.5.2. Implantable Cardioverter-Defibrillator Therapy Before Discharge

Class I

1. **Implantable cardioverter-defibrillator (ICD) therapy is indicated before discharge in patients who develop sustained VT/VF more than 48 hours after STEMI, provided the arrhythmia is not due to transient or reversible ischemia, reinfarction, or metabolic abnormalities.[491–493] (*Level of Evidence: B*)**

Life-threatening ventricular arrhythmias that occur >48 hours after STEMI usually are associated with significant LV systolic dysfunction and signify poor prognosis. Although previous RCTs[492,494,495] have not specifically addressed this population of patients with STEMI, they have shown clear and consistent benefit of ICD therapy for survivors of sustained VT or VF arrest.[493] In the absence of a reversible cause, late (>48 hours) in-hospital sustained VT/VF is an indication for ICD therapy for secondary prevention of SCD. For other at-risk patients, particularly those with significantly reduced left ventricular ejection fraction (LVEF), candidacy for ICD therapy for primary prevention of SCD should be reassessed at ≥40 days after discharge (Section 10.3). See the "2008 ACCF/AHA/HRS Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities."[496]

9.5.3. AF and Other Supraventricular Tachyarrhythmias

AF, atrial flutter, and other supraventricular tachyarrhythmias occur frequently in patients with STEMI and are triggered by excessive sympathetic stimulation, atrial stretch due to LV or

RV volume/pressure overload, atrial infarction, pericarditis, electrolyte abnormalities, hypoxia, or underlying lung disease. By far the most common supraventricular arrhythmia is AF, which occurs in 8% to 22% of patients with STEMI, with higher rates in elderly patients and those with HF and hypertension. In a contemporary study, the incidence of new-onset AF during hospitalization was 6.3%.[497] New-onset AF was significantly associated with shock, HF, stroke, and 90-day mortality.[497] These observations mirrored those seen in earlier trials.[317,422,428,497–499] The cumulative incidence of AF among MI survivors with EF ≤0.40 over approximately 2 years of follow-up approaches 30%.[500]

Management of AF during hospitalization for STEMI is based on the usual considerations of rhythm versus rate control and the indications for anticoagulation according to current guidelines.[501,502] For hemodynamically unstable patients or those with ongoing ischemic symptoms, treatment should be implemented according to the 2010 Advanced Cardiac Life Support guideline for management of unstable supraventricular tachyarrhythmias.[490] If medical treatment is unsuccessful, synchronized, direct current cardioversion may be indicated. Provision of anticoagulation in the context of DAPT creates additional challenges related to the risk of bleeding (Section 9.7).

9.5.4. Bradycardia, AV Block, and Intraventricular Conduction Defects

9.5.4.1. Pacing in STEMI: Recommendation

Class I

1. **Temporary pacing is indicated for symptomatic bradyarrhythmias unresponsive to medical treatment. (*Level of Evidence: C*)**

Sinus bradycardia is common early after STEMI, particularly with inferior location. It is mediated through increased vagal tone, is usually self-limited, and generally requires no treatment. It may be necessary to withhold beta blockers until the bradycardia resolves. Symptomatic or hemodynamically important sinus bradycardia should be treated with atropine or temporary pacing if not responsive.[504]

The development of AV block and intraventricular conduction delays is associated with the extent of infarction. The incidence of abnormal conduction has decreased substantially in the reperfusion era. In a survey of nearly 3 million hospital discharges after MI from 1996 to 2003, the incidence of complete heart block was 3.7% in inferior/posterior MI and 1.0% in anterior/lateral MI.[505] AV block of varying degree and persistent bundle-branch block develop in approximately 7% and 5% of patients with STEMI, respectively.[506,507] High-grade (ie, second- or third-degree) AV block and persistent bundle-branch block are independently associated with worse short- and long-term prognosis in both inferior/posterior and anterior/lateral MI but are more ominous in anterior/lateral MI because of a relatively greater extent of myocardial injury.[506–508]

First-degree AV block does not require treatment. High-grade AV block with inferior/posterior STEMI usually is transient and associated with a narrow complex/junctional escape rhythm that can be managed conservatively. Application of transcutaneous pacing pads for potential use is reasonable. Prophylactic placement of a temporary pacing system is recommended for high-grade AV block and/or new bundle-branch (especially LBBB) or bifascicular block in patients with anterior/lateral MI. Choice of pacing system (transcutaneous versus transvenous) varies across institutions. Indications for permanent pacing for persistent AV block or bundle-branch block after STEMI are reviewed in the 2008 ACC/AHA/HRS device-based therapy guidelines.[496]

9.6. Pericarditis

9.6.1. Management of Pericarditis After STEMI: Recommendations

Class I

1. **Aspirin is recommended for treatment of pericarditis after STEMI.[509] (*Level of Evidence: B*)**

Class IIb

1. **Administration of acetaminophen, colchicine, or narcotic analgesics may be reasonable if aspirin, even in higher doses, is not effective. (*Level of Evidence: C*)**

Class III: Harm

1. **Glucocorticoids and nonsteroidal anti-inflammatory drugs are potentially harmful for treatment of pericarditis after STEMI.[510,511] (*Level of Evidence: B*)**

The incidence of acute pericarditis after STEMI has decreased with the aggressive use of reperfusion therapy.[512,513] Pericarditis should be considered in the differential diagnosis of recurrent chest pain after STEMI, particularly when the discomfort is pleuritic or positional, radiates to the trapezius ridge, and is associated with a pericardial friction rub. Recurrent or worsening ST elevation without early T-wave inversion may be present. Distinction from reinfarction or acute stent thrombosis is crucial. In rare circumstances, if pain is persistent (>1 week) and accompanied by systemic features of malaise, fever, and increased inflammatory biomarkers, Dressler syndrome should be considered. In most cases, the pain is self-limited and responds to conservative measures. The use of colchicine has been extrapolated from its efficacy in other settings. Although pericarditis is not an absolute contraindication to anticoagulation,[514] caution should be exercised because of the potential for hemorrhagic conversion.[515]

Asymptomatic pericardial effusions are common after STEMI.[516,517] It is important to exclude free-wall rupture when a pericardial effusion is present,[518,519] especially if the

width of the effusion is >1 cm.[520] When tamponade is present, free-wall rupture, hemorrhagic conversion, or aortic dissection should be considered. Anticoagulation should be discontinued in the presence of a significant (≥1 cm) or enlarging pericardial effusion.

9.7. Thromboembolic and Bleeding Complications

9.7.1. Thromboembolic Complications

9.7.1.1. Anticoagulation: Recommendations¶

Class I

1. **Anticoagulant therapy with a vitamin K antagonist should be provided to patients with STEMI and AF with CHADS2 score# greater than or equal to 2, mechanical heart valves, venous thromboembolism, or hypercoagulable disorder. (*Level of Evidence: C*)**
2. **The duration of triple antithrombotic therapy with a vitamin K antagonist, aspirin, and a $P2Y_{12}$ receptor inhibitor should be minimized to the extent possible to limit the risk of bleeding.** (*Level of Evidence: C*)**

Class IIa

1. **Anticoagulant therapy with a vitamin K antagonist is reasonable for patients with STEMI and asymptomatic LV mural thrombi. (*Level of Evidence: C*)**

Class IIb

1. **Anticoagulant therapy may be considered for patients with STEMI and anterior apical akinesis or dyskinesis. (*Level of Evidence: C*)**
2. **Targeting vitamin K antagonist therapy to a lower international normalized ratio (eg, 2.0 to 2.5) might be considered in patients with STEMI who are receiving DAPT. (*Level of Evidence: C*)**

Previous recommendations for the use of vitamin K antagonists, either alone or in combination with low-dose aspirin, for secondary prevention or for reducing the risk of systemic thromboembolism after STEMI, must be reconsidered in the era of DAPT.[4,48] The availability of several $P2Y_{12}$ receptor inhibitors has virtually eliminated the former reliance on vitamin K antagonists as an alternative to aspirin for aspirin-allergic patients. A meta-analysis of RCTs comparing warfarin plus aspirin to aspirin alone in patients with ACS showed that in studies with an international normalized ratio goal of 2.0 to 3.0, combination therapy was associated with a significant reduction in major adverse events at the expense of an increased risk of major bleeding.[521] None of the trials included patients treated with primary PCI or DAPT.

Triple therapy with a vitamin K antagonist, aspirin, and a $P2Y_{12}$ receptor inhibitor should be restricted to specific clinical situations after STEMI in which the risk of systemic or venous thromboembolism or stent thrombosis is considered to exceed that of bleeding. Patient preferences and values should be taken into consideration, because individuals may weigh these outcomes differently. The novel oral anticoagulants such as dabigatran have not been evaluated in this context, and thus no recommendation for their use can be made. The duration of vitamin K antagonist therapy can be limited to 3 months in patients with or at risk for LV thrombus (eg, those with anteroapical akinesis or dyskinesis), whereas the duration of DAPT could be predicated on stent type or whether STEMI treatment included a stent.[219,522,523] For patients undergoing primary PCI who require anticoagulation, avoidance of a DES is strongly preferred. When triple therapy is used, an international normalized ratio targeted to a range of 2.0 to 2.5 might be reasonable, though prospective data are lacking. Use of DAPT alone with aspirin and clopidogrel also might be considered for patients with STEMI who have AF and low to intermediate CHADS2 scores (0 to 1), with reconsideration of the indications for anticoagulation over time.[296,522]

The incidence of venous thromboembolic events after STEMI has declined significantly,[526] though patients with HF or on prolonged bed rest remain at risk.[527] The approach to the prevention and treatment of venous thromboembolic disease during hospitalization, with both pharmacological and mechanical measures, is similar to that for other critically ill patients.[528]

9.7.1.2. Heparin-Induced Thrombocytopenia

HIT, with or without associated thrombosis, can infrequently complicate the course of patients with ACS,[529] particularly patients who previously have been exposed to heparin or who receive heparin over several hospital days. From 1% to 5% of all patients receiving heparin will develop HIT, and of these, 25% to 50% will develop thrombotic complications. In the CATCH (Complications After Thrombocytopenia Caused by Heparin) registry,[530,531] thrombocytopenia was common among those who received heparin for >96 hours (36.4%) and was associated with a significantly increased risk of death, MI, or HF. Recognition of HIT frequently was delayed, and treatment often did not include a direct thrombin inhibitor. Data on the use of direct thrombin inhibitors in patients with STEMI who develop HIT are limited.[532,533] For patients with STEMI and HIT who require stenting, bivalirudin would be the preferred anticoagulant. Management of patients with HIT who require urgent CABG can be more difficult.[534]

9.7.2. Bleeding Complications

Despite variable definitions for major and minor bleeding used in clinical trials, bleeding that complicates the course of an ACS, including STEMI, is independently associated with recurrent MI, stroke, death, longer hospital stay, and increased cost. The risk of death increases as a function of the severity of bleeding, independent of the success or failure of reperfusion therapy. In a pooled analysis from 4 ACS trials, the adjusted hazard ratio for death within 30 days ranged from 1.6 with mild bleeding to 10.6 with severe bleeding.[535] Most bleeding is procedure related, although gastrointestinal and intracerebral bleeding may be more life threatening. Factors likely to contribute to adverse outcomes with ACS-related

¶These recommendations apply to patients who receive intracoronary stents during PCI for STEMI. Among individuals with STEMI who do not receive an intracoronary stent, the duration of DAPT beyond 14 days has not been studied adequately for patients who undergo balloon angioplasty alone, are treated with fibrinolysis alone, or do not receive reperfusion therapy. In this subset of patients with STEMI who do not receive an intracoronary stent, the threshold for initiation of oral anticoagulation for secondary prevention, either alone or in combination with aspirin, may be lower, especially if a shorter duration (ie, 14 days) of DAPT is planned.[521]

#CHADS2 (Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, previous Stroke/transient ischemic attack [doubled risk weight]) score.

**Individual circumstances will vary and depend on the indications for triple therapy and the type of stent placed during PCI. After this initial treatment period, consider therapy with a vitamin K antagonist plus a single antiplatelet agent. For patients treated with fibrinolysis, consider triple therapy for 14 days, followed by a vitamin K antagonist plus a single antiplatelet agent.[522-525]

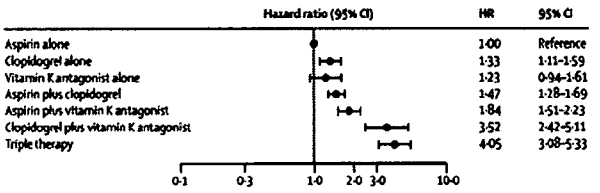

Figure 4. Adjusted risk of nonfatal and fatal bleeding in patients treated with aspirin, clopidogrel, and/or vitamin K antagonists after first MI. Compared with aspirin alone, triple therapy is associated with a 3- to 4-fold increased risk of fatal and nonfatal bleeding. CI indicates confidence interval; HR, hazard ratio; and MI, myocardial infarction. Adapted with permission from Sørensen et al.[533]

bleeding include patient comorbidities,[536,537] discontinuation of antiplatelet or anticoagulant therapy in response to bleeding,[536,538] and blood transfusion.[539,540] Additional considerations include types of antiplatelet or anticoagulant agent at time of PCI,[248,541,542] number of antithrombotic agents used,[533] dosing,[543] duration of therapy, crossover from low-molecular-weight heparin to UFH, HF or shock, diabetes mellitus, peripheral artery disease, and prior warfarin use. If triple antithrombotic therapy is required after discharge, the risk of bleeding increases (Figure 4).[533]

Risk factors for bleeding in patients with ACS have been identified from several clinical trials[535,544–546] (Table 13). Predictive models for major bleeding in patients with ACS and in patients undergoing PCI have been reported from the NCDR ACTION Registry–GWTG.[547,548] An analysis from the ACTION Registry–GWTG suggests that the CRUSADE bleeding risk score, developed in patients with non–ST-elevation MI, may be extended to the STEMI population.[549] Major bleeding occurred in 2.8% of >40 000 patients with acute MI in the GRACE Registry.[536] Patients who experienced a major bleeding episode were more likely to die in hospital than were those who did not bleed (20.9% versus 5.6%; $P<0.001$), even after adjustment for several relevant demographic and clinical variables. One in 5 patients with a major bleed did not survive to hospital discharge; these patients accounted for 10% of all hospital deaths and were older, more severely ill, and more likely to undergo invasive procedures. In ExTRACT-TIMI 25 (Enoxaparin and Thrombolysis Reperfusion for Acute Myocardial Infarction Treatment—Thrombolysis In Myocardial Infarction 25), high 30-day mortality rates after major bleeding in patients with STEMI treated with fibrinolysis and either unfractionated or low-molecular-weight heparin were driven largely by the very poor prognosis associated with ICH (65% mortality rate).[537] The overall incidence of ICH in this study was 0.6%.[332] The relationship between non-ICH bleeding and death in both ExTRACT-TIMI 25 and TRITON-TIMI 38 may have been confounded by patient attributes, severity of illness, and treatment protocols.[537,550] To minimize the risk of bleeding complications, an assessment of patient, procedural, and pharmacological risk factors should be performed at time of presentation with STEMI and continuously thereafter. As an example, a longer time to PCI may be justifiable if the risk of hemorrhage with fibrinolysis is considered prohibitive.

Table 13. Selected Risk Factors for Bleeding in Patients With ACS

Advanced age (>75 y)
Female sex
HF or shock
Diabetes mellitus
Body size
History of GI bleeding
Presentation with STEMI or NSTEMI (vs UA)
Severe renal dysfunction (CrCl <30 mL/min)
Elevated white blood cell count
Anemia
Use of fibrinolytic therapy
Invasive strategy
Inappropriate dosing of antithrombotic medications
Chronic oral anticoagulant therapy

ACS indicates acute coronary syndrome; CrCl, creatinine clearance; GI, gastrointestinal; HF, heart failure; NSTEMI, non–ST-elevation myocardial infarction; STEMI, ST-elevation myocardial infarction; and UA, unstable angina.[553,554,543,547]

Evidence suggests that although anemia is a risk factor for bleeding, the threshold for transfusion should be high.[551] Absent ongoing ischemia, transfusion should be avoided unless the hemoglobin level is <8 mg/dL. The optimal hemoglobin level in the transfused patient is not known, but the number of units provided should be minimized.[539,552]

9.7.2.1. Treatment of ICH

Older age, female sex, low body weight (<70 kg [female] and <80 kg [male]), prior stroke, and hypertension on presentation (with a graded increase beginning at >160 to 170 mm Hg systolic) are the major risk factors for ICH. Once ICH is recognized, all antiplatelet and anticoagulant therapy should be stopped. Brain imaging with emergency neurological and neurosurgical consultation is required. Consideration can be given to the use of protamine, fresh frozen plasma, prothrombin complex concentrates, activated factor VII,[555] and platelets as indicated. Resumption and timing of anticoagulant and/or antiplatelet therapy after ICH should be individualized and guided by neurosurgical consultation.[556]

9.7.2.2. Vascular Access Site Bleeding

Vascular access site bleeding is the most common type of bleeding after STEMI, particularly after PCI. PCI trials have identified female sex, advanced age, renal insufficiency, anemia, IABP, use of GP IIb/IIIa antagonists, and low-molecular-weight heparin within 48 hours of PCI as risk factors for femoral access site bleeding.[557] Larger sheath size, postprocedural heparin use, higher activated clotting times, and late postprocedural sheath removal increases the risk of access site bleeding and should be avoided. Radial artery access may decrease bleeding complications and should be considered whenever feasible,[558] but procedural success with this technique is dependent on operator experience.[559,560] Among patients with STEMI in the RIVAL (Radial Versus Femoral Access for Coronary Angiography and Intervention in Patients with Acute Coronary Syndromes) trial, radial artery access appeared to reduce the rate of the primary composite outcome (death, MI, stroke, non–CABG-related

major bleeding) and the individual secondary outcomes of death, MI, stroke, and overall mortality. However, rates of major bleeding were not lower with radial versus femoral access in patients with STEMI, though rates of major vascular complications were significantly reduced.[561] Although arterial closure devices have been associated with decreased femoral access site bleeding, more rapid hemostasis, and shorter duration of bed rest,[251,562,563] their routine use cannot be advocated specifically to reduce vascular complications after PCI, given the lack of robust, directionally consistent data on their efficacy and safety compared with manual compression.[564–566] Retroperitoneal bleeding should be suspected when the following are seen: unheralded intraprocedural or postprocedural hypotension and bradycardia (or tachycardia), high vascular puncture site, and an otherwise unexplained decrease in hemoglobin. Prompt computed tomographic imaging of the abdomen and pelvis may be helpful. Conservative management usually suffices, but early vascular interventional or surgical consultation should be obtained.[219]

9.8. Acute Kidney Injury

The risk of renal failure with STEMI relates to a host of factors, including patient age, prehospital renal function, medications, contrast volume, and hemodynamic status. Contrast-induced nephropathy after angiography and intervention for STEMI is always a risk, and attention to minimization of contrast volume and optimal hydration is required.[219]

9.9. Hyperglycemia

There is a U-shaped relationship between glucose levels and death in STEMI and ACS.[567] The mortality rate associated with hypoglycemia appears to be as high as the mortality rate associated with hyperglycemia.[568,569] Concern about overly aggressive glycemic control in critically ill patients was raised by the NICE-SUGAR (Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation) trial.[570] In this study of medical and surgical intensive care unit patients, tight glucose control (81 to 108 mg/dL) compared to modest control (<180 mg/dL) was associated with increased mortality rate (primarily from cardiovascular causes) and more episodes of hypoglycemia. Blood glucose levels should be maintained below 180 mg/dL if possible while avoiding hypoglycemia. There is no established role for glucose-insulin-potassium infusions in patients with STEMI.[571–573]

10. Risk Assessment After STEMI

Initial risk stratification should be performed early (Section 3) with the use of information available at the time of presentation. However, risk assessment is a continuous process that requires recalibration on the basis of data obtained during the hospital stay. Such data include the success of reperfusion therapy, events that occur during the hospital course (such as hemorrhagic complications), and the findings from noninvasive and invasive testing, particularly as they relate to the assessment of LV systolic function. For example, in patients treated with fibrinolytic therapy, clinical and ECG indicators of failed reperfusion identify individuals who should undergo urgent coronary angiography with intent to perform PCI.[356] In addition, the emergence of HF or significant LV systolic dysfunction is among the strongest predictors of higher-mortality risk after STEMI.

Stable patients with a low risk of complications may be candidates for early discharge. Among patients with STEMI managed with fibrinolysis, it has been suggested that an uncomplicated course after 72 hours of hospitalization identifies a group with sufficiently low risk to enable discharge.[574,575] Newby and colleagues calculated that extending the hospital stay of these patients by another day would cost $105 629 per year of life saved. However, the duration of hospitalization in patients treated with reperfusion therapy may be determined by other needs, such as patient education or titration of medications to optimum doses.[576]

Physicians and patients must individualize strategies for risk reduction, using lifestyle interventions, disease-modifying pharmacological therapies, and additional coronary revascularization when indicated. All patients with STEMI are considered to be at sufficiently high risk to merit interventions for secondary prevention, including the use of cardiac rehabilitation, aspirin, lipid-lowering therapy, beta blockers, and ACE inhibitors when indicated.[257] Additional risk assessment should be used to guide decisions about performance of coronary angiography in patients who did not undergo an invasive evaluation as part of their initial treatment strategy and to guide consideration of interventions to reduce the risk of SCD due to arrhythmia.

10.1. Use of Noninvasive Testing for Ischemia Before Discharge: Recommendations

Class I

1. **Noninvasive testing for ischemia should be performed before discharge to assess the presence and extent of inducible ischemia in patients with STEMI who have not had coronary angiography and do not have high-risk clinical features for which coronary angiography would be warranted.[577–579] (*Level of Evidence: B*)**

Class IIb

1. **Noninvasive testing for ischemia might be considered before discharge to evaluate the functional significance of a noninfarct artery stenosis previously identified at angiography. (*Level of Evidence: C*)**
2. **Noninvasive testing for ischemia might be considered before discharge to guide the postdischarge exercise prescription. (*Level of Evidence: C*)**

Noninvasive testing for ischemia provides valuable information about the presence of residual ischemia in patients who have not undergone cardiac catheterization during initial management of STEMI and may be useful in assessing the functional significance of a noninfarct artery stenosis identified at angiography. In the latter instance, stress imaging to localize ischemia would be appropriate.[580,581] Exercise testing early after STEMI may also be performed to 1) assess

functional capacity and the ability to perform tasks at home and at work, 2) evaluate the efficacy of medical therapy, and 3) assess the risk of a subsequent cardiac event. Symptom-limited exercise testing is a key feature of the intake evaluation for enrollment in a program of cardiac rehabilitation ≥2 weeks after discharge.[582]

Low-level exercise testing after MI appears to be safe if patients have undergone in-hospital cardiac rehabilitation, including low-level exercise; have had no symptoms of angina or HF; and have a stable baseline ECG 48 to 72 hours before the test.[583] Two different protocols have been used for early post-MI exercise testing: the traditional submaximal exercise test (done at 3 to 5 days in patients without complications) or a symptom-limited exercise test (done at 5 days or later) without stopping at a prespecified target heart rate or metabolic equivalent level. RCTs of early exercise testing after PCI have excluded patients with recent MI.[584] Limited data exist on the safety of early symptom-limited exercise testing after MI; therefore, clinical judgment must be used.[585] Pharmacological stress myocardial perfusion imaging has been shown to have predictive value for postinfarction cardiac events and is useful and safe in patients who are unable to exercise.[586] The optimum timing for provocative testing for ischemia after STEMI remains unresolved. It is argued that a predischarge exercise test may provide psychological benefit to the patient and will permit detection of profound ischemia or other indicators of high risk that could be associated with postdischarge cardiac events that might occur before a symptom-limited stress test scheduled weeks later.[585] A predischarge study also provides parameters for exercise prescription in the first few days after return home, before enrollment in cardiac rehabilitation. On the other hand, deferring exercise testing until approximately 3 weeks after STEMI in clinically low-risk patients appears safe and reasonable and enables more optimal assessment of functional capacity. It is the consensus of the writing committee that patients without complications *who have not undergone coronary angiography* and who might be potential candidates for revascularization should undergo provocative testing before hospital discharge. In patients with noninfarct artery disease who have undergone successful PCI of the infarct artery and have an uncomplicated course, it is reasonable to proceed with discharge and plans for close clinical follow-up with stress imaging within 3 to 6 weeks.

10.2. Assessment of LV Function: Recommendation

Class I

1. **LVEF should be measured in all patients with STEMI. (*Level of Evidence: C*)**

LV function is one of the strongest predictors of survival in patients with STEMI. LV function most commonly is evaluated with contrast ventriculography at the time of cardiac catheterization or with transthoracic echocardiography on day 2 or 3. Echocardiography is the most frequently used imaging modality to evaluate regional and global LV function after STEMI and can help characterize any associated mechanical complications when they are clinically suspected. Because of the dynamic nature of LV functional recovery after STEMI, clinicians should consider the timing of the imaging study relative to the index event. In patients with significant LV systolic dysfunction revealed during the initial hospitalization, LV function should be reevaluated ≥40 days later, especially to address the potential need for ICD therapy after allowance for recovery from myocardial stunning.[496,587,588]

10.3. Assessment of Risk for SCD: Recommendation

Class I

1. **Patients with an initially reduced LVEF who are possible candidates for ICD therapy should undergo reevaluation of LVEF 40 or more days after discharge.[496,587–589] (*Level of Evidence: B*)**

The timing and character of ventricular arrhythmias and residual LV systolic function are the strongest predictors of SCD risk after STEMI. Management considerations for patients with ventricular arrhythmias during the hospital phase are reviewed in Section 9.5. Hospital survivors with an initially reduced LVEF (≤0.40) who do not merit ICD therapy before discharge should undergo reassessment of LV function ≥40 days later to determine their eligibility for ICD therapy. The recommended delay to ICD therapy in this setting stems from the results of DINAMIT (Defibrillator in Acute Myocardial Infarction Trial), in which defibrillator implantation 6 to 40 days after MI in patients with EF ≤0.35 and impaired cardiac autonomic function was not shown to reduce overall cardiac death risk. The observed reduction in arrhythmic deaths was offset by a relative increase in the numbers of nonarrhythmic deaths.[587] The IRIS (Immediate Risk Stratification Improves Survival) trial[588] also showed that early ICD therapy in patients with LVEF ≤0.40 and a high heart rate, nonsustained VT regardless of LVEF, or both did not result in improved survival. The utility of a wearable cardioverter-defibrillator in high-risk patients during the first 4 to 6 weeks after STEMI is under investigation http://clinicaltrials.gov/ct2/show/NCT00628966).

The indications for ICD therapy ≥40 days after STEMI are based on LVEF and New York Heart Association class, as derived from the results of the landmark MADIT 2 (Multicenter Automatic Defibrillator Implantation Trial 2) and SCDHeFT (Sudden Cardiac Death in Heart Failure) trials.[496,589–591] If LVEF remains ≤0.35 and the patient has New York Heart Association class II or III HF symptoms, or if the LVEF is ≤0.30 independent of symptoms, then ICD implantation is recommended.[496] Indications for cardiac resynchronization therapy in the late, convalescent phase of STEMI include residual LV function, New York Heart Association class, QRS duration, and LBBB morphology.[592]

In addition to determination of LVEF, several other noninvasive strategies have been proposed to identify patients at high risk for arrhythmic events after STEMI, such as signal-averaged or high-resolution ECG, heart rate variability, baroreflex sensitivity, and T-wave alternans.[591] These strategies have not been adopted widely because of their limited

performance characteristics and are not recommended for routine use.

11. Posthospitalization Plan of Care

11.1. Posthospitalization Plan of Care: Recommendations

Class I

1. **Posthospital systems of care designed to prevent hospital readmissions should be used to facilitate the transition to effective, coordinated outpatient care for all patients with STEMI.[593–597] (*Level of Evidence: B*)**
2. **Exercise-based cardiac rehabilitation/secondary prevention programs are recommended for patients with STEMI.[598–601] (*Level of Evidence: B*)**
3. **A clear, detailed, and evidence-based plan of care that promotes medication adherence, timely follow-up with the healthcare team, appropriate dietary and physical activities, and compliance with interventions for secondary prevention should be provided to patients with STEMI. (*Level of Evidence: C*)**
4. **Encouragement and advice to stop smoking and to avoid secondhand smoke should be provided to patients with STEMI.[602–605] (*Level of Evidence: A*)**

11.1.1. The Plan of Care for Patients With STEMI

Education of patients with STEMI and their families is critical and often challenging, especially when transitions of care occur. Failure to understand and comply with a plan of care may account for the high rate of STEMI rehospitalization rates seen in the United States.[19,606] One key intervention to ensure effective coordination is to provide to patients and caregivers, during the hospital stay, a comprehensive plan of care and educational materials that promote compliance with recommended evidence-based therapies.[607–609] The posthospitalization plan of care for patients with STEMI should address in detail several complex issues, including medication adherence and titration, timely follow-up, dietary interventions, physical and sexual activities, cardiac rehabilitation, compliance with interventions for secondary prevention (Table 14), and reassessment of arrhythmic and HF risks. In addition, providers should pay close attention to psychosocial and socioeconomic issues, including access to care, risk of depression, social isolation, and healthcare disparities.[610–612]

11.1.2. Smoking Cessation

The value of smoking cessation for the secondary prevention of cardiovascular disease has been demonstrated in several prospective observational studies. A meta-analysis of cohort studies in patients after acute MI showed that smoking cessation reduced the subsequent cardiovascular mortality rate by nearly 50%,[602] ranking it among the most powerful secondary prevention strategies.[603] The SAVE (Sleep Apnea Cardiovascular Endpoints) study investigators reported that in selected patients with LV systolic dysfunction after MI, smoking cessation, compared with continued smoking, is associated with a 40% lower hazard of all-cause mortality and a 30% lower hazard of death, recurrent MI, or HF hospitalization.[605]

Reasonable evidence from RCTs indicates that counseling hospitalized smokers after acute MI increases smoking cessation rates, provided that the initial contact during the hospital stay is followed by repeated contacts, usually by telephone, for ≥3 months after discharge.[603,604] Similarly, the odds of smoking cessation are greater among patients who receive discharge recommendations for cardiac rehabilitation.[504] Patients with depressive symptoms during the MI hospitalization and early convalescence are less likely to quit smoking and may require more intensive treatment to achieve cessation.[603,604] Counseling should be provided to the patient and family, along with pharmacological therapy as deemed safe, and access to formal smoking-cessation programs should be facilitated.

11.1.3. Cardiac Rehabilitation

The objectives of contemporary exercise-based cardiac rehabilitation are to increase functional capacity, decrease or alleviate anginal symptoms, reduce disability, improve quality of life, modify coronary risk factors, and reduce morbidity and mortality rates.[598,613,614] Core components include patient assessment; ongoing medical surveillance; nutritional counseling; BP, lipid, and diabetes mellitus management; smoking cessation; psychosocial counseling; physical activity counseling; exercise training; and pharmacological treatment, as appropriate.[614]

Among 601 099 US Medicare beneficiaries who were hospitalized for coronary conditions or revascularization procedures, mortality rates were 21% to 34% lower among participants in cardiac rehabilitation programs than among nonparticipants.[599] It has been suggested that contemporary reperfusion and cardioprotective drug therapies may diminish the impact of adjunctive exercise-based cardiac rehabilitation programs on post-MI survival rate. Taylor et al[600] conducted a systematic review and meta-analysis of RCTs of cardiac rehabilitation with ≥6 months of follow-up. The study population included 8940 patients, a greater number were women (20% of the cohort), patients ≥65 years of age, and individuals who had undergone revascularization procedures. Compared with usual care, cardiac rehabilitation was associated with a reduction in total and cardiac mortality rates of 20% and 26%, respectively. Subgroup analyses showed that the decreased mortality rates did not differ across several patient subsets, between programs limited to exercise and those providing more comprehensive secondary interventions, or between pre- and post-1995 studies, which suggests that the mortality benefits of cardiac rehabilitation persist in the modern era. However, despite these impressive outcomes, cardiac rehabilitation services remain vastly underutilized.[582,615]

11.1.4. Systems of Care to Promote Care Coordination

Meaningful evidence has facilitated a much better understanding of the systems changes necessary to achieve safer care.[616] This includes the adoption by all US hospitals of a standardized set of "Safe Practices" endorsed by the National Quality Forum,[617] which overlap in many ways with the National Patient Safety Goals espoused by The Joint Commission.[618] Examples of patient safety standards that should be ensured for all patients discharged after STEMI include

Table 14. Plan of Care for Patients With STEMI

Plan of Care	Resources/References
Medications	
• Antithrombotic therapies	Sections 4.4, 5.1, 6.4
• Beta blockers	Section 8.1
• ACE inhibitors/ARBs/aldosterone antagonists	Section 8.2
• Statins	Section 8.3
	ESC STEMI Guideline[48]
	ACC/AHA 2012 SIHD Guideline[614]
Physical activity/cardiac rehabilitation	
• Physical activity	AHA/ACC 2011 Update: Secondary Prevention and Risk Reduction Therapy[249]
• Cardiorespiratory fitness (MET capacity)	AACVPR/ACCF/AHA 2010 Update: Performance Measures on Cardiac Rehabilitation[616]
Risk factor modification/lifestyle interventions	AHA/ACC 2011 Update: Secondary Prevention and Risk Reduction Therapy[249]
• Smoking cessation	ACCP Tobacco Cessation Toolkit[615]
• Diet/nutrition	AHA/ACC 2011 Update: Secondary Prevention and Risk Reduction Therapy[249]
Management of comorbidities	
• Overweight/obesity	AHA/ACC 2011 Update: Secondary Prevention and Risk Reduction Therapy[249]
• Lipids	AHA/ACC 2011 Update: Secondary Prevention and Risk Reduction Therapy[249]
• Hypertension	NHLBI National Hypertension Education Program (JNC VII)[617]
• Diabetes	AHA/ADA CVD Prevention in DM Patients[618]
• HF	ACC/AHA/HFSA HF Guideline[619]
• Arrhythmia/arrhythmia risk	ACC/AHA/HRS DBT & AF Guidelines[496,501]
Psychosocial factors	
• Sexual activity	AHA Scientific Statement on Sexual Activity and Cardiovascular Disease[627a]
• Gender-specific issues	Cardiovascular Disease Prevention in Women Guidelines[620]
• Depression, stress, and anxiety	AHA Scientific Statement on Depression[621]
• Alcohol use	AHA/ACC 2011 Update: Secondary Prevention and Risk Reduction Therapy[249]
• Culturally sensitive issues	
Provider follow-up	
• Cardiologist	H2H Quality Initiative http://www.h2hquality.org
• Primary care provider	
• Advanced practice nurse/physician assistant	
• Other relevant medical specialists	
• Electronic personal health records	
• Influenza vaccination	Centers for Disease Control Adult Vaccinations[622]
Patient/family education	
• Plan of care for acute MI	AHA CPR Guideline[201]
• Recognizing symptoms of MI	
• Activating EMS, signs and symptoms for urgent vs emergency evaluations	
• CPR training for family members	
• Risk assessment & prognosis	
• Advanced directives	
• Social networks/social isolation	
Socioeconomic factors	
• Access to health insurance coverage	http://www.qualityforum.org/Topics/Care_Coordination.Aspx
• Access to healthcare providers	
• Disability	
• Social services	
• Community services	

AACVPR indicates American Association of Cardiovascular and Pulmonary Rehabilitation; ACC, American College of Cardiology; ACCF, American College of Cardiology Foundation; ACCP, American College of Chest Physicians; ACE, angiotensin-converting enzyme; ADA, American Diabetes Association; AF, atrial fibrillation; AHA, American Heart Association; ARB, angiotensin receptor blocker; CPR, cardiopulmonary resuscitation; CVD, cardiovascular disease; DBT, device-based therapy; DM, diabetes mellitus; EMS, emergency medical services; ESC, European Society of Cardiology; H2H, hospital-to-home; HF, heart failure; HFSA, Heart Failure Society of America; HRS, Heart Rhythm Society; JNC, Joint National Committee; MET, metabolic equivalent; MI, myocardial infarction; NHLBI, National Heart, Lung, and Blood Institute; SIHD, stable ischemic heart disease; and STEMI, ST-elevation myocardial infarction.

improved communication among physicians, nurses, and pharmacists; medication reconciliation; careful transitions between care settings; and consistent documentation. The National Quality Forum also has endorsed a set of patient-centered "Preferred Practices for Care Coordination,"[619] which detail comprehensive specifications that are necessary to achieve the goals of successful care coordination for patients and their families. Systems of care designed to support patients with STEMI and other cardiac diseases can result in significant improvement in patient outcomes. To provide the interventions and services listed in Table 14, appropriate resources must be applied to ensure that all patients with STEMI have full access to evidence-based therapies and follow-up care. There is a growing emphasis on penalizing hospitals for avoidable hospital readmissions. Hence, it is imperative for health systems to work in partnership with physicians, nurses, pharmacists, communities, payers, and public agencies to support the interventions that achieve such comprehensive care.

Patient characteristics may be important predictors of readmission after MI; however, only a few variables have been identified consistently.[620,621] From a policy perspective, a validated risk-standardized model that uses readmission rates to profile hospitals is not currently available.

12. Unresolved Issues and Future Research Directions

The writing committee has identified several areas pertaining to the management of patients with STEMI that deserve further research. Although the observations from the Swedish STEMI registry showing an association between the increased use of evidence-based treatments and declining mortality rates after STEMI are encouraging,[18] additional efforts to improve patient outcomes are needed. There is widespread acknowledgment that progress in closing existing knowledge and performance gaps will require contributions from a wide range of investigators, dedicated clinicians, hospital and health plan administrators, regional emergency response systems, and both government and private payers.[631]

12.1. Patient Awareness

Delay times from onset of symptoms to activation of STEMI care pathways remain unacceptably long.[51,631] Multicultural efforts to educate, reassure, and motivate at-risk patients and their families are needed. Comparable efforts to improve adherence and attention to healthy lifestyle behaviors as the cornerstones of secondary prevention are required at time of discharge and as an integral feature of cardiac rehabilitation programs.

12.2. Regional Systems of Care

The adoption of regional systems of care for patients with STEMI across diverse geographical areas has proved challenging, and inappropriate delays to initiation of reperfusion therapy are common.[632] As previously emphasized, attention should be focused on *reducing the total ischemic time*, from onset of symptoms to successful reperfusion. Several factors in addition to patient activation of EMS contribute to delays, not all of which can be reconciled. Areas for continued research include prehospital EMS protocols, the approach to out-of-hospital cardiac arrest, triage and transfer algorithms, rapid availability of expert PCI services, and further refinement of the clinical and time-related factors that should prompt earlier use of fibrinolytic therapy coupled with immediate transfer for PCI.[129,633–635] The lack of correlation between shorter D2B times and reduced mortality should drive further efforts to improve all aspects of STEMI care.[636] Regional systems should track, analyze, and report all STEMI and out-of-hospital cardiac arrest events as part of an ongoing process-improvement program.

12.3. Transfer and Management of Non–High-Risk Patients After Administration of Fibrinolytic Therapy

The indications for and timing of transfer for angiography with a view toward revascularization of *non–high-risk patients* after successful fibrinolysis are still debated. Although there has been increasing activation of this pathway, the evidence base for its justification is still limited.[358,360,365]

12.4. Antithrombotic Therapy

The optimum choice of $P2Y_{12}$ receptor inhibitor and anticoagulant agents for patients with STEMI can be challenging. Individual genetic variability in drug absorption, metabolism, and effectiveness has been highlighted by the experience with clopidogrel in patients with ACS.[285,637] The risks of bleeding also may vary across racial and ethnic groups.[12] The roles of platelet function testing and genetic screening for clopidogrel metabolism in the acute phase of STEMI care are uncertain,[289] especially with the availability of alternative $P2Y_{12}$ receptor inhibitors. More information specific to patients with STEMI is needed with regard to the use of prasugrel, ticagrelor, novel factor Xa and IIa antagonists, and platelet protease–activated receptor 1 antagonists.[638,639] The efficacy and safety of combination ("triple") antithrombotic therapy must be addressed continuously,[525,537] while less hazardous approaches are tested. Bleeding rates with radial versus femoral artery access for PCI warrant further prospective study.[561]

12.5. Reperfusion Injury

Aside from manual aspiration thrombectomy, efforts to counteract the "no-reflow" phenomenon and to limit myocardial reperfusion injury have had limited success. The value of aspiration thrombectomy in patients with anterior STEMI has been questioned.[223] Remote ischemic preconditioning has engendered little enthusiasm. Trials evaluating the use of antithrombotic and vasodilator agents have been disappointing. New biological, pharmacological, and mechanical strategies should be investigated to facilitate prompt recovery of tissue-level perfusion.[220,640–642,644] In addition, high-dose statin pretreatment before primary or delayed PCI for STEMI requires further study.[645]

12.6. Approach to Noninfarct Artery Disease

There is great variability in the evaluation and management of nonculprit coronary artery disease in stable patients without HF or shock, both at the time of primary PCI and later during the hospital course. Physiological assessment of lesion significance is often not performed, and the decision to proceed with PCI is made on anatomic grounds. More work is needed to clarify the indications for and timing of noninfarct artery revascularization.[218,224,228,229]

12.7. Prevention of SCD

Prediction of electrical vulnerability and SCD risk after STEMI is fraught with imprecision. Treatment decisions rely almost exclusively on parameters of LV systolic function. Optimal therapy for at-risk individuals in the time window between discharge and 40 days, the time point after which ICD therapy is currently recommended, has not been established. Improved prediction rules and validated treatment recommendations are urgently needed.[646]

12.8. Prevention of HF

Much progress has been made to limit LV remodeling, though there remains substantial room for improvement, beginning with the timeliness of reperfusion and initiation of ACE inhibitor/ARB therapy.[627] The superimposition of ischemic mitral regurgitation adds further to the risks of HF and death. Continued exploration of the roles of cell- and gene-based therapies after STEMI is encouraged.[647–656]

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KEY WORDS: AHA Scientific Statements ■ anticoagulants ■ antiplatelets ■ door-to-balloon ■ fibrinolysis ■ percutaneous coronary intervention ■ reperfusion ■ ST-elevation myocardial infarction ■ thrombolysis

Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section*
Patrick T. O'Gara, Chair	Harvard Medical School—Professor of Medicine	None	None	None	None	None	None	None
Frederick G. Kushner, Vice Chair	Tulane University School of Medicine—Clinical Professor of Medicine; Heart Clinic of Louisiana—Medical Director	None	None	None	None	• Novartis†	None	8.1 8.2
Deborah D. Ascheim	Mount Sinai School of Medicine—Associate Professor; InCHOIR—Clinical Director of Research	None	None	None	None	None	None	None
Donald E. Casey, Jr.	Atlantic Health—Chief Medical Officer and Vice President of Quality	None	None	None	None	None	None	None
Mina K. Chung	Cleveland Clinic Foundation—Associate Professor of Medicine	• Biotronik† • Boston Scientific† • Nexcura † • PGx† • Sanofi-aventis† • St. Jude Medical†	None	None	• Biotronik† • Boston Scientific† • GlaxoSmithKline† • Medtronic† • Siemens Medical Solutions† • St. Jude Medical† • ZOLL†	• Medtronic† • Boston Scientific† • St. Jude Medical†	None	None
James A. de Lemos	UT Southwestern Medical School—Professor of Medicine	• Johnson & Johnson • Tethys • AstraZeneca • Daiichi-Sankyo	• BMS/ Sanofi-aventis	None	• Bristol-Myers Squibb (DSMB) • Roche • Merck/Schering-Plough • Daiichi-Sankyo	None	None	4.4.1 4.4.2 5.1.4.1 5.1.4.2 6.4.1 6.4.2 7.2 9.6
Steven M. Ettinger	Penn State Heart & Vascular Institute—Professor of Medicine and Radiology	None	None	None	• Medtronic§	None	None	4.3.1
James C. Fang	University Hospitals Case Medical Center—Director, Heart Transplantation	• Accorda • Novartis • Thoratec	None	None	None	• Medtronic	None	9.5.4.1
Francis M. Fesmire	Heart Stroke Center—Director	• Abbott	None	None	None	None	• Plaintiff, Missed ACS, 2010	8.3
Barry A. Franklin	William Beaumont Hospital—Director, Cardiac Rehabilitation and Exercise Laboratories	None	None	None	None	None	None	None
Christopher B. Granger	Duke Clinical Research Institute—Director, Cardiac Care Unit; Assistant Professor of Medicine	• AstraZeneca • Boehringer Ingelheim‡ • Bristol-Myers Squibb • GlaxoSmithKline • Hoffman La Roche • Novartis • Sanofi-aventis‡ • The Medicines Company	None	None	• Astellas • AstraZeneca • Boehringer Ingelheim‡ • Bristol-Myers Squibb • Eli Lilly • GlaxoSmithKline • Medtronic • Merck • Sanofi-aventis‡ • The Medicines Company	None	None	4.4.1 6.4.2 9.7.1

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Appendix 1. Continued

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section*
Harlan M. Krumholz	Yale University School of Medicine—Professor of Medicine	• United HealthCare (Science Advisory Group)	None	None	None	None	None	None
Jane A. Linderbaum	Mayo Clinic—Assistant Professor of Medicine	None	None	None	None	None	None	None
David A. Morrow	Harvard Medical School—Associate Professor of Medicine	• Beckman-Coulter • Boehringer Ingelheim • Daiichi-Sankyo • Eli Lilly • Genentech • Merck • Novartis • OrthoClinical Diagnostics/Johnson & Johnson • Roche Diagnostics • Sanofi-aventis • Schering-Plough Research Institute • Siemens Medical Solutions	None	None	• AstraZeneca‡ • Beckman-Coulter‡ • Daiichi-Sankyo‡ • Eli Lilly‡ • GlaxoSmithKline‡ • Merck‡ • Nanosphere‡ • Novartis‡ • Roche Diagnostics‡ • Sanofi-aventis‡ • Schering-Plough Research Institute‡ • Siemens Medical Solutions‡ • Singulex‡	• AstraZeneca‡	None	3.2 4.4.1 4.4.2 5.1 5.1.4.1 6.4.1 6.4.2 7.2 8.2 8.3 9.6
L. Kristin Newby	Duke University Medical Center, Division of Cardiology—Professor of Medicine	• Amgen‡ • AstraZeneca • BioVascular • Johnson & Johnson • Novartis	None	None	• BG Medicine • Bristol-Myers Squibb • diaDexus‡ • Eli Lilly • GlaxoSmithKline‡ • Johnson & Johnson • Merck‡ • Regado • Schering-Plough‡	None	None	4.4.1 7.2
Joseph P. Ornato	Department of Emergency Medicine Virginia Commonwealth University—Professor and Chairman	• European Resuscitation Council‡ • ZOLL Circulation	None	None	• NIH/NINDS Neurological Emergency Treatment Trials Consortium—PI‡	None	None	None
Narith Ou	Mayo Clinic—Pharmacotherapy Coordinator, Cardiology	None	None	None	None	None	None	None
Martha J. Radford	NYU Langone Medical Center—Chief Quality Officer; NYU School of Medicine—Professor of Medicine (Cardiology)	None	None	None	None	None	None	None
Jacqueline E. Tamis-Holland	St Luke's-Roosevelt Hospital Center—Director, Interventional Cardiology Fellowship Program; Columbia University, College of Physicians and Surgeons—Assistant Professor of Clinical Medicine	None	None	None	None	None	None	None

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Appendix 1. Continued

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section*
Carl L. Tommaso	Skokie Hospital—Director of Catheterization Laboratory; North Shore University Health Systems	None	None	None	None	None	None	None
Cynthia M. Tracy	George Washington University Medical Center—Associate Director, Division of Cardiology	None	None	None	None	None	None	None
Y. Joseph Woo	Hospital of the University of Pennsylvania—Associate Professor of Surgery	None	None	None	None	None	None	None
David X. Zhao	Vanderbilt University Medical Center—Director, Cardiac Catheterization and Interventional Cardiology	None	None	None	• Abbot Vascular • Accumetrics • AGA Medical • Osiris • Volcano	None	None	4.3.1

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10 000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

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*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry and other entities could apply.

†No financial benefit.

‡Significant relationship.

§Dr. Ettinger's relationship with Medtronic was added just before balloting of the recommendations, so it was not relevant during the writing stage; however, the addition of this relationship makes the writing committee out of compliance with the minimum 50% no relevant RWI requirement.

ACS indicates acute coronary syndromes; DSMB, data safety monitoring board; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; and PI, principal investigator.

Appendix 2. Reviewer Relationships With Industry and Other Entities (Relevant)—2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Elliott M. Antman	Official Reviewer—ACCF Board of Trustees	None	None	None	• Accumetrics • AstraZeneca • Beckman Coulter • Bristol-Myers Squibb Pharmaceutical Research Institute • Daiichi-Sankyo* • Eli Lilly* • GlaxoSmithKline • Merck • Millennium Pharmaceuticals • Novartis Pharmaceuticals • Ortho-Clinical Diagnostics • Sanofi-Synthelabo Recherche • Schering-Plough Research Institute	None	None
Gary J. Balady	Official Reviewer—AHA	None	None	None	None	None	None
Christopher P. Cannon	Official Reviewer—AHA	• Novartis†	None	None	• Accumetrics* • AstraZeneca* • Bristol-Myers Squibb† • GlaxoSmithKline • Merck*	• GlaxoSmithKline • Merck (DSMB)	None
Judith S. Hochman	Official Reviewer—ACCF/AHA Task Force on Practice Guidelines	• BMS/Sanofi • Eli Lilly • GlaxoSmithKline	None	None	None	• Johnson & Johnson Pharmaceutical Research & Development (DSMB) • Merck/Schering Plough (DSMB)	None
Austin H. Kutscher	Official Reviewer—ACCF Board of Governors	None	None	None	None	None	None
Charles J. Davidson	Organizational Reviewer—SCAI	• Abbott* • Abbott Vascular	None	None	• Edwards Lifesciences*	None	None
Deborah B. Diercks	Organizational Reviewer—ACEP	• Abbott Cardiovascular • Daiichi-Sankyo	None	None	• Beckman Coulter† • Nanosphere†	None	None
Jonathan M. Tobis	Organizational Reviewer—SCAI	None	• AGA Medical • Boston Scientific	None	• AGA Medical*	None	None
Jeffrey L. Anderson	Content Reviewer—ACCF/AHA Task Force on Practice Guidelines	None	None	None	• Toshiba†	• AstraZeneca (DSMB)	Defendant, Postoperative Ablation Case, 2010
James C. Blankenship	Content Reviewer	None	None	None	• AstraZeneca† • Boston Scientific† • Novartis† • Schering-Plough†	None	None
Jeffrey J. Cavendish	Content Reviewer—ACCF Prevention of Cardiovascular Disease Committee	None	None	None	None	None	None
Harold L. Dauerman	Content Reviewer	None	None	None	None	None	None
John S. Douglas, Jr.	Content Reviewer	None	None	None	• Abbott† • Medtronic† • The Medicines Company†	None	None
Stephen G. Ellis	Content Reviewer	• Abbott Vascular • Boston Scientific†	None	None	None	None	None

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Appendix 2. Continued

Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Joseph Fredi	Content Reviewer—ACCF Surgeons' Scientific Council	• AGA Medical†	None	None	None	None	None
Anthony Gershlick	Content Reviewer	• Abbott • AstraZeneca • Boehringer Ingelheim • Boston Scientific • Cordis • Eli Lilly • Medtronic	None	None	• Boehringer Ingelheim	None	None
Howard C. Herrmann	Content Reviewer	• AstraZeneca • Merck Sharpe and Dohme	None	None	• Accumetrics • Boston Scientific* • Edwards Lifesciences* • eValve • Medtronic* • St. Jude Medical • The Medicines Company*	None	None
James Bernard Hermiller	Content Reviewer—ACCF Interventional Scientific Council	• Abbott • Boston Scientific • St. Jude Medical	• Eli Lilly	None	None	None	None
Fred M. Kosumoto	Content Reviewer	None	None	None	None	None	None
Glenn Levine	Content Reviewer	None	None	None	None	None	None
Roxana Mehran	Content Reviewer	• Abbott Vascular • AstraZeneca • Ortho-McNeill	None	None	• BMS/Sanofi-aventis* • The Medicines Company*	None	None
M. Eugene Sherman	Content Reviewer—ACCF Board of Governors	None	Eli Lilly*	None	None	None	None
Daniel I. Simon	Content Reviewer	• Cordis/Johnson & Johnson • Daiichi-Sankyo • Eli Lilly • Medtronic • Sanofi-aventis • The Medicines Company	None	None	None	None	Defendant, DES Intellectual Property Case, 2010
Richard W. Smalling	Content Reviewer—ACCF Interventional Scientific Council	• AGA Medical	None	None	• AGA Medical* • Cordis* • eValve*	• AGA Medical • Cordis • eValve	None
William G. Stevenson	Content Reviewer—ACCF/AHA Task Force on Practice Guidelines	None	None	None	None	None	None
William A. Tansey III	Content Reviewer	None	None	None	None	None	None
David D. Waters	Content Reviewer	• Bristol-Myers Squibb • Pfizer	None	None	None	• Merck/Schering-Plough • Sanofi-aventis (DSMB)	None
Christopher J. White	Content Reviewer	None	None	None	• Boston Scientific† • St. Jude Medical	None	None

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Appendix 2. Continued

Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Clyde W. Yancy	Content Reviewer—ACCF/AHA Task Force on Practice Guidelines	None	None	None	None	None	None
Yerem Yeghiazarians	Content Reviewer	None	None	None	None	None	None

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*Significant relationship.

†No financial benefit.

ACCF indicates American College of Cardiology Foundation; ACEP, American College of Emergency Physicians; AHA, American Heart Association; DES, drug-eluting stent; DSMB, data safety monitoring board; and SCAI, Society for Cardiovascular Angiography and Interventions.

Appendix 3. Abbreviation List

ACE = angiotensin-converting enzyme
ACS = acute coronary syndrome
AF = atrial fibrillation
ARB = angiotensin receptor blocker
AV = atrioventricular
BMS = bare-metal stent
BP = blood pressure
CABG = coronary artery bypass graft
COX-2 = cyclooxygenase-II enzyme
CPR = cardiopulmonary resuscitation
CrCl = creatinine clearance
D2B = door-to-balloon (device)
DAPT = dual antiplatelet therapy
DES = drug-eluting stent
ECG = electrocardiogram/electrocardiographic
ED = emergency department
EF = ejection fraction
EMS = emergency medical services
FMC = first medical contact
GP = glycoprotein
HF = heart failure
HIT = heparin-induced thrombocytopenia
IABP = intra-aortic balloon counterpulsation
ICD = implantable cardioverter-defibrillator
ICH = intracranial hemorrhage
LBBB = left bundle-branch block
LDL = low-density lipoprotein
LV = left ventricular
LVEF = left ventricular ejection fraction
MI = myocardial infarction
NRMI = National Registry of Myocardial Infarction
PCI = percutaneous coronary intervention
RCT = randomized controlled trial
RV = right ventricular
SCD = sudden cardiac death
STEMI = ST-elevation myocardial infarction
TIMI = Thrombolysis In Myocardial Infarction
UFH = unfractionated heparin
VF = ventricular fibrillation
VT = ventricular tachycardia

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2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention : A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

Writing Committee Members, Glenn N. Levine, Eric R. Bates, James C. Blankenship, Steven R. Bailey, John A. Bittl, Bojan Cercek, Charles E. Chambers, Stephen G. Ellis, Robert A. Guyton, Steven M. Hollenberg, Umesh N. Khot, Richard A. Lange, Laura Mauri, Roxana Mehran, Issam D. Moussa, Debabrata Mukherjee, Brahmajee K. Nallamothu and Henry H. Ting

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2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

WRITING COMMITTEE MEMBERS*

Glenn N. Levine, MD, FACC, FAHA, Chair†; Eric R. Bates, MD, FACC, FAHA, Vice Chair*†; James C. Blankenship, MD, FACC, FSCAI, Vice Chair*‡; Steven R. Bailey, MD, FACC, FSCAI*‡; John A. Bittl, MD, FACC†§; Bojan Cercek, MD, FACC, FAHA†; Charles E. Chambers, MD, FACC, FSCAI‡; Stephen G. Ellis, MD, FACC*†; Robert A. Guyton, MD, FACC*‖; Steven M. Hollenberg, MD, FACC*†; Umesh N. Khot, MD, FACC*†; Richard A. Lange, MD, FACC, FAHA§; Laura Mauri, MD, MSC, FACC, FSCAI*†; Roxana Mehran, MD, FACC, FAHA, FSCAI*‡; Issam D. Moussa, MD, FACC, FAHA, FSCAI‡; Debabrata Mukherjee, MD, FACC, FSCAI†; Brahmajee K. Nallamothu, MD, FACC¶; Henry H. Ting, MD, FACC, FAHA†

ACCF/AHA TASK FORCE MEMBERS

Alice K. Jacobs, MD, FACC, FAHA, Chair; Jeffrey L. Anderson, MD, FACC, FAHA, Chair-Elect; Nancy Albert, PhD, CCNS, CCRN, FAHA; Mark A. Creager, MD, FACC, FAHA; Steven M. Ettinger, MD, FACC; Robert A. Guyton, MD, FACC; Jonathan L. Halperin, MD, FACC, FAHA; Judith S. Hochman, MD, FACC, FAHA; Frederick G. Kushner, MD, FACC, FAHA; E. Magnus Ohman, MD, FACC; William Stevenson, MD, FACC, FAHA; Clyde W. Yancy, MD, FACC, FAHA

*Writing committee members are required to recuse themselves from voting on sections where their specific relationship with industry and other entities may apply; see Appendix 1 for recusal information.

†ACCF/AHA Representative.

‡Society for Cardiovascular Angiography and Interventions Representative.

§Joint Revascularization Section Author.

‖ACCF/AHA Task Force on Practice Guidelines Liaison.

¶ACCF/AHA Task Force on Performance Measures Liaison.

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Preamble

The medical profession should play a central role in evaluating the evidence related to drugs, devices, and procedures for the detection, management, and prevention of disease. When properly applied, expert analysis of available data on the benefits and risks of these therapies and procedures can improve the quality of care, optimize patient outcomes, and favorably affect costs by focusing resources on the most effective strategies. An organized and directed approach to a thorough review of evidence has resulted in the production of clinical practice guidelines that assist physicians in selecting the best management strategy for an individual patient. Moreover, clinical practice guidelines can provide a foundation for other applications, such as performance measures, appropriate use criteria, and both quality improvement and clinical decision support tools.

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have jointly produced guidelines in the area of cardiovascular disease since 1980. The ACCF/AHA Task Force on Practice Guidelines (Task Force), charged with developing, updating, and revising practice guidelines for cardiovascular diseases and procedures, directs and oversees this effort. Writing committees are charged with regularly reviewing and evaluating all available evidence to develop balanced, patient-centric recommendations for clinical practice.

Experts in the subject under consideration are selected by the ACCF and AHA to examine subject-specific data and write guidelines in partnership with representatives from other medical organizations and specialty groups. Writing committees are asked to perform a formal literature review; weigh the strength of evidence for or against particular tests, treatments, or procedures; and include estimates of expected outcomes where such data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that may

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Table 1. Applying Classification of Recommendations and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	CLASS I *Benefit >>> Risk* Procedure/Treatment SHOULD be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment MAY BE CONSIDERED	CLASS III *No Benefit* or CLASS III *Harm* Procedure/ Test / Treatment COR III: No Benefit / Not Helpful / No Proven Benefit COR III: Harm / Excess Cost w/o Benefit or Harmful / Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited population evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

influence the choice of tests or therapies are considered. When available, information from studies on cost is considered, but data on efficacy and outcomes constitute the primary basis for the recommendations contained herein.

In analyzing the data and developing recommendations and supporting text, the writing committee uses evidence-based methodologies developed by the Task Force.[1] The Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm. The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. The writing committee reviews and ranks evidence supporting each recommendation with the weight of evidence ranked as LOE A, B, or C according to specific definitions that are included in Table 1. Studies are identified as observational, retrospective, prospective, or randomized where appropriate. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and are ranked as LOE C. When recommendations at LOE C are supported by historical clinical data, appropriate references (including clinical reviews) are cited if available. For issues for which sparse data are available, a survey of current practice among the clinicians on the writing committee is the basis for LOE C recommendations and no references are cited. The schema for COR and LOE is summarized in Table 1, which also provides suggested phrases for writing recommendations within each COR. A new addition to this methodology is separation of the

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Class III recommendations to delineate if the recommendation is determined to be of "no benefit" or is associated with "harm" to the patient. In addition, in view of the increasing number of comparative effectiveness studies, comparator verbs and suggested phrases for writing recommendations for the comparative effectiveness of one treatment or strategy versus another have been added for COR I and IIa, LOE A or B only.

In view of the advances in medical therapy across the spectrum of cardiovascular diseases, the Task Force has designated the term *guideline-directed medical therapy (GDMT)* to represent optimal medical therapy as defined by ACCF/AHA guideline recommended therapies (primarily Class I). This new term, GDMT, will be used herein and throughout all future guidelines.

Because the ACCF/AHA practice guidelines address patient populations (and healthcare providers) residing in North America, drugs that are not currently available in North America are discussed in the text without a specific COR. For studies performed in large numbers of subjects outside North America, each writing committee reviews the potential influence of different practice patterns and patient populations on the treatment effect and relevance to the ACCF/AHA target population to determine whether the findings should inform a specific recommendation.

The ACCF/AHA practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the circumstances presented by that patient. As a result, situations may arise for which deviations from these guidelines may be appropriate. Clinical decision making should involve consideration of the quality and availability of expertise in the area where care is provided. When these guidelines are used as the basis for regulatory or payer decisions, the goal should be improvement in quality of care. The Task Force recognizes that situations arise in which additional data are needed to inform patient care more effectively; these areas will be identified within each respective guideline when appropriate.

Prescribed courses of treatment in accordance with these recommendations are effective only if followed. Because lack of patient understanding and adherence may adversely affect outcomes, physicians and other healthcare providers should make every effort to engage the patient's active participation in prescribed medical regimens and lifestyles. In addition, patients should be informed of the risks, benefits, and alternatives to a particular treatment and be involved in shared decision making whenever feasible, particularly for COR IIa and IIb, where the benefit-to-risk ratio may be lower.

The Task Force makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the members of the writing committee. All writing committee members and peer reviewers of the guideline are asked to disclose all such current relationships, as well as those existing 12 months previously. In December 2009, the ACCF and AHA implemented a new policy for relationships with industry and other entities (RWI) that requires the writing committee chair plus a minimum of 50% of the writing committee to have no *relevant* RWI (Appendix 1 for the ACCF/AHA definition of relevance). These statements are reviewed by the Task Force and all members during each conference call and/or meeting of the writing committee and are updated as changes occur. All guideline recommendations require a confidential vote by the writing committee and must be approved by a consensus of the voting members. Members are not permitted to write, and must recuse themselves from voting on, any recommendation or section to which their RWI apply. Members who recused themselves from voting are indicated in the list of writing committee members, and section recusals are noted in Appendix 1. Authors' and peer reviewers' RWI pertinent to this guideline are disclosed in Appendixes 1 and 2, respectively. Additionally, to ensure complete transparency, writing committee members' comprehensive disclosure information—including RWI not pertinent to this document—is available as an online supplement. Comprehensive disclosure information for the Task Force is also available online at www.cardiosource.org/ACC/About-ACC/Leadership/Guidelines-and-Documents-Task-Forces.aspx. The work of the writing committee was supported exclusively by the ACCF, AHA, and the Society for Cardiovascular Angiography and Interventions (SCAI) without commercial support. Writing committee members volunteered their time for this activity.

In an effort to maintain relevance at the point of care for practicing physicians, the Task Force continues to oversee an ongoing process improvement initiative. As a result, in response to pilot projects, several changes to these guidelines will be apparent, including limited narrative text, a focus on summary and evidence tables (with references linked to abstracts in PubMed) and more liberal use of summary recommendation tables (with references that support LOE) to serve as a quick reference.

In April 2011, the Institute of Medicine released 2 reports: *Finding What Works in Health Care: Standards for Systematic Reviews* and *Clinical Practice Guidelines We Can Trust*.[2,3] It is noteworthy that the ACCF/AHA guidelines were cited as being compliant with many of the standards that were proposed. A thorough review of these reports and of our current methodology is under way, with further enhancements anticipated.

The recommendations in this guideline are considered current until they are superseded by a focused update or the full-text guideline is revised. Guidelines are official policy of both the ACCF and AHA.

Alice K. Jacobs, MD, FACC, FAHA,
Chair ACCF/AHA Task Force on Practice Guidelines

1. Introduction

1.1. Methodology and Evidence Review

The recommendations listed in this document are, whenever possible, evidence based. An extensive evidence review was conducted through November 2010, as well as selected other

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references through August 2011. Searches were limited to studies, reviews, and other evidence conducted in human subjects and that were published in English. Key search words included but were not limited to the following: *ad hoc angioplasty, angioplasty, balloon angioplasty, clinical trial, coronary stenting, delayed angioplasty, meta-analysis, percutaneous transluminal coronary angioplasty, randomized controlled trial (RCT), percutaneous coronary intervention (PCI) and angina, angina reduction, antiplatelet therapy, bare-metal stents (BMS), cardiac rehabilitation, chronic stable angina, complication, coronary bifurcation lesion, coronary calcified lesion, coronary chronic total occlusion (CTO), coronary ostial lesions, coronary stent (BMS and drug-eluting stents [DES]; and BMS versus DES), diabetes, distal embolization, distal protection, elderly, ethics, late stent thrombosis, medical therapy, microembolization, mortality, multiple lesions, multi-vessel, myocardial infarction (MI), non–ST-elevation myocardial infarction (NSTEMI), no-reflow, optical coherence tomography, proton pump inhibitor (PPI), return to work, same-day angioplasty and/or stenting, slow flow, stable ischemic heart disease (SIHD), staged angioplasty, STEMI, survival,* and *unstable angina (UA).* Additional searches cross-referenced these topics with the following subtopics: *anticoagulant therapy, contrast nephropathy, PCI-related vascular complications, unprotected left main PCI, multivessel coronary artery disease (CAD), adjunctive percutaneous interventional devices, percutaneous hemodynamic support devices,* and *secondary prevention.* Additionally, the committee reviewed documents related to the subject matter previously published by the ACCF and AHA. References selected and published in this document are representative and not all-inclusive.

To provide clinicians with a comprehensive set of data, whenever deemed appropriate or when published, the absolute risk difference and number needed to treat or harm will be provided in the guideline, along with confidence intervals (CIs) and data related to the relative treatment effects such as odds ratio (OR), relative risk, hazard ratio (HR), or incidence rate ratio. The focus of this guideline is the safe, appropriate, and efficacious performance of PCI. The risks of PCI must be balanced against the likelihood of improved survival, symptoms, or functional status. This is especially important in patients with SIHD.

1.2. Organization of the Writing Committee

The committee was composed of physicians with expertise in interventional cardiology, general cardiology, critical care cardiology, cardiothoracic surgery, clinical trials, and health services research. The committee included representatives from the ACCF, AHA, and SCAI.

1.3. Document Review and Approval

This document was reviewed by 2 official reviewers nominated by the ACCF, AHA, and SCAI, as well as 21 individual content reviewers (including members of the ACCF Interventional Scientific Council and ACCF Surgeons' Scientific Council). All information on reviewers' RWI was distributed to the writing committee and is published in this document (Appendix 2). This document was approved for publication by the governing bodies of the ACCF, AHA, and SCAI.

1.4. PCI Guidelines: History and Evolution

In 1982, a 2-page manuscript titled "Guidelines for the Performance of Percutaneous Transluminal Coronary Angioplasty" was published in *Circulation.*[4] The document, which addressed the specific expertise and experience physicians should have to perform balloon angioplasty, as well as laboratory requirements and the need for surgical support, was written by an ad hoc group whose members included Andreas Grüntzig. In 1980, the ACC and the AHA established the Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures, which was charged with the development of guidelines related to the role of new therapeutic approaches and of specific noninvasive and invasive procedures in the diagnosis and management of cardiovascular disease. The first ACC/AHA Task Force report on guidelines for coronary balloon angioplasty was published in 1988.[5] The 18-page document discussed and made recommendations about lesion classification and success rates, indications for and contraindications to balloon angioplasty, institutional review of angioplasty procedures, ad hoc angioplasty after angiography, and on-site surgical backup. Further iterations of the guidelines were published in 1993,[6] 2001,[7] and 2005.[8] In 2007 and 2009, focused updates to the guideline were published to expeditiously address new study results and recent changes in the field of interventional cardiology.[9,10] The 2009 focused update is notable in that there was direct collaboration between the writing committees for the STEMI guidelines and the PCI guidelines, resulting in a single publication of focused updates on STEMI and PCI.[10]

The evolution of the PCI guideline reflects the growth of knowledge in the field and parallels the many advances and innovations in the field of interventional cardiology, including primary PCI, BMS and DES, intravascular ultrasound (IVUS) and physiologic assessments of stenosis, and newer antiplatelet and anticoagulant therapies. The 2011 iteration of the guideline continues this process, addressing ethical aspects of PCI, vascular access considerations, CAD revascularization including hybrid revascularization, revascularization before noncardiac surgery, optical coherence tomography, advanced hemodynamic support devices, no-reflow therapies, and vascular closure devices. Most of this document is organized according to "patient flow," consisting of preprocedural considerations, procedural considerations, and postprocedural considerations. In a major undertaking, the STEMI, PCI, and coronary artery bypass graft (CABG) surgery guidelines were written concurrently, with additional collaboration with the SIHD guideline writing committee, allowing greater collaboration between the different writing committees on topics such as PCI in STEMI and revascularization strategies in patients with CAD (including unprotected left main PCI, multivessel disease revascularization, and hybrid procedures).

In accordance with direction from the Task Force and feedback from readers, in this iteration of the guideline, the text has been shortened, with an emphasis on summary

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statements rather than detailed discussion of numerous individual trials. Online supplemental evidence and summary tables have been created to document the studies and data considered for new or changed guideline recommendations.

2. CAD Revascularization

Recommendations and text in this section are the result of extensive collaborative discussions between the PCI and CABG writing committees, as well as key members of the SIHD and UA/NSTEMI writing committees. Certain issues, such as older versus more contemporary studies, primary analyses versus subgroup analyses, and prospective versus post hoc analyses, have been carefully weighed in designating COR and LOE; they are addressed in the appropriate corresponding text. The goals of revascularization for patients with CAD are to 1) improve survival and/or 2) relieve symptoms.

Revascularization recommendations in this section are predominantly based on studies of patients with symptomatic SIHD and should be interpreted in this context. As discussed later in this section, recommendations on the type of revascularization are, in general, applicable to patients with UA/NSTEMI. In some cases (eg, unprotected left main CAD), specific recommendations are made for patients with UA/NSTEMI or STEMI.

Historically, most studies of revascularization have been based on and reported according to angiographic criteria. Most studies have defined a "significant" stenosis as ≥70% diameter narrowing; therefore, for revascularization decisions and recommendations in this section, a "significant" stenosis has been defined as ≥70% diameter narrowing (≥50% for left main CAD). Physiological criteria, such as an assessment of fractional flow reserve (FFR), has been used in deciding when revascularization is indicated. Thus, for recommendations about revascularization in this section, coronary stenoses with FFR ≤0.80 can also be considered to be "significant."[11,12]

As noted, the revascularization recommendations have been formulated to address issues related to 1) improved survival and/or 2) improved symptoms. When one method of revascularization is preferred over the other for improved survival, this consideration, in general, takes precedence over improved symptoms. When discussing options for revascularization with the patient, he or she should understand when the procedure is being performed in an attempt to improve symptoms, survival, or both.

Although some results from the SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) study are best characterized as subgroup analyses and "hypothesis generating," SYNTAX nonetheless represents the latest and most comprehensive comparison of PCI and CABG.[13,14] Therefore, the results of SYNTAX have been considered appropriately when formulating our revascularization recommendations. Although the limitations of using the SYNTAX score for certain revascularization recommendations are recognized, the SYNTAX score is a reasonable surrogate for the extent of CAD and its complexity and serves as important information that should be considered when making revascularization decisions. Recommendations that refer to SYNTAX scores use them as surrogates for the extent and complexity of CAD.

Revascularization recommendations to improve survival and symptoms are provided in the following text and are summarized in Tables 2 and 3. References to studies comparing revascularization with medical therapy are presented when available for each anatomic subgroup.

See Online Data Supplements 1 and 2 for additional data regarding the survival and symptomatic benefits with CABG or PCI for different anatomic subsets.

2.1. Heart Team Approach to Revascularization Decisions: Recommendations

Class I

1. **A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD.[14–16] *(Level of Evidence: C)***

Class IIa

1. **Calculation of the Society of Thoracic Surgeons (STS) and SYNTAX scores is reasonable in patients with unprotected left main and complex CAD.[13,14,17–22] *(Level of Evidence: B)***

One protocol used in RCTs[14–16,23] often involves a multidisciplinary approach referred to as the Heart Team. Composed of an interventional cardiologist and a cardiac surgeon, the Heart Team 1) reviews the patient's medical condition and coronary anatomy, 2) determines that PCI and/or CABG are technically feasible and reasonable, and 3) discusses revascularization options with the patient before a treatment strategy is selected. Support for using a Heart Team approach comes from reports that patients with complex CAD referred specifically for PCI or CABG in concurrent trial registries have lower mortality rates than those randomly assigned to PCI or CABG in controlled trials.[15,16]

The SIHD, PCI, and CABG guideline writing committees endorse a Heart Team approach in patients with unprotected left main CAD and/or complex CAD in whom the optimal revascularization strategy is not straightforward. A collaborative assessment of revascularization options, or the decision to treat with GDMT without revascularization, involving an interventional cardiologist, a cardiac surgeon, and (often) the patient's general cardiologist, followed by discussion with the patient about treatment options, is optimal. Particularly in patients with SIHD and unprotected left main and/or complex CAD for whom a revascularization strategy is not straightforward, an approach has been endorsed that involves terminating the procedure after diagnostic coronary angiography is completed: this allows a thorough discussion and affords both the interventional cardiologist and cardiac surgeon the opportunity to discuss revascularization options with the patient. Because the STS score and the SYNTAX score have been shown to predict adverse outcomes in patients undergoing CABG and PCI, respectively, calculation of these scores is often useful in making revascularization decisions.[13,14,17–22]

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Table 2. Revascularization to Improve Survival Compared With Medical Therapy

Anatomic Setting	COR	LOE	References
UPLM or complex CAD			
CABG and PCI	I—Heart Team approach recommended	C	14–16
CABG and PCI	IIa—Calculation of STS and SYNTAX scores	B	13,14,17–22
UPLM*			
CABG	I	B	24–30
PCI	IIa—For SIHD when *both* of the following are present • Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (eg, a low SYNTAX score of ≤22, ostial or trunk left main CAD) • Clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (eg, STS-predicted risk of operative mortality ≥5%)	B	13,17,19,23,31–48
	IIa—For UA/NSTEMI if not a CABG candidate	B	13,36–39,44,45,47–49
	IIa—For STEMI when distal coronary flow is TIMI flow grade <3 and PCI can be performed more rapidly and safely than CABG	C	33,50,51
	IIb—For SIHD when *both* of the following are present • Anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (eg, low-intermediate SYNTAX score of <33, bifurcation left main CAD) • Clinical characteristics that predict an increased risk of adverse surgical outcomes (eg, moderate-severe COPD, disability from prior stroke, or prior cardiac surgery; STS-predicted risk of operative mortality >2%)	B	13,17,19,23,31–48,52
	III: Harm—For SIHD in patients (versus performing CABG) with unfavorable anatomy for PCI but who are good candidates for CABG	B	13,17,19,24–32
3-vessel disease with or without proximal LAD artery disease*			
CABG	I	B	26,30,53–56
	IIa—It is reasonable to choose CABG over PCI in patients with complex 3-vessel CAD (eg, SYNTAX score >22) who are good candidates for CABG	B	32,46,56,71,72
PCI	IIb—Of uncertain benefit	B	26,46,53,56,82
2-vessel disease with proximal LAD artery disease*			
CABG	I	B	26,30,53–56
PCI	IIb—Of uncertain benefit	B	26,53,56,82
2-vessel disease without proximal LAD artery disease*			
CABG	IIa—With extensive ischemia	B	60–63
	IIb—Of uncertain benefit without extensive ischemia	C	56
PCI	IIb—Of uncertain benefit	B	26,53,56,82
1-vessel proximal LAD artery disease			
CABG	IIa—With LIMA for long-term benefit	B	30,56,69,70
PCI	IIb—Of uncertain benefit	B	26,53,56,82
1-vessel disease without proximal LAD artery involvement			
CABG	III: Harm	B	30,53,60,61,94–98
PCI	III: Harm	B	30,53,60,61,94–98
LV dysfunction			
CABG	IIa—EF 35% to 50%	B	30,64–68
CABG	IIb—EF <35% without significant left main CAD	B	30,64–68,83,84
PCI	Insufficient data		N/A
Survivors of sudden cardiac death with presumed ischemia-mediated VT			
CABG	I	B	57–59
PCI	I	C	57
No anatomic or physiologic criteria for revascularization			
CABG	III: Harm	B	30,53,60,61,94–98
PCI	III: Harm	B	30,53,60,61,94–98

*In patients with multivessel disease who also have diabetes, it is reasonable to choose CABG (with LIMA) over PCI[62,74–81] (*Class IIa; LOE: B*).

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; COR, class of recommendation; EF, ejection fraction; LAD, left anterior descending; LIMA, left internal mammary artery; LOE, level of evidence; LV, left ventricular; N/A, not applicable; PCI, percutaneous coronary intervention; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; STS, Society of Thoracic Surgeons; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; TIMI, Thrombolysis in Myocardial Infarction; UA/NSTEMI, unstable angina/non–ST-elevation myocardial infarction; UPLM, unprotected left main disease; and VT, ventricular tachycardia.

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Table 3. Revascularization to Improve Symptoms With Significant Anatomic (≥50% Left Main or ≥70% Non–Left Main CAD) or Physiological (FFR ≤0.80) Coronary Artery Stenoses

Clinical Setting	COR	LOE	References
≥1 significant stenoses amenable to revascularization and unacceptable angina despite GDMT	I—CABG I—PCI	A	82,99–108
≥1 significant stenoses and unacceptable angina in whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences	IIa—CABG IIa—PCI	C	N/A
Previous CABG with ≥1 significant stenoses associated with ischemia and unacceptable angina despite GDMT	IIa—PCI	C	86,89,92
	IIb—CABG	C	93
Complex 3-vessel CAD (eg, SYNTAX score >22) with or without involvement of the proximal LAD artery and a good candidate for CABG	IIa—CABG preferred over PCI	B	32,46,56,71,72
Viable ischemic myocardium that is perfused by coronary arteries that are not amenable to grafting	IIb—TMR as an adjunct to CABG	B	109–113
No anatomic or physiologic criteria for revascularization	III: Harm—CABG III: Harm—PCI	C	N/A

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COR, class of recommendation; FFR, fractional flow reserve; GDMT, guideline-directed medical therapy; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and TMR, transmyocardial laser revascularization.

2.2. Revascularization to Improve Survival: Recommendations

Left Main CAD Revascularization

Class I

1. **CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main coronary artery stenosis.[24–30] *(Level of Evidence: B)***

Class IIa

1. **PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (eg, a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (eg, STS-predicted risk of operative mortality ≥5%).[13,17,19,23,31–48] *(Level of Evidence: B)***
2. **PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG.[13,36–39,44,45,47–49] *(Level of Evidence: B)***
3. **PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is less than TIMI (Thrombolysis In Myocardial Infarction) grade 3, and PCI can be performed more rapidly and safely than CABG.[33,50,51] *(Level of Evidence: C)***

Class IIb

1. **PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (eg, low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (eg, moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality >2%).[13,17,19,23,31–48,52] *(Level of Evidence: B)***

Class III: HARM

1. **PCI to improve survival should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG.[13,17,19,24–32] *(Level of Evidence: B)***

Non–Left Main CAD Revascularization

Class I

1. **CABG to improve survival is beneficial in patients with significant (≥70% diameter) stenoses in 3 major coronary arteries (with or without involvement of the proximal left anterior descending [LAD] artery) or in the proximal LAD plus 1 other major coronary artery.[26,30,53–56] *(Level of Evidence: B)***
2. **CABG or PCI to improve survival is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by significant (≥70% diameter) stenosis in a major coronary artery. *(CABG Level of Evidence: B[57–59]; PCI Level of Evidence: C[57])***

Class IIa

1. **CABG to improve survival is reasonable in patients with significant (≥70% diameter) stenoses in 2 major coronary arteries with severe or extensive**

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myocardial ischemia (eg, high-risk criteria on stress testing, abnormal intracoronary hemodynamic evaluation, or >20% perfusion defect by myocardial perfusion stress imaging) or target vessels supplying a large area of viable myocardium.[60–63] *(Level of Evidence: B)*

2. CABG to improve survival is reasonable in patients with mild-moderate left ventricular (LV) systolic dysfunction (ejection fraction [EF] 35% to 50%) and significant (≥70% diameter stenosis) multi-vessel CAD or proximal LAD coronary artery stenosis, when viable myocardium is present in the region of intended revascularization.[30,64–68] *(Level of Evidence: B)*
3. CABG with a left internal mammary artery (LIMA) graft to improve survival is reasonable in patients with significant (≥70% diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia.[30,56,69,70] *(Level of Evidence: B)*
4. It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (eg, SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG.[32,46,56,71,72] *(Level of Evidence: B)*
5. CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the LAD artery.[62,74–81] *(Level of Evidence: B)*

Class IIb

1. The usefulness of CABG to improve survival is uncertain in patients with significant (≥70%) diameter stenoses in 2 major coronary arteries not involving the proximal LAD artery and without extensive ischemia.[56] *(Level of Evidence: C)*
2. The usefulness of PCI to improve survival is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease.[26,53,56,82] *(Level of Evidence: B)*
3. CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe LV systolic dysfunction (EF <35%) whether or not viable myocardium is present.[30,64–68,83,84] *(Level of Evidence: B)*
4. The usefulness of CABG or PCI to improve survival is uncertain in patients with previous CABG and extensive anterior wall ischemia on noninvasive testing.[85–93] *(Level of Evidence: B)*

Class III: HARM

1. CABG or PCI should not be performed with the primary or sole intent to improve survival in patients with SIHD with 1 or more coronary stenoses that are not anatomically or functionally significant (eg, <70% diameter non–left main coronary artery stenosis, FFR >0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium.[30,53,60,61,94–98] *(Level of Evidence: B)*

2.3. Revascularization to Improve Symptoms: Recommendations

Class I

1. CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite GDMT.[82,99–108] *(Level of Evidence: A)*

Class IIa

1. CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences. *(Level of Evidence: C)*
2. PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT.[86,89,92] *(Level of Evidence: C)*
3. It is reasonable to choose CABG over PCI to improve symptoms in patients with complex 3-vessel CAD (eg, SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG.[32,46,56,72,73] *(Level of Evidence: B)*

Class IIb

1. CABG to improve symptoms might be reasonable for patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses not amenable to PCI, and unacceptable angina despite GDMT.[93] *(Level of Evidence: C)*
2. Transmyocardial laser revascularization (TMR) performed as an adjunct to CABG to improve symptoms may be reasonable in patients with viable ischemic myocardium that is perfused by arteries that are not amenable to grafting.[109–113] *(Level of Evidence: B)*

Class III: HARM

1. CABG or PCI to improve symptoms should not be performed in patients who do not meet anatomic (≥50% diameter left main or ≥70% non–left main stenosis diameter) or physiological (eg, abnormal FFR) criteria for revascularization. *(Level of Evidence: C)*

2.4. CABG Versus Contemporaneous Medical Therapy

In the 1970s and 1980s, 3 RCTs established the survival benefit of CABG compared with contemporaneous (although minimal by current standards) medical therapy without revascularization in certain subjects with stable angina: the Veter-

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ans Affairs Cooperative Study,[114] European Coronary Surgery Study,[55] and CASS (Coronary Artery Surgery Study).[115] Subsequently, a 1994 meta-analysis of 7 studies that randomized a total of 2649 patients to medical therapy or CABG[30] showed that CABG offered a survival advantage over medical therapy for patients with left main or 3-vessel CAD. The studies also established that CABG is more effective than medical therapy for relieving anginal symptoms. These studies have been replicated only once during the past decade. In MASS II (Medicine, Angioplasty, or Surgery Study II), patients with multivessel CAD who were treated with CABG were less likely than those treated with medical therapy to have a subsequent MI, need additional revascularization, or experience cardiac death in the 10 years after randomization.[104]

Surgical techniques and medical therapy have improved substantially during the intervening years. As a result, if CABG were to be compared with GDMT in RCTs today, the relative benefits for survival and angina relief observed several decades ago might no longer be observed. Conversely, the concurrent administration of GDMT may substantially improve long-term outcomes in patients treated with CABG in comparison with those receiving medical therapy alone. In the BARI 2D (Bypass Angioplasty Revascularization Investigation 2 Diabetes) trial of patients with diabetes mellitus, no significant difference in risk of mortality in the cohort of patients randomized to GDMT plus CABG or GDMT alone was observed, although the study was not powered for this endpoint, excluded patients with significant left main CAD, and included only a small percentage of patients with proximal LAD artery disease or LV ejection fraction (LVEF) <0.50.[116] The PCI and CABG guideline writing committees endorse the performance of the ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches) trial, which will provide contemporary data on the optimal management strategy (medical therapy or revascularization with CABG or PCI) of patients with SIHD, including multivessel CAD, and moderate to severe ischemia.

2.5. PCI Versus Medical Therapy

Although contemporary interventional treatments have lowered the risk of restenosis compared with earlier techniques, meta-analyses have failed to show that the introduction of BMS confers a survival advantage over balloon angioplasty[117–119] or that the use of DES confers a survival advantage over BMS.[119,120]

No study to date has demonstrated that PCI in patients with SIHD improves survival rates.[26,53,56,82,116,119,121–124] Neither COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation)[82] nor BARI 2D,[116] which treated all patients with contemporary optimal medical therapy, demonstrated any survival advantage with PCI, although these trials were not specifically powered for this endpoint. Although 1 large analysis evaluating 17 RCTs of PCI versus medical therapy (including 5 trials of subjects with acute coronary syndromes [ACS]) found a 20% reduction in death with PCI compared with medical therapy,[123] 2 other large analyses did not.[119,122] An evaluation of 13 studies reporting the data from 5442 patients with nonacute CAD showed no advantage of PCI over medical therapy for the individual endpoints of all-cause death, cardiac death or MI, or nonfatal MI.[124] Evaluation of 61 trials of PCI conducted over several decades shows that despite improvements in PCI technology and pharmacotherapy, PCI has not been demonstrated to reduce the risk of death or MI in patients without recent ACS.[119]

The findings from individual studies and systematic reviews of PCI versus medical therapy can be summarized as follows:

- PCI reduces the incidence of angina.[82,99,104,107,108,125]
- PCI has not been demonstrated to improve survival in stable patients.[119,121,122]
- PCI may increase the short-term risk of MI.[82,121,125,126]
- PCI does not lower the long-term risk of MI.[82,116,119,121,122,126]

2.6. CABG Versus PCI

The results of 26 RCTs comparing CABG and PCI have been published: Of these, 9 compared CABG with balloon angioplasty,[75,105,128–142] 14 compared CABG with BMS implantation,[88,143–160] and 3 compared CABG with DES implantation.[14,161,162]

2.6.1. CABG Versus Balloon Angioplasty or BMS

A systematic review of the 22 RCTs comparing CABG with balloon angioplasty or BMS implantation concluded the following[163]:

1. Survival was similar for CABG and PCI (with balloon angioplasty or BMS) at 1 year and 5 years. Survival was similar for CABG and PCI in subjects with 1-vessel CAD (including those with disease of the proximal portion of the LAD artery) or multivessel CAD.
2. Incidence of MI was similar at 5 years after randomization.
3. Procedural stroke occurred more commonly with CABG than with PCI (1.2% versus 0.6%).
4. Relief of angina was accomplished more effectively with CABG than with PCI 1 year after randomization and 5 years after randomization.
5. During the first year after randomization, repeat coronary revascularization was performed less often after CABG than after PCI (3.8% versus 26.5%). This was also demonstrated after 5 years of follow-up (9.8% versus 46.1%). This difference was more pronounced with balloon angioplasty than with BMS.

A collaborative analysis of data from 10 RCTs comparing CABG with balloon angioplasty (6 trials) or with BMS implantation (4 trials)[164] permitted subgroup analyses of the data from the 7812 patients. No difference was noted with regard to mortality rate 5.9 years after randomization or the composite endpoint of death or MI. Repeat revascularization and angina were noted more frequently in those treated with balloon angioplasty or BMS implantation.[164] The major new observation of this analysis was that CABG was associated with better outcomes in patients with diabetes mellitus and in those >65 years old. Of interest, the relative outcomes of

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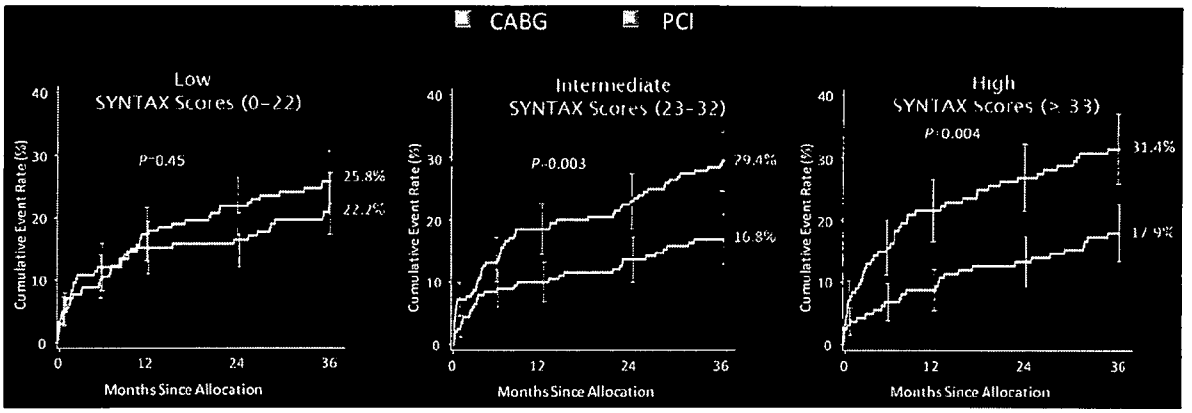

Figure 1. Cumulative incidence of MACE in patients with 3-vessel CAD based on SYNTAX score at 3-year follow-up in the SYNTAX trial treated with either CABG or PCI. CABG indicates coronary artery bypass graft; CAD, coronary artery disease; MACE, major adverse cardiovascular event; PCI, percutaneous coronary intervention; and SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery. Adapted with permission from Kappetein.[46]

CABG and PCI were not influenced by other patient characteristics, including the number of diseased coronary arteries.

The aforementioned meta-analysis and systematic review[163,164] comparing CABG and balloon angioplasty or BMS implantation were limited in several ways:

1. Many trials did not report outcomes for other important patient subsets. For example, the available data are insufficient to determine if race, obesity, renal dysfunction, peripheral arterial disease, or previous coronary revascularization affected the comparative outcomes of CABG and PCI.
2. Most of the patients enrolled in these trials were male, and most had 1- or 2-vessel CAD and normal LV systolic function (EF >50%)—subjects known to be unlikely to derive a survival benefit and less likely to experience complications after CABG.[30]
3. The patients enrolled in these trials represented only a small fraction (generally <5% to 10%) of those who were screened. For example, most screened patients with 1-vessel CAD and many with 3-vessel CAD were not considered for randomization.

See Online Data Supplements 3 and 4 for additional data comparing CABG with PCI.

2.6.2. CABG Versus DES

Although the results of 9 observational studies comparing CABG and DES implantation have been published,[32,165–172] most of them had short (12 to 24 months) follow-up periods. In a meta-analysis of 24 268 patients with multivessel CAD treated with CABG or DES,[173] the incidences of death and MI were similar for the 2 procedures, but the frequency with which repeat revascularization was performed was roughly 4 times higher after DES implantation. Only 1 large RCT comparing CABG and DES implantation has been published. The SYNTAX trial randomly assigned 1800 patients (of a total of 4337 who were screened) to receive DES or CABG.[14,46] Major adverse cardiac events (MACE), a composite of death, stroke, MI, or repeat revascularization during the 3 years after randomization, occurred in 20.2% of CABG patients and 28.0% of those undergoing DES implantation ($P<0.001$). The rates of death and stroke were similar; however, MI (3.6% for CABG, 7.1% for DES) and repeat revascularization (10.7% for CABG, 19.7% for DES) were more likely to occur with DES implantation.[46]

In SYNTAX, the extent of CAD was assessed using the SYNTAX score, which is based on the location, severity, and extent of coronary stenoses, with a low score indicating less complicated anatomic CAD. In post hoc analyses, a low score was defined as ≤22; intermediate, 23 to 32; and high, ≥33. The occurrence of MACE correlated with the SYNTAX score for DES patients but not for those undergoing CABG. At 12-month follow-up, the primary endpoint was similar for CABG and DES in those with a low SYNTAX score. In contrast, MACE occurred more often after DES implantation than after CABG in those with an intermediate or high SYNTAX score.[14] At 3 years of follow-up, the mortality rate was greater in subjects with 3-vessel CAD treated with PCI than in those treated with CABG (6.2% versus 2.9%). The differences in MACE between those treated with PCI or CABG increased with an increasing SYNTAX score (Figure 1).[46]

Although the utility of using a SYNTAX score in everyday clinical practice remains uncertain, it seems reasonable to conclude from SYNTAX and other data that outcomes of patients undergoing PCI or CABG in those with relatively uncomplicated and lesser degrees of CAD are comparable, whereas in those with complex and diffuse CAD, CABG appears to be preferable.[46]

See Online Data Supplements 5 and 6 for additional data comparing CABG with DES.

2.7. Left Main CAD

2.7.1. CABG or PCI Versus Medical Therapy for Left Main CAD

CABG confers a survival benefit over medical therapy in patients with left main CAD. Subgroup analyses from RCTs performed 3 decades ago included 91 patients with left main CAD in the Veterans Administration Cooperative Study.[28] A meta-analysis of these trials demonstrated a 66% reduction in relative risk in mortality with CABG, with the benefit extending to 10 years.[30] The CASS Registry[24] contained data

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from 1484 patients with ≥50% diameter stenosis left main CAD initially treated surgically or nonsurgically. Median survival duration was 13.3 years in the surgical group; and 6.6 years in the medical group. The survival benefit of CABG over medical therapy appeared to extend to 53 asymptomatic patients with left main CAD in the CASS Registry.[29] Other therapies that subsequently have been shown to be associated with improved long-term outcome, such as the use of aspirin, statins, and internal mammary artery grafting, were not widely used in that era.

RCTs and subgroup analyses that compare PCI with medical therapy in patients with "unprotected" left main CAD do not exist.

2.7.2. Studies Comparing PCI Versus CABG for Left Main CAD

Of all subjects undergoing coronary angiography, approximately 4% are found to have left main CAD,[175] >80% of whom have significant (≥70% diameter) stenoses in other epicardial coronary arteries.

Published cohort studies have found that major clinical outcomes are similar with PCI or CABG 1 year after revascularization and that mortality rates are similar at 1, 2, and 5 years of follow-up; however, the risk of needing target-vessel revascularization is significantly higher with stenting than with CABG.

In the SYNTAX trial, 45% of screened patients with unprotected left main CAD had complex disease that prevented randomization; 89% of these underwent CABG.[13,14] In addition, 705 of the 1800 patients who were randomized had revascularization for unprotected left main CAD. The majority of patients with left main CAD and a low SYNTAX score had isolated left main CAD or left main CAD plus 1-vessel CAD; the majority of those with an intermediate score had left main CAD plus 2-vessel CAD; and most of those with a high SYNTAX score had left main CAD plus 3-vessel CAD. At 1 year, rates of all-cause death and MACE were similar for the 2 groups.[13] Repeat revascularization rates were higher in the PCI group than the CABG group (11.8% versus 6.5%), but stroke occurred more often in the CABG group (2.7% versus 0.3%). At 3 years of follow-up, the incidence of death in those undergoing left main CAD revascularization with low or intermediate SYNTAX scores (≤32) was 3.7% after PCI and 9.1% after CABG ($P=0.03$), whereas in those with a high SYNTAX score (≥33), the incidence of death after 3 years was 13.4% after PCI and 7.6% after CABG ($P=0.10$).[46] Because the primary endpoint of SYNTAX was not met (ie, noninferiority comparison of CABG and PCI), these subgroup analyses need to be considered in that context.

In the LE MANS (Study of Unprotected Left Main Stenting Versus Bypass Surgery) trial,[23] 105 patients with left main CAD were randomized to receive PCI or CABG. Although a low proportion of patients treated with PCI received DES (35%) and a low proportion of patients treated with CABG received internal mammary grafts (72%), the outcomes at 30 days and 1 year were similar between the groups. In the PRECOMBAT (Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease) trial of 600 patients with left main disease, the composite endpoint of death, MI, or stroke at 2 years occurred in 4.4% of patients treated with PCI patients and 4.7% of patients treated with CABG, but ischemia-driven target-vessel revascularization was more often required in the patients treated with PCI (9.0% versus 4.2%).[52]

The results from these 3 RCTs suggest (but do not definitively prove) that major clinical outcomes in *selected* patients with left main CAD are similar with CABG and PCI at 1- to 2-year follow-up, but repeat revascularization rates are higher after PCI than after CABG. RCTs with extended follow-up of ≥5 years are required to provide definitive conclusions about the optimal treatment of left main CAD. In a meta-analysis of 8 cohort studies and 2 RCTs,[41] death, MI, and stroke occurred with similar frequency in the PCI- and CABG-treated patients at 1, 2, and 3 years of follow-up. Target-vessel revascularization was performed more often in the PCI group at 1 year (OR: 4.36), 2 years (OR: 4.20), and 3 years (OR: 3.30).

See Online Data Supplements 7 to 12 for additional data comparing PCI with CABG for left main CAD.

2.7.3. Revascularization Considerations for Left Main CAD

Although CABG has been considered the "gold standard" for unprotected left main CAD revascularization, more recently PCI has emerged as a possible alternative mode of revascularization in carefully selected patients. Lesion location is an important determinant when considering PCI for unprotected left main CAD. Stenting of the left main ostium or trunk is more straightforward than treating distal bifurcation or trifurcation stenoses, which generally requires a greater degree of operator experience and expertise.[176] In addition, PCI of bifurcation disease is associated with higher restenosis rates than when disease is confined to the ostium or trunk.[39,177] Although lesion location influences technical success and long-term outcomes after PCI, location exerts a negligible influence on the success of CABG. In subgroup analyses, patients with left main CAD and a SYNTAX score ≥33 with more complex or extensive CAD had a higher mortality rate with PCI than with CABG.[46] Physicians can estimate operative risk for all CABG candidates using a standard instrument, such as the risk calculator from the STS database. The above considerations are important factors when choosing among revascularization strategies for unprotected left main CAD and have been factored into revascularization recommendations. Use of a Heart Team approach has been recommended in cases in which the choice of revascularization is not straightforward. As discussed in Section 2.9.7, the ability of the patient to tolerate and comply with dual antiplatelet therapy (DAPT) is also an important consideration in revascularization decisions.

The 2005 PCI guideline[8] recommended routine angiographic follow-up 2 to 6 months after stenting for unprotected left main CAD. However, because angiography has limited ability to predict stent thrombosis and the results of SYNTAX suggest good intermediate-term results for PCI in subjects with left main CAD, this recommendation was removed in the 2009 STEMI/PCI focused update.[10]

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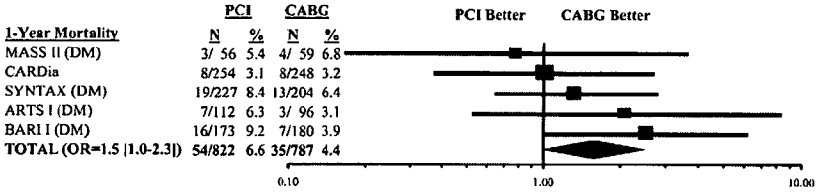

Figure 2. 1-year mortality after revascularization for multivessel disease and diabetes mellitus. An OR of >1 suggests an advantage of CABG over PCI. ARTS I indicates Arterial Revascularization Therapy Study I[185]; BARI I, Bypass Angioplasty Revascularization Investigation I[74]; CABG, coronary artery bypass graft; CAD, coronary artery disease; CARDia, Coronary Artery Revascularization in Diabetes[186]; CI, confidence interval; MASS II, Medicine, Angioplasty, or Surgery Study II[78]; OR, odds ratio; PCI, percutaneous coronary intervention; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and W, weighted.[76]

Experts have recommended immediate PCI for unprotected left main CAD in the setting of STEMI.[51] The impetus for such a strategy is greatest when left main CAD is the site of the culprit lesion, antegrade coronary flow is diminished (eg, TIMI flow grade 0, 1, or 2), the patient is hemodynamically unstable, and it is believed that PCI can be performed more quickly than CABG. When possible, the interventional cardiologist and cardiac surgeon should decide together on the optimal form of revascularization for these subjects, although it is recognized that these patients are usually critically ill and therefore not amenable to a prolonged deliberation or discussion of treatment options.

2.8. Proximal LAD Artery Disease

A cohort study[53] and a meta-analysis[30] from the 1990s suggested that CABG confers a survival advantage over contemporaneous medical therapy for patients with disease in the proximal segment of the LAD artery. Cohort studies and RCTs[30,133,146,148,161,178–181] as well as collaborative- and meta-analyses[164,182–184] showed that PCI and CABG result in similar survival rates in these patients.

See Online Data Supplement 13 for additional data regarding proximal LAD artery revascularization.

2.9. Clinical Factors That May Influence the Choice of Revascularization

2.9.1. Diabetes Mellitus

An analysis performed in 2009 of data on 7812 patients (1233 with diabetes) in 10 RCTs demonstrated a worse long-term survival rate in patients with diabetes mellitus after balloon angioplasty or BMS implantation than after CABG.[164] The BARI 2D trial[116] randomly assigned 2368 patients with type 2 diabetes and CAD to undergo intensive medical therapy or prompt revascularization with PCI or CABG, according to whichever was thought to be more appropriate. By study design, those with less extensive CAD more often received PCI, whereas those with more extensive CAD were more likely to be treated with CABG. The study was not designed to compare PCI with CABG. At 5-year follow-up, no difference in rates of survival or MACE between the medical therapy group and those treated with revascularization was noted. In the PCI stratum, no significant difference in MACE between medical therapy and revascularization was demonstrated (DES in 35%; BMS in 56%); in the CABG stratum, MACE occurred less often in the revascularization group. One-year follow-up data from the SYNTAX study demonstrated a higher rate of repeat revascularization in patients with diabetes mellitus treated with PCI than with CABG, driven by a tendency for higher repeat revascularization rates in those with higher SYNTAX scores undergoing PCI.[76] In summary, in subjects requiring revascularization for multivessel CAD, current evidence supports diabetes mellitus as an important factor when deciding on a revascularization strategy, particularly when complex or extensive CAD is present (Figure 2).

See Online Data Supplements 14 and 15 for additional data regarding diabetes mellitus.

2.9.2. Chronic Kidney Disease

Cardiovascular morbidity and mortality rates are markedly increased in patients with chronic kidney disease (CKD) when compared with age-matched controls without CKD. The mortality rate for patients on hemodialysis is >20% per year, and approximately 50% of deaths among these patients are due to a cardiovascular cause.[187,188]

To date, randomized comparisons of coronary revascularization (with CABG or PCI) and medical therapy in patients with CKD have not been reported. Some, but not all, observational studies or subgroup analyses have demonstrated an improved survival rate with revascularization compared with medical therapy in patients with CKD and multivessel CAD,[189–191] despite the fact that the incidence of periprocedural complications (eg, death, MI, stroke, infection, renal failure) is increased in patients with CKD compared with those without renal dysfunction. Some studies have shown that CABG is associated with a greater survival benefit than PCI among patients with severe renal dysfunction.[190–196]

2.9.3. Completeness of Revascularization

Most patients undergoing CABG receive complete or nearly complete revascularization, which seems to influence long-term prognosis positively.[197] In contrast, complete revascularization is accomplished less often in subjects receiving PCI (eg, in <70% of patients), but the extent to which the absence of complete initial revascularization influences outcome is less clear. Rates of late survival and survival free of MI appears to be similar in patients with and without complete revascularization after PCI. Nevertheless, the need for subsequent CABG is usually higher in those whose initial revascularization procedure was incomplete (compared with those with complete revascularization) after PCI.[198–200]

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2.9.4. LV Systolic Dysfunction

Several older studies and a meta-analysis of the data from these studies reported that patients with LV systolic dysfunction (predominantly mild to moderate in severity) had better survival with CABG than with medical therapy alone.[30,64–68] For patients with more severe LV systolic dysfunction, however, the evidence that CABG results in better survival compared with medical therapy is lacking. In the STICH (Surgical Treatment for Ischemic Heart Failure) trial of subjects with LVEF <35% with or without viability testing, CABG and GDMT resulted in similar rates of survival (death from any cause, the study's primary outcome) after 5 years of follow-up. For a number of secondary outcomes at this time point, including 1) death from any cause or hospitalization for heart failure, 2) death from any cause or hospitalization for cardiovascular causes, 3) death from any cause or hospitalization for any cause, or 4) death from any cause or revascularization with PCI or CABG, CABG was superior to GDMT. Although the primary outcome (death from any cause) was similar in the 2 treatment groups after an average of 5 years of follow-up, the data suggest the possibility that outcomes would differ if the follow-up were longer in duration; as a result, the study is being continued to provide follow-up for up to 10 years.[83,84]

Only very limited data comparing PCI with medical therapy in patients with LV systolic dysfunction are available.[68] In several ways, these data are suboptimal, in that many studies compared CABG with balloon angioplasty, many were retrospective, and many were based on cohort or registry data. Some of the studies demonstrated a similar survival rate in patients having CABG and PCI,[71,164,201–203] whereas others showed that those undergoing CABG had better outcomes.[32] The data that exist at present on revascularization in patients with CAD and LV systolic dysfunction are more robust for CABG than for PCI, although data from contemporary RCTs in this patient population are lacking. Therefore, the choice of revascularization in patients with CAD and LV systolic dysfunction is best based on clinical variables (eg, coronary anatomy, presence of diabetes mellitus, presence of CKD), magnitude of LV systolic dysfunction, patient preferences, clinical judgment, and consultation between the interventional cardiologist and the cardiac surgeon.

2.9.5. Previous CABG

In patients with recurrent angina after CABG, repeat revascularization is most likely to improve survival in subjects at highest risk, such as those with obstruction of the proximal LAD artery and extensive anterior ischemia.[85–93] Patients with ischemia in other locations and those with a patent LIMA to the LAD artery are unlikely to experience a survival benefit from repeat revascularization.[92]

Cohort studies comparing PCI and CABG among post-CABG patients report similar rates of mid- and long-term survival after the 2 procedures.[85,88–91,93,204] In the patient with previous CABG who is referred for revascularization for medically refractory ischemia, factors that may support the choice of repeat CABG include vessels unsuitable for PCI, number of diseased bypass grafts, availability of the internal mammary artery for grafting chronically occluded coronary arteries, and good distal targets for bypass graft placement. Factors favoring PCI over CABG include limited areas of ischemia causing symptoms, suitable PCI targets, a patent graft to the LAD artery, poor CABG targets, and comorbid conditions.

2.9.6. Unstable Angina/Non–ST-Elevation Myocardial Infarction

The main difference between management of the patient with SIHD and the patient with UA/NSTEMI is that the impetus for revascularization is stronger in the setting of UA/NSTEMI, because myocardial ischemia occurring as part of an ACS is potentially life threatening, and associated anginal symptoms are more likely to be reduced with a revascularization procedure than with GDMT.[205–207] Thus, the indications for revascularization are strengthened by the acuity of presentation, the extent of ischemia, and the ability to achieve full revascularization. The choice of revascularization method is generally dictated by the same considerations used to decide on PCI or CABG for patients with SIHD.

2.9.7. DAPT Compliance and Stent Thrombosis: Recommendation

Class III: HARM

1. **PCI with coronary stenting (BMS or DES) should not be performed if the patient is not likely to be able to tolerate and comply with DAPT for the appropriate duration of treatment based on the type of stent implanted.[208–211] *(Level of Evidence: B)***

The risk of stent thrombosis is increased dramatically in patients who prematurely discontinue DAPT, and stent thrombosis is associated with a mortality rate of 20% to 45%.[208] Because the risk of stent thrombosis with BMS is greatest in the first 14 to 30 days, this is the generally recommended minimum duration of DAPT therapy for these individuals. Consensus in clinical practice is to treat DES patients for at least 12 months with DAPT to avoid late (after 30 days) stent thrombosis.[208,212] Therefore, the ability of the patient to tolerate and comply with at least 30 days of DAPT with BMS treatment and at least 12 months of DAPT with DES treatment is an important consideration in deciding whether to use PCI to treat patients with CAD.

2.10. TMR as an Adjunct to CABG

TMR has been used on occasion in patients with severe angina refractory to GDMT in whom complete revascularization cannot be achieved with PCI and/or CABG. Although the mechanism by which TMR might be efficacious in these patients is unknown,[213,214] several RCTs of TMR as sole therapy demonstrated a reduction in anginal symptoms compared with intensive medical therapy alone.[109–111,215–217] A single randomized multicenter comparison of TMR (with a holmium:YAG laser) plus CABG and CABG alone in patients in whom some myocardial segments were perfused by arteries considered not amenable to grafting[112] showed a significant reduction in perioperative mortality rate (1.5% versus 7.6%, respectively), and the survival benefit of the TMR–CABG combination was present after 1 year of follow-up.[112] At the same time, a large retrospective analysis of data

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from the STS National Cardiac Database as well as a study of 169 patients from the Washington Hospital Center who underwent combined TMR–CABG, showed no difference in adjusted mortality rate compared with CABG alone.[113,218] In short, a TMR–CABG combination does not appear to improve survival compared with CABG alone. In selected patients, however, such a combination may be superior to CABG alone in relieving angina.

2.11. Hybrid Coronary Revascularization: Recommendations

Class IIa

1. **Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) is reasonable in patients with 1 or more of the following[219–225] *(Level of Evidence: B):***
   a. **Limitations to traditional CABG, such as heavily calcified proximal aorta or poor target vessels for CABG (but amenable to PCI);**
   b. **Lack of suitable graft conduits;**
   c. **Unfavorable LAD artery for PCI (ie, excessive vessel tortuosity or CTO).**

Class IIb

1. **Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) may be reasonable as an alternative to multivessel PCI or CABG in an attempt to improve the overall risk-benefit ratio of the procedures. *(Level of Evidence: C)***

Hybrid coronary revascularization, defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries,[226] is intended to combine the advantages of CABG (ie, durability of the LIMA graft) and PCI.[227] Patients with multivessel CAD (eg, LAD and ≥1 non-LAD stenoses) and an indication for revascularization are potentially eligible for this approach. Hybrid revascularization is ideal in patients in whom technical or anatomic limitations to CABG or PCI alone may be present and for whom minimizing the invasiveness (and therefore the risk of morbidity and mortality) of surgical intervention is preferred[221] (eg, patients with severe preexisting comorbidities, recent MI, a lack of suitable graft conduits, a heavily calcified ascending aorta, or a non-LAD coronary artery unsuitable for bypass but amenable to PCI, and situations in which PCI of the LAD artery is not feasible because of excessive tortuosity or CTO).

Hybrid coronary revascularization may be performed in a hybrid suite in one operative setting or as a staged procedure (ie, PCI and CABG performed in 2 different operative suites, separated by hours to 2 days, but typically during the same hospital stay). Because most hospitals lack a hybrid operating room, staged procedures are usually performed. With the staged procedure, CABG before PCI is preferred, because this approach allows the interventional cardiologist to 1) verify the patency of the LIMA-to-LAD artery graft before attempting PCI of other vessels and 2) minimize the risk of perioperative bleeding that would occur if CABG were performed after PCI (ie, while the patient is receiving DAPT). Because minimally invasive CABG may be associated with lower graft patency rates compared with CABG performed through a midline sternotomy, it seems prudent to angiographically image all grafts performed through a minimally invasive approach to confirm graft patency.[221]

To date, no RCTs involving hybrid coronary revascularization have been published. Over the past 10 years, several small, retrospective series of hybrid revascularization using minimally invasive CABG and PCI have reported low mortality rates (0 to 2%) and event-free survival rates of 83% to 92% at 6 to 12 months of follow-up. The few series that have compared the outcomes of hybrid coronary revascularization with standard CABG report similar outcomes at 30 days and 6 months.[219–225]

3. PCI Outcomes

3.1. Definitions of PCI Success

The success of a PCI procedure is best defined by 3 interrelated components: angiographic findings, procedural events, and clinical outcomes.

3.1.1. Angiographic Success

A successful PCI produces sufficient enlargement of the lumen at the target site to improve coronary artery blood flow. A successful balloon angioplasty is defined as the reduction of a minimum stenosis diameter to <50% with a final TIMI flow grade 3 (visually assessed by angiography) without side branch loss, flow-limiting dissection, or angiographic thrombus.[7] For coronary stents, a minimum stenosis diameter of <20% (as visually assessed by angiography) has previously been the clinical benchmark of an optimal angiographic result. Given improvements in technology and techniques, as well as recognition of the importance of an adequately deployed stent to decrease the risks of stent restenosis and thrombosis,[12,228,229] the writing committee concluded that a minimum diameter stenosis of <10% (with an optimal goal of as close to 0% as possible) should be the new benchmark for lesions treated with coronary stenting. As with balloon angioplasty, there should be final TIMI flow grade 3, without occlusion of a significant side branch, flow-limiting dissection, distal embolization, or angiographic thrombus. Problems with determining angiographic success include disparities between the visual assessment and computer-aided quantitative stenosis measurement and self-reporting of success in clinical reports or databases.

3.1.2. Procedural Success

A successful PCI should achieve angiographic success without associated in-hospital major clinical complications (eg, death, MI, stroke, emergency CABG).[7,8] Issues regarding the diagnosis and prognostic implications of procedure-related MI are discussed in Sections 3.3 and 5.10.

3.1.3. Clinical Success

In the short term, a clinically successful PCI requires both anatomic and procedural success along with relief of signs and/or symptoms of myocardial ischemia. Long-term clinical success requires that the short-term clinical success remain

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durable and that relief of signs and symptoms of myocardial ischemia persist >9 months after the procedure. Restenosis is the principal cause of lack of long-term clinical success after a short-term clinical success has been achieved. Restenosis is not a complication; it is the expected biological response to vascular injury. The frequency of clinically important restenosis may be judged by the frequency with which subsequent revascularization procedures are performed on target arteries after the index procedure.

3.2. Predictors of Clinical Outcome After PCI

Factors associated with increased PCI complication rates include advanced age, diabetes, CKD, ACS, congestive heart failure, and multivessel CAD.[8,230–232] Several models have been developed and refined over the past 2 decades to predict mortality with PCI.[230,233–236] At present, perhaps the best accepted system is from the ACC National Cardiovascular Data Registry (NCDR) CathPCI Risk Score system, which uses clinical variables and PCI setting to predict inpatient mortality (Appendix 4A).[236] In general, these models perform very well (C statistic: approximately 0.90), although predictive capability decreases in high-risk patients.

Models have also been developed to predict procedural success. Presently, the modified ACC/AHA score[230] and the SCAI score (Appendix 4B)[237] are both in use, with the latter slightly outperforming the former. Discrimination as measured by the C statistic is generally good to very good (0.70 to 0.82), depending on the outcome variable and patient population.

The angiographic SYNTAX score[238] has been developed to predict long-term risk of MACE after multivessel intervention. The SYNTAX score and its potential utility in helping guide revascularization strategies are discussed in Section 2. Composite models including angiographic and clinical variables have been developed but generally require validation in larger cohorts of patients.

3.3. PCI Complications

In an analysis of the NCDR CathPCI database of patients undergoing PCI between 2004 and 2007, the overall inhospital mortality rate was 1.27%, ranging from 0.65% in elective PCI to 4.81% in STEMI.[236] Factors associated with an increased risk of PCI-related death include advanced age, comorbidities (eg, diabetes, CKD, congestive heart failure), multivessel CAD, high-risk lesions, and the setting of PCI (eg, STEMI, urgent or emergency procedure, cardiogenic shock).[56,230–232,236]

Causes of procedural and periprocedural MI include acute artery closure, embolization and no-reflow, side branch occlusion, and acute stent thrombosis. The incidence of procedure-related MI depends to a great degree on the definition of MI used, the patient population studied, and whether or not cardiac biomarkers are routinely assessed after PCI. The definition and clinical significance of PCI-related MI have been controversial. Criteria for defining a PCI-related MI have evolved over time.[8,239,240] The 2007 universal definition of MI[240] states that after PCI, elevations of cardiac biomarkers above the 99th percentile upper reference limit indicate periprocedural myocardial necrosis. Increases of biomarkers >3 times the 99th percentile upper reference limit were designated as defining PCI-related MI.[240] According to this definition, ≥15% of patients undergoing PCI would be defined as having periprocedural MI.[241,242] Issues in procedure-related MI are discussed in Section 5.10.

The need for emergency CABG has dramatically decreased with advances in PCI technology, particularly coronary stents.[243,244] Recently the NCDR reported the rate of emergency CABG at 0.4%.[244] Procedure-related indications for CABG in 1 large series included coronary dissection (27%), acute artery closure (16%), perforation (8%), and failure to cross the lesion (8%).[245] The strongest predictors of the need for emergency CABG in several analyses are cardiogenic shock (OR: 11.4), acute MI or emergency PCI (OR: 3.2 to 3.8), multivessel disease (OR: 2.3 to 2.4), and type C lesion (OR: 2.6).[243,245] In-hospital mortality for emergency CABG ranges from 7.8% to 14%.[243,245,246]

In a contemporary analysis from the NCDR, the incidence of PCI-related stroke was 0.22%.[247] In-hospital mortality in patients with PCI-related stroke is 25% to 30%.[247,248] Factors associated with an increased risk of stroke include fibrinolytic therapy administered before PCI (OR: 4.7), known cerebrovascular disease (OR: 2.20), STEMI as the indication for PCI (OR: 3.2), use of an intra-aortic balloon pump (IABP) (OR: 2.6), older age (OR: 1.17 per 5-year increase), and female sex.[247–249] Initial imaging after a stroke in 1 small series revealed hemorrhagic etiology in 18%, ischemic etiology in 58%, and no clear etiology in 24%.[248] One potential algorithm for the treatment of catheterization-related stroke has been recently proposed.[250] This document includes no specific recommendations for the management of PCI-related stroke but refers the reader to the AHA/American Stroke Association guidelines for the management of adults with stroke.[251]

Vascular complications from PCI are primarily related to vascular access. Important femoral vascular complications include access site hematoma, retroperitoneal hematoma, pseudoaneurysm, arteriovenous fistula, and arterial dissection and/or occlusion.[252] The incidence of these vascular complications in various reports generally ranges from 2% to 6% and has decreased with time.[249,253–257] Factors associated with an increased risk of vascular complication include age ≥70 years, body surface area <1.6 m^2, emergency procedures, peripheral artery disease, periprocedural use of glycoprotein (GP) IIb/IIIa inhibitors, and female sex (if not corrected for body surface area).[249,253,254,257,258] Ultrasound guidance has been used for femoral artery access to potentially decrease complications.[259] As discussed in Section 5.11, vascular closure devices have not been clearly demonstrated to decrease vascular complication rates. Radial site access decreases the rate of access-related bleeding and complications compared with femoral access.[255,260] Loss of the radial pulse has been reported in ≤5% of radial procedures.[261] Infrequent to rare complications occurring with the radial artery approach include compartment syndrome, pseudoaneurysm (<0.01%), and sterile abscess (occurring with previous-generation hydrophilic sheaths).[262] Radial artery spasm may occur and treatment at times may be challenging.

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Table 4. Summary of Recommendations for Preprocedural Considerations and Interventions in Patients Undergoing PCI

Recommendations	COR	LOE	References
Contrast-induced AKI			
Patients should be assessed for risk of contrast-induced AKI before PCI.	I	C	270,271
Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.	I	B	272–275
In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized.	I	B	276–278
Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI.	III: No Benefit	A	279–283
Anaphylactoid reactions			
Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate prophylaxis before repeat contrast administration.	I	B	252,284–286
In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial.	III: No Benefit	C	287–289
Statins			
Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.	IIa	B: Chronic statin therapy	290–296 297
Bleeding risk			
All patients should be evaluated for risk of bleeding before PCI.	I	C	N/A
CKD			
In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted.	I	B	298–300
Aspirin			
Patients already on daily aspirin therapy should take 81 mg to 325 mg before PCI.	I	B	301–304
Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI.	I	B	301,303,304

AKI indicates acute kidney injury; CKD, chronic kidney disease; COR, class of recommendation; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; and PCI, percutaneous coronary intervention.

Local hematomas may occur from small-branch vessel hydrophilic wire perforation or inexperience with wristband use.

The risk of coronary perforation is approximately 0.2%, most commonly by wire perforation during PCI for CTO or by ablative or oversized devices during PCI of heavily diseased or tortuous coronary arteries.[263] The risk of tamponade and management of the perforation varies with the type of perforation.[264]

Periprocedural bleeding is now recognized to be associated with subsequent mortality,[265,266] and the avoidance of bleeding complications has become an important consideration in performing PCI. The risk of bleeding is associated with patient factors (eg, advanced age, low body mass index, CKD, baseline anemia), as well as the degree of platelet and thrombin inhibition, vascular access site, and sheath size.[267–269] Issues of periprocedural bleeding are discussed in Section 4.7.

The incidence of contrast-induced acute kidney injury (AKI) or "contrast nephropathy" in published reports depends on the definition of contrast nephropathy used and the frequency of risk factors for contrast-induced AKI in the patient population studied. Important risk factors for contrast-induced AKI include advanced age, CKD, congestive heart failure, diabetes, and the volume of contrast administered. Contrast-induced AKI and strategies to prevent it are discussed in Section 4.4.

4. Preprocedural Considerations

Table 4 contains recommendations for preprocedural considerations and interventions in patients undergoing PCI.

4.1. Cardiac Catheterization Laboratory Requirements

4.1.1. Equipment

Defibrillators are considered by The Joint Commission to be life-support equipment requiring routine assessment and completion of appropriate logs. Many hospitals require periodic inspection of consoles for ancillary devices used in coronary intervention (eg, Doppler wires, pressure-tipped sensor wires, and IVUS catheters). Point-of-care testing devices (eg, activated clotting time and arterial blood gas machines) require routine calibration. Duration of storage of digital cine images is often mandated by law. Operating parameters for x-ray imaging equipment are adjusted at installation and periodically assessed by a qualified physicist in cooperation with the equipment manufacturer. Familiarity with radiation dose–reducing features of catheterization laboratory equipment and assistance from a qualified physicist are important for radiation dose minimization and image optimization.

4.1.2. Staffing

An interventional cardiologist must be present in the laboratory for the duration of each procedure and is responsible for

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procedure outcome. Nursing and technical personnel are also required to be present in the catheterization laboratory, with specific staffing dependent on state requirements and laboratory caseload and mix. Catheterization laboratory technical staff may include nurse practitioners, registered nurses, licensed vocational or practical nurses, physician assistants, nursing assistants, radiology technicians, or catheterization laboratory technicians. All catheterization laboratory staff are usually certified in basic life support, advanced cardiovascular life support, and, where appropriate, pediatric advanced life support. Catheterization laboratory personnel have a nursing degree/certification or invasive cardiovascular credentials such as registered cardiovascular invasive specialist or American Society of Radiation technologists.[305]

4.1.3. 'Time-Out' Procedures

In 2003, The Joint Commission mandated a universal protocol requiring proper preoperative identification of the patient by the members of the catheterization laboratory team, marking of the operative site, and a final time-out just before the procedure.[306] Although initially intended to prevent wrong-site surgery, this has been expanded to include all invasive procedures despite limited scientific evidence of its effectiveness.[307] The intent of the time-out is for all members of the team to improve patient care by collectively discussing the case. The content of a time-out includes confirmation of the correct patient, correct side and site, agreement on the procedure to be performed, correct patient position, and availability of needed equipment, supplies, and implants. The timeout may be checklist driven or conversational, depending on laboratory preferences.[308] The writing committee strongly endorses the practice of conducting a time-out before all PCI procedures.

4.2. Ethical Aspects

The 3 principles of medical ethics are beneficence, autonomy, and justice. Beneficence involves the physician's duty to act in the best interests of the patient and avoid maleficence, or harm (*primum non nocere*). Autonomy describes the physician's duty to help the patient maintain control over his or her medical treatments. Justice describes the physician's duty to treat the individual patient responsibly with due consideration of other patients and stakeholders in the healthcare system. Ethical considerations specific to PCI have been previously discussed[309] and are highlighted below:

- Place the patient's best interest first and foremost when making clinical decisions (beneficence).
- Ensure that patients actively participate in decisions affecting their care (autonomy).
- Consider how decisions regarding one patient may also affect other patients and providers (justice).
- Plan and perform procedures and provide care with the intention of improving the patient's quality of life and/or decreasing the risk of mortality, independent of reimbursement considerations and without inappropriate bias or influence from industry, administrators, referring physicians, or other sources.
- Before performing procedures, obtain informed con sent after giving an explanation regarding the details of the procedure and the risks and benefits of both the procedure and alternatives to the procedure.
- Plan and perform procedures according to standards of care and recommended guidelines, and deviate from them when appropriate or necessary in the care of individual patients.
- Seek advice, assistance, or consultation from colleagues when such consultation would benefit the patient.

4.2.1. Informed Consent

Obtaining informed consent for procedures is a legal and ethical necessity. Ideally, informed consent is obtained long enough before the procedure that the patient can fully consider informed consent issues and discuss them with family or other providers, avoiding any sense of coercion. Ad hoc PCI, or PCI immediately following diagnostic procedures, presents special problems. When informed consent for PCI is obtained before diagnostic catheterization is performed, it is impossible to predict the levels of risk and benefit from an ad hoc PCI.[310,311] If diagnostic catheterization reveals anatomy that poses a particularly high risk or for which the superiority of PCI compared with other strategies is unclear, the precatheterization informed consent discussion may be inadequate. In such cases, deferral of PCI until additional informed consent discussions and/or consultations occur may be appropriate, even though it inconveniences the patient and the healthcare system. It is the responsibility of the interventionalist to act in the patient's best interest in these circumstances.

Informed consent before emergency procedures is particularly difficult.[312–314] The patient presenting with STEMI is usually in distress and often sedated, making true informed consent impossible. Rapid triage, transport, and treatment of STEMI patients create a pressured atmosphere that by necessity limits a prolonged and detailed informed consent process. Nevertheless, the interventionist must attempt to provide information about the risks and benefits of different strategies to the patient and family and balance the benefit of thorough discussion with the benefits of rapid intervention.

4.2.2. Potential Conflicts of Interest

Decisions about the performance and timing of PCI may pose additional ethical dilemmas. When considering whether to perform multivessel PCI in 1 stage versus 2 stages, safety and convenience for the patient must guide the decision, regardless of payment policies that maximize reimbursement when PCI is staged.[311] A separate issue is self-referral, through which diagnostic catheterization often leads seamlessly to PCI by the same operator.[315] The interventionist has an ethical obligation to the patient to consider all treatment options, consult with additional specialists (eg, cardiac surgeons) when their input would be helpful to the patient, avoid unnecessary interventional procedures, and allow the patient to consult family members and other physicians.[311]

4.3. Radiation Safety: Recommendation

Class I

1. **Cardiac catheterization laboratories should routinely record relevant available patient procedural**

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radiation dose data (eg, total air kerma at the international reference point [$K_{a,r}$], air kerma air product [P_{KA}], fluoroscopy time, number of cine images), and should define thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose. ***(Level of Evidence: C)***

The issue of radiation exposure during imaging procedures has received increased attention, and the writing committee believes that radiation safety should be addressed in this guideline. Current standards for cardiac catheterization laboratories include the following:

- Specific procedures and policies are in place to mini mize patient (and operator) risk.
- A radiation safety officer coordinates all radiation safety issues and works conjointly with the medical or health physicist.
- Patient radiation exposure is reduced to as low a level as reasonably can be achieved.
- Patients at increased risk for high procedural radiation exposure are identified.
- Informed consent includes radiation safety informa tion, particularly for the high-risk patient.

A basic primer on the physics of x-ray imaging, essential to the safe practice of radiation dose management, has been published in an ACCF/AHA/Heart Rhythm Society/SCAI clinical competence statement.[316] Appendix 4C summarizes strategies to minimize patient and operator radiation exposure. Adverse radiation effects are now well recognized as infrequent but potentially serious complications of prolonged interventional procedures.[317] Fluoroscopic time does not include cine acquisition imaging and is therefore not an accurate measure of patient radiation dose. Total air kerma at the interventional reference point ($K_{a,r}$, in G_y) and air kerma area product (P_{KA}, in $Gycm^2$) are required to be reported on interventional x-ray systems since 2006. These are useful in the assessment of potential tissue adverse effects or long-term radiation sequelae, respectively, and it is reasonable to include them in the catheterization record at the conclusion of each procedure. Appendix 4D summarizes considerations for patient follow-up based on radiation dose during the procedure.[317]

4.4. Contrast-Induced AKI: Recommendations

Class I

1. **Patients should be assessed for risk of contrast-induced AKI before PCI.**[270,271] ***(Level of Evidence: C)***
2. **Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.**[272–275] ***(Level of Evidence: B)***
3. **In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized.**[276–278] ***(Level of Evidence: B)***

Class III: NO BENEFIT

1. **Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI.**[279–283] ***(Level of Evidence: A)***

See Online Data Supplements 16 to 18 for additional data regarding contrast-induced AKI.

Contrast-induced AKI or "contrast nephropathy" is one of the leading causes of hospital-acquired AKI. Major risk factors for contrast-induced AKI include advanced age, CKD, congestive heart failure, diabetes, and the volume of contrast administered. A risk-scoring system is available to predict the risk of contrast nephropathy using these risk factors and additional variables.[270] Thus far, the only strategies clearly shown to reduce the risk of contrast-induced AKI are hydration and minimizing the amount of contrast media. Other than saline hydration, measures that were believed to reduce the risk of contrast-induced AKI have been found to be neutral, to have deleterious effects, or to be characterized by heterogeneous and conflicting data.

Studies of hydration to reduce the risk of contrast-induced AKI suggest that isotonic saline is preferable to half isotonic saline, intravenous (IV) hydration is preferable to oral hydration, hydration for hours before and after exposure to contrast media is preferable to a bolus administration of saline immediately before or during contrast media exposure, and administration of isotonic saline alone is preferable to administration of isotonic saline plus mannitol or furosemide.[272–275,320] On the basis of these studies, a reasonable hydration regimen would be isotonic crystalloid (1.0 to 1.5 mL/kg per hour) for 3 to 12 hours before the procedure and continuing for 6 to 24 hours after the procedure.[272–275,284,320,321]

Prior studies of N-acetyl-L-cysteine and sodium bicarbonate have produced conflicting results. Some, often small, earlier studies suggested benefit, but many other more contemporary studies and meta-analyses found no clear evidence of benefit, and there are potential issues of publication bias and poor methodology issues in several analyses.[279–282,322–332] The recently completed largest randomized study on N-acetyl-L-cysteine and contrast nephropathy in patients undergoing angiographic procedures, ACT (Acetylcysteine for Contrast-Induced Nephropathy Trial), demonstrated no benefit in primary or secondary endpoints. An updated meta-analysis using only high-quality trials similarly demonstrated no benefit.[283] Taken as a whole, these studies do not support any recommendation for the use of N-acetyl-L-cysteine, they do, however, provide sufficient data to conclude that N-acetyl-L-cysteine does not prevent contrast-induced AKI in patients undergoing angiographic procedures.

The correlation between the volume of contrast media and the risk of contrast-induced AKI has been documented in several studies.[276,277] Thus, minimization of contrast media volume is important to prevent contrast-induced AKI in patients undergoing angiography. The volume of contrast already administered during diagnostic catheterization is an important factor when considering possible "ad hoc" PCI.

Comparative studies of different contrast media (eg, low-osmolar versus iso-osmolar, one agent versus another agent) have produced variable and sometimes contradictory re-

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sults.[334–339] Thus, current data are insufficient to justify specific recommendations about low- and isoosmolar contrast media. This issue is discussed in detail in the 2011 UA/NSTEMI focused update.[340] For a further discussion of contrast media and PCI, the reader is referred to a position statement by the SCAI.[284]

4.5. Anaphylactoid Reactions: Recommendations

Class I

1. **Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration.[252,284–286]** ***(Level of Evidence: B)***

Class III: NO BENEFIT

1. **In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial.[287–289]** ***(Level of Evidence: C)***

The incidence of anaphylactoid reactions to contrast media is ≤1%, and the incidence of severe reactions may be as low as 0.04%.[284] Limited data suggest that in patients with a history of prior anaphylactoid reaction, the recurrence rate without prophylaxis is in the range of 16% to 44%.[341] Adequate pretreatment of patients with prior anaphylactoid reactions reduces the recurrence rate to close to zero.[284–286] A regimen of 50 mg of prednisone administered 13 hours, 7 hours, and 1 hour before the procedure (as well as 50 mg of diphenhydramine 1 hour before the procedure) has been shown to reduce the risk of recurrent anaphylactoid reaction.[286] In practice, a regimen of 60 mg of prednisone the night before and morning of the procedure (as well as 50 mg of diphenhydramine 1 hour before the procedure) is often used.[252] There are minimal data on the "pretreatment" of patients undergoing emergency PCI.[342] One group has suggested IV steroids (eg, 80 mg to 125 mg of methylprednisolone, 100 mg of hydrocortisone sodium succinate), as well as oral or IV diphenhydramine and possible IV cimetidine.[284] For a more detailed discussion of issues related to contrast-induced anaphylactoid reactions, the reader is referred to several dedicated discussions on contrast agents.[284,341]

There are no data to suggest that those patients with seafood or shellfish allergies are at risk for an anaphylactoid reaction from exposure to contrast media. Iodine does not mediate seafood, shellfish, or contrast media reactions. The common misconception that seafood allergies and contrast reactions are cross-reactions to iodine probably arose from a survey published in 1975 in which 15% of patients with a history of contrast reaction reported a personal history of shellfish allergy, but nearly identical proportions of patients reported allergies to other foods, such as milk and egg, in the same survey.[287] Pretreatment of patients with steroids based only on a history of seafood or shellfish allergy has a small but non-zero risk of adverse effect (eg, hyperglycemia in a patient with diabetes) without any demonstrated benefit.[288,289]

4.6. Statin Treatment: Recommendation

Class IIa

1. **Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.** ***(Level of Evidence: A for statin-naïve patients[290–296]; (Level of Evidence: B for those on chronic statin therapy[297])***

See Online Data Supplement 19 for additional data regarding preprocedural statin treatment.

Statins have long-term benefits in patients with CAD[343,344] and ACS.[345,346] The benefits of statins in ACS begin early, before substantial lipid lowering has occurred,[345,347] suggesting pleiotropic effects of statins. These might include anti-inflammatory effects, improvement of endothelial function, decrease of oxidative stress, or inhibition of thrombogenic responses.[348] Statins were beneficial when pretreatment was started from 7 days to just before PCI.[290–297]

4.7. Bleeding Risk: Recommendation

Class I

1. **All patients should be evaluated for risk of bleeding before PCI.** ***(Level of Evidence: C)***

Periprocedural bleeding is now recognized as a major risk factor for subsequent mortality.[265,266] Bleeding may lead to mortality directly (because of the bleeding event) or through ischemic complications that occur when antiplatelet or anticoagulant agents are withdrawn in response to the bleeding. Bleeding may also be a marker of comorbidities associated with worse prognosis (eg, occult cancer). The risk of bleeding is associated with a number of patient factors (eg, advanced age, low body mass index, CKD, baseline anemia), as well as the degree of platelet and thrombin inhibition, vascular access site, and sheath size.[267–269] The overall approach to PCI should be individualized to minimize both ischemic and bleeding risks.

Measures to minimize the risks of bleeding complications are discussed in several sections of this guideline. These include use of anticoagulation regimens associated with a lower risk of bleeding, weight-based dosing of heparin and other agents, use of activated clotting times to guide unfractionated heparin (UFH) dosing, avoidance of excess anticoagulation,[349] dosing adjustments in patients with CKD (eg, eptifibatide, tirofiban, bivalirudin),[350] use of radial artery access site,[255] and avoidance of femoral vein cannulation when possible. Vascular closure devices have not been clearly demonstrated to decrease bleeding complications and are discussed in detail in Section 5.11.

4.8. PCI in Hospitals Without On-Site Surgical Backup: Recommendations

Class IIa

1. **Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished.[351,352]** ***(Level of Evidence: B)***

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Class IIb

1. **Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.[352–354] *(Level of Evidence: B)***

Class III: HARM

1. **Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. *(Level of Evidence: C)***

See Online Data Supplement 20 for additional data regarding hospitals without on-site surgical backup.

Primary and elective PCI can be performed at hospitals without on-site cardiac surgical backup with a high success rate, low in-hospital mortality rate, and low rate for emergency CABG.[351,353,354] The best outcomes for patients with STEMI are achieved at hospitals with 24/7 access to primary PCI.[355] Criteria for the performance of PCI without on-site surgical backup have been proposed in an SCAI expert consensus document.[352] Consideration of elective PCI without on-site cardiac surgical backup is thought to be appropriate only when performed by experienced operators with complication rates and outcomes equivalent or superior to national benchmarks. Accurate assessment of complication rates and patient outcomes via a regional or national data registry, so that outcomes can be compared with established benchmarks, is an important quality control component of any PCI program. Desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery. It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

Tables 5 and 6 list the SCAI expert consensus document requirements for PCI programs without on-site surgical backup. Table 7 gives the requirements for primary PCI and emergency CABG at hospitals without on-site cardiac surgery, and Table 8 lists the requirements for patient and lesion selection and backup strategy for nonemergency PCI.[352]

Table 5. SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.
On-call schedule with operation of laboratory 24 h/d, 365 d/y.*
Experienced coronary care unit nursing staff comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, and management of IABP. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (eg, respiratory care, blood bank).
Written agreements for emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of 2 times per year.
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and IABP equipment compatible with transport vehicles. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal.
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. Pressure wire device and IVUS equipment are optimal but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities because of the greater risk of perforation.
Meticulous clinical and angiographic selection criteria for PCI (Tables 6 and 7).
Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked, and <90 min outlier cases should be carefully reviewed for process improvement opportunities.
On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.
Participation in a national data registry where available, such as the ACC NCDR in the United States.

*Required for US facilities but may not be possible for all facilities worldwide.

ACC indicates American College of Cardiology; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; NCDR, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-elevation myocardial infarction.

Adapted with permission from Dehmer et al.[352]

5. Procedural Considerations

5.1. Vascular Access: Recommendation

Class IIa

1. **The use of radial artery access can be useful to decrease access site complications.[255,260,356–362] *(Level of Evidence: A)***

See Online Data Supplement 21 for additional data regarding radial access.

Femoral artery access remains the most commonly used approach in patients undergoing PCI in the United States. Choosing a femoral artery puncture site is facilitated by fluoroscopic landmark identification or ultrasound guidance. Low punctures have a high incidence of peripheral artery complications, whereas high punctures have an increased risk of retroperitoneal hemorrhage. In patients with a synthetic graft, arterial access is possible after the graft is a few months old and complication rates are not increased.[254]

Radial site access is used frequently in Europe and Canada but not in the United States.[260] A learning curve exists for the radial approach that will affect procedure time and radiation dose, with a trend toward lower procedural success rates for radial versus femoral access.[255] However, compared with femoral access, radial access decreases the rate of access-

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Table 6. SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup

1. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
3. Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.
4. Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request, and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at this time.
5. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse transfer agreement.
7. Transferring and receiving facilities establish a rigorous protocol for rapid transfer of patients, including the proper personnel with appropriate experience.
8. A transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
10. Initial informed consent for PCI discloses that the procedure is being done without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery (approximately 0.3%) and state that a written plan for transfer exists.
11. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

IABP indicates intra-aortic balloon pump; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.
Adapted with permission from Dehmer et al.[352]

Table 7. SCAI Expert Consensus Document Requirements for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in patients with

- >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired
- Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography
- Lesions in other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms)
- Lesions with TIMI flow grade 3 that are not amenable to stenting in patients with left main or 3-vessel disease that will require coronary bypass surgery
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention

Transfer emergently for coronary bypass surgery patients with

- High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support
- Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer

IABP indicates intra-aortic balloon pump; LV, left ventricular; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis in Myocardial Infarction.
Adapted with permission from Dehmer et al.[352]

related bleeding and complications.[255,260,363] In a recent large RCT comparing radial and femoral access in patients with ACS undergoing PCI, there was no difference in the primary composite endpoint (death, MI, stroke, major bleeding), although there was a lower rate of vascular complications with the use of radial access.[362] Radial artery access is particularly appealing in patients with coagulopathy, elevated international normalized ratio due to warfarin, or morbid obesity.

5.2. PCI in Specific Clinical Situations

5.2.1. UA/NSTEMI: Recommendations

Class I

1. **An early invasive strategy (ie, diagnostic angiography with intent to perform revascularization) is indicated in UA/NSTEMI patients who have refractory angina or hemodynamic or electrical instability (without serious comorbidities or contraindications to such procedures).[207,364,365] *(Level of Evidence: B)***
2. **An early invasive strategy (ie, diagnostic angiography with intent to perform revascularization) is indicated in initially stabilized UA/NSTEMI patients (without serious comorbidities or contraindications to such procedures) who have an elevated risk for clinical events.[207,365–367] *(Level of Evidence: A)***
3. **The selection of PCI or CABG as the means of revascularization in the patient with ACS should generally be based on the same considerations as those without ACS.[53,156,207,368] *(Level of Evidence: B)***

Class III: NO BENEFIT

1. **An early invasive strategy (ie, diagnostic angiography with intent to perform revascularization) is not recommended in patients with extensive comorbidities (eg, liver or pulmonary failure, cancer) in whom *(Level of Evidence: C)***
   a. **The risks of revascularization and comorbid conditions are likely to outweigh the benefits of revascularization,**
   b. **There is a low likelihood of ACS despite acute chest pain, or**
   c. **Consent to revascularization will not be granted regardless of the findings.**

The goals of coronary angiography and revascularization in UA/NSTEMI patients are to reduce the risk of death and MI and provide symptom relief. To improve prognosis, early risk stratification is essential for selection of medical and/or invasive treatment strategies. Indications for revascularization depend on the patient's clinical risk characteristics and coronary anatomy and are in general stronger in the presence of high-risk clinical presentation (eg, dynamic electrocardio-

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Table 8. SCAI Expert Consensus Document Requirements for Patient and Lesion Selection and Backup Strategy for Nonemergency PCI by Experienced Operators at Hospitals Without On-Site Cardiac Surgery

Patient risk: expected clinical risk in case of occlusion caused by procedure

High patient risk: Patients with any of the following

- Decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders
- LVEF <25%
- Left main stenosis (≥50% diameter) or 3-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries)
- Single-target lesion that jeopardizes >50% of remaining viable myocardium

Lesion risk: probability that procedure will cause acute vessel occlusion

Increased lesion risk: lesions in open vessels with any of the following characteristics

- Diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments
- More than moderate calcification of a stenosis or proximal segment
- Location in an extremely angulated segment (>90%)
- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- Substantial thrombus in the vessel or at the lesion site
- Any other feature that may, in the operator's judgment, impede successful stent deployment

Aggressive measures to open CTOs are also discouraged because of an increased risk of perforation

Strategy for surgical backup based on lesion and patient risk

- High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.
- High-risk patients with non–high-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.
- Non–high-risk patients with high-risk lesions require no additional precautions.
- Non–high-risk patients with non–high-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.

CTO indicates chronic total occlusion; CVA, cerebrovascular accident; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

Adapted with permission from Dehmer et al.[352]

gram [ECG] changes, elevated troponin, high Global Registry of Acute Coronary Events score), recurrent symptoms, threatened viable myocardium, CKD, and larger ischemic burden (Appendix 4E). For choice of revascularization technique, the anatomical considerations are generally those used for stable CAD, although PCI may initially be performed in the index lesion to stabilize the patient (Section 2).

Contemporary studies variably comparing strategies of very early (within hours of admission), early (within 24 hours of admission), and delayed (1 to 7 days after admission) cardiac catheterization and revascularization support a strategy of *early* angiography and revascularization to reduce the risk of recurrent ischemia and MI, particularly among those at high risk (eg, Global Registry of Acute Coronary Events score >140),[367,369,370] whereas a delayed approach is reasonable in low-intermediate risk patients (based on clinical course). There is no evidence that incremental benefit is derived by angiography and PCI performed within the first few hours of hospital admission.[207,367,371–378]

5.2.2. ST-Elevation Myocardial Infarction

5.2.2.1. Coronary Angiography Strategies in STEMI: Recommendations

Class I

1. **A strategy of immediate coronary angiography with intent to perform PCI (or emergency CABG) in patients with STEMI is recommended for**
   a. **Patients who are candidates for primary PCI.[351,379–382] *(Level of Evidence: A)***
   b. **Patients with severe heart failure or cardiogenic shock who are suitable candidates for revascularization.[383,384] *(Level of Evidence: B)***

Class IIa

1. **A strategy of immediate coronary angiography (or transfer for immediate coronary angiography) with intent to perform PCI is reasonable for patients with STEMI, a moderate to large area of myocardium at risk, and evidence of failed fibrinolysis.[385,386] *(Level of Evidence: B)***
2. **A strategy of coronary angiography (or transfer for coronary angiography) 3 to 24 hours after initiating fibrinolytic therapy with intent to perform PCI is reasonable for hemodynamically stable patients with STEMI and evidence for successful fibrinolysis when angiography and revascularization can be performed as soon as logistically feasible in this time frame.[387–391] *(Level of Evidence: A)***

Class IIb

1. **A strategy of coronary angiography performed before hospital discharge might be reasonable in stable patients with STEMI who did not undergo cardiac catheterization within 24 hours of STEMI onset. *(Level of Evidence: C)***

Class III: NO BENEFIT

1. **A strategy of coronary angiography with intent to perform PCI is not recommended in patients with STEMI in whom the risks of revascularization are likely to outweigh the benefits or when the patient or designee does not want invasive care. *(Level of Evidence: C)***

The historical reperfusion strategies of "primary PCI," "immediate PCI," "rescue PCI," "deferred PCI," "facilitated PCI," and the "pharmacoinvasive strategy" have evolved in parallel with advances in antithrombotic therapy and STEMI prehospital and hospital systems of care. The clinical challenge in primary PCI is achieving rapid time to treatment and increasing patient access to this preferred reperfusion strategy. The clinical challenge in patients treated with fibrinolytic therapy is deciding for whom and when to perform coronary angiography.

In unstable patients (eg, severe heart failure or cardiogenic shock, hemodynamically compromising ventricular arrhyth-

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Table 9. Indications for Coronary Angiography in STEMI

Indications	COR	LOE	References
Immediate coronary angiography			
Candidate for primary PCI	I	A	351,379–382
Severe heart failure or cardiogenic shock (if suitable revascularization candidate)	I	B	383,384
Moderate to large area of myocardium at risk and evidence of failed fibrinolysis	IIa	B	385,386
Coronary angiography 3 to 24 h after fibrinolysis			
Hemodynamically stable patients with evidence for successful fibrinolysis	IIa	A	387–391
Coronary angiography before hospital discharge			
Stable patients	IIb	C	N/A
Coronary angiography at any time			
Patients in whom the risks of revascularization are likely to outweigh the benefits or the patient or designee does not want invasive care	III: No Benefit	C	N/A

COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

mias) not treated initially with primary PCI, a strategy of immediate coronary angiography with intent to perform PCI is implemented unless invasive management is considered futile or unsuitable given the clinical circumstances.[383,384]

In stable patients treated with fibrinolytic therapy and clinical suspicion of reperfusion failure, a strategy of immediate coronary angiography followed by PCI improves outcome in those at high risk.[385,386] Such a strategy is also implemented in patients with evidence for infarct artery reocclusion (Table 9). The clinical diagnosis of failed fibrinolysis is difficult but is best made when there is <50% ST-segment resolution 90 minutes after initiation of therapy in the lead showing the greatest degree of ST-segment elevation at presentation. Given the association between bleeding events and adverse cardiac events, a reasonable approach is to select moderate- and high-risk patients for PCI and treat low-risk patients with medical therapy. ECG and clinical findings of anterior MI or inferior MI with right ventricular involvement or precordial ST-segment depression, as well as ongoing pain, usually predicts increased risk and the greatest potential benefit.[392] Conversely, patients with symptom resolution, improving ST-segment elevation, or inferior MI localized to 3 ECG leads probably gain little benefit.

In stable patients treated with fibrinolytic therapy and clinical evidence for successful reperfusion, an early invasive strategy with cardiac catheterization performed within 24 hours decreases reinfarction and recurrent ischemic events.[388,390,391] Because of the associated increased bleeding risk, very early (<2 to 3 hours) catheterization after administration of fibrinolytic therapy with intent to perform revascularization should be reserved for patients with evidence of failed fibrinolysis and significant myocardial jeopardy for whom immediate angiography and revascularization would be appropriate.[393]

5.2.2.2. Primary PCI of the Infarct Artery: Recommendations

Class I

1. **Primary PCI should be performed in patients within 12 hours of onset of STEMI.[379–382] *(Level of Evidence: A)***
2. **Primary PCI should be performed in patients with STEMI presenting to a hospital with PCI capability within 90 minutes of first medical contact as a systems goal.[394,395] *(Level of Evidence: B)***
3. **Primary PCI should be performed in patients with STEMI presenting to a hospital without PCI capability within 120 minutes of first medical contact as a systems goal.[396–398] *(Level of Evidence: B)***
4. **Primary PCI should be performed in patients with STEMI who develop severe heart failure or cardiogenic shock and are suitable candidates for revascularization as soon as possible, irrespective of time delay.[383,384] *(Level of Evidence: B)***
5. **Primary PCI should be performed as soon as possible in patients with STEMI and contraindications to fibrinolytic therapy with ischemic symptoms for less than 12 hours.[399,400] *(Level of Evidence: B)***

Class IIa

1. **Primary PCI is reasonable in patients with STEMI if there is clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 hours after symptom onset.[401–403] *(Level of Evidence: B)***

Class IIb

1. **Primary PCI might be considered in asymptomatic patients with STEMI and higher risk presenting between 12 and 24 hours after symptom onset. *(Level of Evidence: C)***

Class III: HARM

1. **PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI without hemodynamic compromise.[404–408] *(Level of Evidence: B)***

Primary PCI is preferred to fibrinolytic therapy when time-to-treatment delays are short and the patient presents to a high-volume, well-equipped center staffed with expert interventional cardiologists and skilled support staff. Compared with fibrinolytic therapy in RCTs, primary PCI produces higher rates for infarct artery patency, TIMI flow grade 3, and

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Table 10. Indications for PCI in STEMI

Indications	COR	LOE	References
Primary PCI*			
STEMI symptoms within 12 h	I	A	379–382
Severe heart failure or cardiogenic shock	I	B	383,384
Contraindications to fibrinolytic therapy with ischemic symptoms <12 h	I	B	399,400
Clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 h after symptom onset	IIa	B	401–403
Asymptomatic patients presenting between 12 and 24 h after symptom onset and higher risk	IIb	C	N/A
Noninfarct artery PCI at the time of primary PCI in patients without hemodynamic compromise	III: Harm	B	404–408
Delayed or elective PCI in patients with STEMI			
Clinical evidence for fibrinolytic failure or infarct artery reocclusion	IIa	B	385,386
Patent infarct artery 3 to 24 h after fibrinolytic therapy	IIa	B	390,391
Ischemia on noninvasive testing	IIa	B	410,411
Hemodynamically significant stenosis in a patent infarct artery >24 h after STEMI	IIb	B	413–417
Totally occluded infarct artery >24 h after STEMI in a hemodynamically stable asymptomatic patient without evidence of severe ischemia	III: No Benefit	B	418–420

*Systems goal of performing primary PCI within 90 min of first medical contact when the patient presents to a hospital with PCI capability[394,395] (*Class I; LOE: B*) and within 120 min when the patient presents to a hospital without PCI capability[396–398] (*Class I; LOE: B*).

COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

lower rates for recurrent ischemia, reinfarction, emergency repeat revascularization procedures, intracranial hemorrhage, and death.[379] Early, successful PCI also greatly decreases the complications of STEMI that result from longer ischemic times or unsuccessful fibrinolytic therapy, allowing earlier hospital discharge and resumption of daily activities. The greatest mortality benefit of primary PCI is in high-risk patients. PCI outcomes may not be as successful with prolonged time-to-treatment or low-volume hospitals and operators (Table 10).

Several reports have shown excellent outcomes for patients with STEMI undergoing interhospital transfer where first medical contact–to-door balloon time modestly exceeded the systematic goal of <90 minutes.[396–398,409] In these reports, the referring hospital and the receiving hospital established a transfer protocol that minimized transfer delays, and outcomes were similar to those of direct-admission patients. On the basis of these results, the PCI and STEMI guideline writing committees have modified the first medical contact–to-device time goal from 90 minutes to 120 minutes for interhospital transfer patients,[397] while emphasizing that systems should continue to strive for times ≤90 minutes. Hospitals that cannot meet these criteria should use fibrinolytic therapy as their primary reperfusion strategy.

PCI of a noninfarct artery at the time of primary PCI in stable patients is associated with worse clinical outcomes unless the patient is in cardiogenic shock where PCI of a severe stenosis in a coronary artery supplying a large territory of myocardium might improve hemodynamic stability.[404,406,408] Delayed PCI can be performed in noninfarct arteries at a later time if clinically indicated.[410–412]

5.2.2.3. Delayed or Elective PCI in Patients With STEMI: Recommendations

Class IIa

1. **PCI is reasonable in patients with STEMI and clinical evidence for fibrinolytic failure or infarct artery reocclusion.[385,386] *(Level of Evidence: B)***
2. **PCI is reasonable in patients with STEMI and a patent infarct artery 3 to 24 hours after fibrinolytic therapy.[390,391] *(Level of Evidence: B)***
3. **PCI is reasonable in patients with STEMI who demonstrate ischemia on noninvasive testing.[410,411] *(Level of Evidence: B)***

Class IIb

1. **PCI of a hemodynamically significant stenosis in a patent infarct artery greater than 24 hours after STEMI may be considered as part of an invasive strategy.[413–417] *(Level of Evidence: B)***

Class III: NO BENEFIT

1. **PCI of a totally occluded infarct artery greater than 24 hours after STEMI should not be performed in asymptomatic patients with 1- or 2-vessel disease if patients are hemodynamically and electrically stable and do not have evidence of severe ischemia.[418–420] *(Level of Evidence: B)***

Studies and meta-analyses suggest potential benefit for PCI in fibrinolytic failure.[385,386] In stable patients treated with fibrinolytic therapy and clinical evidence for successful reperfusion, an early invasive strategy with cardiac catheterization performed within 24 hours decreases reinfarction and recurrent ischemic events.[388,390,391]

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PCI for a hemodynamically significant stenosis in a patent infarct artery >24 hours after STEMI as part of a revascularization strategy improves outcome.[410,411,413–417] PCI of an occluded infarct artery 1 to 28 days after MI in asymptomatic patients without evidence of myocardial ischemia has no incremental benefit beyond optimal medical therapy with aspirin, beta blockers, angiotensin-converting enzyme inhibitors, and statins in preserving LV function and preventing subsequent cardiovascular events.[418–420] It is important to note that elective PCI of an occluded infarct artery has not been studied in patients with New York Heart Association functional class III or IV heart failure, rest angina, serum creatinine >2.5 mg/dL, left main or 3-vessel CAD, clinical instability, or severe inducible ischemia on stress testing in an infarct zone that is not akinetic or dyskinetic.

5.2.3. Cardiogenic Shock: Recommendations

Class I

1. **PCI is recommended for patients with acute MI who develop cardiogenic shock and are suitable candidates.[384,421–423] *(Level of Evidence: B)***
2. **A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy.[384,424–427] *(Level of Evidence: B)***

See Online Data Supplement 22 for additional data regarding cardiogenic shock.

Cardiogenic shock is the leading cause of in-hospital mortality complicating STEMI. Revascularization is the only treatment proven to decrease mortality rates.[384,421–423] Although revascularization is almost always accomplished through PCI, selected patients with severe 3-vessel or left main disease can benefit from emergency CABG. Revascularization attempts may be futile and not indicated in cases of severe multiorgan failure.[427] Patient selection for revascularization is more important in the elderly, but several observational reports demonstrate acceptable outcomes in patients with few comorbidities and a reasonable potential for survival.[428–431] Patients who present to hospitals without PCI capability are usually emergently transported to a PCI center, because mortality without transfer is markedly elevated.[432]

5.2.3.1. Procedural Considerations for Cardiogenic Shock

Patients with cardiogenic shock should receive standard pharmacological therapies, including aspirin, a $P2Y_{12}$ receptor antagonist, and anticoagulation.[427,433] Inotropic and vasopressor therapy improves perfusion pressure. Historically, negative inotropes and vasodilators are avoided. IV GP IIb/IIIa inhibitors have been shown to provide benefit in observational studies but not in 1 small RCT.[433]

Endotracheal intubation and mechanical ventilation with positive end-expiratory pressure is usually necessary in patients with respiratory failure. Placement of a temporary pacemaker is indicated for patients with bradycardia or high-degree atrioventricular heart block. A pulmonary artery catheter can provide information to dose and titrate inotropes and pressors. Further hemodynamic support is available with IABP counterpulsation or percutaneous LV assist devices, although no data support a reduction in mortality rates.[434]

Contrast medium injections should be minimized. Orthogonal angiograms of the left coronary artery and a left anterior oblique angiogram of the right coronary artery are usually sufficient to identify the infarct artery.[435] Although most patients undergoing revascularization will receive a stent as part of the procedure, there are conflicting data on the impact of stenting over balloon angioplasty. Some studies reveal lower mortality rates,[436–438] whereas others reveal no benefit[439] or higher mortality rates.[440] There are no data comparing the choice of BMS versus DES in cardiogenic shock; however, BMS are often used because compliance with long-term DAPT is often unclear in the emergency setting.

In patients with multivessel disease, revascularization of the noninfarct artery may be necessary to maximize myocardial perfusion. Alternatively, in patients with multivessel disease and particularly left main disease, emergency CABG as a primary reperfusion strategy may be preferred.[50,441] Refractory cardiogenic shock unresponsive to revascularization may necessitate institution of more intensive cardiac support with a ventricular assist device or other hemodynamic support devices to allow for myocardial recovery or subsequent cardiac transplantation in suitable patients.

5.2.4. Revascularization Before Noncardiac Surgery: Recommendations

Class IIa

1. **For patients who require PCI and are scheduled for elective noncardiac surgery in the subsequent 12 months, a strategy of balloon angioplasty, or BMS implantation followed by 4 to 6 weeks of DAPT, is reasonable.[442–448] *(Level of Evidence: B)***
2. **For patients with DES who must undergo urgent surgical procedures that mandate the discontinuation of DAPT, it is reasonable to continue aspirin if possible and restart the $P2Y_{12}$ inhibitor as soon as possible in the immediate postoperative period.[444] *(Level of Evidence: C)***

Class III: HARM

1. **Routine prophylactic coronary revascularization should not be performed in patients with stable CAD before noncardiac surgery.[449,450] *(Level of Evidence: B)***
2. **Elective noncardiac surgery should not be performed in the 4 to 6 weeks after balloon angioplasty or BMS implantation or the 12 months after DES implantation in patients in whom the $P2Y_{12}$ inhibitor will need to be discontinued perioperatively.[208,447, 451,452] *(Level of Evidence: B)***

The 2007 and 2009 ACC/AHA Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery gave detailed recommendations for the evaluation of patients undergoing noncardiac surgery.[444] Patients with evidence of ACS should receive standard therapy, including early revascularization, to minimize the risk of adverse events. Patients with known significant left main or 3-vessel CAD who would otherwise benefit from revascularization in terms of survival

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or symptomatic relief also generally undergo revascularization before elective noncardiac surgery.

Two RCTs[449,450] found no benefit with routine preoperative revascularization before noncardiac surgery. Noncardiac surgery early after coronary stenting, particularly in the first 4 weeks, is associated with a high risk of stent thrombosis and death.[444,446,448] When emergency surgery is necessary, the patient should proceed to surgery without prior PCI. When surgery is required within 30 days and coronary revascularization is required before surgery, many clinicians perform balloon angioplasty alone to avoid the need for DAPT. In situations where preoperative revascularization is required and surgery can be deferred for at least 30 days, many clinicians use BMS and discontinue DAPT after 30 days. If surgery is elective and can be deferred for 1 year, most clinicians would consider DES to reduce the long-term risk of restenosis. A dilemma occurs when a patient has undergone PCI and then unexpectedly requires noncardiac surgery. Many patients can undergo surgery on DAPT, where the risk-benefit ratio will favor continued dual antiplatelet inhibition. If it is necessary to hold $P2Y_{12}$ inhibitor therapy, most clinicians will still continue aspirin uninterrupted during the perioperative period if the bleeding risk is not prohibitive. When the risk of delaying surgery or performing surgery while the patient is on DAPT exceeds the risk of stent thrombosis from stopping DAPT, the $P2Y_{12}$ inhibitor is stopped before surgery and resumed as soon as possible afterward. No $P2Y_{12}$ inhibitor "bridging" strategy (eg, GP IIb/IIIa inhibitor, antithrombin therapy) has been validated.

5.3. Coronary Stents: Recommendations

Class I

1. **Before implantation of DES, the interventional cardiologist should discuss with the patient the need for and duration of DAPT and the ability of the patient to comply with and tolerate DAPT.[212]** ***(Level of Evidence: C)***
2. **DES are useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged DAPT** ***(Level of Evidence: A for elective PCI[453,453a,454–456]; Level of Evidence: C for UA/NSTEMI[453]; Level of Evidence: A for STEMI[453,456–459]).***
3. **Balloon angioplasty or BMS should be used in patients with high bleeding risk, inability to comply with 12 months of DAPT, or anticipated invasive or surgical procedures within the next 12 months, during which time DAPT may be interrupted.[208,460–462]** ***(Level of Evidence: B)***

Class III: HARM

1. **PCI with coronary stenting should not be performed if the patient is not likely to be able to tolerate and comply with DAPT.[208–211]** ***(Level of Evidence: B)***
2. **DES should not be implanted if the patient is not likely to be able to tolerate and comply with prolonged DAPT or this cannot be determined before stent implantation.[208,460–462]** ***(Level of Evidence: B)***

Coronary stent implantation is commonly performed during PCI to prevent recoil, abrupt closure, and late restenosis.[463,464] BMS are composed of either stainless steel or cobalt chromium alloys. Because the risk of stent thrombosis is greatest within the first 30 days after implantation, the use of DAPT is required for 30 days after implantation of BMS.[208]

In the United States, 4 types of DES are currently approved: sirolimus-eluting stents, paclitaxel-eluting stents, zotarolimus-eluting stents, and everolimus-eluting stents. DES vary according to stent scaffold material and design, drug content, and the polymer used for drug elution; however, several common clinical features are present. First, sirolimus-eluting stents, paclitaxel-eluting stents, and zotarolimus-eluting stents have been demonstrated in RCTs to be associated with a reduced need for repeat revascularization and no increase in death or MI compared with BMS at 4 years' follow-up.[465] Everolimus-eluting stents have been demonstrated in RCTs to be associated with a lower need for repeat revascularization than paclitaxel-eluting stents, and, by inference, a lower risk for repeat revascularization than BMS,[466,467] with no increase in death or MI at 2-year follow-up.[468] Second, each of these stents is presumed to be associated with delayed healing based on pathologic studies and longer periods of risk for thrombosis compared with BMS and require longer duration of DAPT.[469] In the RCTs that led to the US Food and Drug Administration (FDA) approval of these stents, the recommended minimum duration of DAPT therapy was 3 to 6 months. Recently, the consensus of clinical practice has been 12 months of DAPT following DES implantation to avoid late (after 30 days) thrombosis,[208] based on observational studies of paclitaxel-eluting stents and sirolimus-eluting stents that indicate lower risk of late stent thrombosis with >6 months of therapy.[212] Extending DAPT beyond 1 year is considered reasonable by some practitioners based on observational data analysis,[212] but RCTs to determine whether longer DAPT is associated with reduction in stent thrombosis risk have not been completed. Finally, DES therapy is more expensive than BMS. Cost-effectiveness analysis has shown a reduction in total cost associated with DES because of avoidance of repeat procedures, yet it may be reasonable to consider use of BMS in patient subsets in which the risk of restenosis is low.[470]

This risk-benefit profile is most favorable for DES over BMS when the risk of restenosis with BMS is high (Table 11). Pooled and meta-analyses have demonstrated that in patients with diabetes, use of DES decreases the risk of restenosis compared with BMS.[471,472] DES may be more appealing for unprotected left main PCI, given the rate and clinical consequences of restenosis in this location.[473–475] The risk of stent thrombosis is higher in populations or lesion types excluded from RCTs of DES (eg, STEMI, smaller arteries [<2.5 mm diameter], longer lesions, bifurcations).[210,465] Importantly, these features also predict both stent thrombosis[476] and restenosis in BMS.[477] The greatest risk of stent thrombosis is within the first year, ranging from 0.7% to 2.0%, depending on patient and lesion complexity. Late stent thrombosis risk after 1 year with DES is observed at a rate of 0.2% to 0.4% per year.[210,478]

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Table 11. Clinical Situations Associated With DES or BMS Selection Preference

DES Generally Preferred Over BMS (Efficacy Considerations)	BMS Preferred Over DES (Safety Considerations)
• Left main disease	• Unable to tolerate or comply with DAPT
• Small vessels	• Anticipated surgery requiring discontinuation of DAPT within 12 mo
• In-stent restenosis	
• Bifurcations	
• Diabetes	• High risk of bleeding
• Long lesions	
• Multiple lesions	
• Saphenous vein grafts	

BMS indicates bare-mental stent(s); DAPT, dual antiplatelet therapy; and DES, drug-eluting stent(s).

Compared with balloon angioplasty, routine BMS implantation during primary PCI decreases risk for target-vessel revascularization and possibly reduces MI rates but does not reduce mortality rates.[479] More recent primary PCI studies and meta-analyses have demonstrated lower restenosis rates without increased risk of adverse stent outcome with DES compared with BMS. Although stent thrombosis rates in trials of STEMI are higher than in trials of elective PCI, the rates of stent thrombosis are not higher with DES compared with BMS in STEMI.[453,456–459]

The greatest risk for DES thrombosis is early discontinuation of DAPT.[208,460–462] It is therefore important to determine that the patient will likely be able to tolerate and comply with DAPT before implantation of DES. Therefore, DES should not be used in the presence of financial barriers to continuing prolonged DAPT, social barriers that may limit patient compliance, or medical issues involving bleeding risks or the need for invasive or surgical procedures in the following year that would interrupt antiplatelet therapy. The need for use of long-term warfarin and the associated increased risk of bleeding with long-term "triple therapy" is also a consideration in deciding on DES versus BMS.[480]

Patients implanted with most contemporary coronary stents can undergo magnetic resonance imaging (MRI) examination any time after implantation.[481,482] The effect of the MRI examination on heating of the drug or polymer coating used in DES is unknown. There is no indication for antibiotic prophylaxis before dental or invasive procedures in patients with coronary stents.[483]

5.4. Adjunctive Diagnostic Devices

5.4.1. FFR: Recommendation

Class IIa

1. **FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with SIHD.[12,97,484–486] *(Level of Evidence: A)***

See Online Data Supplement 23 for additional data regarding FFR.

The limitations of coronary angiography for determination of lesion severity have been well described. Angiography may under- or overestimate lesion stenosis. Various physiologic measurements can be made in the catheterization laboratory, including coronary flow reserve and FFR. The correlation of ischemia on stress testing with FFR values of <0.75 has been established in numerous comparative studies with high sensitivity (88%), specificity (100%), positive predictive value (100%), and overall accuracy (93%).[487] The 5-year outcomes for patients with medical therapy based on an FFR >0.75 were superior compared with PCI in the DEFER (Deferral Versus Performance of Balloon Angioplasty in Patients Without Documented Ischemia) study.[485] The FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) study identified the benefit for deferring PCI in patients with multivessel disease and lesion FFR >0.80, with reduced rates of cardiac events at both 1 and 2 years.[97,486] Whereas both FFR and IVUS have been used for assessment of intermediate angiographic stenosis with favorable outcomes, FFR may reduce the need for revascularization when compared with IVUS.[488] Although IVUS is often considered in the assessment of equivocal left main stenosis, FFR may be similarly effective.[484]

5.4.2. IVUS: Recommendations

Class IIa

1. **IVUS is reasonable for the assessment of angiographically indeterminant left main CAD.[489–491] *(Level of Evidence: B)***
2. **IVUS and coronary angiography are reasonable 4 to 6 weeks and 1 year after cardiac transplantation to exclude donor CAD, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information.[492–494] *(Level of Evidence: B)***
3. **IVUS is reasonable to determine the mechanism of stent restenosis.[495] *(Level of Evidence: C)***

Class IIb

1. **IVUS may be reasonable for the assessment of non–left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis).[489,496,497] *(Level of Evidence: B)***
2. **IVUS may be considered for guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting.[490,495,498] *(Level of Evidence: B)***
3. **IVUS may be reasonable to determine the mechanism of stent thrombosis.[495] *(Level of Evidence: C)***

Class III: NO BENEFIT

1. **IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being contemplated. *(Level of Evidence: C)***

IVUS provides a unique coronary artery assessment of lesion characteristics, minimal and maximal lumen diameters, cross-sectional area, and plaque area. Diagnostic uses for IVUS include the assessment of angiographic indeterminant coronary artery stenoses, determination of the mechanism of stent restenosis or thrombosis, and postcardiac transplantation surveillance of CAD.[488,490–492,499] For left main coronary artery stenoses, a minimal lumen diameter of <2.8 mm or a

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minimal lumen area of <6 mm^2 suggests a physiologically significant lesion for which patients may benefit from revascularization. A minimal lumen area >7.5 mm^2 suggests that revascularization may be safely deferred.[490] A minimal lumen area between 6 and 7.5 mm^2 requires further physiological assessment, such as measurement of FFR.[487,500] For non–left main stenoses, minimal lumen diameter >2.0 mm and minimal lumen area >4.0 mm^2 correlate with low event rates.[489] However, in smaller-diameter arteries (minimal lumen area <3.0 mm^2), measurement of FFR may more accurately reflect a significant stenosis.[488] Studies correlating IVUS measures with ischemia have not specified the size of coronary arteries for which such correlations are valid.[488,489,497]

IVUS assessment after stent thrombosis may serve to identify stent underexpansion or malapposition.[499] IVUS is superior to angiography in the early detection of the diffuse, immune-mediated, cardiac allograft vasculopathy; recommendations about the use of IVUS for this purpose were published in 2010 by the International Society of Heart and Lung Transplantation.[492] Whereas IVUS has been an important research tool in interventional cardiology, most clinical studies of IVUS have not been able to demonstrate that its routine use results in a reduction of MACE or restenosis rates.[498,501,502] IVUS has been inappropriately used in clinical practice to justify implanting stents in mildly diseased segments that may require no intervention.[503]

5.4.3. Optical Coherence Tomography

Compared with IVUS, optical coherence tomography has greater resolution (10 to 20 micronmeter axially) but more limited depth of imaging (1 to 1.5 mm).[504,505] Unlike IVUS, optical coherence tomography requires that the artery be perfused with saline solution or crystalloid during image acquisition and therefore does not permit imaging of ostial lesions. Clinical studies have shown low optical coherence tomography complication rates,[506,507] similar to those of IVUS.[508] The excellent resolution of optical coherence tomography permits detailed in vivo 2-dimensional imaging of plaque morphological characteristics (eg, calcification, lipid, thrombus, fibrous cap thickness, and plaque ulceration or rupture)[508–510] and evaluation of the arterial response to stent implantation (eg, stent strut neointimal thickness and apposition)[511–513] and may be of value in clinical research. The appropriate role for optical coherence tomography in routine clinical decision making has not been established.

5.5. Adjunctive Therapeutic Devices

5.5.1. Coronary Atherectomy: Recommendations

Class IIa

1. **Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation.[514,515]** ***(Level of Evidence: C)***

Class III: NO BENEFIT

1. **Rotational atherectomy should not be performed routinely for de novo lesions or in-stent restenosis.[516–519]** ***(Level of Evidence: A)***

Rotational atherectomy in RCTs was associated with higher rates of MACE at 30 days and no reduction in restenosis. It has a limited role in facilitating the dilation or stenting of lesions that cannot be crossed or expanded with PCI.[520,521] Devices for directional coronary atherectomy are no longer marketed in the United States.

5.5.2. Thrombectomy: Recommendation

Class IIa

1. **Aspiration thrombectomy is reasonable for patients undergoing primary PCI.[522–524]** ***(Level of Evidence: B)***

The benefit of thrombectomy in patients with STEMI appears to be dependent on the type of thrombectomy technique used.[522–526] No clinical benefit for routine rheolytic thrombectomy (AngioJet device, MEDRAD Interventional, Minneapolis, MN and Pittsburgh, PA) has been demonstrated in primary PCI.[524–526] Two RCTs[522,523] and a meta-analysis[524] support the use of manual aspiration thrombectomy during primary PCI to improve microvascular reperfusion and decrease MACE. It is not known whether a strategy of selective thrombus aspiration in patients with a large thrombus burden might be equivalent to routine thrombus aspiration.

5.5.3. Laser Angioplasty: Recommendations

Class IIb

1. **Laser angioplasty might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty.[527]** ***(Level of Evidence: C)***

Class III: NO BENEFIT

1. **Laser angioplasty should not be used routinely during PCI.[516,518,528]** ***(Level of Evidence: A)***

RCTs of laser angioplasty have not demonstrated improved clinical or angiographic PCI outcomes, although some practitioners think that laser angioplasty may be of use in the treatment of lesions that are difficult to dilate with balloon angioplasty.[527]

5.5.4. Cutting Balloon Angioplasty: Recommendations

Class IIb

1. **Cutting balloon angioplasty might be considered to avoid slippage-induced coronary artery trauma during PCI for in-stent restenosis or ostial lesions in side branches.[529]** ***(Level of Evidence: C)***

Class III: NO BENEFIT

1. **Cutting balloon angioplasty should not be performed routinely during PCI.[516,529,530]** ***(Level of Evidence: A)***

Although some small, single-center trials have suggested that cutting balloon angioplasty was more efficacious than bal-

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loon angioplasty, it was not found to be safer or more effective in several large trials.[516,529,531] When balloon dilation is required for in-stent restenosis, however, cutting balloons are less likely to slip and may offer a technical advantage over conventional balloons.[529] Scoring balloons have been used by some cardiologists as an alternative to cutting balloons, but no RCTs have been reported.[531]

5.5.5. Embolic Protection Devices: Recommendation

Class I

1. **Embolic protection devices (EPDs) should be used during saphenous vein graft (SVG) PCI when technically feasible.[532–535] *(Level of Evidence: B)***

The incidence of MACE doubles in SVG PCI compared with native-artery PCI.[536] A distal balloon occlusion EPD decreased the 30-day composite outcome of death, MI, emergency CABG, or target-lesion revascularization (9.6% versus 16.5%) in the only RCT.[532] Subsequent noninferiority comparisons have demonstrated similar benefit with proximal occlusion and distal filter EPDs, with benefit limited to reduction in periprocedural MI[534,535] (Section 5.10). Distal EPDs do not improve survival or reinfarction rates in patients undergoing native-artery PCI.[524,537]

5.6. Percutaneous Hemodynamic Support Devices: Recommendation

Class IIb

1. **Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients. *(Level of Evidence: C)***

IABP counterpulsation is frequently used as an adjunct to PCI in hemodynamically unstable patients.[538,539] In single-center series, the routine prophylactic use of IABP during PCI in high-risk patients was associated with lower mortality and fewer major complications compared with rescue use of IABP.[540,541] In the only RCT in high-risk PCI patients (BCIS-1 [Balloon Pump-Assisted Coronary Intervention Study]),[542] there was no difference in the primary composite outcome between routine and provisional use of IABP. There were also no differences in major secondary endpoints except major procedural complications (eg, prolonged hypotension, ventricular tachycardia/fibrillation, cardiopulmonary arrest), which were lower in the routine IABP group. Bleeding and access site complication rates tended to be higher in the routine IABP group. The "bailout" rate of IABP insertion in the provisional IABP group was 12%, mostly for procedural hypotension.[542] A meta-analysis of IABP therapy in patients with STEMI did not show improved outcomes with the use of IABP.[434]

The Impella Recover LP 2.5 System (Abiomed, Aachen, Germany/Danvers, Massachusetts) is a 12.5 Fr catheter that is inserted percutaneously through a 13 Fr femoral artery sheath and placed across the aortic valve into the left ventricle, through which a transaxial blood pump provides flows of up to 2.5 L/min. This has been used in patients with cardiogenic shock[543,544] as well as elective PCI.[545] The hemodynamic effects of the Impella 2.5 have been studied in high-risk PCI patients, demonstrating beneficial LV unloading effect (decreased end-diastolic pressure and wall stress) with no change in global or systolic LV function.[546] The PROTECT I (A Prospective Feasibility Trial Investigating the Use of the IMPELLA Recover LP 2.5 System in Patients Undergoing High-Risk PCI) trial in 20 patients undergoing high-risk PCI with the Impella 2.5 system concluded that this device was safe, easy to implant, and hemodynamically effective.[547] The Europella Registry included 144 patients undergoing high-risk PCI and reported the safety, feasibility, and potential usefulness of the device and that RCTs were warranted.[548] The randomized PROTECT II (A Prospective, Multicenter, Randomized Controlled Trial of the IMPELLA Recover LP 2.5 System Versus Intra Aortic Balloon Pump in Patients Undergoing Non Emergent High Risk PCI) trial, which was designed to demonstrate superiority of Impella over IABP in terms of 1-month adverse events, was halted for futility after interim analysis of study results.[549]

The TandemHeart (CardiacAssist, Inc, Pittsburgh, PA) is a left atrial to aorta catheter-based system that includes a centrifugal blood pump providing flows of up to 4 L/min. This device uses a 21 Fr cannula percutaneously inserted into the femoral vein for transseptal access of the left atrium with a 15 Fr catheter placed in the contralateral femoral artery and positioned above the aortic bifurcation. An extracorporeal pump then returns oxygenated blood from the left atrium to the arterial system, thereby unloading the left ventricle.[550,551] The hemodynamic effects have been studied in patients undergoing high-risk PCI.[552] Several small studies have addressed the clinical efficacy of the TandemHeart in high-risk patients undergoing PCI.[551,553–556] In a single-center report of 68 patients undergoing high-risk PCI using either TandemHeart or Impella Recover 2.5, success rates (>90%) and vascular complications (7%) were similar.[553]

High-risk patients may include those undergoing unprotected left main or last-remaining-conduit PCI, those with severely depressed EF undergoing PCI of a vessel supplying a large territory, and/or those with cardiogenic shock. Patient risk, hemodynamic support, ease of application/removal, and operator and laboratory expertise are all factors involved in consideration of use of these devices. With devices that require large cannula insertion, the risk of vascular injury and related complications are important considerations regarding necessity and choice of device.

5.7. Interventional Pharmacotherapy

5.7.1. Procedural Sedation

The term *conscious sedation* is falling out of favor with the recognition that there is a spectrum of procedural sedation levels. Most patients undergoing PCI fall under the definition of either minimal sedation (anxiolysis) or moderate sedation (depressed consciousness with the ability to respond purposefully to verbal commands).[557] Nonetheless, an underlying principle of procedural sedation is that the physician should be prepared to manage one level of sedation deeper than the level intended. Thus, cardiologists should be cognizant of the principles of managing deep sedation (depressed conscious-

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ness without easy arousal that may require assistance in maintaining airway patency or spontaneous ventilation).

A full review of procedural sedation is beyond the scope of this document, but practice guidelines for sedation and analgesia by nonanesthesiologists, along with The Joint Commission standards, provides a reasonable framework. These guidelines outline several general principles.[558,559] Before the procedure the patient should be assessed for predictors of difficult intubation or a history of prior difficult intubation. The patient should be monitored by someone dedicated to observing the level and effects of sedation. Level of consciousness, respiratory rate, blood pressure, cardiac rhythm, and oxygen saturation by pulse oximetry should be monitored. Available equipment should include a high-flow oxygen source, suction, airway management equipment, a defibrillator, resuscitation drugs, and reversal agents appropriate for the drugs being used. A free-flowing IV line should be established. Supplemental oxygen is usually administered, even in the absence of preexisting hypoxia, to provide a margin of safety.

Agents used for sedation are best given in incremental doses, allowing adequate time for the development and assessment of peak effect. The most commonly used agents are listed in Appendix 4F.

5.7.2. Oral Antiplatelet Therapy: Recommendations

Class I

1. **Patients already taking daily aspirin therapy should take 81 mg to 325 mg before PCI.[301–304] *(Level of Evidence: B)***
2. **Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI.[301,303,304] *(Level of Evidence: B)***
3. **After PCI, use of aspirin should be continued indefinitely.[560–563] *(Level of Evidence: A)***
4. **A loading dose of a $P2Y_{12}$ receptor inhibitor should be given to patients undergoing PCI with stenting[564–568] *(Level of Evidence: A)*. Options include**
   a. **Clopidogrel 600 mg (ACS and non-ACS patients)[564–566] *(Level of Evidence: B)***
   b. **Prasugrel 60 mg (ACS patients)[567] *(Level of Evidence: B)***
   c. **Ticagrelor 180 mg (ACS patients)[568] *(Level of Evidence: B)***
5. **The loading dose of clopidogrel for patients undergoing PCI after fibrinolytic therapy should be 300 mg within 24 hours and 600 mg more than 24 hours after receiving fibrinolytic therapy.[565,569] *(Level of Evidence: C)***
6. **Patients should be counseled on the need for and risks of DAPT before placement of intracoronary stents, especially DES, and alternative therapies should be pursued if patients are unwilling or unable to comply with the recommended duration of DAPT.[208] *(Level of Evidence: C)***
7. **The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:**
   a. **In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily,[570] prasugrel 10 mg daily,[567] and ticagrelor 90 mg twice daily.[568] *(Level of Evidence: B)***
   b. **In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if patients are not at high risk of bleeding.[208,212,571] *(Level of Evidence: B)***
   c. **In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks).[208,572] *(Level of Evidence: B)***

Class IIa

1. **After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses.[302,573–576] *(Level of Evidence: B)***
2. **If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (eg, <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable. *(Level of Evidence: C)***

Class IIb

1. **Continuation of DAPT beyond 12 months may be considered in patients undergoing DES implantation.[567,568] *(Level of Evidence: C)***

Class III: HARM

1. **Prasugrel should not be administered to patients with a prior history of stroke or transient ischemic attack.[567] *(Level of Evidence: B)***

Aspirin reduces the frequency of ischemic complications after PCI. Although the minimum effective aspirin dosage in the setting of PCI has not been established, aspirin 325 mg given at least 2 hours, and preferably 24 hours, before PCI is recommended,[302,303] after which aspirin 81 mg daily should be continued indefinitely.

Several investigations have explored various loading doses of clopidogrel before or during PCI. Compared with a 300-mg loading dose, doses of either 600 mg or 900 mg achieve greater degrees of platelet inhibition with fewer low responders.[577] A meta-analysis of 7 studies that included 25,383 patients undergoing PCI demonstrated that intensified loading of clopidogrel with 600 mg reduces the rate of MACE without an increase in major bleeding compared with 300 mg.[578] Another study suggested that a 600-mg loading dose of clopidogrel is associated with improvements in procedural angiographic endpoints and 1-year clinical outcomes in patients with STEMI who undergo primary PCI compared with a 300-mg dose.[579] There is no benefit with increasing the loading dose to 900 mg compared with 600 mg.[577] Clopidogrel 75 mg daily should be given for a minimum of 4 weeks after balloon angioplasty or BMS

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implantation (a minimum of 2 weeks if increased bleeding risk is present)[580] and for at least 12 months after DES implantation (unless the risk of bleeding outweighs the anticipated benefit). Patients should be counseled on the need for and risks of DAPT before stent implantation, especially DES implantation, and alternative therapies pursued (BMS or balloon angioplasty) if they are unwilling or unable to comply with the recommended duration of DAPT.

The efficacy of clopidogrel pretreatment remains controversial. Although some studies have suggested that pretreatment with clopidogrel is associated with decreased platelet aggregation and a significantly lower incidence of periprocedural MI after elective PCI, others have suggested no benefit to pretreatment compared with administration of the drug in the catheterization laboratory.[572,581,582]

When prasugrel was compared with clopidogrel in patients with ACS in TRITON–TIMI 38 (Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel–Thrombolysis In Myocardial Infarction), prasugrel was associated with a significant 2.2% reduction in absolute risk and a 19% reduction in relative risk in the composite endpoint of cardiovascular death, nonfatal MI, or nonfatal stroke, and a significant increase in the rate of TIMI major hemorrhage (1.8% versus 2.4%).[567] Prasugrel is contraindicated in patients with a history of transient ischemic attack or stroke. Patients weighing <60 kg have an increased risk of bleeding on the 10 mg daily maintenance dose. The package insert suggests that consideration should be given to lowering the maintenance dose to 5 mg daily, although the effectiveness and safety of the 5-mg dose has not been studied. Prasugrel is not recommended for patients >75 years of age because of the increased risk of fatal and intracranial bleeding and lack of benefit, except in patients with diabetes or a history of prior MI. Prasugrel should not be started in patients likely to undergo urgent CABG. Prasugrel has not been studied in elective PCI, and thus no recommendation can be made regarding its use in this clinical setting.

Ticagrelor reversibly binds the $P2Y_{12}$ receptor. Unlike clopidogrel or prasugrel, ticagrelor is not a thienopyridine. It also does not require metabolic conversion to an active metabolite. Compared with clopidogrel in patients with ACS in the PLATO (Platelet Inhibition and Patient Outcomes) trial, ticagrelor was associated with a significant 1.9% reduction in absolute risk and a 16% reduction in relative risk in the primary composite endpoint of vascular death, nonfatal MI, or nonfatal stroke.[568] Importantly, a significant reduction in vascular mortality and all-cause mortality was observed. Although CABG-related bleeding was not significantly increased with ticagrelor compared with clopidogrel, a significantly greater incidence of major bleeding was observed in patients not undergoing CABG. Ticagrelor was associated with higher rates of transient dyspnea and bradycardia compared with clopidogrel, although only a very small percentage of patients discontinued the study drug because of dyspnea. Based on post hoc analysis of the PLATO study, specifically the results in the US patient cohort, a black box warning states that maintenance doses of aspirin above 100 mg reduce the effectiveness of ticagrelor and should be avoided. After any initial dose, ticagrelor should be used with aspirin 75 mg to 100 mg per day.[583] Given the twice-daily dosing and reversible nature of the drug, patient compliance may be a particularly important issue to consider and emphasize. Ticagrelor has not been studied in elective PCI or in patients who received fibrinolytic therapy; thus, no recommendations about its use in these clinical settings can be made.

5.7.3. IV Antiplatelet Therapy: Recommendations

STEMI

Class IIa

1. **In patients undergoing primary PCI treated with UFH, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban), whether or not patients were pretreated with clopidogrel.[584–590] *(For GP IIb/IIIa inhibitor administration in patients not pretreated with clopidogrel, Level of Evidence: A; for GP IIb/IIIa inhibitor administration in patients pretreated with clopidogrel, Level of Evidence: C)***

Class IIb

1. **In patients undergoing primary PCI with abciximab, it may be reasonable to administer intracoronary abciximab.[589,591–604] *(Level of Evidence: B)***

Class III: NO BENEFIT

1. **Routine precatheterization laboratory (eg, ambulance or emergency department) administration of GP IIb/IIIa inhibitors as part of an upstream strategy for patients with STEMI undergoing PCI is not beneficial.[605–612] *(Level of Evidence: B)***

UA/NSTEMI

Class I

1. **In UA/NSTEMI patients with high-risk features (eg, elevated troponin level) not treated with bivalirudin and not adequately pre-treated with clopidogrel, it is useful at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) in patients treated with UFH.[613–618] *(Level of Evidence: A)***

Class IIa

1. **In UA/NSTEMI patients with high-risk features (eg, elevated troponin level) treated with UFH and adequately pretreated with clopidogrel, it is reasonable at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).[616,619] *(Level of Evidence: B)***

SIHD

Class IIa

1. **In patients undergoing elective PCI treated with UFH and not pretreated with clopidogrel, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).[619–621] *(Level of Evidence: B)***

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Class IIb

1. **In patients undergoing elective PCI with stent implantation treated with UFH and adequately pretreated with clopidogrel, it might be reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).[619,622–624] *(Level of Evidence: B)***

See Online Data Supplement 24 for additional data regarding IV antiplatelet therapy.

In the era before DAPT, trials of adequately dosed GP IIb/IIIa inhibitors in patients undergoing balloon angioplasty and coronary stent implantation demonstrated a reduction in the incidence of composite ischemic events with GP IIb/IIIa treatment, primarily through a reduction of enzymatically defined MI.[613,615,618,620,621] Earlier RCTs of GP IIb/IIIa inhibitors were generally conducted in patients treated with UFH. In some trials, use of GP IIb/IIIa inhibitors are associated with some increased bleeding risk, and trials of these agents have generally excluded patients at high risk of bleeding (eg, coagulopathy).[584,587–589,613–618,620–626] Thus, recommendations about use of GP IIb/IIIa inhibitors are best construed as applying to those patients not at high risk of bleeding complications. Abciximab, double-bolus eptifibatide (180 mcg/kg bolus followed 10 minutes later by a second 180 mcg/kg bolus), and high-bolus dose tirofiban (25 mcg/kg) all result in a high degree of platelet inhibition,[627–629] have been demonstrated to reduce ischemic complications in patients undergoing PCI,[608,609,613,615,618–621] and appear to lead to comparable angiographic and clinical outcomes.[630,631]

Trials of GP IIb/IIIa inhibitors in the setting of STEMI and primary PCI were conducted in the era before routine stenting and DAPT. The results of these and more recent trials, as well as several meta-analyses, have yielded mixed results.[584–590] Therefore, it is reasonable to administer GP IIb/IIIa inhibitors in patients with STEMI undergoing PCI, although these agents cannot be definitively recommended as routine therapy. These agents might provide more benefit in selective use, such as in patients with large anterior MI and/or large thrombus burden. Trials of precatheterization laboratory (eg, ambulance or emergency room) administered GP IIb/IIIa inhibitors in patients with STEMI undergoing PCI, with or without fibrinolytic therapy, have generally shown no clinical benefit, and GP IIb/IIIa inhibitor use in this setting may be associated with an increased risk of bleeding.[605–610,612] Studies of intracoronary GP IIb/IIIa inhibitor administration (predominantly using abciximab) consist of several small RCTs, retrospective analyses, retrospective and prospective registries, cohort analyses, and case reports. Although most of these published studies have reported some benefit of intracoronary administration in terms of acute angiographic parameters, infarct size, left ventricle myocardial salvage, and composite clinical endpoints, several other studies have not detected any benefit with intracoronary administration.[589,591–604]

Trials of GP IIb/IIIa inhibitors in patients with UA/NSTEMI undergoing PCI demonstrated reduced ischemic outcomes, particularly in those with high-risk features such as positive biomarkers. Most trials were conducted in a prior PCI era and without $P2Y_{12}$ inhibitor pretreatment,[613,615,618,632,633] although several trials have also demonstrated benefit in patients with high-risk features pretreated with clopidogrel.[616,619] In most older studies of stable patients undergoing balloon angioplasty or coronary stenting, treatment with GP IIb/IIIa inhibitors resulted in a reduction of composite ischemic events, primarily enzymatically defined MI.[613–618,620,621,634,635] More contemporary trials of patients pretreated with a thienopyridine have not demonstrated any benefit with GP IIb/IIIa inhibitor therapy in patients with stable symptoms undergoing elective PCI.[619,622–624]

5.7.4. Anticoagulant Therapy

5.7.4.1. Use of Parenteral Anticoagulants During PCI: Recommendation

Class I

1. **An anticoagulant should be administered to patients undergoing PCI. *(Level of Evidence: C)***

Anticoagulant therapy prevents thrombus formation at the site of arterial injury, on the coronary guidewire, and in the catheters used for PCI.[8] With rare exceptions,[636] all PCI studies have used some form of anticoagulant. It is the consensus of the writing committee that PCI be performed with the use of some form of anticoagulant therapy. Suggested dosing regimens of parenteral agents used in PCI are given in Table 12. Recommendations for antiplatelet and antithrombin pharmacotherapy in PCI are given in Table 13.

5.7.4.2. UFH: Recommendation

Class I

1. **Administration of IV UFH is useful in patients undergoing PCI. *(Level of Evidence: C)***

As the only anticoagulant available for PCI for many years, UFH became the standard of care by default.[8] The dose of UFH for PCI has been based on empiricism and experience from RCTs. Suggested UFH dosing regimens are given in Table 12. When UFH is used during PCI, most cardiologists assess the degree of anticoagulation by measuring the activated clotting time. Although measurements are useful to show that an anti-IIa anticoagulant has been given, the value of the activated clotting time in current practice has been questioned. Although studies in the balloon angioplasty era did demonstrate a relationship between activated clotting time levels and ischemic complications,[653–655] more recent analyses from the coronary stent era have not found a clear relationship between activated clotting time and outcomes.[349,656,657] There may, however, be a modest relation between bleeding and activated clotting time levels.[349,657] In addition, not only are there differences between activated clotting time levels measured by Hemochron and HemoTec devices, but both devices have less than optimal precision.[658] Thus, although traditional target activated clotting time levels are included in this document, the utility of measured activated clotting time levels in current practice should be considered uncertain.

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Table 12. Dosing of Parenteral Anticoagulants During PCI

Drug	Patient Has Received Prior Anticoagulant Therapy	Patient Has Not Received Prior Anticoagulant Therapy
UFH	• IV GPI planned: additional UFH as needed (eg, 2000 to 5000 U) to achieve an ACT of 200 to 250 s • No IV GPI planned: additional UFH as needed (eg, 2000 to 5000 U) to achieve an ACT of 250 to 300 s for HemoTec, 300 to 350 s for Hemochron	• IV GPI planned: 50 to 70 U/kg bolus to achieve an ACT of 200 to 250 s • No IV GPI planned: 70 to 100 U/kg bolus to achieve target ACT of 250 to 300 s for HemoTec, 300 to 350 s for Hemochron
Enoxaparin	• For prior treatment with enoxaparin, if the last SC dose was administered 8 to 12 h earlier or if only 1 SC dose of enoxaparin has been administered, an IV dose of 0.3 mg/kg of enoxaparin should be given. • If the last SC dose was administered within the prior 8 h, no additional enoxaparin should be given.	0.5 to 0.75 mg/kg IV bolus
Bivalirudin	For patients who have received UFH, wait 30 min, then give 0.75 mg/kg IV bolus, then 1.75 mg/kg per h IV infusion.	0.75 mg/kg bolus, 1.75 mg/kg per h IV infusion
Fondaparinux	For prior treatment with fondaparinux, administer additional IV treatment with an anticoagulant possessing anti-IIa activity, taking into account whether GPI receptor antagonists have been administered.	N/A
Argatroban	200 mcg/kg IV bolus, then 15 mcg/kg per min IV infusion	350 mcg/kg bolus, then 25 mcg/kg per min IV infusion

ACT indicates activated clotting time; IV, intravenous; GPI, glycoprotein inhibitor; N/A, not applicable; PCI, percutaneous coronary intervention; SC, subcutaneous; and UFH, unfractionated heparin.

Most cardiologists remove femoral sheaths when the activated clotting time falls to <150 to 180 seconds or when the activated partial thromboplastin time falls to <50 seconds. Full-dose anticoagulation is no longer used after successful PCI procedures. Almost all large clinical trials have enrolled patients who underwent transfemoral PCI, but recent small studies assessing the transradial approach have used similar doses of UFH[659] and similar activated clotting time target levels.[660]

5.7.4.3. Enoxaparin: Recommendations

Class I

1. **An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received fewer than 2 therapeutic subcutaneous doses (eg, 1 mg/kg) or received the last subcutaneous enoxaparin dose 8 to 12 hours before PCI.[649,661–664] *(Level of Evidence: B)***

Class IIb

1. **Performance of PCI with enoxaparin may be reasonable in patients either treated with "upstream" subcutaneous enoxaparin for UA/NSTEMI or who have not received prior antithrombin therapy and are administered IV enoxaparin at the time of PCI.[646–650] *(Level of Evidence: B)***

Class III: HARM

1. **UFH should not be given to patients already receiving therapeutic subcutaneous enoxaparin.[649,665] *(Level of Evidence: B)***

Trials of enoxaparin relevant to PCI include both studies in which patients with UA/NSTEMI were started on upstream subcutaneous enoxaparin therapy that was continued up to the time of PCI and trials in which patients who had received no prior antithrombin therapy were treated with IV enoxaparin at the time of PCI.[646–650,661–663,666] In the SYNERGY (Superior Yield of the New strategy of Enoxaparin, Revascularization and Glycoprotein IIb/IIIa Inhibitors) trial, there was an increased incidence of bleeding in those treated with upstream enoxaparin, later attributed at least in part to the fact that some patients being treated with enoxaparin were also administered UFH at the time of PCI (so-called "stacking").[649,665] Almost all patients undergoing elective PCI who are administered enoxaparin (0.5 mg/kg IV) will have a peak anti-Xa level >0.5 IU/mL.[647] Most clinical studies have used a regimen of 0.5 to 0.75 mg IV.[667] Several studies have used this regimen in elective patients and those with STEMI.[646] Patients who have received multiple doses of subcutaneously administered enoxaparin who undergo PCI within 8 hours of the last subcutaneous dose generally have adequate degrees of anticoagulation to undergo PCI, but the degree of anticoagulation may diminish in the 8- to 12-hour period after the last subcutaneous dose. In such patients, as well as in patients who have received only 1 subcutaneous dose of enoxaparin, the addition of enoxaparin (0.3 mg/kg IV) at the time of PCI provides an additional degree of anticoagulation and has become standard practice.[648,661–664] Patients who undergo PCI >12 hours after the last subcutaneous dose are usually treated with full-dose de novo anticoagulation using an established regimen (eg, full-dose UFH or bivalirudin).

5.7.4.4. Bivalirudin and Argatroban: Recommendations

Class I

1. **For patients undergoing PCI, bivalirudin is useful as an anticoagulant with or without prior treatment with UFH.[625,637–645] *(Level of Evidence: B)***

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Table 13. Recommendations for Antiplatelet and Antithrombin Pharmacotherapy at the Time of PCI

	COR	LOE	References	Relevant Caveats/Comments
Oral antiplatelet agents				
Aspirin	I	B	301–304,560–563	N/A
$P2Y_{12}$ inhibitors	I	A	564–568	• A loading dose of a $P2Y_{12}$ inhibitor should be given to patients undergoing PCI with stenting.
• Clopidogrel	I	B	564–566	• 600-mg loading dose now recommended.
• Prasugrel	I	B	567	• Contraindicated in patients with prior TIA/CVA: ***Class III: Harm; LOE: B.*** • Generally not recommended in patients >75 y of age (Section 5.7.2). • Consideration of using a lower maintenance dose in patients weighing <60 kg suggested by FDA (Section 5.7.2).
• Ticagrelor	I	B	568	• Issues of patient compliance may be especially important.
GP IIb/IIIa inhibitors (abciximab, double-bolus eptifibatide, high-bolus dose tirofiban)				
• No clopidogrel pretreatment	STEMI: IIa	A	584–590	• UA/NSTEMI recommendation applies to those with high-risk features. • GPI use in STEMI may be most appropriate in those with large anterior MI and/or large thrombus burden. • IC abciximab administration in STEMI: ***Class IIb; LOE: B.*** • Precatheterization laboratory GPI administration in STEMI: ***Class III: No Benefit; LOE: B.*** • Recommendations apply to those not at high risk for bleeding complications.
	UA/NSTEMI: I	A	613–618	
	SIHD: IIa	B	619–621	
• Clopidogrel pretreatment	STEMI: IIa	C	584–590	
	UA/NSTEMI: IIa	B	616,619	
	SIHD: IIb	B	619,622–624	
Antithrombin agents				
UFH	I	C	N/A	• Dosing based on whether or not GPI was administered.
Bivalirudin	I	B	625,637–645	• Lower bleeding rates associated with bivalirudin are mitigated when used concomitantly with a GPI.
Enoxaparin	IIb	B	646–650	• Recommendations apply to administration of IV enoxaparin at the time of PCI for those who have not received prior antithrombin therapy or who have received "upstream" SC enoxaparin therapy for UA/NSTEMI. • An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received <2 therapeutic SC doses (eg, 1 mg/kg) or received the last SC enoxaparin dose 8 to 12 h before PCI: ***Class I; LOE: B.*** • Patients treated with SC enoxaparin within 12 h of PCI should not receive additional treatment with UFH during PCI ("stacking"): ***Class III: Harm; LOE: B.***
Anti-Xa inhibitors				
Fondaparinux	III: Harm	C	651,652	• PCI should not be performed with fondaparinux as the sole antithrombin agent in patients treated with upstream fondaparinux. An additional anticoagulant with anti-IIa activity should be administered.

ACT indicates activated clotting time; COR, class of recommendation; CVA, cerebrovascular accident; FDA, US Food and Drug Administration; GP, glycoprotein; GPI, glycoprotein IIb/IIIa inhibitor; IC, intracoronary; IV, intravenous; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; PCI, percutaneous coronary intervention; SC, subcutaneous; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; TIA, transient ischemic attack; UA/NSTEMI, unstable angina/non–ST-elevation myocardial infarction; and UFH, unfractionated heparin.

2. For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace UFH.[668,669] *(Level of Evidence: B)*

Bivalirudin is being increasingly used in clinical practice[670] as evidence emerges from clinical trials across the spectrum of CAD.[638–644] In individual trials and meta-analyses, the use of bivalirudin has been associated with reduced bleeding compared with UFH plus a GP IIb/IIIa inhibitor, although concerns about ischemic events have emerged in individual studies.[625,637–645] Longer-term follow-up of the major bivalirudin trials, however, suggests that small or nominal increases in ischemic events have not translated into long-term consequences and that treatment at or before the time of PCI with clopidogrel may mitigate any increased early ischemic risk.[637–645] Thus, a treatment strategy of bivalirudin compared with heparin (or enoxaparin) plus GP IIb/IIIa inhibitor appears to lower the risk of bleeding complications. The lower bleeding rates associated with bivalirudin (compared with UFH plus a GP IIb/IIIa inhibitor) are mitigated when used concomitantly with a GP IIb/IIIa inhibitor.[639] A strategy of use of provisional GP IIb/IIIa inhibitor in patients treated with bivalirudin is widely accepted.[639,643,644]

In patients with heparin-induced thrombocytopenia,[671,672] a direct-thrombin inhibitor (argatroban) has been approved as an alternative parenteral anticoagulant to be used during PCI.[668] The use of bivalirudin for heparin-induced thrombocytopenia has been reported as well.[669]

5.7.4.5. Fondaparinux: Recommendation

Class III: HARM

1. Fondaparinux should not be used as the sole anticoagulant to support PCI. An additional anticoagulant

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with anti-IIa activity should be administered because of the risk of catheter thrombosis.[651,652] *(Level of Evidence: C)*

Fondaparinux, a pentasaccharide, is an indirect factor Xa inhibitor but has no effect on thrombin. On the basis of reports of catheter thrombosis when fondaparinux is used alone during primary PCI,[651,652] the writing committee recommends that an anticoagulant with anti-IIa activity be used in patients undergoing PCI.[651,652] One study suggested that clinical outcomes were better when fondaparinux was replaced during PCI by a standard dose of UFH (85 U/kg, 60 U/kg with GP IIb/IIIa inhibitors) rather than by a low dose (50 U/kg).[673]

5.7.5. No-Reflow Pharmacological Therapies: Recommendation

Class IIa

1. **Administration of an intracoronary vasodilator (adenosine, calcium channel blocker, or nitroprusside) is reasonable to treat PCI-related no-reflow that occurs during primary or elective PCI.[674–689] *(Level of Evidence: B)***

See Online Data Supplement 25 for additional data regarding no-reflow therapies.

No-reflow is a broad term used to describe 2 distinct entities. The first is "interventional no-reflow" attributed to vasospasm and downstream embolization of debris dislodged during PCI, usually in the setting of atherectomy, thrombus, or degenerated SVGs. The second entity is suboptimal reperfusion of an infarct artery, attributed to endothelial injury in addition to embolization and vasospasm. Angiographic no-reflow is the most obvious sequela of the same pathophysiology that produces abnormal TIMI frame counts and TIMI blush scores, so these measures are often used interchangeably. The principal clinical sequela of no-reflow is myonecrosis. Efforts to prevent no-reflow overlap with strategies to reduce MI size and prevent periprocedural MI.

In the setting of MI, several drugs have been shown to reduce the incidence of no-reflow. Evidence for a beneficial effect on no-reflow exists for abciximab, adenosine, nicorandil, and nitroprusside.[674,675,680,682,683,685,687,688,690] However, their adoption into clinical practice has depended on their effect on hard clinical endpoints such as infarct size and mortality. These benefits, and consequentially the use of these agents, have been limited.

For interventional no-reflow, several therapies have proven effective after no-reflow has started. These include adenosine, calcium channel blockers, and nitroprusside.[676,678,679,681,684,686,689,691] There are fewer data to support the use of epinephrine.[692] No-reflow after rotational atherectomy was less common with nicorandil compared with verapamil infusions in 3 studies,[693–695] and an infusion of nicorandil/adenosine during rotational atherectomy prevented no-reflow in 98% of patients.[677] Trials of pre-PCI intracoronary verapamil, nicardipine, and adenosine have reported them to be safe but have not demonstrated reductions in post-PCI no-reflow.[696–698] Mechanical devices to prevent interventional and myocardial infarct reperfusion no-reflow are also covered in Section 5.5.5.

5.8. PCI in Specific Anatomic Situations

5.8.1. CTOs: Recommendation

Class IIa

1. **PCI of a CTO in patients with appropriate clinical indications and suitable anatomy is reasonable when performed by operators with appropriate expertise.[699–703] *(Level of Evidence: B)***

See Online Data Supplements 26 to 28 for additional data regarding CTOs.

Approximately one third of patients with suspected CAD who undergo coronary angiography have ≥1 CTO (defined as occlusion of a duration >3 months).[704] Although stress-induced ischemia can be elicited in the majority of patients with CTO despite the presence of collaterals,[706,707] only 8% to 15% of these patients undergo PCI.[708,709] The disparity between the frequency of CTOs and percutaneous treatment underscores not only the technical and procedural complexities of this lesion subtype but also the clinical uncertainties regarding which patients benefit from CTO revascularization. Studies suggest that patients who undergo successful, rather than failed, recanalization of CTOs fare better in terms of symptom status and need for CABG,[699] as well as LV function.[710] However, the impact of successful CTO recanalization on long-term survival remains unsettled.[701,711,712] The decision to try PCI for a CTO (versus continued medical therapy or surgical revascularization) requires an individualized risk-benefit analysis encompassing clinical, angiographic, and technical considerations. Consultation with a cardiothoracic surgeon and use of the Heart Team approach in cases of CTO in which a large territory is subtended and/or multivessel CAD is present are frequently done.

From a technical perspective, successful recanalization of CTOs has steadily increased over the years because of adoption of dedicated wires, novel techniques, and increased operator experience.[702] In patients who undergo successful CTO recanalization, use of DES significantly reduces the need for repeated target-vessel revascularization, compared with BMS and balloon angioplasty, without compromising safety.[703,713–719]

5.8.2. SVGs: Recommendations

Class I

1. **EPDs should be used during SVG PCI when technically feasible.[532–535] *(Level of Evidence: B)***

Class III: NO BENEFIT

1. **Platelet GP IIb/IIIa inhibitors are not beneficial as adjunctive therapy during SVG PCI.[212,571,720,721] *(Level of Evidence: B)***

Class III: HARM

1. **PCI is not recommended for chronic SVG occlusions.[722–724] *(Level of Evidence: C)***

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See Online Data Supplement 29 for additional data regarding SVG.

Adverse cardiac event rates are doubled after SVG PCI compared with native-artery PCI.[536] A distal balloon occlusion EPD decreased the 30-day composite outcome of death, MI, emergency CABG, or target-lesion revascularization (9.6% versus 16.5%) in the only RCT comparing embolic protection with no embolic protection.[532] Subsequent noninferiority comparisons have demonstrated similar benefit with proximal occlusion and distal filter EPDs, with benefit limited to reduction in periprocedural MI.[534,535] PCI in chronic SVG occlusion is associated with low success rates, high complication rates, and poor long-term patency rates.[722,723] Restenosis and target-vessel revascularization rates are lower with DES compared with BMS, although mortality and stent thrombosis rates are similar.[725] The use of covered stents is limited to the treatment of the uncommon complication of SVG perforation. Balloon angioplasty for distal SVG anastomotic stenoses has low restenosis rates,[724] so stenting is commonly reserved at this location for suboptimal balloon angioplasty results or restenosis. Routine GP IIb/IIIa inhibitor therapy has not proven beneficial in SVG PCI.[720] Fibrinolytic therapy is no longer used for thrombus-containing lesions, but rheolytic or manual aspiration thrombectomy is sometimes employed.

5.8.3. Bifurcation Lesions: Recommendations

Class I

1. **Provisional side-branch stenting should be the initial approach in patients with bifurcation lesions when the side branch is not large and has only mild or moderate focal disease at the ostium.[726–729] *(Level of Evidence: A)***

Class IIa

1. **It is reasonable to use elective double stenting in patients with complex bifurcation morphology involving a large side branch where the risk of side-branch occlusion is high and the likelihood of successful side-branch reaccess is low.[730–733] *(Level of Evidence: B)***

Side-branch occlusion or severe stenosis after stenting the main artery in coronary bifurcation PCI occurs in 8% to 80% of unselected patients.[732,734] The frequency of side-branch occlusion is related to complex bifurcation morphology (severe and/or long side-branch ostial stenosis, large plaque burden in the side-branch ostium, and/or unfavorable side-branch angulation).[732,735,736] Side-branch occlusion after PCI is associated with Q-wave and non–Q-wave MI.[734,735] Therefore, preservation of physiologic flow in the side branch after PCI is important.[736] There are 2 bifurcation PCI strategies: provisional stenting (stenting the main vessel with additional balloon angioplasty or stenting of the side branch only in the case of an unsatisfactory result) and elective double stenting of the main vessel and the side branch. When there is an unsatisfactory result in the side branch from the provisional stent in the main branch, sometimes balloon angioplasty alone in the side branch will improve the result and stenting the side branch is not necessary. Some experts have suggested that using the side-branch balloon alone will distort the main branch stent and thus this always needs to be a kissing balloon inflation.

In patients with low-risk bifurcation lesions (minimal or moderate ostial side-branch disease [<50% diameter stenosis] of focal length [5 to 6 mm]), provisional stenting yields similar clinical outcome to elective double stenting, with lower incidence of periprocedural biomarker elevation.[726–729] Conversely, in patients with high-risk bifurcations, elective double stenting is associated with a trend toward higher angiographic success rates, lower in-hospital MACE, and better long-term patency of the side branch compared with provisional stenting.[193] Culotte, Crush, and T-stent techniques have been studied in RCTs.[726–729,737] Use of DES yields better outcomes than BMS,[738] and sirolimus-eluting stents yield better outcomes than paclitaxel-eluting stents.[739–742] Clinical evidence supports the use of final kissing balloon inflation after elective double stenting.[743]

5.8.4. Aorto-Ostial Stenoses: Recommendations

Class IIa

1. **IVUS is reasonable for the assessment of angiographically indeterminant left main CAD.[744,745] *(Level of Evidence: B)***
2. **Use of DES is reasonable when PCI is indicated in patients with an aorto-ostial stenosis.[746,747] *(Level of Evidence: B)***

Aorto-ostial stenoses of native coronary arteries (left main coronary artery and right coronary artery) are most commonly caused by atherosclerosis, but they can also occur in patients with congenital malformations, radiation exposure, vasculitides, and aortic valve replacement. The angiographic diagnosis of aorto-ostial disease is not always straightforward, especially in the ostial left main coronary artery, where eccentricity and angulation can be mistaken for stenosis.[490,748] Aorto-ostial disease can be evaluated with IVUS[744,745]; FFR (with IV adenosine) has also been used.[484,749] The treatment of aorto-ostial stenoses with balloon angioplasty has been associated with lower procedural success rates, more frequent in-hospital complications, and a greater likelihood of late restenosis.[750] Although atherectomy devices (directional atherectomy, rotational atherectomy, and excimer laser angioplasty) have improved acute angiographic results over balloon angioplasty, restenosis has remained a limitation.[751] In patients with aorto-ostial stenoses undergoing PCI, use of DES has been shown to reduce restenosis compared with BMS.[176,746,752]

5.8.5. Calcified Lesions: Recommendation

Class IIa

1. **Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation.[514,515,520] *(Level of Evidence: C)***

The presence of coronary calcification is a marker for significant CAD and increased long-term mortality.[753] Calcified coronary lesions are not a homogenous entity, and their response to PCI varies according to severity of calcification.

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Severely calcified lesions respond poorly to balloon angioplasty,[230,754] and when stents are implanted in such lesions, an incomplete and asymmetrical stent expansion occurs in the majority of cases.[755] Attempts to remedy the underexpanded stents with aggressive high-pressure balloon dilatation may result in coronary artery rupture.[756] All the published prospective RCTs that evaluated the various catheter-based coronary interventional devices excluded patients with severely calcified lesions. Therefore, the evidence base for best PCI practices in patients with severely calcified lesions comes from nonrandomized single-arm studies. Among the various adjunct devices that are used to facilitate PCI in severely calcified lesions, only rotational atherectomy has been shown to have potential utility.[514,757] Although rotational atherectomy increases the chances of angiographic success in severely calcified lesions, its use as a stand-alone device has not led to a reduction in restenosis.[520,521,758] Several retrospective studies have shown that in patients with severely calcified lesions, the use of rotational atherectomy before implantation of BMS[514] or DES[515] is safe. Intermediate-term patency is more favorable with DES than BMS.[759]

5.9. PCI in Specific Patient Populations

Several specific patient subsets with higher risks for PCI, and at times higher absolute clinical benefit, have traditionally been underrepresented in RCTs and are described below.

5.9.1. Elderly

The elderly constitute a growing proportion of patients considered for PCI.[760] In 1 series examining trends over a 25-year period, the proportion of patients undergoing PCI who were 75 to 84 years of age doubled, and those >85 years of age increased 5-fold.[761] Age is one of the strongest predictors of mortality after PCI,[762] and elderly patients present with a substantially higher clinical risk profile[760] Nonetheless, the angiographic success rates and clinical benefits of PCI in elderly patients are similar to younger patients.[763] In fact, the absolute benefit is typically greater because of higher absolute risk of adverse outcomes in these patients.[764] However, increased risks of complications such as major bleeding and stroke mandate careful consideration of the benefits and risks of PCI in elderly patients.[373]

5.9.2. Diabetes

Patients with diabetes represent approximately one third of patients undergoing PCI in the United States. Restenosis, which had been a major limitation of PCI, is significantly reduced in patients with diabetes treated with DES compared with BMS.[471] However, there are no definitive data from RCTs supporting different clinical outcomes for different types of DES,[765] with a recent meta-analysis of 35 RCTs involving 3852 patients with diabetes unable to find major differences between patients receiving sirolimuseluting stents or paclitaxel-eluting stents.[472] Numerous analyses and clinical studies have evaluated how the presence of diabetes may impact the clinical outcome of patients undergoing PCI and decisions about PCI or CABG.[14,116,163,164,186] These studies and the approach to revascularization decisions in diabetes are addressed in Section 4.

Diabetes is an important risk factor for the development of contrast-induced AKI. Strategies to reduce the risk of contrast-induced AKI in patients with diabetes are discussed in Section 4.4.

5.9.3. Women

Cardiovascular disease is the leading cause of death in women in the United States and Europe,[766] and an estimated 35% of PCIs in the United States are performed in women.[767,768] Women undergoing PCI usually have more risk factors (including hypertension, advanced age, elevated cholesterol, and more significant and diffuse CAD) compared with men.[769] Women with STEMI are also less likely to receive early medical treatments and experience longer delays to reperfusion therapy.[770,771] In subgroup analyses of clinical trials, use of DES appears to be similarly efficacious in women and men.[772]

5.9.4. CKD: Recommendation

Class I

1. **In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted.[298–300] *(Level of Evidence: B)***

CKD is an independent risk factor for the development and progression of CAD,[773,774] and is also associated with worse prognosis after MI or PCI.[369,775] A glomerular filtration rate of <60 mL/min per 1.73 m^2 of body surface area should be considered abnormal. Patients with CKD undergoing PCI have a higher risk of complications, including bleeding,[776] AKI, and death,[236,777] but CKD is not a strong predictor of restenosis after BMS or DES.[778] Strategies to reduce the risk of contrast-induced AKI in patients with CKD are discussed in Section 4.4. Platelet dysfunction and overdosing of antiplatelet and antithrombin drugs[350] in patients with CKD contribute to the increased risk of bleeding. The Cockcroft-Gault formula is commonly used as a surrogate marker for estimating creatinine clearance, which in turn estimates glomerular filtration rate.[298,299,779,780] Medications that require dosage adjustments in patients with CKD include eptifibatide, tirofiban, bivalirudin, enoxaparin, and fondaparinux.[781]

5.9.5. Cardiac Allografts

Cardiac allograft vasculopathy is a major cause of death in cardiac transplant recipients after their first year of survival.[782] In general, revascularization for cardiac allograft vasculopathy with PCI is only palliative, with no evidence supporting benefit in regard to long-term survival or avoidance of retransplantation. The restenosis rate after PCI in patients with cardiac allograft vasculopathy is high, although stent implantation reduces early and midterm restenosis compared with balloon angioplasty. DES have been shown to have a tendency to lower restenosis rates compared with BMS.[783,784] Thus, many clinicians perform stenting with DES or BMS in cardiac transplant patients with discrete lesions who have an abnormal stress test or symptoms suggestive of myocardial ischemia.

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5.10. Periprocedural MI Assessment: Recommendations

Class I

1. **In patients who have signs or symptoms suggestive of MI during or after PCI or in asymptomatic patients with significant *persistent* angiographic complications (eg, large side-branch occlusion, flow-limiting dissection, no-reflow phenomenon, or coronary thrombosis), creatine kinase-MB and/or troponin I or T should be measured.** ***(Level of Evidence: C)***

Class IIb

1. **Routine measurement of cardiac biomarkers (creatine kinase-MB and/or troponin I or T) in all patients after PCI may be reasonable.** ***(Level of Evidence: C)***

Major events leading to ischemia or MI after PCI include acute closure, embolization and no-reflow, side-branch occlusion, and acute stent thrombosis. Issues surrounding the routine assessment of cardiac biomarkers after PCI are complex, especially given that the definition of PCI-related MI has evolved over the years and most events are asymptomatic. The most recent consensus definition of MI considers troponin elevations of 3 times the upper limit of normal as a PCI-related MI in patients with normal baseline levels; this is further classified as a type 4a MI.[240] This definition is supported by studies with delayed-enhancement MRI confirming that there is irreversible injury in the myocardium associated with biomarker elevations and that the size of this injury correlates with the degree of elevation.[785] Furthermore, a meta-analysis of 15 observational studies found that troponin elevations at any level were linked with worse in-hospital and long-term outcomes; elevations >3 times the upper limit of normal predicted even worse outcomes.[242] Other observational data, however, have raised concerns about whether the relationship is causal.[786,787] A recent study found creatinine kinase-MB to correlate better with MRI-detected MI than troponin level.[788] Definitions of PCI-related MI are being reevaluated by the Task Force for the Redefinition of Myocardial Infarction. Although there may be value for individual operators and hospitals to routinely measure cardiac biomarkers to track rates of PCI-related MI, at present there are not compelling data to recommend this for all PCI procedures.

5.11. Vascular Closure Devices: Recommendations

Class I

1. **Patients considered for vascular closure devices should undergo a femoral angiogram to ensure their anatomic suitability for deployment.** ***(Level of Evidence: C)***

Class IIa

1. **The use of vascular closure devices is reasonable for the purposes of achieving faster hemostasis and earlier ambulation compared with the use of manual compression.[257,789–791]** ***(Level of Evidence: B)***

Class III: NO BENEFIT

1. **The routine use of vascular closure devices is not recommended for the purpose of decreasing vascular complications, including bleeding.[256,257,789–792]** ***(Level of Evidence: B)***

See Online Data Supplement 30 for additional data regarding vascular closure devices.

Vascular (arteriotomy) closure devices have been extensively reviewed,[790] most recently in a 2010 AHA scientific statement,[257] which issued several formal recommendations. The results of 4 meta-analyses have found that vascular closure devices decrease time to hemostasis compared with manual compression but do not decrease vascular complications, bleeding complications, or the need for blood transfusions.[256,789,791,793] Future studies of vascular closure devices need to be randomized, include "high-risk" patients and "high-risk" anatomy, use blinded endpoint adjudication as much as possible, use well-defined and comprehensive complication endpoints, and be adequately powered to detect clinically important endpoints, particularly bleeding and vascular complications.

6. Postprocedural Considerations

Postprocedural considerations in patients undergoing PCI are discussed below and summarized in Table 14. Some recommendations and text regarding DAPT in Section 5.7.2 are intentionally repeated in this section for reader ease of use.

6.1. Postprocedural Antiplatelet Therapy: Recommendations

Class I

1. **After PCI, use of aspirin should be continued indefinitely.[560–563]** ***(Level of Evidence: A)***
2. **The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:**
   a. **In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily,[570] prasugrel 10 mg daily,[567] and ticagrelor 90 mg twice daily.[568]** ***(Level of Evidence: B)***
   b. **In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if the patient is not at high risk of bleeding.[208,212,571]** ***(Level of Evidence: B)***
   c. **In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks).[572]** ***(Level of Evidence: B)***
3. **Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist.[208]** ***(Level of Evidence: C)***

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Table 14. Postprocedural Recommendations for Patients Undergoing PCI

Recommendations	COR	LOE	References
Aspirin			
After PCI, use of aspirin should be continued indefinitely.	I	A	560–563
After PCI, it is reasonable to use aspirin 81 mg/d in preference to higher maintenance doses.	IIa	B	302,573–576
$P2Y_{12}$ inhibitors			
In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 mo. Options include clopidogrel 75 mg/d, prasugrel 10 mg/d, and ticagrelor 90 mg twice daily.	I	B	567,568,570
In patients receiving DES for a non-ACS indication, clopidogrel 75 mg/d should be given for at least 12 mo if patients are not at high risk of bleeding.	I	B	208,212,571
In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 mo and ideally up to 12 mo (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 wk).	I	B	572
Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist.	I	C	208
PPIs should be used in patients with a history of prior GI bleeding who require DAPT.	I	C	794
If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (eg, <12 mo) of $P2Y_{12}$ inhibitor therapy is reasonable.	IIa	C	N/A
Use of PPIs is reasonable in patients with an increased risk of GI bleeding (eg, advanced age, concomitant use of warfarin, steroids, NSAIDs, *Helicobacter pylori* infection) who require DAPT.	IIa	C	794
Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 mo may be considered in patients undergoing placement of DES.	IIb	C	N/A
Routine use of a PPI is not recommended for patients at low risk of GI bleeding, who have much less potential to benefit from prophylactic therapy.	III: No Benefit	C	794
Exercise testing			
For patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.	IIa	C	567,568
Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.	III: No Benefit	C	795
Cardiac rehabilitation			
Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for patients at moderate to high risk, for whom supervised exercise training is warranted.	I	A	796–804
Secondary prevention (recommendations included from the 2011 AHA/ACCF Secondary Prevention and Risk Reduction Therapy Guideline)[805]			
Lipid management with lifestyle modification and lipid-lowering pharmacotherapy			
Lifestyle modification	I	B	806,807
Statin therapy	I	A	344,806,808–810,810a
Statin therapy which lowers LDL cholesterol to <100 mg/dL and achieves at least a 30% lowering of LDL cholesterol	I	C	344,806,808–810,810a
Statin therapy which lowers LDL cholesterol to <70 mg/dL in very high-risk* patients	IIa	B	345,808–810,810a,811,812
Blood pressure control (with a blood pressure goal of <140/90 mm Hg)			
Lifestyle modification	I	B	813–817
Pharmacotherapy	I	A	813,818,819
Diabetes management (eg, lifestyle modification and pharmacotherapy) coordinated with the patient's primary care physician and/or endocrinologist	I	C	N/A
Complete smoking cessation	I	A	820–823

*Presence of established cardiovascular disease plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued cigarette smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides ≥200 mg/dL plus non–HDL cholesterol ≥130 mg/dL with low HDL cholesterol [<40 mg/dL]), and 4) acute coronary syndromes.

ACS indicates acute coronary syndromes; BMS, bare-metal stent(s); COR, class of recommendation; DAPT, dual antiplatelet therapy; DES, drug-eluting stent(s); GI, gastrointestinal; HDL, high-density lipoprotein; LDL, low-density lipoprotein; LOE, level of evidence; N/A, not applicable; NSAID, nonsteroidal anti-inflammatory drug; PCI, percutaneous coronary intervention; and PPI, proton pump inhibitor.

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Class IIa

1. **After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses.[302,573–576] *(Level of Evidence: B)***
2. **If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (eg, <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable. *(Level of Evidence: C)***

Class IIb

1. **Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 months may be considered in patients undergoing placement of DES.[567,568] *(Level of Evidence: C)***

Continued treatment with the combination of aspirin and a $P2Y_{12}$ inhibitor antagonist after PCI appears to reduce MACE.[570,572] On the basis of RCT protocols, secondary prevention measures, and expert consensus opinion, aspirin 81 mg daily should be given indefinitely after PCI.

Likewise, $P2Y_{12}$ inhibitors should be given for a minimum of 1 month after BMS (minimum 2 weeks for patients at significant increased risk of bleeding)[580] and for 12 months after DES and ideally in all patients who are not at high risk of bleeding.

The 2009 STEMI/PCI guidelines update[10] listed the recommendation "if the risk of morbidity because of bleeding outweighs the anticipated benefit afforded by thienopyridine therapy, earlier discontinuation *should be considered*" as a Class I recommendation, although the language used, in part, was consistent with a Class IIa recommendation. To clarify the intent of the recommendation, as well as to acknowledge the inherent difficulties in weighing bleeding and stent thrombosis risks, the recommendation is designated a Class IIa recommendation, using the phrase "earlier discontinuation *is reasonable.*" Recommendations regarding $P2Y_{12}$ inhibitor discontinuation before elective or urgent CABG are provided in the "2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery."[824]

6.1.1. PPIs and Antiplatelet Therapy: Recommendations

Class I

1. **PPIs should be used in patients with a history of prior gastrointestinal (GI) bleeding who require DAPT.[794] *(Level of Evidence: C)***

Class IIa

1. **Use of PPIs is reasonable in patients with an increased risk of GI bleeding (eg, advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, *Helicobacter pylori* infection) who require DAPT.[794] *(Level of Evidence: C)***

Class III: NO BENEFIT

1. **Routine use of a PPI is not recommended for patients at low risk of GI bleeding, who have much less potential to benefit from prophylactic therapy.[794] *(Level of Evidence: C)***

See Online Data Supplement 31 for additional data regarding the clopidogrel–PPI interaction.

PPIs are often prescribed prophylactically when clopidogrel is started to prevent GI complications such as ulceration and bleeding due to DAPT.[825] There is pharmacodynamic evidence that omeprazole interferes with clopidogrel metabolism,[826,827] but there is no clear evidence implicating other PPIs. However, even with omeprazole, there are no convincing data supporting an important clinical drug–drug interaction.[826] The FDA communication about an ongoing safety review of clopidogrel advises that healthcare providers avoid the use of clopidogrel in patients with impaired *CYP2C19* function due to known genetic variation or drugs that inhibit *CYP2C19* activity. The FDA notes that there is no evidence that other drugs that reduce stomach acid, such as histamine-2 receptor antagonists (except cimetidine) or antacids, interfere with clopidogrel responsiveness. The COGENT (Clopidogrel and the Optimization of Gastrointestinal Events) trial randomized patients with DAPT to clopidogrel and omeprazole or clopidogrel and placebo, and while there was no difference in cardiovascular events between the 2 groups, GI events were halved in those randomized to omeprazole.[828] It is reasonable to carefully evaluate the indication for PPI therapy in patients treated with clopidogrel, based on the presence or absence of the risk factors discussed above.[794] The need for GI protection increases with the number of risk factors for bleeding. Prior upper GI bleeding is the strongest and most consistent risk factor for GI bleeding on antiplatelet therapy. Patients with ACS and prior upper GI bleeding are at substantial cardiovascular risk, so DAPT with concomitant use of a PPI may provide the optimal balance of risk and benefit. It should be noted that PPIs, by decreasing adverse GI effects related to clopidogrel, might decrease patients' discontinuation of clopidogrel. In patients in whom there is a clear indication for PPI therapy, some clinicians may choose to use a PPI other than omeprazole.

6.1.2. Clopidogrel Genetic Testing: Recommendations

Class IIb

1. **Genetic testing might be considered to identify whether a patient at high risk for poor clinical outcomes is predisposed to inadequate platelet inhibition with clopidogrel.[829] *(Level of Evidence: C)***
2. **When a patient predisposed to inadequate platelet inhibition with clopidogrel is identified by genetic testing, treatment with an alternate $P2Y_{12}$ inhibitor (eg, prasugrel or ticagrelor) might be considered.[829] *(Level of Evidence: C)***

Class III: NO BENEFIT

1. **The routine clinical use of genetic testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended.[829] *(Level of Evidence: C)***

On March 12, 2010, the FDA approved a new label for clopidogrel with a "boxed warning" about the diminished effectiveness of clopidogrel in patients with impaired ability to convert the drug into its active metabolite.[829] Patients with decreased *CYP2C19* function because of genetic polymorphisms metabolize clopidogrel poorly and have higher rates of cardiovascular events after ACS and PCI than patients with

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normal *CYP2C19* function. The warning also notes that tests are available to identify patients with genetic polymorphisms and that alternative treatment strategies should be considered for patients who are poor metabolizers. The clopidogrel boxed warning leaves the issue of whether to perform *CYP2C19* testing up to the individual physician. It does not specifically require genetic testing or other changes in evaluation or treatment and does not imply that there are solid evidence-based reasons for such actions. Rather, it serves to inform clinicians of genetic variations in response to clopidogrel and to emphasize that clinicians should use this knowledge to make decisions about how to treat individual patients. At the present time, the evidence base is insufficient to recommend routine genetic testing in patients undergoing PCI. There may be a potential role for genetic testing for patients undergoing elective high-risk PCI procedures (eg, unprotected left main, bifurcating left main, or last patent coronary artery).

6.1.3. Platelet Function Testing: Recommendations

Class IIb

1. **Platelet function testing may be considered in patients at high risk for poor clinical outcomes.[829] *(Level of Evidence: C)***
2. **In patients treated with clopidogrel with high platelet reactivity, alternative agents, such as prasugrel or ticagrelor, might be considered.[829] *(Level of Evidence: C)***

Class III: NO BENEFIT

1. **The routine clinical use of platelet function testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended.[829] *(Level of Evidence: C)***

Platelet function testing to tailor antiplatelet therapy has received considerable interest. The GRAVITAS (Gauging Responsiveness With A VerifyNow Assay-Impact On Thrombosis And Safety) trial and several other ongoing trials test the concept that tailoring antiplatelet therapy based on platelet responsiveness assessed in an ex vivo $P2Y_{12}$ assay will improve cardiovascular outcomes.[830] In GRAVITAS, treatment with high-dose clopidogrel for 6 months in patients with high platelet reactivity on standard-dose clopidogrel was not beneficial. At the present time, the evidence base is insufficient to recommend routine platelet function testing. The results of 2 ongoing trials (DANTE [Dual Antiplatelet Therapy Tailored on the Extent of Platelet Inhibition] and ARCTIC [Double Randomization of a Monitoring Adjusted Antiplatelet Treatment Versus a Common Antiplatelet Treatment for DES Implantation, and Interruption Versus Continuation of Double Antiplatelet Therapy, One Year After Stenting]) will provide further information on the issue (www.clinicaltrials.gov).

6.2. Stent Thrombosis

The majority of stent thrombosis occurs early (0 to 30 days after PCI). In broad clinical practice, the expected rate of early stent thrombosis is <1%, and beyond 30 days it is 0.2% to 0.6% per year.[210,831] Acute stent thrombosis often presents as STEMI, and emergency revascularization is indicated. Acute stent thrombosis is associated with mortality rates of 20% to 45%.[832] Survivors are also at risk of recurrent stent thrombosis.[833]

Mechanical and pharmacological factors are the most frequent cause of acute stent thrombosis. After the usual measures to restore flow in the infarct-related artery, it is important to consider the etiology of stent thrombosis as it pertains to further therapy and avoidance of recurrence. IVUS may identify factors such as an undersized stent, incomplete stent apposition, residual stenosis, or dissection and can guide subsequent treatment. The most common cause of acute stent thrombosis is nonadherence to DAPT; however, resistance to aspirin or thienopyridines and prothrombotic states such as congenital or acquired thrombophilic states (malignancy) are additional risk factors.[834,835]

Given the poor prognosis of stent thrombosis and the uncertainties surrounding treatment, the importance of prevention must be emphasized. This includes ensuring compliance with DAPT and adequate stent sizing and expansion.[836]

6.3. Restenosis: Recommendations

Class I

1. **Patients who develop clinical restenosis after balloon angioplasty should be treated with BMS or DES if anatomic factors are appropriate and if the patient is able to comply with and tolerate DAPT.[837] *(Level of Evidence: B)***
2. **Patients who develop clinical restenosis after BMS should be treated with DES if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT.[838–840] *(Level of Evidence: A)***

Class IIa

1. **IVUS is reasonable to determine the mechanism of stent restenosis.[495] *(Level of Evidence: C)***

Class IIb

1. **Patients who develop clinical restenosis after DES may be considered for repeat PCI with balloon angioplasty, BMS, or DES containing the same drug or an alternative antiproliferative drug if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT.[495] *(Level of Evidence: C)***

6.3.1. Background and Incidence

After balloon angioplasty, mechanisms contributing to restenosis include smooth muscle cell migration and proliferation, platelet deposition, thrombus formation, elastic recoil, and negative arterial remodeling. Stents block elastic recoil and negative remodeling, and the predominant mechanism for restenosis after stent implantation is neointimal hyperplasia. Restenosis rates vary, depending on whether angiographic restenosis (defined as >50% diameter stenosis at follow-up angiography) or clinical restenosis (symptomatic and requiring target-lesion revascularization or target-vessel revascularization) is measured, as well as on patient characteristics, coronary anatomy considerations, and device type (balloon angioplasty, BMS, or DES). The incidence of angiographic restenosis rates for uncomplicated lesions treated in RCTs

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ranges from 32% to 42% after balloon angioplasty[463,464] and from 16% to 32% after BMS,[463,464] and is generally <10% after DES.[454,841] Less than half of patients with angiographic restenosis present with symptomatic, clinically relevant restenosis at 1-year follow-up, and a pooled analysis of 6186 patients from 6 trials of BMS showed target-lesion revascularization was performed in 12% and target-vessel revascularization in 14% at 1 year.[842,843] Patients with clinical restenosis typically present with recurrent exertional angina, but 5% to 10% of patients present with acute MI and 25% with UA.[844,845]

Factors associated with an increased risk of restenosis in various models include clinical setting (STEMI, ACS, daily angina), patient characteristics (diabetes, age <55 to 60 years, prior PCI, male sex, multivessel CAD), lesion location (unprotected left main, SVG), and procedural characteristics (minimum stent diameter ≤2.5 mm, total stent length ≥40 mm).[778,846]

PCI strategies for treating restenosis after balloon angioplasty, BMS, and DES are reviewed in the following sections. In addition to repeat PCI, intensified medical therapy or CABG are often also reasonable strategies, dependent on initial treatment (eg, balloon angioplasty, BMS), pattern of restenosis, likelihood of recurrent restenosis, ability to intensify medical therapy, suitability for CABG, and patient preference. Repeat PCI with BMS or DES is not appropriate if the patient is not able to comply with and tolerate DAPT.

6.3.2. Restenosis After Balloon Angioplasty

For clinical restenosis after balloon angioplasty, stent implantation is superior to repeat balloon angioplasty or atheroablation devices. The REST (REstenosis STent) study showed that target-lesion revascularization rates were 10% for stent-treated patients and 27% for balloon-treated patients (P=0.001).[837]

6.3.3. Restenosis After BMS

In-stent restenosis is classified according to these angiographic characteristics: Pattern I includes focal lesions ≤10 mm in length; Pattern II is in-stent restenosis >10 mm within the stent; Pattern III includes in-stent restenosis >10 mm extending outside the stent; and Pattern IV is totally occluded in-stent restenosis.[847] Treatment of in-stent restenosis with balloon angioplasty, repeat BMS, or atheroablation devices for Patterns I to IV resulted in 1-year target-lesion revascularization rates of 19%, 35%, 50%, and 83%, respectively. For clinical restenosis after BMS, repeat stenting with DES is preferred. Studies have demonstrated lower recurrent restenosis rates with DES compared with BMS or vascular brachytherapy.[495,838–840]

6.3.4. Restenosis After DES

Clinical restenosis after placement of DES is becoming increasingly common due to the large numbers of patients who have been treated with DES. The predominant angiographic pattern for DES in-stent restenosis is focal (≤10 mm in length). Several biologic, mechanical, and technical factors may contribute to DES in-stent restenosis, including drug resistance, hypersensitivity, stent underexpansion, stent strut fracture, nonuniform stent strut coverage, gap in stent coverage, and residual uncovered atherosclerotic lesion. IVUS might be considered to determine the cause for in-stent restenosis and help guide treatment strategy. Interventionists may treat focal DES restenosis with balloon angioplasty and treat nonfocal DES restenosis with BMS, CABG, or repeat DES with the same or an alternative antiproliferative drug.[848,849] Small, observational cohort studies have demonstrated angiographic restenosis rates of 25% to 30% with repeat DES either with the same or an alternative drug.[495,849,850] There are no RCTs, and the most appropriate treatment of restenosis of DES remains unknown.

6.4. Clinical Follow-Up

At the time of discharge, patients are instructed to contact their physician or seek immediate medical attention if symptoms recur. Most physicians will give the patient instructions on return to work and timing of return to full activities. The importance of strict compliance with aspirin and $P2Y_{12}$ inhibitor therapy is ideally emphasized to the patient at the time of discharge and during follow-up visits.

Secondary prevention measures after PCI are an essential part of long-term therapy, reducing both future morbidity and mortality associated with CAD, and are discussed in Section 6.5. A follow-up visit after PCI is usually scheduled to assess the patient's clinical status, the patient's compliance with secondary prevention therapies, and the success of secondary prevention measures (eg, blood pressure control, low-density lipoprotein levels, smoking cessation). Routine, periodic stress testing of asymptomatic patients is not considered part of standard patient follow-up.

6.4.1. Exercise Testing: Recommendations

Class IIa

1. **In patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.** ***(Level of Evidence: C)***

Class III: NO BENEFIT

1. **Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.**[795] ***(Level of Evidence: C)***

Treadmill exercise testing before cardiac rehabilitation provides information about peak exercise capacity and heart rate, helping to stratify patients for the level of supervision during training, and seems reasonable for this purpose[851]; nuclear imaging to assess ischemia in this context usually adds little.

The role of exercise testing to evaluate restenosis is much less certain. Although the presence of symptoms may not be a reliable means of detecting restenosis, there is no evidence that the detection of silent restenosis leads to improved outcome.[852,853] Routine testing of all patients after PCI will also lead to many false-positive tests, particularly in the era of DES. As restenosis rates decline from 30% to 10%, the false-positive rate of stress imaging increases from 37% to 77%.[854] A recent analysis of a national health insurance claims database and accompanying editorial find that stress testing after PCI is likely overused and rarely leads to repeat revascularization.[855,856] In summary, there is no proven ben-

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efit or indication for routine periodic stress testing in patients after PCI, and, thus, it is not indicated.[8,851] In cases in which there is a clear clinical indication for stress testing in a patient after PCI, exercise ECG alone is an insensitive predictor of restenosis[857,858]; therefore, stress imaging is the preferred stress test.[8] In cases of recurrent angina after PCI in which the pretest likelihood of restenosis is high and repeat revascularization based on symptoms is likely indicated, most practitioners will proceed directly to cardiac catheterization rather than first obtain stress imaging.

6.4.2. Activity and Return to Work

The timing of return to physical activity depends on the presenting condition as well as previous functional status. For STEMI, for example, daily walking is encouraged immediately, and driving can begin within 1 week after uncomplicated MI if allowed by local motor vehicle laws.[859] Sexual activity usually can be resumed within days, provided exercise tolerance is adequate, normally assessed by the ability to climb a flight of stairs.[859] Similar recommendations have been issued for UA/NSTEMI.[860] Patients with UA who have undergone successful revascularization and are otherwise doing well may return to physical activity on an accelerated schedule, usually within a few days.[860]

Return to work is more complex. Return to work rates after MI range from 63% to 94% and are confounded by factors such as job satisfaction, financial stability, and company policies.[861] The physical demands and degree of stress of a particular job require that recommendations be individualized. In the PAMI-2 (Primary Angioplasty in Myocardial Infarction) trial, patients were encouraged to return to work 2 weeks after primary PCI for STEMI, and no adverse events were reported.[862] In the RITA (Randomized Intervention Treatment of Angina) trial, revascularization with PCI led to earlier return to work compared with CABG, and subsequent employment rates were associated with relief of angina.[105] Many practitioners use graded exercise treadmill testing to determine the safety of activity and return to work by measuring the metabolic equivalent of task (MET) level achieved and comparing that level to energy levels required to perform different activities.[863]

6.4.3. Cardiac Rehabilitation: Recommendation

Class I

1. **Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted.[796–804] *(Level of Evidence: A)***

Participation in cardiac rehabilitation is associated with significant reductions in all-cause mortality (OR: 0.80, 95% CI: 0.68 to 0.93) and cardiac mortality.[796,797] Reports from community-based surveys, which in general enroll older and higher-risk patients than clinical trials, have confirmed that participation in comprehensive rehabilitation is independently associated with a reduction in recurrent MI and reduced mortality.[799] Cardiac rehabilitation is also associated with improvements in exercise tolerance, cardiac symptoms, lipid levels, cigarette smoking cessation rates (in conjunction with a smoking cessation program), stress levels, improved medical regimen compliance, and improved psychosocial well-being.[800] Cardiac rehabilitation is cost-effective as well.[864] Physician referral may be the most powerful predictor of patient participation in a cardiac rehabilitation program.[865]

6.5. Secondary Prevention

The treatment of the patient does not end with PCI; secondary prevention measures are a critical component of patient management. Important secondary prevention measures were presented in detail in the "2006 AHA/ACC Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease"[562] and have recently been updated in the "AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2011 Update."[805] The reader is referred to this document for detailed discussions of secondary prevention. Among the important recommendations are the following:

- Lipid management with lifestyle modification *(Class I; Level of Evidence: B)*[805–807] and statin therapy are recommended. *(Level of Evidence: A)*[344,805,808–810,810a] An adequate statin dose should be employed which reduces low-density lipoprotein cholesterol to <100 mg/dL AND achieves at least a 30% lowering of low-density lipoprotein cholesterol. *(Class I; Level of Evidence: C)*[806–810,810a] It is reasonable to treat patients with statin therapy which lowers low-density lipoprotein cholesterol to <70 mg/dL in very high risk* patients. *(Class IIa; Level of Evidence: C)*[345,808–810,810a,811,812] Patients who have triglycerides ≥200 mg/dL should be treated with statins to lower non–high-density lipoprotein cholesterol to <130 mg/dL. *(Class I; Level of Evidence: B)*[344,809,810,866] In patients who are very high risk* and have triglycerides ≥200 mg/dL, a non–high-density lipoprotein cholesterol goal of <100 mg/dL is reasonable. *(Class IIa; Level of Evidence: C)*[344,809,810,866]
- Blood pressure control with lifestyle modification *(Class I; Level of Evidence: B)*[813–817] and pharmacotherapy *(Class I; Level of Evidence: A)*,[805,813,818,819] with the goal of blood pressure <140/90 mm Hg.
- Diabetes management (eg, lifestyle modification and pharmacotherapy), coordinated with the patient's primary care physician and/or endocrinologist. *(Class I; Level of Evidence: C)*[805]
- Advising patients on the need for complete smoking cessation. *(Class I; Level of Evidence: A)*[805,820–823]

7. Quality and Performance Considerations

7.1. Quality and Performance: Recommendations

Class I

1. **Every PCI program should operate a quality-improvement program that routinely 1) reviews**

*Presence of established cardiovascular disease plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued cigarette smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides ≥200 mg/dL plus non–high-density lipoprotein cholesterol ≥130 mg/dL with low high-density lipoprotein cholesterol [<40 mg/dL]), and 4) acute coronary syndromes.

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quality and outcomes of the entire program; 2) reviews results of individual operators; 3) includes risk adjustment; 4) provides peer review of difficult or complicated cases; and 5) performs random case reviews. ***(Level of Evidence: C)***

2. **Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms.** ***(Level of Evidence: C)***

PCI quality and performance considerations are defined by attributes related to structure, processes, and risk-adjusted outcomes. Structural attributes include elements such as equipment, supplies, staffing, institutional and operator-level volumes, and the availability of electronic medical records. Processes include strategies for the appropriate patient, protocols for pre- and postprocedural care, appropriate procedural execution and management of complications, and participation in databases and registries for benchmarking performance of the program and individual operator. Risk-adjusted outcomes are the end result of these structures and processes of care, and when available are more reliable measures of quality than the institutional and individual operator volumes discussed in Section 7.4.

PCI process and outcomes assessments can be used for internal quality-improvement efforts and public reporting. Public reporting of institutional risk-adjusted outcomes is becoming more common. Although operator-level outcomes can be assessed and risk adjusted, the results are much less reliable due to lack of statistical power resulting from lower volumes. Any public reporting must use statistical methods that meet the high criteria established by the AHA Work Group.[867]

7.2. Training

The cognitive knowledge and technical skill required to perform PCI continue to grow. Details on the training required for interventional cardiology are found in the most recent ACCF Core Cardiology Training Statement.[868]

7.3. Certification and Maintenance of Certification: Recommendation

Class IIa

1. **It is reasonable for all physicians who perform PCI to participate in the American Board of Internal Medicine interventional cardiology board certification and maintenance of certification program.** ***(Level of Evidence: C)***

The American Board of Internal Medicine established interventional cardiology board certification in 1999 as an "added qualification" to the cardiovascular disease board certification. Since 1990 all certificates from the American Board of Internal Medicine are time limited for a 10-year period and require all diplomats to participate in maintenance of certification to maintain their board-certified status. Maintenance of certification in interventional cardiology requires physicians to document a minimum of 150 interventional cases over the 2 years before expiration of the current certification, complete self-assessment modules of their medical knowledge, participate in practice-based quality-improvement activities, and pass a secure, knowledge-based examination.[869–871] For those who cannot meet the case volume requirement, an alternative option is to submit a log of 25 consecutive cases including patient characteristics and procedural outcomes. The maintenance of certification process is likely to change, as the American Board of Internal Medicine intends to evolve maintenance of certification from an episodic event that occurs once every 10 years to a more continuous process of continuous professional development.

7.4. Operator and Institutional Competency and Volume: Recommendations

Class I

1. **Elective/urgent PCI should be performed by operators with an acceptable annual volume (≥75 procedures) at high-volume centers (>400 procedures) with on-site cardiac surgery.[872,873]** ***(Level of Evidence: C)***
2. **Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries.** ***(Level of Evidence: C)***
3. **Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.[872,874–877]** ***(Level of Evidence: C)***

Class IIa

1. **It is reasonable that operators with acceptable volume (≥75 PCI procedures per year) perform elective/urgent PCI at low-volume centers (200 to 400 PCI procedures per year) with on-site cardiac surgery.[872]** ***(Level of Evidence: C)***
2. **It is reasonable that low-volume operators (<75 PCI procedures per year) perform elective/urgent PCI at high-volume centers (>400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year.** ***(Level of Evidence: C)***

Class IIb

1. **The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 procedures per year (<11 PCIs for STEMI per year) is not well established.** ***(Level of Evidence: C)***

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Class III: NO BENEFIT

1. **It is not recommended that elective/urgent PCI be performed by low-volume operators (<75 procedures per year) at low-volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service.[872]** ***(Level of Evidence: C)***

Older observational evidence supported a volume-outcome relationship in PCI at both the institutional and operator level.[873] However, this relationship is complicated and may be inconsistent across low-volume institutions or operators. More recent data on primary PCI suggest that operator experience may modify the volume-outcome relationship at the institutional level.[876,878] Risk-adjusted outcomes remain preferable to institutional and individual operator volumes as quality measures.

Operator and hospital volume recommendations have been carried over from the 2005 PCI guideline. However, the writing committee recognizes that these volume recommendations are controversial. In addition, after extensive review of all relevant data, the writing committee believes that the LOE in support of all the above recommendations is best categorized as LOE C rather than LOE B as it has been in prior guidelines for some recommendations. We encourage the ACCF/AHA/ACP Clinical Competence and Training writing group for PCI and other expert writing groups to review this issue so that new recommendations can be considered by the next PCI guideline writing committee.

7.5. Participation in ACC NCDR or National Quality Database

Assessment of PCI quality and outcomes is important both at the level of the entire program and at the level of the individual physician. This requires collection of clinical and procedural data for PCI that allows regular comparison of risk-adjusted outcomes and complications with national benchmarks. The ACC NCDR CathPCI Registry is an example of a national registry to fulfill the goals of assessing and benchmarking quality and outcomes.

8. Future Challenges

Although this latest guideline reflects significant advancements in the field of PCI, there remain future challenges to the formulation and updating of guidelines for PCI. The proliferation of studies comparing the many newer drugs and devices with older therapies (or other newer therapies), often using different or novel study endpoints, endpoint definitions, and noninferiority designs, pose increasing challenges to objectively evaluating newer therapies and generating recommendations for their use. Numerous potential advances in the field of PCI, including intracoronary stem cell infusions for chronic and acute ischemic heart disease, designer drugs, novel intracoronary imaging technologies such as optical coherence tomography and virtual histology, new stent composition and designs (eg, drug-eluting, biodegradable, bifurcation), and drug-eluting balloons were considered for formal evaluation by the current writing committee, but it was thought that there were insufficient data at present to formulate any formal recommendations on these topics. These and other emerging technologies and treatments will need to be addressed in future PCI guidelines.

Finally, with this proliferation of new technology, the amount of data generated in the evaluation of these potential therapeutic advances will grow dramatically, adding significant challenges to future guideline generations. Of note, the Web site www.clinicaltrials.gov currently lists several hundred PCI-related clinical trials.

Staff

American College of Cardiology Foundation

David R. Holmes, Jr, MD, FACC, President
John C. Lewin, MD, Chief Executive Officer
Janet Wright, MD, FACC, Senior Vice President, Science and Quality
Charlene May, Senior Director, Science and Clinical Policy
Erin A. Barrett, MPS, Senior Specialist, Science and Clinical Policy

American College of Cardiology Foundation/American Heart Association

Lisa Bradfield, CAE, Director, Science and Clinical Policy
Sue Keller, BSN, MPH, Senior Specialist, Evidence-Based Medicine
Jesse M. Welsh, Specialist, Science and Clinical Policy
Debjani Mukherjee, MPH, Associate Director, Evidence-Based Medicine

American Heart Association

Ralph L. Sacco, MS, MD, FAAN, FAHA, President
Nancy Brown, Chief Executive Officer
Rose Marie Robertson, MD, FAHA, Chief Science Officer
Gayle R. Whitman, PhD, RN, FAHA, FAAN, Senior Vice President, Office of Science Operations
Mark D. Stewart, MPH, Science and Medicine Advisor, Office of Science and Medicine

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KEY WORDS: AHA Scientific Statements ■ acute coronary syndromes ■ anticoagulants ■ antiplatelet agents ■ antiplatelet agents ■ arrhythmias, cardiac ■ coronary artery revascularization interventions: stents ■ coronary angiography ■ drug therapy ■ drug delivery systems ■ heart diseases ■ myocardial revascularization ■ platelet aggregation inhibitor ■ ultrasound

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Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Glenn N. Levine (*Chair*)	Baylor College of Medicine—Professor of Medicine; Director, Cardiac Care Unit	None	None	None	None	None	None	None
Eric R. Bates (*Vice Chair*)	University of Michigan—Professor of Medicine	• Bristol-Myers Squibb • Daiichi-Sankyo • Datascope • Eli Lilly • Merck • Sanofi-aventis	None	None	None	None	None	5.7.2 5.7.3 5.7.4.1 5.7.4.2 5.7.4.3 5.7.4.4 5.7.4.5 6.1 6.1.2 6.1.3
James C. Blankenship (*Vice Chair*)	Geisinger Medical Center—Director of Cardiology and Cardiac Catheterization Laboratories	None	None	None	• Abiomed • AstraZeneca • Boston Scientific • Conor Medsystems • Kai Pharmaceutical • Schering-Plough	None	None	2.1 2.2 2.3 2.9.7 2.11 5.2.4 5.3 5.4.1 5.4.2 5.8.4 6.3
Steven R. Bailey	University of Texas Medical Center-Professor of Medicine and Radiology	• Volcano	None	None	• Boston Scientific	None	None	5.4.1 5.4.2
John A. Bittl	Munroe Heart-Interventional Cardiologist	None	None	None	None	None	None	None
Bojan Cercek	Cedars-Sinai Medical Center-Director, Coronary Care Unit	None	None	None	None	None	None	None
Charles E. Chambers	Penn State Milton S. Hershey Medical Center-Professor of Medicine and Radiology	None	None	None	None	None	None	None
Stephen G. Ellis	Cleveland Clinic Foundation-Section Head, Invasive and Interventional Cardiology	• Abbott Vascular • Boston Scientific • Cordis • Daiichi-Sankyo • Eli Lilly	None	None	• Abbott Vascular	None	None	2.2 2.11 5.7.2 6.1
Robert A. Guyton	Emory Clinic, Inc.-Professor and Chief, Division of Cardiothoracic Surgery	None	None	None	• Edwards Lifesciences	None	None	2.1 2.2 2.3 2.9.7 2.11 5.2.4 5.3 5.5.5 6.2 6.3
Steven M. Hollenberg	Cooper University Hospital-Director, Coronary Care Unit	• Eisai	None	None	None	None	None	5.7.4.3
Umesh N. Khot	CV Research Innovations, LLC-President/CEO	None	None	• Merck†	None	None	None	4.6 5.7.3
Richard A. Lange	University of Texas Health Science Center at San Antonio-Professor of Medicine	None	None	None	None	None	None	None

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Laura Mauri	Brigham and Women's Hospital-Associate Professor of Medicine, Harvard Medical School	• Abbott • Conor Medsystems (Johnson & Johnson) • Cordis • Medtronic	None	None	• Lutonix	• Abbott • Abiomed • Boston Scientific • Bristol-Myers Squibb • Conor Medsystems • Cordis • Daiichi-Sankyo • Eli Lilly • Medtronic Cardiovascular • Sanofi-aventis	• Defendant, Conor, interpretation of clinical trial results, 2010	2.9.7 5.2.3 5.3 5.4.2 5.5.1 5.5.2 5.5.4 5.5.5 5.6 5.7.2 5.7.3 5.8.2 5.8.4 5.8.5 5.11 6.1 6.1.2 6.1.3 6.2
Roxana Mehran	Columbia University Medical Center-Associate Professor of Medicine; Director, Data Coordinating Analysis Center	• Abbott Vascular • Abiomed • AlphaMedical • AstraZeneca • Bracco • BMS/ sanofi-aventis • DataScope • Eli Lilly/Daichii-Sankyo • Guerbet • The Medicines Company • Medtronic Vascular • St. Jude	None	None	None	None	None	4.7 5.1 5.2.4 5.3 5.4.1 5.4.2 5.5.1 5.5.2 5.6 5.7.2 5.7.3 5.7.4.1 5.7.4.2 5.7.4.3 5.7.4.4 5.7.4.5 5.8.3 5.8.4 5.11 6.1 6.1.1 6.1.2 6.1.3
Issam D. Moussa	Mayo Clinic-Professor of Medicine; Chair, Division of Cardiovascular Diseases	None	None	None	None	None	None	None
Debabrata Mukherjee	Texas Tech University-Chief, Cardiovascular Medicine	None	None	None	None	None	None	None
Brahmajee K. Nallamothu	University of Michigan-Assistant Professor of Medicine	None	None	None	None	None	None	None
Henry H. Ting	Mayo Clinic-Professor of Medicine; Assistant Dean for Quality	None	None	None	None	None	None	None

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Appendix 2. Reviewer Relationships With Industry and Other Entities (Relevant)—2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Deepak L. Bhatt	Official Reviewer—AHA	None	None	None	• AstraZeneca* • Bristol-Myers Squibb* • Eisai* • Eli Lilly • Ethicon* • The Medicines Company* • PLx Pharma† • Sanofi-aventis*	None	None
Mauricio G. Cohen	Official Reviewer—AHA	• AstraZeneca* • Momenta Pharma • Xoma	• Terumo Medical	None	• Invitrox*	None	None
John P. Erwin III	Official Reviewer—ACCF/AHA Task Force on Performance Measures	None	None	None	None	None	None
Kirk Garratt	Official Reviewer—SCAI	• Boston Scientific • Cordis/Johnson & Johnson • The Medicines Company	• Boston Scientific • BMS/ sanofi-aventis* • Daiichi-Sankyo/ Eli Lilly* • Medtronic • The Medicines Company	• Abbott Vascular • Boston Scientific	None	None	None
Steven L. Goldberg	Official Reviewer—SCAI	• AGA	• Bristol-Myers Squibb • Sanofi-aventis	None	None	None	• Plaintiff, patient litigation, 2010
Alice K. Jacobs	Official Reviewer—ACCF/AHA Task Force on Practice Guidelines	None	None	• Wyeth*	• Abbott Vascular* • Abiomed* • Accumetrics* • Cardiovascular Research Foundation (DSMB)† • Harvard Clinical Research Institute† • TIMI Study Group (DSMB)†	None	None
G.B. John Mancini	Official Reviewer—ACCF Board of Governors	• GlaxoSmithKline • Merck • Pfizer • Sanofi-aventis	None	None	• Merck*	None	None

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W. Douglas Weaver	Official Reviewer—ACCF Board of Trustees	None	None	None	• Boehringher Ingelheim (DSMB) • Boston Scientific (DSMB) • Duke Clinical Research Institute (Johnson & Johnson/Schering Plough)* • GlaxoSmithKline • NHLBI (DSMB) • TIMI Study Group (Johnson & Johnson/ Bayer—DSMB)	None	None
Thomas M. Bashore	Content Reviewer	None	None	None	None	None	None
Christopher E. Buller	Content Reviewer	• Abbott Vascular • Toshiba Medical	None	None	• Novartis • Regado Biosciences	None	None
James A. Burke	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	None	None
John G. Byrne	Content Reviewer—ACCF Surgeons' Scientific Council	• Edwards Lifesciences	None	>None	None	None	None
T. Bruce Ferguson	Content Reviewer—ACCF Surgeons' Scientific Council	None	None	None	• Novadaq Technologies*	None	None
Victor A. Ferrari	Content Reviewer	None	None	None	• NHLBI (DSMB)† • National Institute for Aging/NIH (DSMB)†	None	None
John G. Harold	Content Reviewer	None	None	None	None	None	None
Biswajit Kar	Content Reviewer	None	None	None	• AstraZeneca† • Boston Scientific† • Medtronic†	• VA Cooperative Study†	None
Morton J. Kern	Content Reviewer	• Infraredex • Merit Medical*	• St. Jude Medical* • Volcano Therapeutics*	None	None	None	None
Spencer B. King III	Content Reviewer	• Celonova Biosciences†	None	None	• Merck (DSMB) • Wyeth (DSMB)	None	None
Frederick G. Kushner	Content Reviewer	None	None	None	• Novartis†	None	None
David J. Maron	Content Reviewer	None	None	• Cardiovascular Care Affiliates*	None	None	• Plaintiff, acute coronary syndrome, 2010
Douglass A. Morrison	Content Reviewer	None	None	None	None	None	None

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Thomas C. Piemonte	Content Reviewer—ACCF Board of Governors	None	None	None	None	None	• Defendant, stent perforation, 2010
Peter K. Smith	Content Reviewer	• Eli Lilly	None	None	None	None	None
Sidney C. Smith	Content Reviewer	None	None	None	None	None	None
Richard W. Snyder	Content Reviewer—ACCF Board of Governors	None	None	None	None	• Hospital Corporation of America	None
Patrick L. Whitlow	Content Reviewer	• Edwards Lifesciences* • eValve* • Medtronic*	None	None	None	• ICON	None
David O. Williams	Content Reviewer	• Light Lab/St. Jude Medical	None	None	None	None	None
R. Scott Wright	Content Reviewer	• Hoffman LaRoche*	None	None	None	None	None

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*Significant relationship.

†No financial benefit.

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; DSMB, data safety and monitoring board; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis In Myocardial Infarction.

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Appendix 3. Abbreviation List

ACS = acute coronary syndromes
AKI = acute kidney injury
BMS = bare-metal stent(s)
CABG = coronary artery bypass graft surgery
CAD = coronary artery disease
CKD = chronic kidney disease
CTO = chronic total occlusion
DAPT = dual antiplatelet therapy
DES = drug-eluting stent(s)
ECG = electrocardiogram
EF = ejection fraction
EPD = embolic protection device
FDA = US Food and Drug Administration
FFR = fractional flow reserve
GDMT = guideline-directed medical therapy
GI = gastrointestinal
GP = glycoprotein
IABP = intra-aortic balloon pump
IV = intravenous
IVUS = intravascular ultrasound
LAD = left anterior descending
LIMA = left internal mammary artery
LV = left ventricular
LVEF = left ventricular ejection fraction
MACE = major adverse cardiac event
MI = myocardial infarction
MRI = magnetic resonance imaging
NCDR = National Cardiovascular Data Registry
PCI = percutaneous coronary intervention
PPI = proton pump inhibitor
RCT = randomized controlled trial
SIHD = stable ischemic heart disease
STEMI = ST-elevation myocardial infarction
SVG = saphenous vein graft
TIMI = Thrombolysis In Myocardial Infarction
TMR = transmyocardial laser revascularization
UA/NSTEMI = unstable angina/non-ST-elevation myocardial infarction
UFH = unfractionated heparin

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Appendix 4. Additional Tables/Figures

Appendix 4A. The NCDR CathPCI Risk Score System

Variable	Scoring Response Categories				Risk Score Calculation: Total Points	Risk Score Calculation: Risk of In-Patient Mortality (%)
Age	<60	≥60, <70	≥70, <80	≥80	0	0.0
	0	4	8	14	5	0.1
Cardiogenic shock	No	Yes			10	0.1
	0	25			15	0.2
Prior CHF	No	Yes			20	0.3
	0	5			25	0.6
Peripheral vascular disease	No	Yes			30	1.1
	0	5			35	2.0
Chronic lung disease	No	Yes			40	3.6
	0	4			45	6.3
GFR	<30	30–60	60–90	>90	50	10.9
	18	10	6	0	55	18.3
NYHA functional class IV	No	Yes			60	29.0
	0	4			65	42.7
PCI status (STEMI)	Elective	Urgent	Emergent	Salvage	70	57.6
	12	15	20	38	75	71.2
PCI status (no STEMI)	Elective	Urgent	Emergent	Salvage	80	81.0
	0	8	20	42	85	89.2
					90	93.8
					95	96.5
					100	98.0

CathPCI indicates catheterization percutaneous coronary intervention; CHF, congestive heart failure; GFR, glomerular filtration rate; NCDR, National Cardiovascular Data Registry; NYHA, New York Heart Association; and STEMI, ST-elevation myocardial infarction. Reproduced with permission from Peterson et al.[236]

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Appendix 4B. The SCAI Lesion Classification System

Type I lesions (highest success expected, lowest risk)

1. Does not meet criteria for C lesion
2. Patent

Type II lesions

1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90°
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
2. Patent

Type III lesions

1. Does not meet criteria for C lesion
2. Occluded

Type IV lesions

1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90°
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
   - Occluded for >3 mo
2. Occluded

ACC indicates American College of Cardiology; AHA, American Heart Association; and SCAI, Society for Cardiovascular Angiography and Interventions. Reprinted with permission from Krone et al.[879]

Appendix 4C. Strategies to Reduce Radiation Exposure to Patient and Operator

Precautions to minimize exposure to patient and operator

- Use radiation only when imaging is necessary to support clinical care
- Minimize use of cine
- Minimize use of steep angles of x-ray beam
- Minimize use of magnification modes
- Minimize frame rate of fluoroscopy and cine
- Keep the image receptor close to the patient
- Utilize collimation to the fullest extent possible
- Monitor radiation dose in real time to assess patient risk-benefit during procedure

Precautions to specifically minimize exposure to operator

- Use and maintain appropriate protective garments
- Maximize distance of operator from x-ray source and patient
- Keep above-table and below-table shields in optimal position at all times
- Keep all body parts out of field of view at all times

Precautions to specifically minimize exposure to patient

- Keep table height as high as comfortably possible for operator
- Vary imaging beam angle to minimize exposure to any single skin area
- Keep patient's extremities out of beam

Appendix 4D. Patient Care Consideration Based on Procedural Radiation Dose

$K_{a,r}$*	P_{KA}†	FT‡	Action
>5 Gray	>500 Gray cm^2	>60 min	Physician charts documentation about why exposure at this level occurred, documents whether multiple skin entry angles were used, assesses risk, educates patient about potential for skin injury, and arranges for appropriate follow-up within 30 d. Phone calls may be sufficient with an office visit arranged if issues/questions arise or a potential tissue injury is suspected.
≥10 Gray			Physician contacts radiation safety officer/medical physicist. The radiation safety officer/medical physicist should perform a detailed analysis of PSD. Document a) FOV, b) skin entrance port number, c) known geometry, with a "rough" geometric setup required. Educate patient about the potential for skin injury and document this in chart. Schedule an office visit in 2 to 4 wk.
PSD§ >15 Gray			If calculated PSD is indeed >15 Gray, the physician and/or radiation safety officer/medical physicist should contact hospital risk management within 24 h. Report the event to the Joint Commission and as needed to the appropriate State Department of Health.

*$K_{a,r}$ is total air kerma at reference point; †P_{KA} is air kerma-area product; ‡FT is total fluoroscopy time, does not include cine; §PSD is peak skin dose, which requires calculations made by a qualified physicist.

FOV indicates field of view; and FT, fluoroscopy time.

Adapted with permission from Chambers et al.[317]

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Appendix 4E. General Considerations in Deciding Between Early Invasive Strategy and Initial Conservative Strategy

Early Invasive Strategy Generally Preferred	Initial Conservative Strategy Generally Preferred or Reasonable
• Recurrent angina or ischemia at rest or with low-level activities despite intensive medical therapy • Elevated cardiac biomarkers (TnT or TnI) • New or presumably new ST-segment depression • Signs or symptoms of heart failure • Hemodynamic instability • High-risk score (eg, GRACE, TIMI) • Sustained ventricular tachycardia • PCI within 6 mo • Prior CABG • Diabetes mellitus • Mild to moderate renal dysfunction • Reduced LV function (LVEF <40%)	• Low-risk score (eg, GRACE, TIMI) • Absence of high-risk features • High risk for catheterization-related complications • Patient not a candidate for revascularization (with either PCI or CABG) • Patient prefers conservative therapy

CABG indicates coronary artery bypass graft surgery; GRACE, Global Registry of Acute Coronary Events; LV, left ventricular; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; TIMI, Thrombolysis In Myocardial Infarction; TnI, troponin I; and TnT, troponin T.

Appendix 4F. Agents for Procedural Sedation and Analgesia

Drug	Clinical Effects	Dose	Onset	Duration	Comments
Midazolam	Sedation, anxiolysis. No analgesia.	Initial 0.5 to 1 mg IV, then titrated.	2 to 3 min	45 to 60 min	Reduce dose when used in combination with opioids. May produce paradoxical excitement. Reversible with flumazenil.
Fentanyl	Analgesia	50 mcg IV. May repeat every 3 min, titrate to effect.	3 to 5 min	30 to 60 min	Reduce dosing when combined with benzodiazepines. Reversible with naloxone.
Etomidate	Sedation, anxiolysis. No analgesia.	Sedation: 0.1 mg/kg IV; repeat if inadequate response.	<1 min	5 to 15 min	Respiratory depression may occur; institutional guidelines vary about administration to nonintubated patients by nonanesthesiologists. May cause myoclonus, nausea, and vomiting. Adrenocortical suppression occurs but is rarely of clinical significance. Not reversible.
Propofol	Sedation, anxiolysis. No analgesia.	Load 1 mg/kg IV; may administer additional 0.5 mg/kg doses as needed to enhance or prolong sedation.	<1 min	5 to 15 min	Frequent hypotension and respiratory depression; institutional guidelines vary concerning administration to nonintubated patients by nonanesthesiologists. Avoid with egg or soy allergies. Not reversible.
Reversal Agents					
Naloxone	Opioid reversal	0.4 to 2 mg IV	2 min	20 to 40 min	If shorter acting than reversed drug, serial doses may be required.
Flumazenil	Benzodiazepine reversal	0.2 mg IV. May repeat every 1 min up to 1 mg.	1 to 2 min	30 to 60 min	If shorter acting than reversed drug, serial doses may be required. Do not use in patients receiving long-term benzodiazepines, cyclosporine, isoniazid, lithium, propoxyphene, theophylline, or tricyclic antidepressants.

IV indicates intravenous.

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Correction

In the article by Levine et al, "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention," which published ahead of print on November 7, 2011, and appeared in the December 6, 2011, issue of the journal (*Circulation.* 2011;124:e574–e651), several corrections were needed:

1. On page e608, in Table 12, last row, "Argatroban," third column, "Patient Has Not Received Prior Anticoagulant Therapy," the dosing for argatroban read, "350 mcg/kg bolus, then 15 mcg/kg per min IV infusion." It has been changed to read, "350 mcg/kg bolus, then 25 mcg/kg per min IV infusion."

2. On page e613, in the first column, first paragraph under section "5.10. Periprocedural MI Assessment: Recommendations," the last 2 lines of the Class I recommendation read, ". . . creatinine kinase-MB and troponin I or T should be measured. . .." They have been changed to read, ". . . creatine kinase-MB and/or troponin I or T should be measured. . .." The corrected recommendation now reads,

   In patients who have signs or symptoms suggestive of MI during or after PCI or in asymptomatic patients with significant *persistent* angiographic complications (eg, large side-branch occlusion, flow-limiting dissection, no-reflow phenomenon, or coronary thrombosis), creatine kinase-MB and/or troponin I or T should be measured. (*Level of Evidence: C*).

3. On page e613, in the first column, second paragraph under section "5.10. Periprocedural MI Assessment: Recommendations," the parenthetical expression in the first and second lines of the Class IIb recommendation read, ". . . (creatinine kinase-MB and/or troponin I or T). . .." It has been changed to read, ". . . (creatine kinase-MB and/or troponin I or T). . .." The corrected recommendation now reads,

   Routine measurement of cardiac biomarkers (creatine kinase-MB and/or troponin I or T) in all patients after PCI may be reasonable. (*Level of Evidence: C*).

These corrections have been made to the current online version of the article, which is available at http://circ.ahajournals.org/content/124/23/e574.

(*Circulation.* 2012;125:e412.)
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Circulation is available at http://circ.ahajournals.org DOI: 10.1161/CIR.0b013e31824da922

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2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention—ONLINE AUTHOR LISTING OF COMPREHENSIVE RELATIONSHIPS WITH INDUSTRY AND OTHERS (October 2011)

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Glenn N. Levine *(Chair)*	Baylor College of Medicine—Professor of Medicine; Director, Cardiac Care Unit	None	None	None	None	None	None
Eric R. Bates *(Vice Chair)*	University of Michigan—Professor of Medicine	• Bristol-Myers Squibb • Daiichi Sankyo • Datascope • Eli Lilly • Merck • sanofi-aventis • Takeda	None	None	None	None	None
James C. Blankenship *(Vice Chair)*	Geisinger Medical Center—Director of Cardiology and Cardiac Catheterization Laboratory	None	None	None	• Abiomed • AstraZeneca • Boston Scientific • Conor Medsystems • Kai Pharmaceutical • Novartis • Schering-Plough	None	None
Steven R. Bailey	University of Texas Medical Center—Professor of Medicine and Radiology	• Volcano	None	None	• Boston Scientific	None	None
John A. Bittl	Munroe Heart—Interventional Cardiologist	None	None	None	None	None	None
Bojan Cercek	Cedars-Sinai Medical Center—Director, Coronary Care Unit	None	None	None	None	None	None
Charles E. Chambers	Penn State Milton S. Hershey Medical	None	None	None	None	None	None

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	Center—Professor of Medicine and Radiology						
Stephen G. Ellis	Cleveland Clinic Foundation—Director, Sones Cardiac Catheterization Laboratory	• Abbott Vascular • AcelleRX Therapeutics • Boston Scientific • CardioDX • Celera Diagnostic • Cordis • Viacor	None	None	None	None	None
Robert A. Guyton	Emory Clinic, Inc—Professor and Chief, Division of Cardiothoracic Surgery	None	None	None	• Edwards Lifesciences	None	None
Steven M. Hollenberg	Cooper University Hospital—Director, Coronary Care Unit	• Eisai	None	None	None	None	None
Umesh N. Khot	CV Research Innovations, LLC—President/CEO	None	None	• Merck*	• St. Francis Hospital and Health Centers*	None	None
Laura Mauri	Brigham & Women's Hospital—Assistant Professor of Medicine, Harvard Medical School	• Conor Medsystems (Johnson & Johnson) • Cordis	None	None	• Lutonix	• Abbott • Abiomed • Boston Scientific • Bristol-Myers Squibb • Conor Medsystems • Cordis • Daiichi Sankyo • Eli Lilly • Medtronic Cardiovascular • sanofi-aventis	• Defendant, Interpretation of clinical trial results, 2010
Roxana Mehran	Columbia University Medical Center—Associate Professor of Medicine; Director, Data Coordinating Analysis	• Abbott Vascular • Abiomed • Accumetrics • AlphaMedical • AstraZeneca	None	None	None	• Endothelix	None

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Issam D. Moussa	Weill Medical College of Cornell University—Associate Professor of Medicine	None	None	None	None	None	None
Debabrata Mukherjee	Texas Tech University—Chief, Cardiovascular Medicine	None	None	None	None	None	None
*Brahmajee K. Nallamothu	University of Michigan—Assistant Professor of Medicine	None	None	None	None	None	None
Henry H. Ting	Mayo Clinic—Professor of Medicine; Assistant Dean for Quality	None	None	None	None	None	None

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2011 ACCF/AHA/SCAI Percutaneous Coronary Intervention Guideline Data Supplements

Tables 1 to 15 pertain to the Revascularization Section

Data Supplement 1. Evidence for Survival Benefit After PCI or CABG (With LIMA Grafting to the LAD) in Patients With SIHD Who Are Receiving Medical Therapy and Are Suitable Candidates for Revascularization

Anatomic Subgroups	Evidence Supporting CABG for Survival	Evidence Supporting PCI for Survival	Evidence Supporting Superiority of Either CABG or PCI for Survival	Evidence Supporting Equivalence of CABG and PCI for Survival
Unprotected left main CAD	CASS Registry* (1,2) CASS† (3) VA Cooperative† (4,5) Yusuf et al.† (6) Dzavik et al.* (7)	*None found*	*CABG better:* Wu* (8) *PCI better:* None found	SYNTAX† (10) LE MANS† (11) Boudriot et al.† (12) Chieffo et al.* (13,14) Lee et al.* (15) Lee et al.§ (16) Naik et al.§ (17) White et al.* (18) Palmerini et al.* (19) Park et al.* (20) Sanmartín et al.* (21) Brener et al.* (22) Mäkikallio et al.* (23)
SYNTAX score <33			SYNTAX†(9)	
SYNTAX score ≥33			SYNTAX† (9)	
3-vessel disease with or without proximal LAD disease	*For:* Dzavik et al.* (7) ECSS† (24) Jones et al.* (25) MASS II* (26) Myers et al.† (27) Smith et al.* (28) SYNTAX†(9) Yusuf et al.† (6)	*For:* Dzavik et al.* (7) Smith et al.* (28) *Against:* Boden et al.† (29)	*CABG better:* Bair et al.* (30) Booth et al.† (31) Hannan et al.* (32) Hannan et al.* (33) Jones et al.* (25) MASS II* (26) Malenka et al.* (34)	Bravata et al.† (35) Daemen et al.† (36) Dzavik et al.* (7) ERACI II† (37) Mercado et al.† (38) RITA I† (39) Van Domburg et al.* (40)

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2-vessel disease with proximal LAD disease	*For:* ECSS† (24) Jones et al.* (25) Smith et al.* (28) Yusuf et al.† (6)	*For:* Dzavik et al.* (7) Jones et al.* (25) Smith et al.* (28) *Against:* Boden et al.† (29)	*CABG better:* Hannan et al.* (32) Hannan et al.* (33) Hannan et al.* (41) Jones et al.* (25)	Berger et al.† (42) ERACI II† (37) Malenka et al.* (34)
2-vessel disease without proximal LAD disease	*For:* Smith et al.* (28)	*For:* Jones et al.* (25) Smith et al.* (28) *Against:* Boden et al.† (29) Cecil et al.† (43) Pitt et al.† (44)	*CABG better:* Bair et al.* (30) Booth et al.† (31) Dzavik et al.* (7) Hannan et al.* (41) Hannan et al.* (33) Jones et al.* (25)	Bravata et al.† (35) Daemen et al.† (36) Dzavik et al.* (7) Jones et al.* (25) Mercado et al.† (38) van Domburg et al.* (40)
1-vessel proximal LAD disease	*For:* Smith et al.* (28) *Against:* Greenbaum et al.* (45)	*For:* Jones et al.* (25) Smith et al.* (28) *Against:* Greenbaum et al.* (45)	*CABG better:* Hannan et al. (32)	Aziz et al.† (46) Ben-Gal et al.* (47) Bravata et al.† (35) Cisowski et al.§ (48) Diegeler et al.† (49) Drenth et al.† (50) Fraund et al.* (51) Goy et al.† (52,53) Greenbaum et al.* (45) Hong et al.† (54) Jaffery et al.† (55) Jones et al.* (25) Kapoor et al.† (56) MASS I† (57)
1-vessel disease without proximal LAD involvement	*Against:* Jones et al.* (25) Smith et al.* (28) Yusuf et al.† (6)	*Against:* Jones et al.* (25)	*PCI better:* Hannan et al.* (32) Jones et al * (25)	Jones et al.* (25)

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Multivessel CAD, DM present	*For:* MASS II† (58) Sorajja et al.* (59) *No benefit:* BARI 2D† (60)	*For:* MASS II† (58) *No effect:* BARI 2D† (60) Sorajja et al.* (59)	*CABG better:* BARI I† (61,62) Brener et al.* (63) Hlatky et al.† (64) Javaid et al.* (65) Malenka et al.* (34) Niles et al.* (66) Pell et al.* for 3-V CAD (67) Weintraub et al.† (68)	ARTS I* (69) Bair et al.* (30) Barsness et al.* (70) Bravata et al.† (35) CARDia† (71) Dzavik et al.* (7) MASS II† (58) Pell et al.* for 2-V CAD (67)

*Observational study, including articles on long-term follow-up, clinical trials not specified as randomized, comparative registry studies, comparative studies, prospective cohort studies, prospective observational studies, prospective registries, and prospective studies. †Randomized controlled trials, including meta-analyses. ‡Reviews (systematic or not). §Unknown study design.

ARTS indicates Arterial Revascularization Therapies Study Part; AWESOME, Angina With Extremely Serious Operative Mortality Evaluation; BARI I, Bypass Angioplasty Revascularization Investigation I; BARI 2D, Bypass Angioplasty Revascularization Investigation 2 Diabetes; CAD, coronary artery disease; CARDIA, Coronary Artery Revascularization in Diabetes; DM, diabetes mellitus; ECSS, European Coronary Surgery Study; ERACI II, Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty versus Coronary Artery Bypass Surgery in Multivessel Disease II; LAD, left anterior descending; LIMA, left internal mammary artery; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomised Intervention Treatment of Angina; SIHD, stable ischemic heart disease; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; V, vessel; and VA, Veterans Administration.

Data Supplement 2. Evidence for Relief of Unacceptable Angina in Subsets of Patients With SIHD Who are Receiving GDMT and Have Anatomy Suitable for Revascularization

Anatomic Subgroups	Evidence Supporting CABG + GDMT for Angina	Evidence Supporting PCI + GDMT for Angina	Evidence Supporting Superiority of either CABG or PCI for Angina	Evidence Supporting Equivalence of CABG and PCI for Angina
Multivessel CAD	*Benefit:* Benzer et al.* (72) Bonaros et al.* (73) Favaroto et al.† (74) Hofer et al.* (75) Lukkarinen et al.* (76) MASS II† (26) RITA I† (77)	*No benefit:* Lukkarinen et al.* (76) *Benefit:* Benzer et al.* (72) COURAGE† (29,78) Hambrecht et al.‡ (79) Hofer et al.* (75) MASS II† (26) RITA I† (77) RITA II† (80) Wijeysundera et al.‡ (81)	*CABG better:* Benzer et al.* (72) Bonaros et al.* (73) Lukkarinen et al.* (76) RITA I† (39) *PCI better:* None found	Hofer et al.* (75) MASS II et al.† (26) Takagi et al.‡ (82)
1-vessel CAD excluding the proximal LAD	No data found	Hambrecht et al.† (79) Parisi et al.† (83) Pitt et al.† (44) Pocock et al.† (80)	No data found	No data found

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1-vessel CAD involving the proximal LAD	MASS I† (57)	Hambrecht et al.† (79) Parisi et al.† (83) Pitt et al.† (44) Pocock et al.† (80)	*CABG better:* Ben-Gal et al.* (47) Cisowski et al.† (48) Diegeler et al.‡ (49) Goy et al.† (52) Toutouzas et al.* (130) MASS I† (57)	Cisowski et al.† (84) Drenth et al.§ (85) Thiele et al.† (86)
Special Circumstances				
Patients with prior CABG and small or moderate sized area of ischemia	No data found	Gurfinkel et al.§ (87) Pfautsch et al.* (88) Subramanian et al.* (89)	*CABG better:* Weintraub et al.† (90)	Stephan et al.* (91)

*Observational study, including articles on long-term follow-up, clinical trials not specified as randomized, comparative registry studies, comparative studies, prospective cohort studies, prospective observational studies, prospective registries, and prospective studies. †Randomized controlled trials, including meta-analyses. ‡Reviews (systematic or not). §Unknown study design.

ARTS indicates Arterial Revascularization Therapies Study Part; AWESOME, Angina With Extremely Serious Operative Mortality Evaluation; BARI 2D, Bypass Angioplasty Revascularization Investigation 2 Diabetes; CABG, coronary artery bypass graft; CAD, coronary artery disease; CARDia, Coronary Artery Revascularization in Diabetes; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; GDMT, guideline-directed medical therapy; LAD, left anterior descending artery; LOE, level of evidence; MASS, Medicine, Angioplasty or Surgery Study; PCI, percutaneous coronary intervention; RITA, Randomised Intervention Treatment of Angina; SIHD, stable ischemic heart disease; and TIME, Trial of invasive versus medical therapy in elderly patients.

Data Supplement 3. RCTs of CABG Versus Balloon Angioplasty

					Acute Outcome		Late Outcome						
					Death %	Q Wave MI %	Death %	Q Wave MI %	Angina %	Repeat Revascularization %	Primary Endpoint	Primary Endpoint	Follow-Up in Years
Trial	No.	Age (y)	Female	CAD	CABG/ PCI	CABG/ PCI	CABG/ PCI	CABG/ PCI	CABG/ PCI	CABG/ PCI		CABG/ PCI	
BARI (62,92,93,94)	1,829	61	26%	MV	1.3/1.1	4.6/2.1	26.5/29	36/36	NA/NA	20/77*	D	26.5/29	10
EAST (95,96)	392	61	26%	MV	1.0/1.0	10.3/3.0*	17/21	19.6/16.6	12/20*	27/65*	D+MI+T	27.3/28.8	8[a]
GABI (97)	359	NA	20%	MV	2.5/1.1	8/2.3*	22/25	9.4/4.5	26/29	59/83*	A	26/29	13[b]
Toulouse et al. (98)	152	67	23%	MV	1.3/1.3	6.6/3.9	10.5/13.2	1.3/5.3	5.3/21.1*	9/29*	A	5.2/21.1*	5
RITA I (39, 77,99)	1,011	57	19%	SV/MV	1.2/0.8 RR: 0.88 (95% CI: 0.59 to 1.29)	2.4/3.5	9.0/7.7	7.4/10.8	52/78*	11/44*	D+MI+T	8.6/9.8	5

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ERACI (100,101)	127	58	13%	MV	4.6/1.5	6.2/6.3	4.7/9.5	7.8/7.8	3.2/4.8	6/37*	D+MI+A+Revasc	23/53*	3
MASS (57,102)	142	56	42%	SV (LAD)	1.4/1.4	1.4/0	2.9/5.7	7/11	23/25	0/30*	D+MI+Revasc	3/24*	3
Goy et al. (52, 53)	134	56	20%	SV (LAD)	0/0	0/0	2/9	4/15* RR: 2.6 (95% CI: 1.1 to 5.4; p=0.00004)[c]	29/26	9/38*	D+MI+Revasc	7.6/36.8*	5
CABRI (103,104)	1,054	60	22%	MV	1.3/1.3	N/A/N/A	2.7/3.9 RR: 1.42 (95% CI: 0.731 to 2.76; p=0.297)	3.5/4.9 RR: 1.42 (95% CI: 0.80 to 2.54; p=0.234)	10.1/13.9* RR: 1.54 (95% CI: 1.09 to 2.16; p=0.012)	9/36* RR: 5.23 (95% CI: 3.90 to 7.03; p<0.001)	D	2.7/3.9	1

*Statistically significant; [a]Mortality and repeat revascularization at 8 y, other endpoints at 3 y; [b]Mortality and repeat revascularization at 13 y, other endpoints at 1 y; [c]Relative risk for combined endpoint cardiac death and MI.

A indicates angina; BARI, Bypass Angioplasty Revascularization Investigation; CAD, coronary artery disease; CABG, coronary artery bypass graft; CABRI, Coronary Angioplasty versus Bypass Revascularization Investigation; CI, confidence interval; D, death; EAST, Emory Angioplasty versus Surgery Trial; ERACI, Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty versus Coronary Artery Bypass Surgery in Multivessel Disease; GABI, German Angioplasty Bypass Surgery Investigation; LAD, left anterior descending; MASS, Medicine, Angioplasty, or Surgery Study; MI, myocardial infarction; MV, multivessel; NA, not available; No., number; PCI, percutaneous coronary intervention; RITA, Randomized Intervention Treatment of Angina; Revasc, repeat revascularization; RR, relative risk; SV, single-vessel; and T, thallium defect.

Data Supplement 4. RCTs of CABG Versus BMS

						Death %	Q Wave MI %	Angina %	Repeat Revascularization %	Primary Endpoint	Primary Endpoint %	Follow-Up in Years
Trial	**No.**	**Age (y)**	**Female**	**CAD**	**Enrollment Period**	**CABG/ PCI**	**CABG/ PCI**	**CABG/ PCI**	**CABG/PCI**		**CABG/ PCI**	
SIMA (105)	121	59	21%	SV	1994-1998	4/2	4/5	5/9	8/24	D+MI+Rep Revasc	7/31*	2.4
AWESOME (106,107)	454	67	NA	MV	1995-2000	21/18	NA	NA	22/43*	D	21/20	5
MASS II (26)	408	60	32%	MV	1995-2000	25/24	10/13	NA	7.5/41.9	D+MI+Rep Revasc HR: 1.85 (95% CI: 1.39 to 2.47)	33/42*	10
ERACI II (101,108)	450	62	21%	MV	1996-1998	11.6/7.2	6.2/2.8	18/14	7.2/28.4*	D+MI+CVA+Rep Revasc	23.6/34.7*	5
SoS (109)	988	61	21%	MV	1996-1999	6.8/10.9* HR: 2.91 (95% CI: 1.29 to 6.53; p=0.01)	8.2/4.9	NA	6/21* HR: 3.85 (95% CI: 2.56 to 5.79; p<0.0001)	Rep Revasc	6/21*	6

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ARTS I (110)	1205	61	24%	MV	1997-1998	7.6/8.0 RR: 1.05 (95% CI: 0.71 to 1.55; p=0.83)	5.6/6.7 RR: 1.19 (95% CI: 0.76 to 1.85; p=0.47)	NA	8.8/30.3* RR: 3.46 (95% CI: 2.61 to 4.60; p<0.001)	D+MI+CVA+Rep Revasc	21.8/41.7* RR: 1.91 (95% CI: 1.60 to 2.28; p<0.001)	5
Drenth et al. (50, 85)	102	61	24%	SV	1997-1999	2/0	2/10	15/33	4/16	D+MI+CVA+Rep Revasc	14/29	4
Leipzig (49,111)	220	62	25%	SV	1997-2001	12/10 RR: 0.85 (95% CI: 0.37 to 1.93; p=0.54)	7/5 RR: 0.71 (95% CI: 0.20 to 2.43; p=0.46)	NA	10/32* RR: 3.18 (95% CI: 1.67 to 6.39; p<0.001)	D+MI+Rep Revasc	29/47* RR: 1.64 (95% CI: 1.13 to 2.42; p=0.02)	5
Myoprotect (112)	44	70	30%	MV	1998-2001	24/22	0/4	NA	5/30	D+MI+Rep Revasc	29/48*	1
Octostent (113)	280	60	29%	MV	1998-2000	2.8/0	4.9/4.4	13/22	4.2/15.2	D+MI+CVA+Rep Revasc	9.5/14.5 RR: 0.93 (95% CI: 0.86 to 1.02)	1
AMIST (114)	100	57	22%	SV	1999-2001	25/30	0/4	8/10	0/4	D+MI+Rep Revasc+T	28/34	1
Cisowski et al. (48,84)	100	54	17%	SV	2000-2001	0/3.6	0/0	0/20	0/20	D+MI	0/4	1
Kim et al. (115)	100	62	35%	SV	2000-2001	4.0/4.0	NA	6/19	2/14	NA	NA	1

*Statistically significant. AMIST indicates Angioplasty versus Minimally Invasive Surgery Trial; ARTS, Arterial Revascularization Therapies Study; AWESOME, Angina with Extremely Serious Operative Mortality Evaluation; BMS, bare-metal stent; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CI, confidence interval; CVA, cerebrovascular accident; D, death; ERACI, Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Multivessel Disease; MASS, Medicine, Angioplasty, or Surgery Study; MI, myocardial infarction; MIDCAB, minimally invasive direct coronary artery bypass; MV, multivessel; NA, not available; Octostent, Long-term comparison of stenting versus off-pump; PCI, percutaneous coronary intervention; RITA, Randomized Intervention Treatment of Angina; RR, relative risk; Rep Revasc, repeat revascularization; SIMA, Stenting versus Internal Mammary Artery Study; SoS, Stent or Surgery; SV, single-vessel; and T, thallium defect.

Data Supplement 5. RCTs of CABG Versus DES

						Death %	MI %	Repeat Revascularization %	Primary Endpoint		RR and 95% CI	Follow-Up in Months
Trial	**No.**	**Age (y)**	**Female**	**CAD**	**Enrollment Period**	**CABG/PCI**	**CABG/PCI**	**CABG/PCI**		**CABG/PCI**		
Hong et al. (54)	189	61	36%	SV	2003	2.9/0	2.9/1.7	5.9/1.7	D, MI, Rep Revasc	11.7/4.3	N/A	6
Leipzig (86)	130	66	30%	SV	2003-2007	0/0	7.7/1.5*	0/6.2	D+MI+Rep Revasc	7.7/7.7	N/A	12
SYNTAX (116,117)	1800	65	22%	MV	2005-2007	6.7/8.6	3.6/7.1	10.7/19.7	D+MI+CVA+Rep Revasc	20.2/28.0	MACCE 12 mo follow-up; RR: 1.44 95% CI: 1.15 to 1.81	36

*Statistically significant. CABG indicates coronary artery bypass surgery; CAD, coronary artery disease; CI, confidence interval; CVA, cerebrovascular accident; D, death; MACCE, major adverse cardiac and cerebrovascular events; MI, myocardial infarction; N/A, not applicable; No., number of patients; MV, multivessel; PCI, percutaneous coronary intervention; RR, relative risk; Rep Revasc, repeat revascularization; SV, single vessel; and SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.

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Data Supplement 6. Hazard Ratios in Observational Studies Comparing PCI-DES to CABG

Study	Location	No. Patients (CABG/PCI)	Average Age (y)	Female Patients %	CAD	Enrollment Period	Combined Death/MI/CVA HR and 95% CI	Repeat Revascularization HR and 95% CI	MACCE HR and 95% CI	Follow-Up in Months
Park et al. (118)	Korea	1,495/1,547	62	29%	MVD	2003-2005	0.7* 0.53 to 0.91	2.56* 1.96 to 3.4	1.37* 1.16 to 1.63	31
Hannan et al. (33)	USA	7,437/9,964	66	30%	MVD	2003-2004	0.99 0.89 to 1.098	5.88* 5.31 to 6.51	2.89* 2.72 to 3.08	19
Briguori et al. (119)	Italy	149/69	65	29%	MVD	2002-2004	1.03 0.53 to 1.99	4.01* 1.67 to 9.60	1.48* 0.91 to 2.43	12
Yang et al. (120)	China	231/235	65	22%	MVD	2003-2004	0.7 0.33 to 1.49	13.26* 4.15 to 42.34	3.09* 1.80 to 5.30	25
Lee et al. (121)	USA	103/102	68	35%	MVD	2003-N/A	1.29 0.68 to 2.46	6.73* 2.06 to 21.95	2.25* 1.36-3.72	12
Yang et al. (122)	Korea	390/441	63	29%	MVD	2003-2004	0.75 0.43 to 1.31	4.26* 1.78 to 10.15	1.41* 0.93 to 2.13	12
Javaid et al. (65)	USA	701/979	65	33%	MVD	N/A	1.93 1.37 to 2.73	2.43* 1.73 to 3.41	2.44* 1.87 to 3.19	12
Varani et al. (123)	Italy	95/111	65	31%	MVD	2003-2005	0.47* 0.16 to 1.37	5.91* 1.39 to 25.6	1.52* 0.70 to 3.28	12
Tarantini et al. (124)	Italy	127/93	66	18%	MVD	2005-2005	0.56 0.20 to 1.56	1.91* 0.62 to 5.83	0.96* 0.48 to 1.92	24
Pooled HR							0.94	4.06	1.86	
							p=0.66	*p<0.001*	*p<0.001*	

*Statistically significant. CABG, coronary artery bypass surgery; CAD, coronary artery disease; CI, confidence interval; CVA, cerebrovascular accident; DES, drug-eluting stent; HR, hazard ratio; MACCE, major adverse cardiac and cerebrovascular events; MI, myocardial infarction; Mo, months; MVD, multivessel disease; N/A, not available; No, number; PCI, percutaneous coronary intervention, and y, year.

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Data Supplement 7. Evidence from RCTs and Cohort Studies Comparing PCI with CABG for Unprotected Left Main CAD

Study	Type of Study/ Years of Recruitment	PCI/CABG No. of Patients	Early Results for PCI Versus CABG	1 to 5-Y Results for PCI Versus CABG
SYNTAX (10)	Randomized/2005-2007 45% of screened pts with LM disease not randomized, 89% of these had CABG	357/348	30-d outcomes not reported	3-y follow-up: MACCE 13.0% vs. 14.3% (p=0.60); repeat revascularization 20.0% vs. 11.7% (p=0.004); all-cause death 7.3% vs. 8.4% (change -0.2%, p=0.64).
LE MANS (11)	Randomized/2001-2004 65% of screened pts excluded as not suitable for both procedures	52/53	30-d outcomes: death 0% vs. 0%; MI 2% vs. 4% (p=NS) MACCE 2% vs. 14% (p=0.01) MAE RR: 0.78, p=0.006; MACCE RR: 0.88, p=0.03	1 y follow-up: death 2% vs. 8% (p=NS); MI 2% vs. 6% (p=NS); revascularization 30% vs. 10% (p=0.01); MACCE 32% vs. 26% (p=NS); MACCE RR: 1.09 (95% CI: 0.85 to 1.38); MAE RR: 0.89 (95% CI: 0.64 to 1.23)
Boudriot et al. (12)	Randomized/2003-2009 53% of screened pts excluded	100/201	Early outcomes not reported	12 mo outcomes: death 2.0% vs. 5.0% (p<0.001 for noninferiority); death, MI or revascularization 19.0% vs. 13.9% (p=0.19 for noninferiority)
Brener et al. (22)	Cohort/1997-2006	97/190	In-hospital outcomes: death 3% vs. 4% (p=NS)	3 y follow-up: survival 80% vs. 85%; OR: 1.42 (95% CI: 0.56 to 3.63; p=0.14)
Cedars-Sinai (15,17,18)	Cohort/2003-2005	67/67	30-d outcomes: death 2% vs. 5% (p=NS); MI 0% vs. 2% (p=NS); stroke 0% vs. 8% (p=0.03); MACCE 17% vs. 2%; (p<0.01)	1-2 y follow-up: propensity-adjusted HR for death HR: 1.93 (95% CI: 0.89 to 4.19; p=0.10), MACCE HR: 1.83 (95% CI: 1.01 to 3.32; p=0.05)
Chieffo et al. (13,14)	Cohort/2002-2004	107/142	In-hospital outcomes: death 0% vs. 2.1% (p=NS); MI 9.3% vs. 26.1% (p=0.0009); stroke 0% vs. 2% (p=NS)	5 y adjusted cardiac death OR: 0.50 (95% CI: 0.16 to 1.46; p=0.24), cardiac death or MI OR: 0.41 (95% CI: 0.15 to 1.06; p=0.06); death, MI, or stroke OR: 0.40 (95% CI: 0.15 to 0.99; p=0.04); TVR OR: 4.41(95% CI: 1.83 to 11.37; p=0.0004), MACCE OR: 1.58 (95% CI: 0.83 to 3.05; p=0.18)
MAIN-COMPARE (20,125)	Cohort/2000-2006	1102/1138	30-d outcomes not reported	5-y adjusted risk of death HR: 1.13 (95% CI: 0.88 to 1.44, p=0.35), combined adjusted risk of death, Q-wave MI, or stroke HR: 1.07 (95% CI: 0.84 to 1.37,p=0.59); TVR HR: 5.11 (95% CI: 3.52 to 7.42,p<0.001)
Mäkikallio et al. (23)	Cohort/2005-2207	49/238	30-d outcomes: death 2% vs. 7% (p=0.13)	1-y follow-up: death 4% vs. 11% (p=0.14); PCI vs. CABG (using 1° and 2° endpoint) HR: 2.1 (95% CI: 0.7 to 5.8, p= 0.180)

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Palmerini et al. (19)	Cohort/2002-2005	157/154	30-d outcomes: death 3.2% vs. 4.5% (p=NS); MI 4.5% vs. 1.9%,(p=NS); revascularization 0.6% vs. 0.6% (p=NS)	1-2 y follow-up: death 13.4% vs. 12.3% (p=0.8); MI 8.3% vs. 4.5% (p=0.17); revascularization 25.5% vs. 2.6% (p=0.0001); PCI vs. CABG mortality HR: 0.95 (95% CI: 0.51 to 1.77, p=0.861); cardiac mortality HR: 0.99, (95% CI: 0.49 to 2.04, p=0.994); MI HR: 0.53 (95% CI: 0.21 to 1.32; p=0.170)
Rodés-Cabau et al. (126)	Cohort/2002-2008	104/145	30-d outcomes: MACCE 18.3% vs. 27.6%; death 6.7% vs. 8.3%; MI 12.5% vs. 17.2%; stroke 1.0% vs. 5.5% (all p=NS)	1-2-y follow-up: MACCE 43.3% vs. 35%; death 16.3% vs. 12.4%; MI 23.1% 19.3%; revascularization 9.6% vs. 4.8%; stroke 8.75 vs. 6.2% (all NS). Survival free of cardiac death or MI adjusted HR: 1.28 (95% CI: 0.64 to 2.56; p=0.47); MACCE-free survival adjusted HR: 1.11(95% CI: 0.59 to 2.0; p= 0.73).
Sanmartín et al. (21)	Cohort/2000-2005	96/245	30-d outcomes: MACCE after surgery 2.1% vs. 9.0% (p=0.03).	1-y follow-up: MACCE 10.4% vs. 11.4%, (p=0.50), repeat revascularization 5.2% vs. 0.8% (p=0.02)
Wu et al. (8)	Cohort/2000-2004	135/135	30-d outcomes: death 5.2% vs. 2.2% (p=0.33)	1-y follow-up: death 16.1% vs. 5.9% OR: 3.06 (95% CI: 0.99 to 9.45) 2-y follow-up: death 18.0% vs. 5.9%; HR: 3.1 (95% CI: 1.42 to 7.14; p=0.005); revascularization 37.3% vs. 6.3%; HR: 6.7; (95% CI: 3.0 to 14.3; p<0.001)

CABG indicates coronary artery bypass grafting; CI, confidence interval; d, day; HR, hazard ratio; LEMANS, Study of Unprotected Left Main Stenting Versus Bypass Surgery; LM, left main; MACCE, Major adverse cardiac and cardiovascular events; MAE, major adverse events; MAIN-COMPARE, Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization; MI, myocardial infarction; NS, not significant; OR, odds ratio; pts, patients; PCI, percutaneous coronary intervention; RR, relative risk; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; TVR, target vessel revascularization; and y, year.

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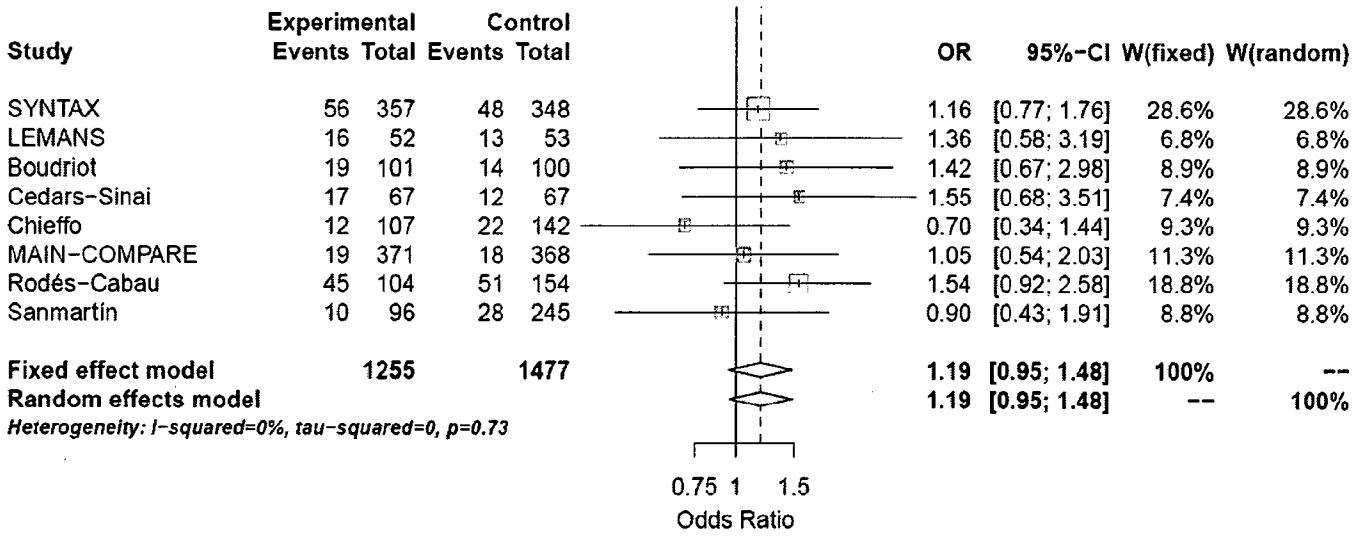
Data Supplement 8. Forest Plot of 1-Year MACCE Rates After PCI or CABG for Unprotected Left Main CAD



References: (10,11,12,13,14,15,17,18,20,125,126). OR >1 suggest an advantage of CABG over PCI.
CABG indicates coronary artery bypass surgery; CAD, coronary artery disease; CI, confidence interval; LEMANS, Study of Unprotected Left Main Stenting Versus Bypass Surgery; MAIN-COMPARE, Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization; MACCE, major adverse cardiac and cerebrovascular event; OR, odds ratio; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and W, weighted.

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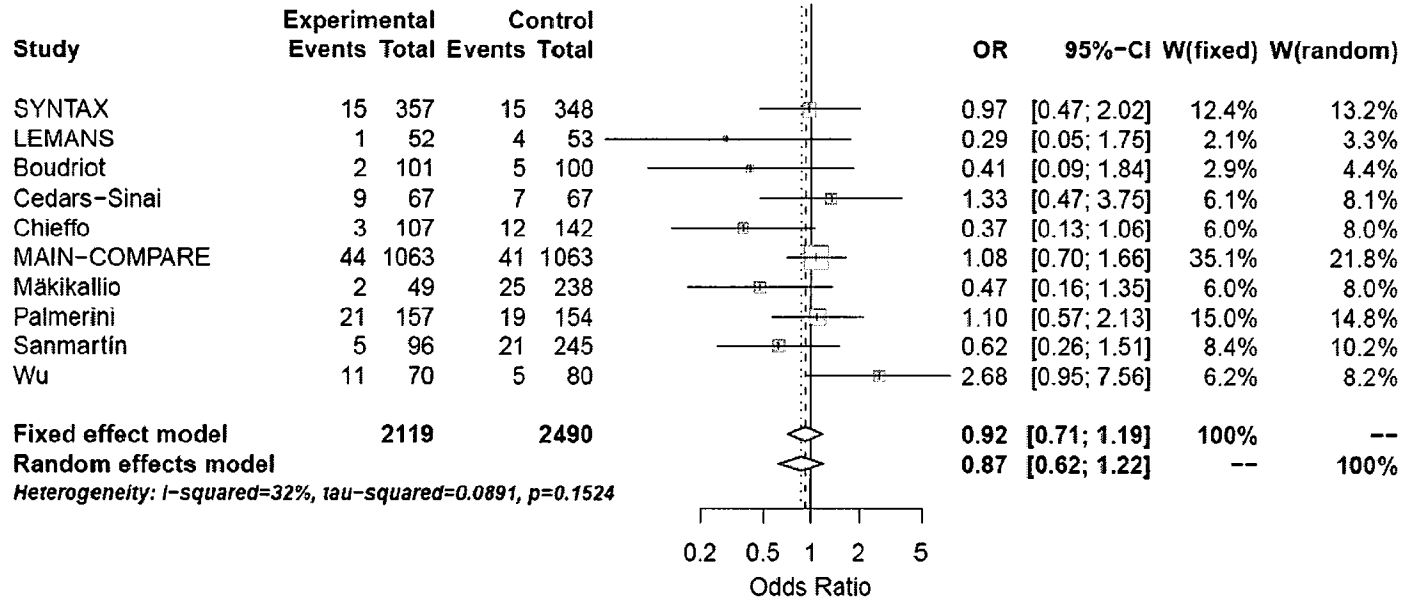
Data Supplement 9. Forest Plot of 1-Year Mortality Rates After PCI or CABG for Unprotected Left Main CAD



References: (8,10,11,12,13,14,15,17,18,19,20,23,125,126). OR >1 suggest an advantage of CABG over PCI.
CABG indicates coronary artery bypass surgery; CAD, coronary artery disease; CI, confidence interval; LEMANS, Study of Unprotected Left Main Stenting Versus Bypass Surgery; MACCE, major adverse cardiac and cerebrovascular event; MAIN-COMPARE, Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization; OR, odds ratio; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and W, weighted.

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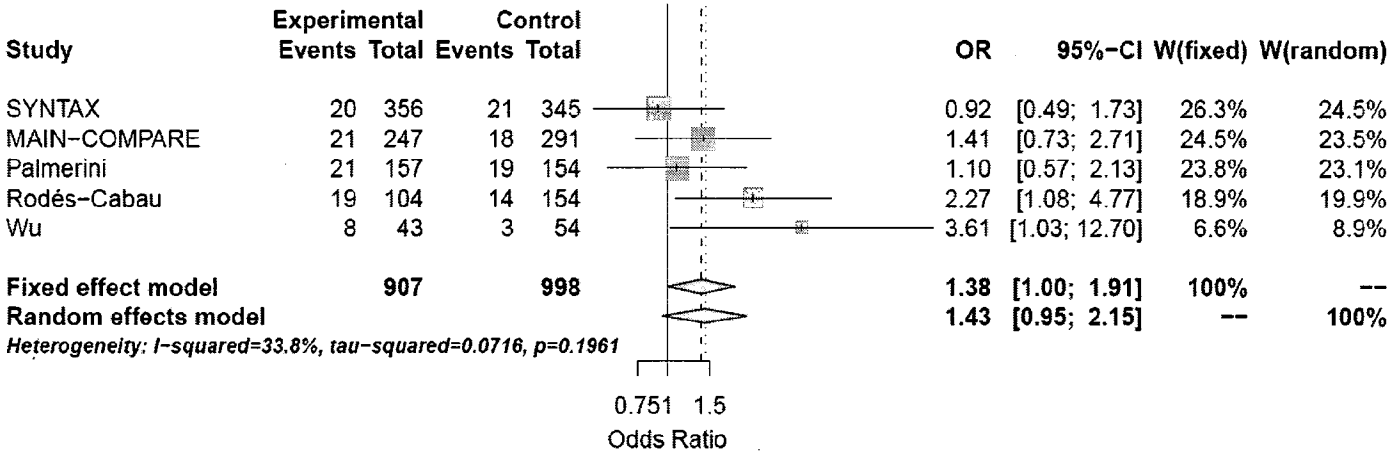
Data Supplement 10. Forest Plot of 2-Year Mortality Rates After PCI or CABG for Unprotected Left Main CAD



References: (8,11,19,20,125 126,127). OR >1 suggest an advantage of CABG over PCI.
CABG indicates coronary artery bypass surgery; CAD, coronary artery disease; CI, confidence interval; MAIN-COMPARE, Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization; OR, odds ratio; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and W, weighted.

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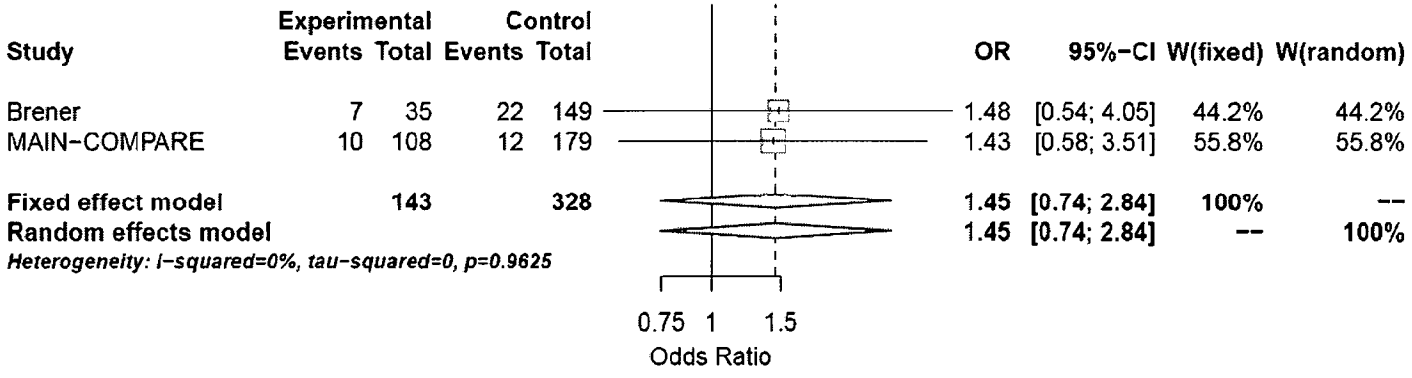
Data Supplement 11. Forest Plot of 3-Year Mortality Rates After PCI or CABG (for Unprotected Left Main CAD)



References: (20, 22). OR >1 suggest an advantage of CABG over PCI.
CABG indicates coronary artery bypass surgery; CAD, coronary artery disease; CI, confidence interval; MAIN-COMPARE, Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization; OR, odds ratio; PCI, percutaneous coronary intervention; and W, weighted.

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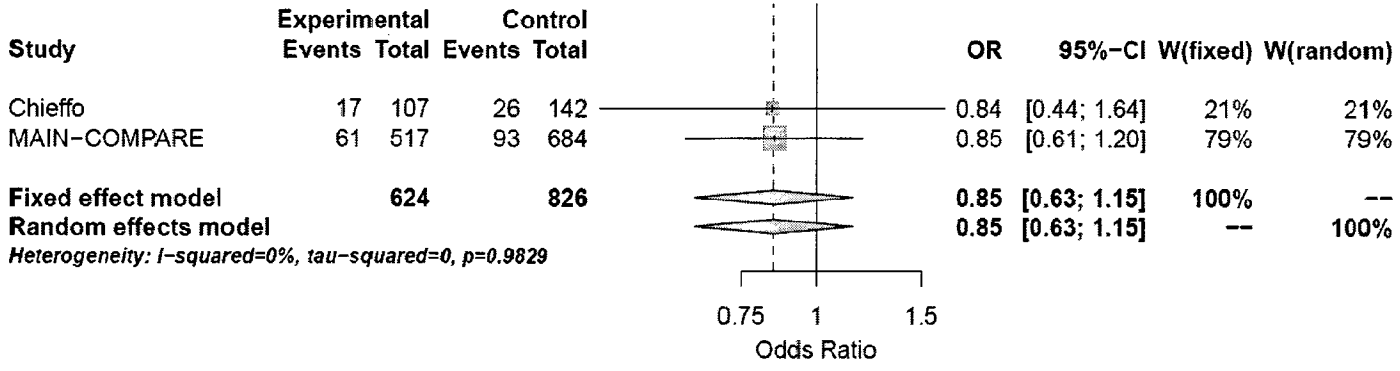
Data Supplement 12. Forest Plot of 5-Year Mortality Rates After PCI or CABG for Unprotected Left Main CAD



References: (14,20). OR >1 suggest an advantage of CABG over PCI.
CABG indicates coronary artery bypass surgery; CAD, coronary artery disease; CI, confidence interval; MAIN-COMPARE, Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization; OR, odds ratio; PCI, percutaneous coronary intervention; and W, weighted.

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Data Supplement 13. Outcomes of PCI Versus CABG for Patients With Single-Vessel Coronary Disease Involving the Proximal Left Anterior Descending Artery

Author	Type of Study/ Years of Recruitment	Number of Patients PCI/CABG	Short-Term Results for PCI Versus CABG	Long-Term Results for PCI Versus CABG
Greenbaum et al. (45)	Retrospective cohort 1986-1994	754/149	At 1 y, HR for event-free survival for CABG to PCI: 0.20; p<0.0001	At 2 to 7 y, HR for event-free survival for CABG to PCI: 0.62; p=NS
Goy et al. (52,53,128)	Randomized 1994-1998	68/66	At 2.4 y: death, MI, revascularization 31% vs. 7% (p<0.001); death or MI 12% vs. 7%	At 5 y: death 9% vs. 3% (p=0.09). At 10 y: death 10% vs. 10% (p=1.0)
Cisowski et al. (48)	Randomized 2000-2001	50/50	At 6 mo: death or MI: 0% vs. 0%; revascularization 12% vs. 2% (p<0.05)	N/A
Diegeler et al. (49)	Randomized 1997- 2001	110/110	At 6 mo: death or MI 3% vs. 6% (p=NS); revascularization 29% vs. 8% (p=0.02)	N/A
Drenth et al. (50,85)	Randomized 1997-99	51/51	At 6 mo: death or MI 6% vs. 10% (p=NS); revascularization 4% vs. 8% (p=NS)	N/A
Reeves et al. (114)	Randomized 1999-2001	50/50	In-hospital: death or MI 0% vs. 0%	At 1.5 y: death 0% vs. 2% (p=NS); MI 4% vs. 0% (p=NS); revascularization 4% vs. 0% (p=NS). Survival analysis for MIDCAB vs. PTCA HR: 0.77 (95% CI: 0.38 to 1.57; p=0.47)
Thiele et al. (86)	Randomized 1997-2001	110/110	N/A	At 5 y: death 10% vs. 12% (p=0.54); MI 5% vs. 7% (p=0.46); revascularization: 32% vs. 10% (p<0.001)
Hong et al. (54)	Randomized 2003	119/70	In-hospital: death or MI 5.1% vs. 4.3% (p=1.00)	At 6 mo: death or MI: 6.8% vs. 10.1% (p=NS); revascularization 5.9% vs. 1.7% (p=NS)
MASS I (57,129)	Randomized	72/70	N/A	At 3 y: death, MI or revascularization 24% vs. 3% (p=0.006)
Fraund et al. (51)	Cohort 1998-2001	256/206	In-hospital death or MI 0.8% vs. 2 % (p=NS)	At 3 y: death or MI 4.7% vs. 5.8% (p=NS); revascularization 7.8% vs. 28.9% (p<0.01)
Ben-Gal et al. (47)	Matched cases from prospective cohort 2002-2003 (PCI were all DES)	83/83	30 d death: 0% vs. 1.1% (p=NS)	At 22 mo: death 1.1% vs. 5.5% (p=NS); revascularization 16.8% vs. 3.6% (p=0.005); independent predictors of MACE (Cox analysis) were assignment to the Cypher group (HR: 4.1; 95% CI: 1.26 to 13.16), multivessel disease (HR: 4.3; 95% CI: 1.44 to 13.16), and prior PCI (HR: 4.36; 95% CI: 1.28 to 14.90)
Toutouzas et al. (130)	Cohort	147/110	Inhospital: death or MI or revascularization 0% vs. 0%	At 2 y: death: 2.0% vs. 1.8% (p=NS); MI 0% vs. 0.9%; (p=NS); revascularization 2% vs. 0% (p=0.51)

CABG indicates coronary artery bypass graft; CI, confidence interval; d, day; DES, drug-eluting stents; HR, hazard ratio; MASS, Medicine, Angioplasty, or Surgery Study; MIDCAB, minimally invasive direct coronary artery bypass ;MI, myocardial infarction; mo, month; NS, not significant; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty and y, year.

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Data Supplement 14. Cohort Studies Comparing CABG to PCI in Patients With Diabetes

Author	Type of Study/ Year of Recruitment	Number of Patients PCI/CABG	Long-Term Results for PCI Versus CABG
Barsness et al. (70)	Retrospective cohort 1984-1990	770 pts with diabetes total	At 5 y: Similar mortality for PCI and CABG pts: unadjusted 86% vs. 89%; p=NS; adjusted 92% vs. 93%
Weintraub et al. (68)	Cohort 1981-1994	834/1,805	At 10 y: death: 64% vs. 53%; p=0.045 for insulin-requiring pts with diabetes ONLY Insulin-requiring subgroup multivariate HR: 1.35; 95% CI: 1.01 to 1.79 for PTCA vs. CABG
Niles et al. (66)	Retrospective cohort 1992-1996	2,766 pts with diabetes total	At 2 y: higher mortality in PCI pts (HR: 2.0; p=0.038) with 3-vessel disease. Trend to higher mortality in PCI pts (HR: 1.3; p=0.2) with 2-vessel disease, compared to CABG
Van Domburg et al. (40)	Cohort 1970-1985	76/82	At 20 y: survival similar for PCI vs. CABG pts Mortality for CABG vs. PTCA RR: 1.03; 95% CI: 0.87 to 1.24
Brener et al. (63)	Retrospective cohort 1995-1999	265/2,054	At 6 y: deaths for NIDDM: 21% vs. 17%; p=0.008 Deaths for IDDM: 31% vs. 23%; p<0.0001 Unadjusted HR: 1.13; 95% CI: 1.0 to 1.4; p=0.07
Javaid et al. (65)	Retrospective cohort DES era	601 pts with diabetes total 344/257	At 1 y: death, stroke, MI, revascularization HR: 3.5; (p<0.001) for 2-vessel CAD HR: 4.8 (p<0.001) for 3-vessel CAD
Hueb et al. (58)	Cohort 1995-2000	120/221	At 5 y: incidence of cardiac death 11.1% vs. 11.8% (p=NS), revascularization 27.5% vs. 3.2% (p<0.001) The incidence of cardiac death was NS different between PCI and MT groups
Bair et al. (30)	Subset of large cohort 1992-2000	353/1,267	At 15 y: death HR: 0.81; p=0.03
Hannan et al. (33)	Subset of large cohort 2003-2004	2,844/3,256	At 18 mo: death HR: 1.03, p=0.75; death or MI HR: 1.19; p=0.07

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; CI, confidence interval; DES, drug-eluting stent; HR, hazard ratio; IDDM, insulin-dependent diabetes mellitus; MI, myocardial infarction; MT, medical therapy; NIDDM, noninsulin-dependent diabetes mellitus; NS, not significant; pts, patients; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; RR, relative risk, and y, year.

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Data Supplement 15. RCTs of PCI With CABG in Patients With Multivessel CAD and Diabetes

Author	Type of Study in Year of Recruitment	Number of Patients PCI/ CABG	Primary Endpoint for PCI and CABG	Comments
SYNTAX (131)	Randomized 2005-2007	Overall 903/897 DM 231/221	DM: 12-mo death, stroke, MI, or revascularization: 26.0% vs. 14.2% (HR: 1.83, 95% CI: 1.22 to 1.73; p=0.003)	Criterion for noninferiority of PCI to CABG was not met in overall study.
CARDIa (71)	Randomized 2002-2007	DM 256/254	DM: 1-y death, stroke or MI: 13.0% vs. 10.5% ([OR: 1.25, 95% CI: 0.75 to 2.09; p=0.39)	Criterion for noninferiority of PCI to CABG was not met.
BARI 2D (60)	Prestratified/randomized to revascularization-medical therapy	DM 798/807	Death from any cause: • Medical: 87.8% • Revascularization: 88.3% • P=0.97	5-y freedom from MACE: • PCI vs. medical (77.0% vs. 78.9; p=0.15) • CABG vs. medical (77.6% vs. 69.5%; p=0.01) • interaction p=0.002
ARTS I (69, 110,132)	Randomized 1997-1998	Overall 600/605 DM 112/96	Overall: 5-y overall freedom from death, stroke, or MI 18.2% vs. 14.9% (RR: 1.22; 95% CI: 0.95 to 1.58; p=0.14) DM: 1-y freedom from death, stroke, MI, or revascularization (63.4% vs. 84.4%; p< 0.001)	
MASS II (58)	Randomized 1995-2000	Overall 205/203 DM 56/59	DM: 1-y death 5.3% vs. 6.8% (p=0.5)	

*ARTS indicates Arterial Revascularization Therapies Study; BARI 2D, Bypass Angioplasty Revascularization Investigation 2 Diabetes; CABG, coronary artery bypass graft; CAD, coronary artery disease; CARDIA, Coronary Artery Revascularization in Diabetes; CI, confidence interval; DM, diabetes mellitus; HR, hazard ratio; LAD, left anterior descending artery; LOE, level of evidence; MACE, major adverse cardiac event; MASS II, Medicine, Angioplasty, or Surgery Study (MASS II); OR, odds ratio; MI, myocardial infarction; PCI, percutaneous coronary intervention; RR, relative risk; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and y, year.

Data Supplement 16. Studies of Acetylcysteine for Prevention of Contrast Induced Nephropathy

Trial, Year	Study Drug / Comparator	Population	Primary Endpoint	Results	Statistics	Comments
ACT, 2011 (133)	Acetylcysteine vs. placebo	2,308 pts undergoing an angiographic procedure with at least one risk factor (age >70 y, chronic renal failure, diabetes mellitus, heart failure (LVEF<45%), or shock	CI-AKI 48 to 96 h after angiography	Acetylcysteine: 12.7%, placebo: 12.7%	p=0.97	No reduction in CI-AKI with Acetylcysteine vs. placebo
LIPSIA-N-ACC, 2010 (134)	Acetylcysteine vs. placebo	251 STEMI pts undergoing primary PCI	1) Occurrence of CI-AKI 2) reperfusion injury measured as myocardial salvage index by MRI	Endpoint 1) Acetylcysteine: 14%, placebo 20% Endpoint 2) Acetylcysteine 43.5, placebo	Endpoint 1) p=0.20 Endpoint 2) p=0.36	No clinical benefit with acetylcysteine with respect to development of CI-AKI and myocardial salvage index

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ACT indicates Acetylcysteine for Contrast-Induced Nephropathy Trial; CI-AKI, contrast-induced acute kidney injury; LVEF, left ventricular ejection fraction; LIPSIA-N-ACC, Leipzig Immediate PercutaneouS Coronary Intervention Acute Myocardial Infarction N-ACC; MRI, magnetic resonance imaging; pts, patients; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; and y, year.

Data Supplement 17. Studies Supporting the Minimization of Contrast Volume to Prevent Contrast Induced Acute Kidney Injury

Trial	Study Drug / Comparator	Population	Primary Endpoint	Results	Statistics	Comments
Marenzi, et al., 2009 (135)	Observational study to investigate the relationship between contrast volume and occurrence of CI-AKI	561 consecutive STEMI pts undergoing primary PCI	CI-AKI within 72 hours postprocedure	A higher volume of contrast media correlated to increased probability to develop CI-AKI: Q1: 10.9%, Q2: 13.6%, Q3: 17.1%, Q4: 27.5%		Volume of contrast media is correlated with incidence of CI-AKI
Laskey et al., 2007 (136)	Observational study into the usefulness of the ratio of contrast volume to creatinine clearance to predict CI-AKI	3,179 consecutive pts undergoing PCI	CI-AKI between 24 to 48 hours postprocedure	Volume to creatinine clearance ratio >3.7 was predictive of CI-AKI	OR 3.8, (95% CI: 2.0 to 7.3) p<0.01	Volume to creatinine clearance ratio can be used to determine maximum amount of contrast media

CI-AKI indicates contrast-induced acute kidney injury; OR, odds ratio; pts, patients; PCI, percutaneous coronary intervention; Q, quartile; and STEMI, ST-elevation myocardial infarction.

Data Supplement 18. Studies of Hydration to Prevent Contrast Induced Acute Kidney Injury

Trial	Study Drug/Comparator	Population	Primary Endpoint	Results	Statistics	Comments
Solomon et al., 1994 (137)	Half-isotonic saline vs. mannitol vs. furosemide	78 pts with chronic renal insufficiency undergoing cardiac angiography.	CI-AKI within 48 h	Saline: 11%, mannitol: 28%, furosemide: 40%	p=0.05	Hydration with saline provides protection against acute decreases in renal function.
Mueller et al., 2002 (138)	Isotonic Saline vs. half-isotonic saline	1620 pts undergoing elective or emergency PCI. Excluded if already on dialysis, had cardiogenic shock or mechanical ventilation.	CI-AKI within 48 h	Half-isotonic saline: 2.0% isotonic saline: 0.7%	p=0.04	Isotonic hydration is superior to half-isotonic hydration in the prevention of contrast-media associated nephropathy.
Trivedi et al., 2003 (139)	IV vs. oral prehydration	53 pts undergoing non-emergent cardiac catheterization. Excluded if CrCl <20mL/min, had decompensated heart failure, unacceptable risk of fluid overload as per primary physician or states of decreased effective arterial volume, e.g., nephritic syndrome, liver cirrhosis.	CI-AKI within 48 h	IV: 3.7% Oral: 34.6%	p<0.01	Intravenous hydration is preferable to oral hydration.

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Bader et al., 2004 (140)	Bolus hydration during contrast media application vs. hydration 12 h before and after contrast media application.	39 pts with normal renal function undergoing cardiac catheterization. Excluded if pregnant, had uncontrolled hypertension, NYHA II-IV heart failure, liver failure or nephritic syndrome.	Change in GFR after 48 h	Change in GFR Bolus: -34.6±25.7 ml/min/1.73m^2 Pre- and posthydration: -18.3±25.0 ml/min/1.73m^2	p<0.05	Hydration hours before and after exposure to contrast media is preferable to a bolus administration of saline immediately before or during contrast media exposure.

CI-AKI indicates contrast-induced acute kidney injury; CrCl, creatinine clearance; GFR, glomerular filtration rate; h, hour; IV, intravenous; NYHA, New York Heart Association; pts, patients; and PCI, percutaneous coronary intervention.

Data Supplement 19. Studies of Periprocedural Statins to Reduce Adverse Outcome in PCI

Study Name	Author and Year	Study Type	Regimen	Study Size	Patient Population/Inclusion & Exclusion Criteria		Endpoints		P-Value	OR (CI)	Study Summary	Study Limitations
					Inclusion Criteria	*Exclusion Criteria*	*Primary Endpoint*	*Secondary Endpoint*				
Statin-naïve												
ARMYDA	Pasceri, 2004 (141)	RCT	Atorvastatin 40 mg/d starting 7 d before PCI	153	Chronic stable angina, elective PCI	ACS	Periprocedural MI (CPK > 2X normal)	1 mo MACE	0	0.25 (95% CI 0.08 to 0.80)	Pretreatment with statins for 1 wk decreases periprocedural MI	Definition of MI (although similar results with threshold 5X normal)
	Brigouri, 2004 (142)	Randomized	statin (atorvastatin, pravastatin, simvastatin) 3 d before PCI	451	Elective PCI	Positive CK or trop at entry	Periprocedural MI (CPK > 5X normal)		0.01	0.47 (95% CI: 0.26 to 0.86)	Pretreatment with statins for 3 d decreases periprocedural MI	Not blinded or placebo controlled
ARMYDA-ACS	Patti, 2007 (143)	RCT	Atorvastatin 80 mg 12 h before PCI and 40 mg preprocedure	171	NSTEMI	STEMI or NSTEMI that couldn't wait (hemodynamically unstable)	30 d MACE	Periprocedural MI (CPK > 3X normal)	0	0.25 (95% CI: 0.08 to 0.79)	In ACS, statins 12 hr before PCI decreases MACE	Definition of MI (although troponins were significant)
	Yun, 2008 (144)	RCT	Rosuvastatin 40 mg before PCI	445	ACS	Cardiogenic shock	Periprocedural MI (CPK > 2X normal)	1 mo MACE	0.04	0.49 (95% CI: 0.23 to 0.96)	In ACS, a single dose of statin before PCI decreases periprocedural MI.	
	Veselka, 2009 (145)	Randomized	Atorvastatin 80 mg/d starting 2d before PCI	200	Elective PCI	ACS, CRI (Cr > 150 mmol)	Periprocedural MI (CPK > 3X normal)		0.65	0.81 (95% CI: 0.33 to 1.98)	Pretreatment with statins for 2 d does **not** decrease periprocedural	Not blinded or placebo controlled

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											MI.	
NAPLES II	Brigouri, 2009 (146)	Randomized	Atorvastatin 80 mg d before PCI	668	Elective PCI of a de novo lesion	Instent restenosis	Periprocedural MI (CPK > 3X normal)	Inhospital MACE	0.01	0.56 (95% CI: 0.35 to 0.89)	Pretreatment with statins for 1 d decreases periprocedural MI	Not blinded or placebo controlled
STATIN STEMI	Kim, 2010 (147)	Randomized	Atorvastatin 80 mg vs. 10 mg in ED before primary PCI for STEMI	171	STEMI	Cardiogenic shock or previous statins	30 d MACE	ST resolution, TIMI perfusion scores	0.26	0.52 (95% CI: 0.17 to 1.63)	Pretreatment with high-dose statins in STEMI may improve myocardial perfusion, but no hard outcome benefit	Underpowered (lower MACE than expected). Dose comparison, not placebo control
Reloading												
ARMYDA-RECAPTURE	Di Sciascio, 2009 (148)	RCT	On statins: reload atorvastatin 80 mg 12 h before PCI and 40 mg preprocedure	383	Elective PCI or NSTEMI	STEMI or NSTEMI that couldn't wait (hemodynamically unstable)	30 d MACE	Periprocedural MI (CPK > 3X normal)	0.04	0.36 (0.15 to 0.89)	Reloading in pts already on statins before PCI decreases MACE	Not blinded
Meta-analysis												
	Zhang, 2010 (149)	Meta-analysis	6 RCTs	2,088			Periprocedural MI			0.51 (0.38 to 0.67)	Pretreatment with statins before PCI reduces periprocedural MI.	Heterogeneity in trial design. 30 d MACE driven by MI in this area (low mortality, stroke, and early TVR)
	Winchester, 2010 (150)	Meta-analysis	10 RCTs	4,085, but not all had PCI			Periprocedural MI			0.59 (0.47 to 0.74)	Pretreatment with statins before PCI reduces periprocedural MI.	For short-term mortality, RR: 0.75 (95% CI: 0.16 to 3.58). Underpowered for this endpoint.

ACE indicates angiotensin-converting enzyme; ACS, acute coronary syndrome; ARMYDA, Atorvastatin for Reduction of MYocardial Damage during Angioplasty; CI, confidence interval; CK, creatine kinase; CPK, creatine phosphokinase; CRI, chronic renal insufficiency; ED, emergency department; MACE, major adverse cardiac event; MI, myocardial infarction; NAPLES, novel approaches for preventing or limiting events; NSTEMI, non-ST-elevation myocardial infarction; pts, patients; PCI, percutaneous coronary intervention; RCT, randomized control trial; RR, relative risk; STEMI, ST-elevation myocardial infarction; and TVR, target vessel revascularization.

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Data Supplement 20. Data on Sites With No Onsite Surgical Backup

Author and Year	Study Type	Study Size (-) Indicates Without Onsite CABG Surgery (+) Indicates With Onsite CABG Surgery	Endpoints	OR/RR (95% CI); P-Value	Study Summary
	On-Site Surgery				
Wennberg et al., 2004 (151)	Medicare claims database 1121 hospitals	1,795 (-) 34,537 (+) 6,373 (-) 583,149 (+)	Primary PCI mortality Emergency CABG Elective PCI mortality Emergency CABG	OR 0.93 (0.80 to 1.08) OR 0.95 (0.73 to 1.22) OR 1.38 (1.14 to 1.67) OR 0.92 (0.73 to 1.17)	No difference non-primary/rescue PCI Worse outcome elective PCI
Carlsson et al., 2007 (152)	SCAAR PCI Registry 24 hospitals	8,838 (-) 25,525 (+)	30 d Mortality: 1.4 vs. 2.2% TIA/CVA: 0.3 vs. 0.4% emergency CABG: 0.1 vs. 0.2%	p<0.001 p=0.09 p=0.025	No difference in outcome More STEMI pts in (+)
Kutcher et al., 2009 (153)	NCDR PCI Registry 465 hospitals	8,736 (-) 299,425 (+)	Mortality Emergency CABG	OR 0.90 (0.72 to 1.14) OR 0.60 (0.37 to 0.98)	No difference in outcome
Tebbe et al., 2009 (154)	PCI Registry 36 hospitals	10,683 (-) 12,465 (+)	Mortality MACE MI TIA/CVA Emergency CABG	OR 0.99 (0.81 to 1.22) OR 1.08 (0.91 to 1.28) OR 1.24 (0.88 to 1.75) OR 1.30 (0.63 to 2.71) OR 1.17 (0.66 to 2.09)	No difference in outcome
Singh et al., 2009 (155)	4 trial meta-analysis	6,817	Mortality MI Emergency CABG	RR: 2.7 (0.6 to 12.9) RR: 1.3 (0.7 to 2.2) RR: 0.46 (0.06 to 3.1)	No difference in outcome
Sanborn et al., 2004 (156)	NRMI-3,-4 P-PCI Registry STEMI	1,874 (-) 24,890 (+)	Mortality: 3.7 vs. 4.8% MI: 1.1 vs. 1.5% CVA: 0.5 vs. 0.7%	p=0.07 p=0.19 p=0.44	No difference in outcome Transfer-outs not counted More likely to receive other meds.
Pride et al., 2009 (157)	NRMI-5 P-PCI Registry STEMI	1,655 (-) 1,768 (+)	Mortality: 3.3 vs. 3.8% MI: 0.9 vs. 1.0 %	p=0.44 p=0.76	No difference in outcomes with propensity analysis. Transfer bias.
Pride et al., 2009 (158)	NRMI-5 PCI Registry NSTEMI	1,282 (-) 1,282 (+)	Mortality: 1.0 vs. 1.3% MI: 0.2 vs. 0.8%	p=0.51 p=0.047	No difference in outcomes with propensity analysis. Transfer bias.
Hannan et al., 2009 (159)	New York State Registry STEMI	1,729 (-) 1,729 (+)	30-day mortality: 2.31 vs. 1.91% Emergency CABG: 0.23 vs. 0.69% 3-y mortality: 7.1 vs. 5.9%	p=0.40 p=0.046 p=0.07	No difference in outcomes with propensity analysis. Higher TVR rates and higher mortality in pts not undergoing PCI.

(-) indicates Without Onsite CABG Surgery; (+) indicates With Onsite CABG Surgery; CABG, coronary artery bypass graft; CI, confidence interval; CVA, cerebrovascular accident; MACE; major adverse cardiac event; MI, myocardial infarction; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; pts, patients; PCI, percutaneous coronary intervention; P-PCI, primary percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry; STEMI, ST-elevation myocardial infarction; TIA, transient ischemic attack; and TVR, target vessel revascularization.

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Data Supplement 21. Studies of Radial Access PCI

Author/Study	Study Population	Endpoint	Radial Access Endpoint %	Femoral Access Endpoint %
Brueck et al., 2009 (160)	1,024 pts randomized equally to femoral versus radial access.	Vascular complications	0.58%	3.71%
Jolly et al., 2009 (161)	Meta-analysis	Bleeding complications	0.05%	2.3%
Pristipino et al., 2009 (162)	Observational study of 1,052 pts.	Bleeding and vascular complications	1.9%	4.2%
Rao et al., 2008 (163)	NCDR database observational study of 593,094 pts	Vascular complications	0.19%	0.7%
Jaffe et al., 2007 (164)	200 octogenarians	Vascular complications	5%	26%
Louvard et al., 2004 (165)	377 octogenarians	Vascular complications	1.6%	6.5%
Agostoni et al., 2004 (166)	Meta-analysis	Access site complications	0.3%	2.8%
Jolly et al., 2011 (167)	7,021 pts with ACS for catheterization/PCI randomized to radial versus femoral access.	Death, MI, stroke, or non-CABG related major bleeding at 30 d	3.7%	4.0%

ACS indicates acute coronary syndrome; CABG, coronary artery bypass graft; d, day; MI, myocardial infarction; NCDR, National Cardiovascular Data Registry, pts, patients; and PCI, percutaneous coronary intervention.

Data Supplement 22. Studies of Cardiogenic Shock in the Elderly

Author and Year	Study Type	Patient Population Number of Patients (%)	Study Size	Endpoints	Results HR/ RR (95% CI), P-Value	Study Summary
Dzavik et al., 2005 (1993-1998) (168)	SHOCK RCT subgroup	56/302 (19%) ≥75 y old	ERV - 24 (12 PCI) IMS - 32	30 d mortality	ERV = 75% IMS = 53% RR: 1.41	Multiple testing, small sample size. ERV pts: lower LVEF, more women, more anterior MI, 6 did not undergo revascularization
Dauerman et al., 2001 (1986-1997) (169)	Worcester Heart Attack Registry cohort	310 ≥65 y old	ERV - 26 IMS - 284	Inhospital mortality	ERV = 56% IMS = 77% p=0.02	
Dzavik et al., 2003 (1993-1997) (170)	SHOCK Registry	277/865 (32%) ≥75 y old	ERV - 62 (45 PCI) IMS - 215	30 d mortality	ERV = 48% IMS = 81% p=0.0003 RR: 0.46 (95% CI 0.28 to 0.75)	Similar mortality as younger pts

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Antoniucci et al., 2003 (1995-2001) (171)	Florence PCI Registry	71/205 (35%) ≥75 y old	PCI - 71	Mortality	6 mo: 51%	Higher mortality than younger pts (51% vs. 25%)
Dauerman et al., 2003 (1990-2000) (172)	Northern New England PCI Registry	74/310 (24%) ≥75 y old	PCI - 74	Mortality	Inhospital: 47%	Higher mortality than younger pts (46.7% vs. 34.5%)
Prasad et al., 2004 (1991-2000) (173)	Mayo PCI Registry	61 ≥75 y old	PCI - 61	Mortality	Inhospital: 44% 30 d: 47%	
Zeymer et al., 2004 (1994-2001) (174)	ALKK PCI Registry	1,333 Average age 63.9±12.6 y)	N/A	Mortality	Inhospital: 63% for pts ≥75 y	14% incidence of "shock"
Klein et al., 2005 (1998-2002) (175)	NCDR PCI Registry	143 70 to 79 y old 74 ≥ 80 y old	PCI - 217	Mortality	Inhospital: 64% Inhospital: 81%	
Migliorini et al., 2006 (1995-2004) (176)	Florence PCI Registry	104/280 (37%) ≥75 y old	PCI - 104	Mortality	30 d: 49% 6 mo: 56%	Second report, same center
Amin et al., 2009 (1999-2005) (177)	Rush/Cook County Registry	80/310 (26%) ≥75 y old	ERV – 29 (15 PCI) IMS - 51	Mortality (follow-up not stated)	HR: 0.56 (0.32 to 0.99)	Higher mortality than younger pts
Lim et al., 2009 (2004-2007) (178)	Melbourne Interventional Group Registry	45/143 (32%) ≥75 y old	PCI - 45	Mortality	Inhospital: 42% 30 d: 43% 1y: 53%	Similar mortality in older pts as younger pts (43% vs. 36%, respectfully)

ALKK indicates Arbeitsgemeinschaft Leitender Kardiologischer Krankenhausärzte; CI, confidence interval; d, day; ERV, early revascularization; HR, hazard ratio; IMS, initial medical stabilization; LVEF, left ventricular ejection fraction; mo, month; MI, myocardial infarction; NCDR, National Cardiovascular Data Registry; pts, patients; PCI, percutaneous coronary intervention; RCT, randomized controlled trial; RR, relative risk; SHOCK, SHould we emergently revascularize Occluded Coronaries in cardiogenic shock; and y, years.

Data Supplement 23. Studies of Fractional Flow Reserve Assessment for Intermediate Coronary Lesions

Study Name	Author(s)/Year Published	Study Type	Study Size	Inclusion/ Exclusion Criteria	Primary Endpoint	Results/ Coronary Artery Bypass Graft P-Values	Summary/ Conclusions
DEFER (179)	Bech et al., 2001	RCT	325 pts	Elective PCI 3 groups based on </≥0.75FFR (deferral, performance, and reference groups)	Absence of cardiac events by 24 mo	Same event in pts with FFR ≥0.75 with PCI or deferred	In pts with SVCAD and no document ischemia, FFR identifies those benefit from PTCA
DEFER (180)	Pijls et al., 2007	RCT	325 pts	Elective PCI SVD with 3 groups (deferral, performance, and reference groups) based on </≥0.75FFR	Absence of cardiac events by 60 mo	Similar to 2 y follow-up No benefit with PCI if FFR ≥0.75	In pts with SVCAD and no document ischemia, FFR identifies those benefit from PTCA
FAME (181)	Tonino et al., 2009	RCT	1,005 pts (DES)	MVD PCI with angiography PCI only vs. angiography and FFR ≤0.80	1 y death, MI, or repeat	18.3% in angiography group; 13.2% in FFR group (p=0.02)	FFR guided PCI in MVD pts improves 1 y composite endpoints-death, MI, and

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					revascularization		revascularization.
FAME (182)	Pijls et al., 2010	RCT	1,005 pts (DES)	MVD pts with angiography PCI only or angiography and FFR ≤0.80	1 y death, MI, or repeat revascularization	22.4% angiography group; 17.9% in FFR group (p=0.08)	FFR guided PCI in MVD pts improves 2 y composite endpoints-death, MI, and revascularization.
(FFR vs. IVUS) (183)	Nam et al., 2010	NRCT	167 pts	40-70% PCI of stenosis with IVUS MLA≤4.0cm^2 or FFR ≤0.8	1 y death, MI, or repeat revascularization	No difference: 3.6% FFR vs. 3.2% IVUS.	No difference in events; more PCI's in IVUS group (91.5%) vs. FFR (33.7%) (p<0.001)
(LM) (184)	Courtis et al., 2009	NRCT	142 consecutive pts	LM 30 to 60% or indeterminate. FFR <0.75 revascularization recommended, >0.80 medical therapy recommended, or 0.75 to 0.80 either recommended.	14 mo follow-up MACE	13% medical vs. 7% revascularization. Death or MI 6 vs. 7%, respectively.	FFR may be helpful but DM and dose of adenosine may influence decision.
(LM) (185)	Hamilos et al., 2010	NRCT	213 pts (209 with follow-up)	Equivalent LM FFR <0.80 surgery; 0.80 medical therapy	Event free survival 3 y follow-up; 5 y estimated.	74.2% medical therapy versus 82.8% surgery (p=0.48)	FFR is beneficial for equivocal LM lesions in deciding need for revascularization.

DEFER indicates Deferral Versus Performance of Balloon Angioplasty in Patients Without Documented Ischemia; DES, drug eluting stent; DM, diabetes mellitus; FAME, Fractional Flow Reserve Versus Angiography for Multivessel Evaluation; FFR, fractional flow reserve; IVUS, intravascular ultrasound; LM, left main; MACE, major adverse cardiac event; MI, myocardial infarction; MLA, mean lesion area; MVD, multivessel disease; NRCT, nonrandomized controlled trial; pts, patients; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; RCT, randomized controlled trial; SVCAD, single-vessel coronary artery disease, SVD, saphenous vein disease; and y, year.

Data Supplement 24. RCTs and Relevant Meta-Analyses of Glycoprotein IIb/IIIa Inhibitors in Trials of PCI

Trial	Study Drug / Comparator	Population	Primary Endpoint	Results	Statistics	Comments
Primarily Elective PCI (Without Routine Clopidogrel Pretreatment)						
EPISTENT (186)	Abciximab vs. placebo	2,399 pts undergoing elective PCI	Death, MI or UTVR at 30 d	5.3% (stent+abciximab) vs. 10.8% (stent+placebo) HR: 0.48	95% CI: 0.33 to 0.69; p<0.001	
ESPRIT (187)	Eptifibatide (double bolus) vs. placebo	2,064 predominantly non-ACS pts undergoing planned stent implantation	Combination of death, MI, UTVR and thrombotic bailout GP IIb/IIIa inhibitor therapy within 48 h after randomization.	6.6% (95% CI 8.7 to 12.4%) with treatment vs. 10.5% (95% CI 5.1 to 8.1%) for pts on placebo. RR: 0.63	95% CI: 0.47 to 0.84; p=0.0015	18% of pts with ACS within 48 h or acute STEMI within 7 d before randomization.
Juergens et al. (188)	Tirofiban (standard dose) vs. placebo	894 pts undergoing planned PCI with stenting	TIMI major bleeding	No differences in major bleeding Death, MI or UTVR at 30 d: 3.9% vs. 3.9%	p=NS Death, MI or UTVR at 30 d: p=NS	
Elective (Stable) and Urgent (ACS) Patients Enrolled (Without Routine Clopidogrel Pretreatment)						
EPILOG (189)	Abciximab vs. placebo	2,792 pts with stable ischemia or unstable angina	Death, MI or UTVR at 30 d	5.2% in abciximab with low dose heparin group vs. 11.7% in placebo group. HR: 0.43	95% CI: 0.30 to 0.60; p<0.001	

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ACS/High Risk (Without Routine Clopidogrel Pretreatment)						
CAPTURE (190)	Abciximab (administered for 18 to 24 h before PCI) vs. placebo	1,265 pts with "refractory unstable angina" undergoing PCI 18 to 24 h after diagnostic catheterization	Death, MI or UTVR at 30 d	11.3% in abciximab vs. 15.9% in placebo group.	p=0.012	Significant reduction in MI rate both before and during PCI with abciximab therapy. No difference in 6 mo composite endpoint.
EPIC (191)	Abciximab vs. placebo	Pts at high risk for abrupt vessel closure	Death, MI, UTVR, IABP or unplanned stent placement at 30 d	Bolus only: 11.4% Bolus + infusion: 8.3% Placebo: 12.8%	p=0.009 overall; p=0.008 for bolus + infusion vs. placebo	
RESTORE (192)	Tirofiban (standard dose) vs. placebo	2,139 pts with ACS undergoing PTCA or DCA	Death, NFMI, UTVR, or stent placement at 30 d	10.3% vs. 12.2%	p=0.160	Composite endpoint was statistically lower at 2 and 7 d follow-up (but not at the 30 d primary endpoint).
STEMI (Without Routine Clopidogrel Pretreatment)						
On-TIME 2 (193)	Tirofiban (high-dose bolus) vs. placebo	936 pts with STEMI treated with prehospital drug/placebo undergoing primary PCI.	Residual ST-segment deviation 1 h after PCI	3.6 mm in pts treated with high-dose bolus tirofiban vs. 4.8 mm in placebo group.	p=0.003	No significant reduction in clinical endpoints in the phase 2 (blinded) study; analysis of combined phase 1 (open label) and phase 2 data did demonstrate reduced clinical endpoints at 30 d.
ACE (194,195)	Abciximab vs. placebo	400 pts with STEMI undergoing primary PCI with stenting.	Death, NFMI, TVR and CVA at 1 mo	4.5% in abciximab group vs. 10.5% in stent only group OR: 0.41	95% CI: 0.17 to 0.97; p=0.041	1 y cardiovascular mortality 5.0% vs. 10.5% (p=0.040).
ISAR-2 (196)	Abciximab vs. placebo	401 pts undergoing stenting within 48 h after onset of AMI.	Late lumen loss after stenting	1° endpoint: N/A	p=0.038	Death, reinfarction and TLR at 30 d 5.0%in abciximab group vs. 10.5% in placebo group.
CADILLAC (197,198)	Abciximab vs. placebo	2,082 pts with STEMI undergoing primary PCI.	Death, reinfarction, disabling CVA, and TVR at 6 mo	1 mo: 4.6% in abciximab group vs. 7.0% in placebo. RR: 0.65 1 y: 16.9% in abciximab group vs. 18.4% in placebo group RR: 0.92	1 mo: 95% CI: 0.46 to 0.93; p=0.01 1 y: 95% CI: 0.76 to 1.10; p=0.29	Composite results of abciximab vs. placebo for entire study population only reported at 1 mo and 1 y.
ADMIRAL (199)	Abciximab vs. placebo	300 pts with STEMI undergoing primary PCI with stenting.	Death, reinfarction, or UTVR	6.0% in abciximab group vs. 14.6% in placebo group. OR: 0.41	95% CI: 0.18 to 0.93; p=0.01	
RAPPORT	Abciximab vs. placebo	483 pts with STEMI	Death, NFMI or TVR at 6	28.2% in abciximab group vs.	p=0.97	7 and 30 d secondary endpoints

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(200)		undergoing primary PCI.	mo	28.1% in placebo group.		of death, MI or UTVR were statistically lower with abciximab.
De Luca, 2005 meta-analysis (201)	Abciximab vs. placebo	STEMI pts undergoing primary PCI or lytic therapy.	30 d mortality	Primary PCI trials only: 2.4% in abciximab group vs. 3.4% in placebo group. OR: 0.68	95% CI: 0.47 to 0.99; p=0.047	
De Luca et al., 2009 meta-regression analysis (202)	GP IIb/IIIa vs. placebo (or bivalirudin)	16 RCTs of primary PCI, including HORIZONS and BRAVE-3.	30 d mortality	2.9% in GP IIb/IIIa vs. 2.8% in placebo (or bivalirudin group). OR: 0.96	95% CI: 0.76 to 1.22; p=0.75	Reinfarction 1.9% in GP IIb/IIIa group vs. 1.5% in placebo group (p=0.22); Major bleeding 4.1% in GP IIb/IIIa group vs. 2.7% in placebo group (p=0.0004); trend toward mortality benefit when HORIZONS not included in analysis (OR: 0.78; 95% CI: 0.58 to 1.04); strong relationship present between patient risk profile and mortality benefit from GP IIb/IIIa.
Pre-Cath Lab Administered GP IIb/IIIa ("Facilitated PCI")						
On-TIME 2 (193)	Tirofiban (high bolus dose) vs. placebo	936 pts with STEMI treated with prehospital drug/placebo undergoing primary PCI	Residual ST-segment deviation 1 h after PCI	3.6 mm in high- bolus tirofiban vs. 4.8 mm in placebo.	p=0.003	No significant reduction in clinical endpoints in the phase 2 (blinded) study; analysis of combined phase 1 (open label) and phase 2 data did demonstrate reduced clinical endpoints at 30 d
FINESSE (203)	Abciximab	Abciximab administered pre-cath lab (including at "spoke" hospital) vs. abciximab+1/2 dose lytic administered in pre-cath lab vs. abciximab in the cath lab.	Death, VF, cardiogenic shock, and CHF at 90 d	Abciximab-facilitated 10.5% vs. 10.7% abciximab in cath lab.	p=0.86	No significant difference in 90 d mortality
RELAx-AMI (204)	Abciximab administered in ER (early group)vs. abciximab in cath labafter coronary angiography (late group)	210 pts with STEMI undergoing primary PCI	Preintervention TIMI flow grade	TIMI3 flow: 24% in early group vs. 10% in late group.	p=0.001	1 mo LVEF better in ER-treated (early group) pts (51% vs. 47% in late group pts; p=0.01)
Keeley et al.,	GP IIb/IIIa administered in	9 trials of GP IIb/IIIa therapy,	Numerous endpoints studied	In analysis of only GP IIb/IIIa		

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2006 Meta-analysis (205)	ER or ambulance vs. GP IIb/IIIa in cath lab	as well as lytic and combination therapy trials		trials, no differences in death, NFMI or UTVR		
Montalescot et al., 2004 Meta-analysis (206)	GP IIb/IIIa administered in ER or ambulance vs. GP IIb/IIIa in cath lab	6 trials enrolling 931 pts treated with abciximab or tirofiban	TIMI flow grade 2 or 3 on first angiogram	41.7% early group vs. 29.8% in late group. OR: 1.69	95% CI: 1.28 to 2.22; p<0.001	Early administration reduced overall mortality from 4.7% to 3.4%; (OR: 0.72; 95% CI: 0.37 to 1.40; p=0.42)
Head-to-Head Comparisons						
EVA-AMI (207)	Eptifibatide vs. abciximab	427 pts with STEMI treated with primary PCI	>70% resolution of ST-segment elevation at 60 min after PCI	62.6% after eptifibatide vs. 56.3% after abciximab.	N/A	
FATA (208) (209)	Tirofiban (high- dose) vs. abciximab	692 pts with STEMI undergoing primary PCI	≥70% ST-segment resolution at 90 min	67.05% after tirofiban vs. 70.45% after abciximab (change -3.4%)	Change CI: -10.35 to +3.56, falling beyond the predefined change ± 10% equivalence boundaries	30 d MACE 2.8% in tirofiban group vs. 1.8% in abciximab group (p=0.34)
MULTISTRATEGY (210)	Tirofiban (high dose) vs. abciximab	722 pts with STEMI undergoing primary PCI	≥50% ST-segment resolution at 90 min	85.3% in tirofiban infusion vs. 83.6% in abciximab infusion.	p<0.001 for noninferiority	30 d MACE similar (4.0% in tirofiban vs. 4.3% in abciximab; p=0.85)
STRATEGY (211)	Tirofiban (high dose) vs. abciximab	175 pts with STEMI undergoing primary PCI	1° endpoint: N/A (see comments) 2° endpoint: MACE at 30 d	30-d Death/reinfarction/stroke/urgent TVR 3% vs. 8%	p=0.33	Pts were randomized to tirofiban + drug-eluting stent or to abciximab + bare metal stent, confounding interpretations of primary and secondary endpoints
Danzi et al. (212)	Tirofiban (high dose) vs. abciximab	100 pts undergoing primary PCI	Change in infarct-zone wall motion score index at 30 d assessed by echocardiography.	Tirofiban: 2.18 at baseline to 1.95 at 30 d Abciximab: 2.20 at baseline to 1.99 at 30 d	p=0.67	Ejection fractions at 1 mo were similar in the two groups
TARGET (213,214)	Tirofiban (standard dose) vs. abciximab	2,398 pts undergoing elective or urgent PCI (STEMI excluded)	Death, MI, or UTVR within 30 d.	7.6% vs. 6.0% HR: 1.26	95% CI: 1.01 to 1.57; p=0.038	In subgroup analysis, tirofiban worse in ACS pts (9.3% vs. 6.3%; p=0.002) but not in pts without ACS (4.5% vs.5.6%; p=0.32)
De Luca et al., Meta-analysis of randomized primary PCI trials (215)	Small molecules vs. abciximab	2,107 pts with STEMI undergoing primary PCI	30 d mortality	2.0% small molecule vs. 2.2% abciximab	p=0.66	Similar post-PCI TIMI flow grade 3 (89.8% small molecule vs. 89.1% abciximab; p=0.72) and ST-segment resolution (68.2% small molecule vs. 67.8% abciximab; p=0.66)

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Gurm et al., Meta-analysis of randomized primary PCI trials (216)	Small molecules vs. abciximab	2,138 pts undergoing primary PCI	30 d mortality rates, reinfarction rates, and major bleeding rates assessed	Death: 1. small molecule vs. 2.3% abciximab OR: 0.84 Reinfarction: 1. small molecule vs. 1.2% abciximab OR: 1.22 Major Bleeding: 1. small molecule vs. 1.3% abciximab OR: 1.21	Death: 95% CI: 0.46 to 1.55; p=0.58 Reinfarction: 95% CI: 0.51 to 2.91; p=0.69 Major Bleeding: 95% CI: 0.58 to 2.49; p=0.61	
IC vs. IV Administration						
EASY-MI (217)	IC vs. IV abciximab	105 pts with STEMI undergoing primary PCI	1° endpoint: PAI ≥95% 10 min after bolus administration. 2° endpoints: numerous acute and 6 mo angiographic and MRI-assessed outcomes	1° endpoint: 53% IC vs. 54% IV 2° endpoints: no difference in myocardial blush grade, peak release of cardiac biomarkers, necrosis size, myocardial perfusion or LVEF	1° endpoint: p=1.00	
Thiele et al. (218)	IC vs. IV abciximab	154 pts with STEMI undergoing primary PCI	Infarct size and extent of microvascular obstruction (expressed as percent of LV) as assessed by MRI at 2 days	Infarct size: 15.1% IC abciximab vs. 23.4% IV abciximab Microvascular obstruction: 1.1% vs. 3.5%	Infarct size: p=0.01 Microvascular obstruction: p=0.01	MACE at 30 days: 5.2% IC abciximab vs. 15.6% IV abciximab (p=0.06)
Galache Osuna et al. (219)	IC bolus vs. IV bolus abciximab	137 pts undergoing PCI	Death, MI or need for revascularization at 1 y	8.5% IC abciximab bolus vs. 6.2% IV abciximab bolus.	p=NS	
Bellandi et al. (220)	IC vs. IV abciximab; IC administration was *distal* to lesion	45 pts with STEMI undergoing primary PCI	Salvage index and LV function recovery as assessed by SPECT	Salvage index: 0.66 vs. 0.4 LVEF recovery: 14.7% vs. 8%	Salvage index: p=0.003 LVEF recovery: p=0.013	
Intracoronary bolus administration of	IC vs. IV abciximab	43 pts with ACS or prior lytic-treated STEMI undergoing PCI	Coronary bed platelet GP IIb/IIIa receptor occupancy	After 1st bolus: 94% vs. 51%	After 1st bolus: p<0.001	Corrected TIMI frame count post-PCI better with IC administration (18 vs. 25;

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eptifibatide during percutaneous coronary stenting for non ST elevation myocardial infarction and unstable angina (221)				After 2nd bolus: 99% vs. 91%	After 2nd bolus: p=0.001	p=0.007)
Wu et al. (222)	IC vs. IV tirofiban (standard dose)	118 elderly pts with STEMI or NSTE-ACS	1° endpoint not specified; numerous angiographic and clinical endpoints assessed	TIMI 3 after PCI: 89.7% study group vs. 71.9% control TMPG grade 3 after PCI: 84.5% study group vs. 66.7% control Composite 30 d MACE: 1.7% study group vs. 7.0% control 30 d LVEF: 67.4% study group vs. 60.7% control	TIMI 3 after PCI: p=0.016 TMPG grade 3 after PCI: p=0.026 Composite 30 d MACE: p=0.350 30 d LVEF: p=0.033	
GP IIb/IIIa After Clopidogrel Pretreatment						
BRAVE-3 (223)	Abciximab vs. placebo	800 pts with STEMI undergoing PCI within 24 hours of symptom onset	SPECT-measured infarct size	15.7±17.2% in abciximab group vs. 16.6±18.6% placebo group	p=0.47	
ISAR-REACT (224)	Abciximab vs. placebo	2,159 pts undergoing elective PCI	Death, MI or UTVR at 30 d	4% abciximab vs. 4% placebo; RR: 1.05	95% CI: 0.69 to 1.59; p=0.82	
ISAR-SWEET (225)	Abciximab vs. placebo	701 pts with diabetes undergoing elective PCI	Death or MI at 1 y	8.3% abciximab vs. 8.6% placebo RR: 0.97	95% CI: 0.58 to 1.62; p=NS	
ISAR-REACT 2 (226)	Abciximab vs. placebo	2,022 "high-risk" ACS pts undergoing PCI	Death, MI or UTVR at 30 d	8.9% abciximab vs. 11.9% placebo; RR: 0.75	95% CI: 0.58 to 0.97; p=0.03	RR: 0.71 in troponin positive pts; RR: 0.99 in troponin negative pts
ISAR-SMART 2 (227)	Abciximab vs. placebo as part of a 2 x 2 randomization	502 pts undergoing small vessel elective PCI	Incidence of restenosis. Secondary endpoint of death or MI at 1 y	Secondary endpoint of death or MI at 1 y: 8.8% abciximab vs. 6.8% placebo; RR: 1.33	95% CI: 0.71 to 2.50; p=0.37	
ADVANCE	Tirofiban (high dose) vs.	202 pts undergoing elective	Death, NFMI, UTVR or	20% tirofiban vs. 35% placebo;	95% CI: 0.29 to	Pts pretreated with either

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(228)	placebo	or urgent PCI (1/3 with stable angina; half with ACS)	bailout GPI therapy at median of 185 d	HR: 0.51	0.88; p=0.01	ticlopidine or clopidogrel Death/MI/TVR at 6 mo lower (HR: 0.57; 95% CI: 0.99 to 0.33; p=0.048)
TOPSTAR (229)	Standard dose tirofiban vs. placebo	109 pts undergoing elective PCI	Incidence and amount of troponin release after 24 h	Incidence: 48% tirofiban vs. 69% placebo. Amount (48 h): 0.0291tirofiban vs. 0.036 placebo	Incidence: p<0.05 Amount (48 h): p=NS	Variably defined primary endpoint(s) in manuscript with no amount of troponin release at 24 h listed in results.
Pannu et al., Meta-analysis (230)	GP IIb/IIIa vs. placebo	5,303 pts undergoing PCI	Death, MI or TVR	OR: 0.84	95% CI: 0.58 to 1.22; p=0.35	

ACE indicates Abciximab and Carbostent Evaluation; ACS, acute coronary syndrome; AIDA STEMI, Abciximab Intracoronary versus intravenously Drug Application in ST-Elevation Myocardial Infarction; ADMIRAL, Abciximab before Direct Angioplasty and Stenting in Myocardial Infarction Regarding Acute and Long-Term Follow-up; ADVANCE, ADditive VAlue of tirofiban administered with the high dose bolus in the prevention of isChEmic complications during high-risk coronary angioplasty; AMI, acute myocardial infarction; BRAVE; Bavarian Reperfusion Alternatives Evaluation; CADILLAC, Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications; cath, catheterization; CI, confidence interval; CVA, cerebrovascular accident; DCA, directional coronary atherectomy; EASY-MI, EArly Discharge after Transradial Stenting of CoronarY Arteries in Acute Myocardial Infarction; EPIC, Evaluation of 7E3 for the Prevention of Ischaemic Complications; EPILOGUE, Evaluation in PTCA (percutaneous transluminal coronary angioplasty) to Improve Long-term Outcome with abciximab GP IIb/IIIa blockade; EPISTENT, Evaluation of Platelet IIb/IIIa Inhibition in STENTing; ER, emergency room; ESPPRIT, Ehnahnce Suppression of the Platelet IIb/IIIa Receptor with Integrilin Therapy; EVA-AMI; Eptifibatide vs. Abciximab in Primary PCI for Acute STEMI; FATA, Facilitated Angioplasty with Tirofiban or Abciximab; FINESSE, Facilitated Intervention With Enhanced Reperfusion Speed to Stop Events; GP, glycoprotein; GPI, glycoprotein inhibitors; HORIZONS; Harmonizing Outcomes with RevascularIZatiON and Stents; HR, hazard ratio; IC, intracoronary; ISAR; Intracoronary Stenting and Antithrombotic Regimen; ISAR-REACT; Intracoronary Stenting and Antithrombotic Regimen: Rapid Early Action for Coronary Treatment; ISAR-SMART, Intracoronary Stenting or Angioplasty for Restenosis Reduction in Small Arteries; ISAR-SWEET, Intracoronary Stenting and Antithrombotic Regimen: Superior Way to Eliminate Elevated Thrombotic Risk in Diabetics; IV, intravenous; LVEF, left ventricular ejection fraction; MACE, major adverse cardiac event; MI, myocardial infarction; MRI, magnetic resonance imaging; NFMI, nonfatal myocardial infarction; NS, not significant; NSTE-ACS; non-ST-elevation acute coronary syndrome; ON-TIME; Ongoing tirofiban in myocardial infarction evaluation; pts, patients; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; RAPPORT, ReoPro and Primary PTCA Organization and Randomized Trial; RCT, Randomized control trials; RELAX-AMI, Randomized Early versus Late AbciXimab in Acute Myocardial Infarction; RESTORE, Randomized Efficacy Study of. Tirofiban for Outcomes and Restenosis; RR, relative risk; SPECT, single photon emission computed tomography; STRATEGY, Single High Dose Bolus Tirofiban and Sirolimus Eluting Stent vs. Abciximab and Bare Metal Stent in Myocardial Infarction; STEMI, ST-elevation myocardial infarction; TARGET, Do Tirofiban and ReoPro Give Similar Efficacy Outcomes? TIMI, Thrombolysis In Myocardial Infarction; TMPG, TIMI myocardial perfusion grades; TOPSTAR, Troponin in Planned PTCA/Stent Implantation With or Without Administration of the Glycoprotein IIb/IIIa Receptor Antagonist Tirofiban; TVR, target vessel revascularization; UTVR, urgent target vessel revascularization; and VF, ventricular fibrillation.

Data Supplement 25. Studies of No-Reflow Therapies During PCI

Author and Year	Study Type	Study Size	Clinical Setting	Patient Population/Inclusion & Exclusion Criteria				Endpoints			Conclusions	Comments
					Drug	*Delivery*	*Dose*	*Death (PCI, CABG)*	*MI (PCI, CABG)*	*TIMI 3 flow (PCI, CABG)*		
Calcium Blockers												
Piana et al., 1994 (231)	Cohort	28	Vein grafts and native coronaries	Post-PCI TIMI flow <3 without mechanical obstruction	Verapamil	Guide or distal perfusion catheter	Mean 234 mcg	2	3.6% Q-wave and 28.6% CK-MB >50 IU/L	80%	"nearly 90% of pts respond promptly to IC verapamil"	

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Weyrens et al., 1995 (232)	Cohort	24	Vein grafts and native coronaries	Post-PCI TIMI 0-I flow with patent treatment site	Diltiazem	Distal perfusion catheter	500 to 2500 mcg boluses	0	4% CK > 3 x normal	96%	"Diltiazem led to prompt improvement in coronary flow in most pts."	
Kaplan et al., 1996 (233)	Cohort	15	SVGs	Post-PCI TIMI flow <3 without mechanical obstruction	Verapamil	Guide or distal perfusion catheter	250 to 1250 mcg	0	6% MI (CK-MB > 25 IU/L)	88%	"IC verapamil is successful in improving no-reflow in all cases"	IC nitroglycerine was of no benefit whatsoever.
Huang et al., 2006 (234)	Cohort	72	Vein grafts and native coronaries	Post-PCI TIMI flow <3 without mechanical obstruction	Nicardipine	Guide or distal perfusion catheter	Mean 460 mcg	1.4%	4.2%	98.6%	"favorable safety and efficacy profile"	
Adenosine												
Fischell et al., 1998 (235)	Cohort	11	SVGs	Post-PCI "slow- or no-reflow" (Mean TIMI flow = 1)	Adenosine	N/A	Mean of 12 boluses	0	75% CPK > normal	90%	"intra-graft adenosine is promising"	
Sdringola et al., 2000 (236)	Cohort	11	SVGs	Post-PCI "slow- or no-reflow" without mechanical obstruction	Adenosine	Via guide catheter	>120 mcg in 11; < 120 mcg in 9	0	40% CPK > 3 x normal	82% with > 120 mcg adenosine; 33% with < 120 mcg adenosine	"intra-graft adenosine promises to be safe and effective"	
Barcin et al., 2004 (237)	Cohort	21	Vein grafts and native coronaries	Post-PCI TIMI flow <3 without mechanical obstruction	Adenosine	Guide (n =12), distal catheter (n=9)	Mean 98 mcg	N/A	15%	30%	"adenosine and nitroprusside is safe and potentially more effective than adenosine alone"	
Nitroprusside												
Hillegass et al., 2001 (238)	Cohort	19	Vein grafts and native coronaries	Post-PCI TIMI flow <3 without mechanical obstruction	Nitroprusside	Via guide catheter	Mean 435 mcg	0	N/A	75%	"nitroprusside is a safe and efficacious agent to treat no-reflow"	
Adenosine and Nitroprusside												

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Barcin et al., 2004 (237)	Cohort	20	Vein grafts and native coronaries	Post-PCI TIMI flow <3	Adenosine and nitroprusside	Guide (n=9), distal catheter (n=11)	Adenosine mean 71 mcg and nitroprusside mean 285 mcg	N/A	10%	60%	"adenosine and nitroprusside is safe and potentially more effective than adenosine alone"	

CABG indicates coronary artery bypass graft; CK-MB, creatine kinase-myocardial band; CPK, creatine phosphokinase; IC, intracoronary; IU, international units; L, liter; mcg, microgram; MI, myocardial infarction; N/A, not applicable; pts, patients; PCI, percutaneous coronary intervention; SVG, saphenous vein grafts; and TIMI, Thrombolysis In Myocardial Infarction.

Data Supplement 26. Impact of Successful Versus Failed Recanalization of Chronic Total Occlusions on Long Term Survival

Study Name	Study Type	No. of Patients	Procedure Success	Duration of Follow-Up, y	Survival %			PCI Success as Predictor of Survival	
					PCI Success	PCI Failure	P-Value	HR (95% CI)	P-Value
Suero JA et al. (239)	Retrospective	2,007	74.4%	10	73.5	65.0	0.001	0.7 (0.5 to 0.8)	<0.0003
Hoye A et al. (240)	Retrospective	874	65.1%	5	93.5	88.0	0.02	0.58 (0.34 to 0.98)	0.04
Prasad A et al. (241)	Retrospective	1,262	51 to 73%	10	N/A	N/A	N/A	1.16 (0.90 to 1.50)	0.25
Safley DM et al. (242)	Retrospective	2,608	71 to 75%	5	88.9	80.2	<0.001*	0.61 (0.42 to 0.89)	<0.05*

* The difference in survival is significant only for patients who underwent successful recanalization of a left anterior descending artery CTO.
CI indicates confidence interval; CTO, chronic total occlusion; PCI, percutaneous coronary intervention, and y, year.

Data Supplement 27. RCTs of Balloon Angioplasty Versus Stenting for Chronic Total Occlusions

Trial	No. of Patients	Reocclusion			Restenosis			TVR		
		PTCA	Stent	P-Value	PTCA	Stent	P-Value	PTCA	Stent	P-Value
SICCO (243)	114	26%	16%	0.058	74%	32%	<0.001	42%	22%	0.025
GISSOC (244)	110	34%	8%	0.004	68%	32%	0.0008	22%	5%	0.04
Mori et al. (245)	96	11%	7%	0.04	57%	28%	0.005	49%	28%	<0.05
SPACTO (246)	85	24%	3%	0.01	64%	32%	0.01	40%	25%	NS
TOSCA (247)	410	20%	11%	0.02	70%	55%	<0.01	15%	8%	0.03

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STOP (248)	96	17%	8%	NS	71%	42%	0.032	42%	25%	NS
PRISON (249)	200	7%	8%	0.99	33%	22%	0.14	29%	13%	<0.0001
SARECCO (250)	110	14%	2%	0.05	62%	26%	0.01	55%	24%	0.05

PTCA indicates percutaneous transluminal coronary angioplasty; TVR indicates target vessel revascularization; SICCO, Stenting in Chronic Coronary Occlusion; GISSOC, Gruppo Italiano di Studi sulla Stent nelle Occlusioni coronariche; NS, not significant; SPACTO, Stent vs. Percutaneous Angioplasty in Chronic Total Occlusion; TOSCA, Total Occlusion Study of Canada; SARECCO, Stent or Angioplasty after Recanalization of Chronic Coronary Occlusions; STOP, Stents in Total Occlusion for Restenosis Prevention; and PRISON, Primary Stenting of Occluded Native Coronary Arteries. Table adapted from Stone et al. (251).

Data Supplement 28. Clinical Trials of DES Versus BMS for Chronic Total Occlusions

Trial	Study Type	No. of Patients		Restenosis			Reocclusion			TVR		
		BMS	DES	BMS	DES	P-Value	BMS	DES	P-Value	BMS	DES	P-Value
Ge L et al. (252)	Retrospective	259	122	33.3%	9.2%	<0.001	6.5%	2.5%	NS	29%	9%	<0.001
Nakamura S et al. (253)	Retrospective	120	60	32%	2%	0.001	6%	0%	0.001	30%	3%	0.001
Kelbaek H et al. (254)	Retrospective	63	64	38%	0%	<0.001	N/A	N/A	N/A	33.3%	4.7%	<0.001
Werner GS et al. (255)	Retrospective	61	61	55%	11.7%	<0.001	21.7%	1.7%	<0.001	32%	6%	<0.001
PRISON II (256)	Randomized	100	100	41%	11%	<0.0001	13%	4%	0.04	22%	8%	0.009
ACROSS/TOSCA-4 (257)	Prospective, single arm	N/A	200	N/A	22.6%	N/A	N/A	2.9%	-	N/A	9.8%	-

ACROSS/TOSCA-4 indicates Approaches to Chronic Occlusions With Sirolimus-Eluting Stents/Total Occlusion Study of Coronary Arteries; BMS, bare metal stent; CTO, chronic total occlusion; DES, drug eluting stent; N/A, not applicable; No, number; PRISON II, Primary Stenting of Totally Occluded Native Coronary Arteries; and TVR, target vessel revascularization

Data Supplement 29. Studies of Embolic Protection Devices for Saphenous Vein Graft PCI

Study Name	Aim of Study	Study Type	Study Size	Patient Population/ Inclusion & Exclusion Criteria		Endpoints		Statistical Analysis (Results)	P-Values & 95% CI	OR HR RR	Study Summary
				Inclusion Criteria	*Exclusion Criteria*	*Primary Endpoint*	*Secondary Endpoint*				

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SAFER (258)	To reduce embolization using a balloon-occlusion system.	Randomized multicenter	801	Angina, ischemia and >50% stenosis in SVG	Recent MI, SVG <3 or >6 mm	MACE (Death, MI, emergency CABG or TVR within 30 d)	CK-MB >3x ULN	Superiority design	0.40 to 0.88; p<0.004	RR: 0.58	9.6% embolic protection device vs. 16.5% placebo
FIRE (259)	To compare the ability of a filter-based system to reduce embolization during SVG intervention with that of a balloon occlusion system.	Randomized multicenter	651	Planned stenting of SVG stenosis	Recent MI, SVG age <6 mo	MACE (Death, MI, TVR within 30 d)	CK-MB >8x, >3x or >1x ULN	Noninferiority design	0.55 to 1.33; p=0.53	HR: 0.86	9.9% (filter) vs. 11.6% (balloon)
PROXIMAL (260)	To compare the ability of proximal occlusion system to reduce embolization during SVG intervention with that of an EPD.	Randomized multicenter	594	Planned stenting of SVG stenosis	Recent MI, SVG age <2 mo	MACE (Death, MI, emergency CABG or TVR within 30 d)		Noninferiority design	0.3 to 1.57; p=0.782	OR: 0.91	9.2% (test-proximal protection when possible, distal when not) vs. 10.0% (control group – distal protection whenever possible)

CABG indicates coronary artery bypass graft; creatine kinase-myocardial band; d, day; EPD, embolic protection device; FIRE, Filter Wire EX Randomized Evaluation; MACE, major adverse cardiac event; MB, myocardial bands; MI, myocardial infarction; PROXIMAL, Proximal Protection During Saphenous Vein Graft Intervention; SAFER, Saphenous Vein Graft Angioplasty Free of Emboli Randomized; SVG, saphenous vein graft; TVR, target vessel revascularization; and ULN, upper limit of normal.

Data Supplement 30. Major Reviews, Meta-Analyses and Studies of Vascular Closure Devices

Study Name	Author/ Year/ Journal	Aim of Study	Study Type	Study Size	Patient Population/ Inclusion/Exclusion	End-points	Statistics	Results/ P-Values	Conclusions/Comments
JACC State-of-the-art paper	Dauerman et al., 2007 JACC (261)	Review and critical analysis of VCD	Review and critical analysis	N/A	Diagnostic catheterization or endovascular procedure	N/A	N/A	N/A	Select Manuscript Conclusions: 1. VCD reliably shortens time to hemostasis and thus allows earlier patient ambulation. 2. Concerns that VCD outcomes are worse are "not supported by review of published meta-analysis, multicenter registries, and longitudinal registries". 3. The largest registry study to date suggested a significant decrease in complications with VCD; "it is possible this reduction in complications is directly related to the VCD or alternatively reflects a reluctance by the operator to use a VCD" in certain situations. 4. Pts believed to be at high risk for VCD use have been routinely excluded from pivotal studies leading to VCD approval. 5. For PCI pts, "contemporary data support a neutral effect on complications".
AHA Scientific Statement	Patel et al., 2010 Circulation	AHA Scientific Statement	Review and critical	N/A	Diagnostic catheterization or endovascular	Various complicati ons	N/A	N/A	Select Manuscript Conclusions: 1. Existing literature on VCDs emanates largely from small and moderate clinical trials (100 to 650 pts). Many of these studies were

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	(262)	on VCD	analysis		procedure				single-center trials and enrolled predominantly low and medium-risk pts. These studies were likely underpowered to detect differences in the rates of infrequent vascular complications. Other studies lacked defined allocation concealment, blinded outcome assessment and/or intention-to-treat analyses. 2. Overall, nonrandomized observational data appear to confirm the efficacy of VCDs, but provide no definitive evidence as to their safety compared to manual compression or to each other. 3. The results of observational registry data and meta-analyses highlight that devices may have different effects, and these clinical effects may not be easily identified in the small randomized trials conducted in populations that may be lower risk than those in clinical use. Recommendations/Guidelines 1. Pts considered for deployment of arteriotomy closure devices at the femoral artery site should undergo a femoral angiogram with identification of sheath insertion site and other features (atherosclerosis, calcification, etc.) to ensure anatomical suitability for their use (Class I, Level of Evidence: C). 2. Facilities with standard manual compression regimens should aim to achieve the reported low vascular complication rates (< 1%), in pts undergoing uncomplicated 5-Fr diagnostic angiography. (Class I, Level of Evidence: C). 3. Use of arteriotomy closure devices is reasonable following invasive cardiovascular procedures performed via the femoral artery to achieve faster hemostasis, shorter duration of bed rest and possibly improved patient comfort. The use of these devices should be weighed against the risk of increased complications in certain patient subsets and also take into account body habitus, location of arteriotomy, size and condition of the parent vessel, sheath size, and presence or absence of systemic disease in the patient (Class IIA – Level of Evidence: B). This recommendation is based on a meta-analysis and several small scale trials. However, in these studies there are trends towards higher rates of complications. (Class IIa, Level of Evidence: B). 4. Arteriotomy closure devices should not be utilized routinely to reduce vascular complications in pts undergoing invasive cardiovascular procedures via the femoral artery approach (Class III, Level of Evidence: B). 5. Complications encountered during or following deployment of arteriotomy closure devices should be collected systematically either as part of local quality efforts or national registries (such as the ACC-NCDR) and systematically reported to the FDA (Class I – Level of

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									Evidence: C).
Management of Pts Undergoing Percutaneous Coronary Revascularization – AHA statement	Levine et al., 2003 Ann Intern Med (263)	AHA commissioned statement to review management of pts undergoing PCI, including identification and prevention of complications.	Review and critical analysis	PCI-related articles	PCI procedures	N/A	N/A	N/A	Select Manuscript Conclusions: 1. VCDs are associated with a risk for vascular complications that is often similar to that seen with manual compression. These complications include pseudoaneurysm, bleeding and hematoma, infection, arterial stenosis or occlusion, and venous thrombosis. 2. Most series report an incidence of major complications ranging from approximately 1% to 5%. 3. Several reports in the surgical literature suggest that vascular closure devices are associated with a higher incidence of large pseudoaneurysms and pseudoaneurysms. Not amenable to ultrasound compression therapy, greater loss of blood and need for transfusions, higher incidence of arterial stenosis or occlusion, more extensive surgical repair, and higher incidence of groin infections compared with manual compression.
N/A	Biancari et al., 2010 AHJ (264)	Assess efficacy of VCD	Meta-analysis of randomized studies	31 prospective randomized studies; 7,528 pts	Diagnostic catheterization or endovascular procedure	Various complications including groin hematoma, bleeding, pseudoaneurysm, blood tx, vascular complications	Meta-analysis	Overall in PCI cohort (VCD vs. no VCD): • Groin bleeding: 3.6 vs. 2.4% OR: 1.76 (95% CI: 0.27 to 5.20) • Blood Tx: 0.6 vs. 0.4% OR: 1.17 (95% CI: 0.44 to 3.15) • Pseudoaneurysm: 2.6% vs. 2.5% (95% CI: 0.70 to 1.66; p=1.08) • Lower limb/vascular complication:	Select Study Conclusions: 1. VCD decreases time to hemostasis. 2. VCD not associated with decreased bleeding complications. 3. Numerically more lower limb ischemia and other arterial ischemic complications and need of surgery for vascular complications with VCD. 4. Significantly more groin infections with VCD. 5. Analysis of only more recent studies (2000 onward) did not demonstrate benefits of VCD (other than time to hemostasis). 6. No individual device showed significant benefits.

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								0.3 vs. 0% (95% CI: 0.82 to 13.60; p=3.34) • Vascular surgery: 1.0 vs. 0.5% (95% CI: 0.89 to 3.56; p=1.79) • Numerically more groin infections and vascular surgeries • Time to hemostasis with VCD 38 min shorter (27 to 48 min) <u>Adverse events after diagnostic cath or PCI in studies published from 2000 onward:</u> • Groin bleeding: 4.0% vs. 0.9% Fixed RR: 3.49 (95% CI: 0.62 to 19.08) • Blood Tx: 0.7% vs. 0.8% Fixed RR: 0.78 (95% CI: 0.35 to	

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								1.71) • Lower limb/vascular complication: 0.3% vs. 0 .0% Fixed RR: 3.07 (95% CI: 0.50 to 13.10) • Pseudoaneurysm: 0.7 vs. 1.1% OR: 0.69 (95% CI: 0.38 to 1.23) • Vascular surgery: 0.6% vs. 0.3% Fixed RR: 1.76 (95% CI: 0.74 to 4.20) • Time to hemostasis with VCD 43 min shorter (31 to 55) <u>All studies</u> • Groin bleeding RR: 1.75 (95% CI: 0.83 to 3.71) with CVD • Risk of lower limb ischemia,	

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								arterial stenosis, and/or device entrapment in femoral artery RR: 3.28 (95% CI: 0.92 to 11.74) • Groin infection RR: 2.48 (95% CI: 1.14 to 5.43) with VCD	
N/A	Koreny et al., 2004 JAMA (265)	Meta-analysis of VCD safety and efficacy	Meta-analysis of randomized trials	30 studies; 4,000 pts	Pts undergoing diagnostic or interventional coronary procedures	Various vascular complications	Meta-analysis	RR for complication with VCD: • Groin hematoma: 1.14 (95% CI: 0.86 to 1.51) • Bleeding: 1.48 (95% CI: 0.88 to 2.48) • AV fistula: 0.83 (95% CI: 0.23 to 2.94) • Pseudoaneurysm: 1.19 (95% CI: 0.75 to 1.88) Time to hemostatis with VCD: • 17 min shorter	Select Study Conclusions: 1. The quality of individual trials was "fair" and there were "many of poor methodological quality", 2. Time to hemostasis was shorter (though notable heterogeneity in the data). 3. Generally no difference in complications; there was "reason for concern that (VCDs) may increase the risk of hematoma and pseudoaneurysm. 4. Sensitivity analysis did not reveal significant differences in the devices studied.

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								with VCD RR for complications with CVD analyzed on in trials that used explicit intention-to-treat approaches: • Hematoma: 1.89 (95% CI: 1.13 to 3.15) • Pseudoaneurysm: 5.40 (95% CI: 1.21 to 24.5)	
N/A	Nikolsky et al., 2004 JACC (266)	Meta-analysis of VCD vascular complications	Meta-analysis of randomized, case-control, and cohort studies	30 studies; 37,066 pts	Pts undergoing percutaneous coronary procedures	Vascular complications (composite of numerous complications)	Meta-analysis	PCI - all studies: VCD OR: 1.11 (95% CI: 0.94 to 1.33) PCI - randomized studies only: VCD OR: 1.35 (95% CI: 0.67 to 1.98) PCI using GP IIb/IIIa: • Angio-Seal OR: 1.17 (95% CI: 0.87 to 1.58) • Perclose OR: 1.05 (95% CI:	Selected Study Conclusions: 1. In PCI studies, no difference in composite endpoint of vascular complications with VCD compared to manual compression. 2. In PCI studies, no statistically signficant difference in vascular complications with either Angio-Seal or Perclose when compared to manual compression; higher complication rate with VasoSeal compared to manual compression. 3. No difference in vascular complication rates with VCD (vs. manual compression) in the setting of PCI using GP IIb/IIIa inhibitors.

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								0.77 to 1.44)	
N/A	Vaitkus et al., 2004 J Invasive Cardiol (267)	Meta-analysis of VCDs to detect any differences in VCDs	Meta-analysis of prospective randomized trials	16 studies; 5,048 pts	Pts undergoing invasive coronary procedures	"Major" complications	Meta-analysis	• Overall analysis of VCDs: OR: 0.89 (95% CI: 0.86 to 0.91) • PCI only pts: OR: 1.00 (95% CI: 0.96 to 1.03) • PCI pts only treated with AngioSeal: OR: 0.51 (95% CI: 0.45 to 0.58) • PCI pts only treated with Perclose: OR: 1.0 (95% CI: 0.13 to 7.48) • PCI pts only treated with VaoSeal: OR: 1.18 (95% CI: 1.16 to 1.20)	Select Study Conclusions: 1. VCDs may be associated with a reduction in risk of complications following invasive coronary procedures, but significant differences may exist among individual devices.

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N/A	Marso et al., 2010 JAMA (268)	Bleeding with VCD	Retrospective registry data of NCDR-CathPCI Registry	1.5 million pts	Pts undergoing PCI	Bleeding (drop hdb > 3 g/dL, blood Tx, prolongation of hospital stay)	Bleeding risk adjustment, propensity score, multinomial regression, etc.	Unadjusted rates: • No VCD: 2.8% • VCD: 2.1% (p<0.001) Adjusted rates: • No VCD: 2.7%; • VCD: 2.5% OR: 0.77 (95% CI: 0.73 to 0.80); NNT=148	Select Study Conclusions: 1. largest evaluation of registry data. 2. VCD associated with significantly lower bleeding rates, particularly among pts at greatest risk for bleeding. found bleeding less likely with VCD. Writing Group Author Caveats: 1. Registry analyses could not take in to account VCD deployment failure and complications related to VCD (infection, vascular damage, neuropathy, etc.). 2. Data is nonrandomized, and hemostasis method would presumably occur after sheathogram, thus likely there was selection bias in who did or did not receive a VCD that study could not account for.
N/A	Hoffer et al., 2003 J Vasc Interv Radiol (269)	Review article	Systematic review	N/A	Pts undergoing diagnostic and therapeutic percutaneous procedures	N/A	N/A	N/A	Select Review Conclusions: 1. Closure devices can rapidly establish hemostatis in the presence of anticoagulation and antiplatelet agents. 2. In pts undergoing therapeutic. interventions, VCD complication rates were similar to manual compression. 3. There is an increased prevalence of infectious and embolic complications with VCD (though not likely to be found statistically significant given low absolute numbers). 4. No device is dramatically different with regard to efficacy and complications.

ACC-NCDR indicates American College of Cardiology-National Cardiovascular Data Registry; AHA, American Heart Association; cath, catheterization; CVD, cardiovascular disease; FDA, Food and Drug Administration; NCDR, National Cardiovascular Data Registry; NNT, number needed to treat; OR, odds ratio; pts, patients; PCI, percutaneous coronary intervention, RR, relative risk; tx, toxicity; and VCD, vascular closure device.

Data Supplement 31. Studies That Have Evaluated Potential Clopidogrel–PPI Interaction

Study	Design and Number of Patients	Conclusions	Comments
Gilard et al. (270)	Observational N=105	Omeprazole decreased the inhibitory effects of clopidogrel as assessed by VASP.	Small, pilot study
Gilard et al. (271)	Double-blind, Placebo-controlled N=124	Omeprarzole decreased clopidogrel inhibitory effect on platelet P2Y12 as assessed by VASP.	1. Clinical endpoints not evaluated 2. Short study duration (7 d) 3. Single PPI (omeprazole) evaluated

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Pezalla et al. (272)	Observational N=1,010	High PPI exposure in pts taking clopidogrel was associated with a higher MI rate vs. placebo.	1. Poorly defined categories (i.e., clopidogrel adherence, low vs. high PPI exposure) 2. Confounding variables (high PPI exposure with more comorbidities)
Kreutz et al. (273)	Retrospective Cohort N=16,690	Concomitant use of a PPI and clopidogrel compared with clopidogrel alone was associated with a higher rate of major adverse cardiovascular events within 1 y after coronary stent placement.	1. Retrospective analysis
Dunn et al. (274)	Retrospective post hoc analysis N=2,116	PPI use independently associated with 28-d and 1-y endpoints.	1. Interaction analysis did not demonstrate effect of PPI use on randomized therapy 2. PPI therapy was assessed only at study entry.
Small et al. (275)	Open-label Crossover N=26	Lansoprazole decreased IPA after clopidogrel dose but not prasugrel.	1. Single PPI (lansoprazole) studied 2. Healthy subjects 3. Pharmacodynamics studied—no clinical implications
Siller-Matula et al. (276)	Case-Control N=300	Pantoprazole and esomeprazole are not associated with impaired response to clopidogrel.	1. Nonrandomized 2. Possible confounding 3. Pharmacodynamics studied—no clinical implications
Ho et al. (277)	Retrospective Cohort N=8,205	Use of PPI and clopidogrel after hospital discharge for ACS was associated with an increased risk of adverse outcomes.	1. Demographics limited to male veterans 2. Cause-specific mortality unavailable 3. Causality not established 4. Possible confounding
Juurlink et al. (278)	Observational N=13,636	Omeprazole attenuates the effects of clopidogrel as compared to pantoprazole or esomeprazole.	1. Comorbid conditions and nonprescription medications unknown 2. Possible miscoding and confounding 3. Patient adherence unknown
Sibbing et al. (279)	Case-Control N=268	Concomitant therapy with PPI other than pantoprazole in pts receiving clopidogrel following AMI associated with loss of benefit and increased risk of reinfarction.	1. Underpowered 2. Platelet function measured at single time point 3. Pharmacodynamic technique (MEA) 4. Pharmacodynamics studied—no clinical implications
Medco reanalysis (280)	Retrospective analysis N=16,690	PPIs interfere with clopidogrel and this interaction is apparent with each of the most commonly prescribed PPIs.	1. Retrospective analysis was based on medical and pharmacy claims
FAST MI (281)	Genetic analysis N=2,208	The use of omeprazole, or any other proton-pump inhibitor, had no effect on the clinical response to clopidogrel.	1. Subgroup analysis 2. Forced statistical modeling 3. Observational
Dallas VA database (282)	Retrospective N=533	Concomitant use of PPI(s) with clopidogrel was associated with an increased risk of MACE post-PCI.	1. Retrospective 2. Observational
Gaspar et al. (283)	Retropsective N=922	PPI prescription in addition to aspirin and clopidogrel was not associated with a worse prognosis in pts with ACS.	1. Retrospective 2. Observational

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TRITON-TIMI 38 Trial (284)	Post hoc subgroup analysis N=13,608	In a large population of subjects treated with clopidogrel or prasugrel, the use of a PPI was not associated with an increased risk of cardiovascular events.	1. Retrospective 2. Subgroup
PRINCIPLE TIMI 44 (285)	Post hoc subgroup analysis N=201	PPI was not associated with increased risk of adverse clinical outcomes for pts treated with clopidogrel or prasugrel. There was a trend towards a modest attenuation of the antiplatelet effects of both clopidogrel and prasugrel with PPI use.	1. Retrospective 2. Subgroup
COGENT (286)	RCT	At 390 d 67 cardiovascular events—a composite of CV death, nonfatal MI, CABG or PCI, or ischemic stroke—occurred in the placebo group and 69 in the omeprazole group, with superimposable event curves.	Trial stopped early as sponsor went bankrupt No evidence of clopidogrel-PPI interaction

ACS indicates acute coronary syndrome; AMI, acute myocardial infarction; COGENT, Clopidogrel and the Optimization of Gastrointestinal Events; CV, cardiovascular; IPA, inhibition of platelet aggregation; MACE, major adverse cardiac event; MEA, multiple electrode platelet aggregometry; MI, myocardial infarction; pts, patients; PPI, proton pump inhibitor; PRINCIPLE-TIMI 44, Prasugrel In Comparison to Clopidogrel for Inhibition of Platelet Activation and Aggregation-TIMI 44; TRITON-TIMI 38, Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel-TIMI 38 trials; and VASP, vasodilator-stimulated phosphoprotein. Adapted with permission from Allen et al. (287).

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EXHIBIT 10

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™
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CDC A-Z INDEX

Heart Disease (/heartdisease/index.htm)

Heart Disease Facts

America's Heart Disease Burden

- About **610,000 people** die of heart disease in the United States every year–that's **1 in every 4 deaths.**[1]
- Heart disease is the leading cause of death for both men and women. **More than half** of the deaths due to heart disease in 2009 were in men.[1]
- Coronary heart disease is the most common type of heart disease, killing over **370,000 people** annually.[1]
- Every year about **735,000 Americans** have a heart attack. Of these, 525,000 are a first heart attack and 210,000 happen in people who have already had a heart attack.[2]

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- Early Action is Key
- Americans at Risk
- Protect Your Heart
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Deaths Vary by Ethnicity

Heart disease is the leading cause of death for people of most ethnicities in the United States, including African Americans, Hispanics, and whites. For American Indians or Alaska Natives and Asians or Pacific Islanders, heart disease is second only to cancer. Below are the percentages of all deaths caused by heart disease in 2008, listed by ethnicity.[4]

Race of Ethnic Group	% of Deaths
African Americans	24.5
American Indians or Alaska Natives	18.0
Asians or Pacific Islanders	23.2
Hispanics	20.8
Whites	25.1
All	25.0

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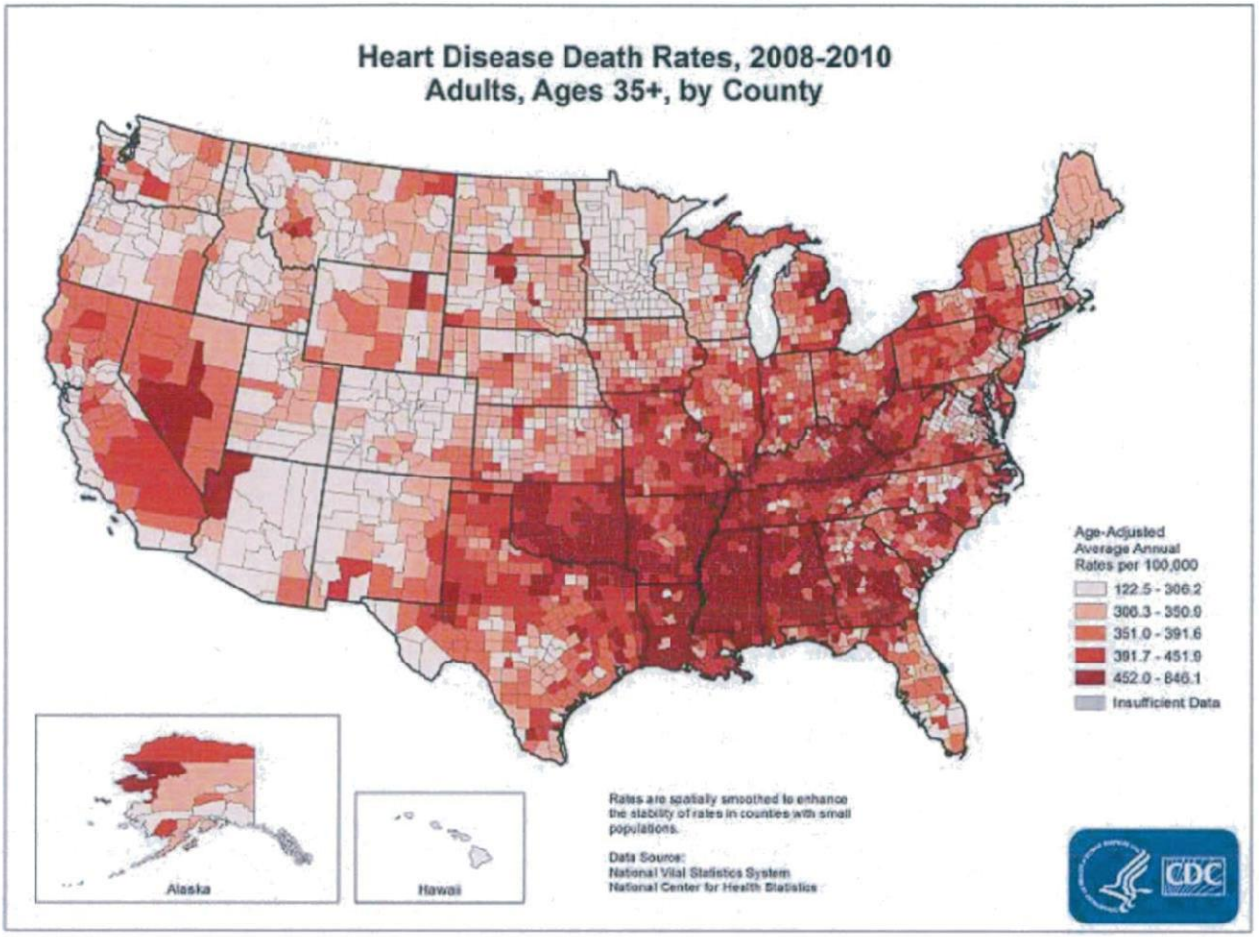
Deaths Vary by Geography

During 2008-2010, death rates due to heart disease were highest in the South and lowest in the West.



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Early Action is Key

Knowing the warning signs and symptoms of a heart attack is key to preventing death, but many people don't know the signs.

- In a 2005 survey, most respondents—92%—recognized chest pain as a symptom of a heart attack. **Only 27%** were aware of all major symptoms and knew to call 9-1-1 when someone was having a heart attack.[5]
- **About 47%** of sudden cardiac deaths occur outside a hospital. This suggests that many people with heart disease don't act on early warning signs.[6]

Heart attacks have several **major warning signs** and symptoms:

- Chest pain or discomfort.
- Upper body pain or discomfort in the arms, back, neck, jaw, or upper stomach.
- Shortness of breath.
- Nausea, lightheadedness, or cold sweats.

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Americans at Risk

High blood pressure, high LDL cholesterol, and smoking are key risk factors for heart disease. About **half of Americans** (49%) have at least one of these three risk factors.[7]

Several other medical conditions and lifestyle choices can also put people at a higher risk for heart disease, including:

- Diabetes
- Overweight and obesity
- Poor diet
- Physical inactivity
- Excessive alcohol use

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Protect Your Heart

Lowering your blood pressure and cholesterol will reduce your risk of dying of heart disease. Here are some tips to protect your heart:

- Follow your doctor's instructions and stay on your medications.
- Eat a healthy diet that is low in salt; low in total fat, saturated fat, and cholesterol; and rich in fresh fruits and vegetables.
- Take a brisk 10-minute walk, 3 times a day, 5 days a week.
- Don't smoke. If you smoke, quit as soon as possible. Visit www.cdc.gov/tobacco and www.smokefree.gov (http://www.smokefree.gov) for tips on quitting.

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Fact Sheets

- Heart Disease Fact Sheet
- Men and Heart Disease
- Women and Heart Disease
- Heart Failure Fact Sheet
- Know the Signs and Symptoms of a Heart Attack
- Cholesterol Fact Sheet
- High Blood Pressure Fact Sheet
- Pulmonary Hypertension Fact Sheet

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Time Delay to Treatment and Mortality in Primary Angioplasty for Acute Myocardial Infarction: Every Minute of Delay Counts

Giuseppe De Luca, Harry Suryapranata, Jan Paul Ottervanger and Elliott M. Antman

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Time Delay to Treatment and Mortality in Primary Angioplasty for Acute Myocardial Infarction

Every Minute of Delay Counts

Giuseppe De Luca, MD; Harry Suryapranata, MD, PhD;
Jan Paul Ottervanger, MD, PhD; Elliott M. Antman, MD

Background—Although the relationship between mortality and time delay to treatment has been demonstrated in patients with acute ST-segment elevation myocardial infarction (STEMI) treated by thrombolysis, the impact of time delay on prognosis in patients undergoing primary angioplasty has yet to be clarified. The aim of this report was to address the relationship between time to treatment and mortality as a continuous function and to estimate the risk of mortality for each 30-minute delay.

Methods and Results—The study population consisted of 1791 patients with STEMI treated by primary angioplasty. The relationship between ischemic time and 1-year mortality was assessed as a continuous function and plotted with a quadratic regression model. The Cox proportional hazards regression model was used to calculate relative risks (for each 30 minutes of delay), adjusted for baseline characteristics related to ischemic time. Variables related to time to treatment were age >70 years ($P<0.0001$), female gender ($P=0.004$), presence of diabetes mellitus ($P=0.002$), and previous revascularization ($P=0.035$). Patients with successful reperfusion had a significantly shorter ischemic time ($P=0.006$). A total of 103 patients (5.8%) had died at 1-year follow-up. After adjustment for age, gender, diabetes, and previous revascularization, each 30 minutes of delay was associated with a relative risk for 1-year mortality of 1.075 (95% CI 1.008 to 1.15; $P=0.041$).

Conclusions—These results suggest that every minute of delay in primary angioplasty for STEMI affects 1-year mortality, even after adjustment for baseline characteristics. Therefore, all efforts should be made to shorten the total ischemic time, not only for thrombolytic therapy but also for primary angioplasty. **(*Circulation*. 2004;109:1223-1225.)**

Key Words: myocardial infarction ■ prognosis ■ mortality ■ angioplasty

Although the relationship between mortality and time delay to treatment has been demonstrated in patients with acute ST-segment elevation myocardial infarction (STEMI) treated by thrombolysis,[1-3] the impact of time delay on prognosis in patients undergoing primary angioplasty has yet to be clarified.[3-6] In a recent study,[7] we have shown that time from symptom onset to balloon inflation, but not door-to-balloon time, is strongly related to 1-year mortality in patients treated by primary angioplasty. The aim of this report was to address the relationship between time to treatment and mortality as a continuous function and to estimate the risk of mortality for each 30-minute delay in treatment.

Methods

From 1994 to 2001, a total of 1791 patients with STEMI underwent primary angioplasty.[7] Informed consent was obtained from each patient (or from their relatives in case of patient's inability) before the angiogram. All patients presenting within 6 hours from symptom onset or between 6 and 24 hours if they had continuous symptoms and signs of ischemia (persistent or recurrent chest pain and/or persistent elevation or reelevation of ST segment) were included.[7] All patients received aspirin (500 mg) and heparin (10 000 IU) intravenously before the procedure. Therapy after stenting changed during the study period. All patients were taking aspirin and were treated with an additional 3 months of warfarin (before 1996) or 1 month of ticlopidine or clopidogrel (since January 1996). Time to treatment was calculated from symptom onset to first balloon inflation (true ischemic time).

Angiographic Data Analysis

All angiograms were analyzed by an independent core laboratory (Diagram, Zwolle, The Netherlands) blinded to all data apart from the coronary angiogram. TIMI (Thrombolysis In Myocardial Infarction) flow and myocardial blush grade were assessed after the angioplasty procedure, as described previously.[8] Residual stenosis was assessed visually. Successful reperfusion was defined as post-procedural TIMI 3 flow, residual stenosis <50%, and myocardial blush grade 2 to 3.

Ejection Fraction

Left ventricular ejection fraction was measured by radionuclide ventriculography at discharge, as described previously.[8]

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From the Department of Cardiology (G.D.L., H.S., J.P.O.), ISALA Klinieken, Zwolle, The Netherlands, and Cardiovascular Division (E.M.A.), Brigham and Women's Hospital, Boston, Mass.

Correspondence to Harry Suryapranata, MD, PhD, Department of Cardiology, ISALA Klinieken, Hospital De Weezenlanden, Groot Wezeland 20, 8011 JW Zwolle, The Netherlands. E-mail h.suryapranata@diagram-zwolle.nl

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Patient Characteristics and Ischemic Time

Variable	Yes	No	P
Age >70 y	237±149	208±139	<0.0001
Female gender	233±137	208±139	0.004
Diabetes	248±195	211±135	0.002
Previous CABG/PCI	217±146	190±68	0.035
Previous infarction	202±76	216±148	NS
Hypertension	203±70	218±156	NS
Hypercholesterolemia	205±121	217±146	NS
Smoking	212±124	217±155	NS
Killip class >1	214±123	214±144	NS
Anterior infarction	215±148	213±135	NS
TIMI flow 0–1 preprocedure	214±128	215±174	NS
Multivessel disease	213±112	215±169	NS
Successful reperfusion*	208±120	229±188	0.006
Stent	211±119	217±161	NS
EF <30%†	237±138	214±140	0.04

CABG indicates coronary artery bypass graft; PCI, percutaneous coronary intervention; EF, ejection fraction at discharge.

*Defined as postprocedural TIMI 3 flow, residual restenosis <50%, and myocardial blush grade 2 to 3.

†Ejection fraction at discharge was available in 1143 patients.

Clinical Outcome

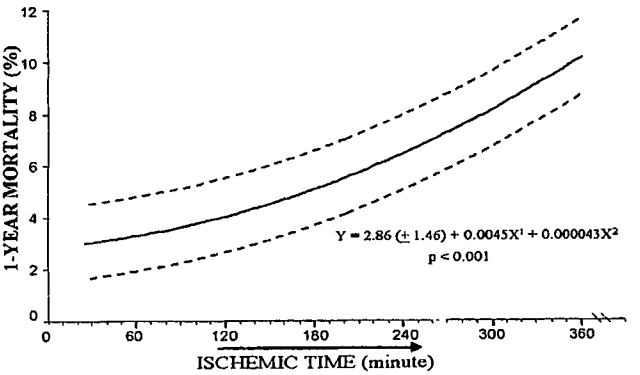
Records of all patients who visited our outpatient clinic were reviewed. For all other patients, information was obtained from the patient's general physician or by direct telephone interview with the patient. For patients who died during follow-up, hospital records and necropsy data were reviewed. No patient was lost to follow-up.

Statistical Analysis

Statistical analysis was performed with the SPSS 10.0 statistical package. Continuous data were expressed as mean±SD and categorical data as percentage. ANOVA and χ^2 test were used appropriately for continuous and categorical variables, respectively. A logistic regression analysis was used to evaluate the relationship between time to treatment and predischarge ejection fraction, after adjustment for baseline characteristics related to ischemic time. The relationship between ischemic time and 1-year mortality was assessed as a continuous function and plotted with a quadratic regression model. Cox proportional hazards regression model was used to calculate relative risks (for each 30-minute delay), adjusted for baseline characteristics related to ischemic time.

Results

Time to treatment according to patients' demographic, clinical, and angiographic characteristics is reported in the Table. Variables significantly related to time to treatment were age >70 years (237±149 versus 208±139 minutes, $P<0.0001$), female gender (233±137 versus 208±139 minutes, $P=0.004$), diabetes (248±195 versus 211±135 minutes, $P=0.002$), and previous revascularization (217±146 versus 190±68 minutes, $P=0.035$). When analyzed as a continuous variable, age was linearly related to ischemic time ($r=0.096$, $P<0.0001$). Ischemic time was inversely associated with predischarge ejection fraction ($r=-0.068$, $P=0.022$). After adjustment for age (as a continuous variable), gender, diabetes, and previous revascularization, each 30-minute delay was associated with an OR of predischarge ejection fraction <30% of 1.087 (95% CI 1.023 to 1.15; $P=0.005$). Patients with successful reperfusion had a significantly shorter ischemic time (208±120 versus 229±188 minutes, $P=0.006$).



Relationship between time to treatment and 1-year mortality, as continuous function, was assessed with quadratic regression model. Dotted lines represent 95% CIs of predicted mortality.

A total of 103 patients (5.8%) had died at 1-year follow-up. The relationship between time to treatment and mortality is depicted in the Figure. After adjustment for age (as a continuous variable), gender, diabetes, and previous revascularization, each 30-minute delay was associated with a relative risk of 1-year mortality of 1.075 (95% CI 1.008 to 1.15; $P=0.041$).

Discussion

The major finding of the present study is that every minute of delay in treatment of patients with STEMI does affect 1-year mortality, not only in thrombolytic therapy but also in primary angioplasty. In fact, the risk of 1-year mortality is increased by 7.5% for each 30-minute delay.

Despite the demonstrated prognostic role of time delay to treatment in patients with STEMI treated by thrombolysis,[1–3] its role in patients treated with primary angioplasty remains controversial.[3–7] In a pooled analysis of all randomized trials that compared thrombolysis and primary angioplasty, Zijlstra et al[3] found that mortality linearly increased with time delay only in patients treated by thrombolysis, whereas it was relatively stable in patients treated by primary angioplasty. Cannon et al,[4] in a cohort of 27 080 patients undergoing primary angioplasty, found that only door-to-balloon time and not symptom onset–to-balloon time was associated with mortality. The absence of any relationship between ischemic time and mortality in primary angioplasty may be related to the potential low-risk profile of patients enrolled in randomized trials.[3] In fact, as reported by Antoniucci et al,[5] symptom onset–to-balloon time was associated with higher mortality, particularly in high-risk patients. These data have been strongly supported by recent reports.[6,7] A major limitation of the study by Cannon et al[4] is that very long door-to-balloon time (>2 hours) was observed in up to 50% of patients, which may affect the relationship between time delay and mortality. This confounding mechanism does not play a major role in single-center studies. In our previous report,[7] symptom onset–to-balloon time (true ischemic time) and not door-to-balloon time was a predictor of 1-year mortality.

A major explanation for our findings is that as demonstrated in animal models,[9–11] infarct size is significantly affected by the duration of coronary occlusion. Therefore,

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late reperfusion is expected to result in less myocardial salvage and a higher mortality rate than found with early reperfusion, even when optimal mechanical reperfusion is applied. In support of these data, Stone et al[12] found preprocedural TIMI-3 flow to be an independent predictor of mortality. Furthermore, a delay in reperfusion may be associated with an older, organized intracoronary thrombus compared with an early reperfusion. This may result in a higher incidence of distal embolization with lower postprocedural TIMI-3 flow and poor myocardial perfusion.[8] In fact, we found that patients with successful reperfusion (postprocedural TIMI-3 flow with residual stenosis <50% and optimal myocardial perfusion [myocardial blush grade 2 to 3]) had a significantly shorter ischemic time.

Because of the time dependence of thrombolytic therapy in obtaining optimal restoration of epicardial flow, time delay to treatment would be expected to increase the relative risk of mortality more remarkably when thrombolysis is administered than when mechanical reperfusion is used. Although primary angioplasty, in comparison with thrombolysis, may guarantee a higher rate of reperfusion in patients presenting late, it cannot prevent myocardial necrosis, which is related to the duration of occlusion, particularly in higher-risk patients.[5–7]

Conclusions

The results of this study strongly support the prognostic implication of time delay in patients with STEMI undergoing primary angioplasty. Therefore, all efforts should be made to shorten total ischemic time, not only for thrombolytic therapy but also for primary angioplasty.

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Widening of Socioeconomic Inequalities in U.S. Death Rates, 1993–2001

Ahmedin Jemal[1]*, Elizabeth Ward[1], Robert N. Anderson[2], Taylor Murray[1], Michael J. Thun[1]

1 Epidemiology and Surveillance Research, American Cancer Society, Atlanta, Georgia, United States of America, 2 Division of Vital Statistics, National Center for Health Statistics, Centers for Disease Control and Prevention, Hyattsville, Maryland, United States of America

Abstract

Background: Socioeconomic inequalities in death rates from all causes combined widened from 1960 until 1990 in the U.S., largely because cardiovascular death rates decreased more slowly in lower than in higher socioeconomic groups. However, no studies have examined trends in inequalities using recent US national data.

Methodology/Principal Findings: We calculated annual age-standardized death rates from 1993–2001 for 25–64 year old non-Hispanic whites and blacks by level of education for all causes and for the seven most common causes of death using death certificate information from 43 states and Washington, D.C. Regression analysis was used to estimate annual percent change. The inequalities in all cause death rates between Americans with less than high school education and college graduates increased rapidly from 1993 to 2001 due to both significant decreases in mortality from all causes, heart disease, cancer, stroke, and other conditions in the most educated and lack of change or increases among the least educated. For white women, the all cause death rate increased significantly by 3.2 percent per year in the least educated and by 0.7 percent per year in high school graduates. The rate ratio (RR) comparing the least versus most educated increased from 2.9 (95% CI, 2.8–3.1) in 1993 to 4.4 (4.1–4.6) in 2001 among white men, from 2.1 (1.8–2.5) to 3.4 (2.9–3–9) in black men, and from 2.6 (2.4–2.7) to 3.8 (3.6–4.0) in white women.

Conclusion: Socioeconomic inequalities in mortality are increasing rapidly due to continued progress by educated white and black men and white women, and stable or worsening trends among the least educated.

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* E-mail: ajemal@cancer.org

Introduction

Socioeconomic inequalities in death rates from all causes combined have widened in the U.S.[1–7] since the early 1960s, largely because heart disease mortality has decreased more rapidly in higher than lower socioeconomic groups.[1,3] However, most of the studies that used individual-level socioeconomic measures have been based on relatively small representative samples of the U.S. population rather than on national data, precluding simultaneous stratification by race, sex, and education in examining cause-specific trends. Further, no studies published in the peer-review literature have examined the trends since 1990 using national vital statistics. Such studies are important in measuring progress towards achieving the Healthy People 2010 objective of eliminating health disparities among subgroups of the population.

In this study, we examined mortality trends for all-causes and seven leading causes of death (cancer, heart disease, stroke, accidents, human immunodeficiency virus [HIV] infection, diabetes, and chronic obstructive pulmonary disease [COPD]) in relation to educational attainment from 1993 through 2001. These seven categories account for 70% of the total deaths. Mortality trends for several conditions decreased markedly over the past 10–15 years (cancer, heart disease, stroke, HIV infection) while others increased (accidents, diabetes, COPD), in part due to changes in risk factors and, for the former, advances in treatment.[8,9] We restricted the analysis to white and black men and women, ages 25–64 years, an age range in which education is usually complete and provides a better index of socioeconomic position than at older ages.[10,11]

Methods

We obtained mortality data from 1993 through 2001 from the National Vital Statistics System (NVSS) administered by the National Center for Health Statistics. Underlying causes of death were classified according to the selection and coding rules of the Ninth Revision of the International Classification of Diseases (ICD-9)[12] for deaths recorded between 1993 and 1998, and according to the Tenth Revision of the International Classification of Diseases (ICD-10)[13] for those recorded between 1999 and 2001. The ICD-9 and ICD-10 codes for all causes and 15 leading causes included in this analysis are given on the web (Table S1).

Information on educational attainment (number of years of schooling) as a marker of socioeconomic position was obtained

from death certificates. Although this information has been included on the standard death certificate since 1989, we restricted our analyses to the time interval 1993 to 2001 for three reasons: most states did not collect death certificate information on education systematically until 1993: race/ethnicity information collected by the Current Population Survey is not consistent with that of death certificates beginning with the 2002 survey (see below): and the question about educational attainment on the death certificate changed beginning with the 2003 mortality data from a highest grade of school completed to collegiate track education, i.e., the ability to identify degree status.[14] We classified educational attainment into four categories according to total years of schooling: less than high school graduate (<12 years of education), high school graduate (12 years), some college (13–15 years), and college graduate or post graduate (≥16 years).

We restricted the analyses to deaths among non-Hispanic whites and blacks (4,257,269), because of problems with reporting other racial and ethnic subgroups.[15] We excluded 609,093 deaths that occurred in seven states (Georgia, Kentucky, New York, Oklahoma, Rhode Island, South Dakota, and West Virginia) because completeness of education on death certificate in these states was less than 80% in at least one of the nine calendar years considered in this study. Another 126,238 deaths that occurred in the remaining 43 states and the District of Colombia were excluded due to missing data on education on the death certificates. The final analysis was based on 3,521,938 deaths recorded from 1993 to 2001; these comprised 97% of the total deaths among non-Hispanic whites and blacks in the 43 states and District of Colombia.

We obtained population data (the denominators for rate calculations) for the corresponding age, sex, race/ethnicity, education, state and time intervals from the U.S. Bureau of Census based on the Current Population Survey, a nationally representative sample of U.S. households.

Death rates (per 100,000) from all causes combined and from 15 leading causes were calculated by sex, race/ethnicity, educational attainment, and calendar year. Rates within the age range 25–64 years were age-standardized using the 2000 U.S. population standard. Temporal trends from all causes and seven selected cancer sites by educational attainment were assessed by fitting a weighted least squares regression models to the log-transformed annual age-standardized rates, weighted by the inverse of the variance, using joinpoint regression program, Version 3.0 software.[16] The annual percentage change or slope of the line segment was considered statistically significant if two-sided, $P<0.05$. Similarly, we also assessed the linearity of the annual percent changes across education levels within each race-, sex-, disease-specific category by fitting a weighted least square regression model to the log-transformed coefficients of the slopes, weighted by the inverse of the variance.[16] The educational disparity was assessed by calculating the ratio of the death rate for all causes combined in the least educated group (<12 years of education) to the most educated group (college degree or more) for 1993 and 2001. We also calculated the contribution of specific conditions to the overall decrease (in the case of heart disease, cancer, stroke, and HIV infection) or increase (diabetes, COPD, accidents) in mortality rates in the general population.[8,17] This calculation was expressed as a percentage of the total change.

Results

Table 1 and Figure 1 show trends in death rates from all causes combined from 1993 through 2001 among white and black men and women, 25–64 years old, in relation to educational attainment. The all cause death rate decreased significantly during this interval among the most educated (≥16 years) men and women, with the largest decrease in black men. In contrast, the all cause death rate increased in those with less than a high school education. The annual percent increase was largest among white women with less than 12 years of education (3.2% per year), but was also statistically significant (0.7% per year) in white women who had completed high school (Table 1). Between 1993 and 2001, the ratio of the all cause death rate in persons with <12 years versus ≥16 years of education increased from 2.9 (95% CI, 2.8–3.1) to 4.4 (4.1–4.6) in white men, from 2.1 (1.8–2.5) to 3.4 (2.9–3–9) in black men, from 2.6 (2.4–2.7) to 3.8 (3.6–4.0) in white women and from 1.8 (1.5–2.1) to 2.0 (1.8–2.3) over this nine-year interval. Among black women this ratio increased, but the trend was not statistically significant.

Among men, the temporal decrease in all cause death rates became larger with each additional increment of educational attainment. For example, the annual percentage decrease among black men was 2.6% for those with 12 years of education, 4.0% in men with 13–15 years of education, and 6.4% in those with ≥16 years of education. Among women, death rates from all causes combined decreased during this time interval only in black and white women with ≥16 years of education (Table 1).

Table 2 depicts trends in death rates from 1993 through 2001 for persons with <12 years of education and for those with ≥16 years of education for four major causes of death that are known to be decreasing in the general population. For all of these conditions, death rates decreased among the most educated. In contrast, the only condition for which the death rate decreased significantly among those with <12 years of education was HIV infection among white men. For white women with <12 years of education, the death rate from cancer increased by 1.1% per year and that from heart disease and stroke increased by 1.8% annually during the same time interval. The trends in death rates and the number of deaths in 1993 and 2001 for each race, sex, disease, and education specific group are provided in Tables S2 on the web.

Table 3 shows mortality trends among the least (<12 years of education) and most (≥16 years) educated persons by race and sex for three major conditions (accidents, diabetes, and COPD) known to have stable or increased death rates in the general population. Among the least educated, death rates increased for each of these conditions except for diabetes in black men and women for whom it did not change significantly. In contrast, among the most educated group, rates significantly decreased for COPD in white and black men and white women, for diabetes in black men and women and for accidents in black men, or remained stable for the remaining sex, race, and disease categories. The increases in death rates from 1993 through 2001 were inversely related to educational attainment (Table S3 on the web). For COPD, the death rate increased significantly among the least educated while decreasing significantly among men and women who had completed college in all sub groups except for black women for whom it did not change significantly.

In persons with <12 years of education, about 40% of the total increase in all cause death rates between 1993 and 2001 in white men was due to increases from accidents, cancer, and suicide, and nearly 50% of the total increase in white women was from accidents, cancer, COPD, and heart disease (Table S4 on web). In both white men and women, accidents contributed the largest percentage. In blacks, increases from accidents and nephritis in men and from accidents, HIV, and septicemia in women were offset by decreases from heart disease and cancer.

In persons with ≥16 years of education, about 90% of the total decrease in death rates from all causes between 1993 and 2001

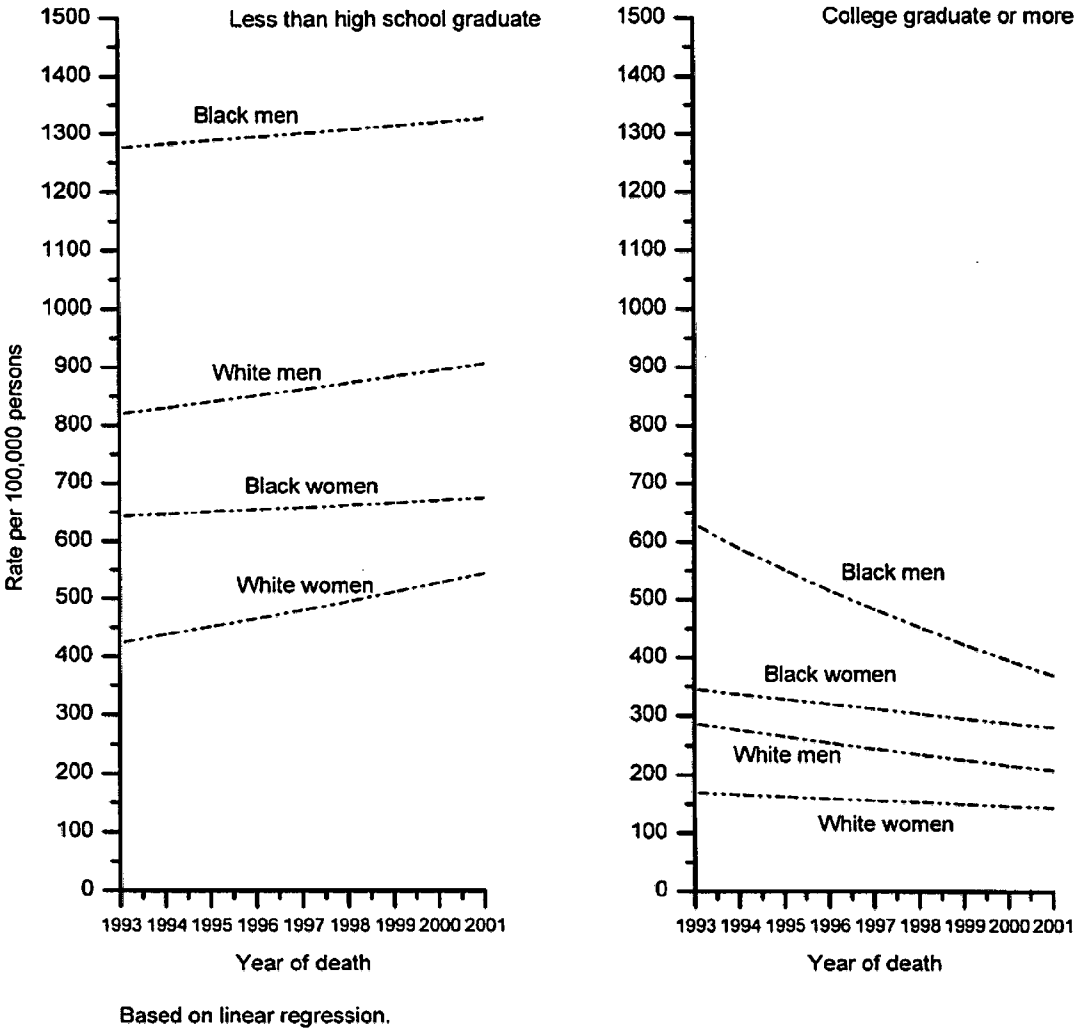

Figure 1. Temporal trends in age-standardized death rates from all causes combined among 25–64 year old U.S. adults by educational attainment, 1993–2001.
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among white men and 78% among black men were due to reduction in death rates from HIV infection, heart disease, and cancer, with HIV infection alone contributing over 50% in this age range (Table S4 on the web). In women with comparable education, the reduction in death rates from cancer, heart disease, and stroke during the corresponding time interval accounted for about 80% of the total decrease in all cause mortality rates in whites and 65% of the decrease in blacks. The reduction in death rates from cancer alone accounted for 65% and 35% of the total decrease in all-cause mortality among the most educated white and black women, respectively.

Discussion

Our principal finding is that socioeconomic inequalities in mortality continue to increase in the U.S. due to reductions in death rates among the most educated combined with lack of progress or worsening trends in the least educated. As noted, the ratio of the all cause death rate in persons with <12 years versus ≥16 years of education increased from 2.9 (95% CI, 2.8–3.1) to 4.4 (4.1–4.6) in white men, from 2.1 (1.8–2.5) to 3.4 (2.9–3–9) in black men, and from 2.6 (2.4–2.7) to 3.8 (3.6–4.0) in white women. Contributing to the inequality is the unprecedented decrease in the all-cause death rate among the most educated men (totaling 36% in black men and 25% in white men over the nine-year interval) largely due to decreases in death rates from HIV infection, cancer, and heart disease.

Lower educational attainment, a marker of socioeconomic position, is associated with a host of environmental, social and economic factors that detrimentally affect health over a life time. People with less education have fewer financial resources, less access to health insurance or stable employment, and less health literacy. Social and economic factors increase the vulnerability of low socioeconomic communities to risk factors such as smoking, obesity, physical inactivity, hypertension, and HIV infection.[18–22] People without health insurance are less likely to receive basic preventive services or standard timely treatment.[23,24] Those with lower health literacy are less likely to seek medical attention for asymptomatic conditions or to navigate the health care system effectively.[25,26] The prevalence of most major risk factors

Table 1. Trends in age-standardized death rates (per 100,000) from all causes combined among 25–64 year old U.S. adults by race, sex, and education, 1993–2001

		Whites					Blacks				
		1993		2001			1993		2001		
Sex	Education in years	No. of Deaths	Rate	No. of Deaths	Rate	Annual %*	No. of Deaths	Rate	No. of Deaths	Rate	Annual %*
Men											
	All	197085	471.5	198728	414.9	−1.9†	49922	1019.3	49566	807.8	−3.2†
	<12 Years	46187	836.8	38638	931.1	1.3	18622	1253.5	14861	1283.1	0.5
	12 Years	83895	591.6	88435	596.0	−0.4	21553	1251.7	23722	1039.7	−2.6†
	13–15 Years	33479	348.9	37255	296.2	−2.3†	6310	631.5	7249	472.7	−4.0†
	16+ Years	33524	284.7	34400	212.7	−3.9†	3437	596.2	3734	381.6	−6.4†
	P value trend					0.001					0.008
	Rate difference (<12 vs. 16+)		552.2		718.4			657.3		901.5	
	Rate ratio, 95% CI (<12 vs. 16+)	2.9 (2.8–3.1)		4.4 (4.1–4.6)			2.1 (1.8–2.5)		3.4 (2.9–3.9)		
Women											
	All	110539	255.6	122950	247.3	−0.5†	29297	501.9	34341	476.7	−0.9†
	<12 Years	24473	422.4	21711	553.4	3.2†	9888	622.6	8614	622.3	0.6
	12 Years	53250	296.1	57153	321.8	0.7†	12688	612.9	15478	634.2	−0.5
	13–15 Years	18976	184.9	24865	177.7	−0.1	4375	331.1	6612	327.3	0.1
	16+ Years	13840	165.4	19221	146.1	−2.0†	2346	350.7	3637	308.2	−2.5†
	P value trend					0.01					0.26
	Rate difference (<12 vs. 16+)		257.1		407.3			272.0		314.2	
	Rate ratio, 95% CI (<12 vs. 16+)	2.6 (2.4–2.7)		3.8 (3.6–4.0)			1.8 (1.5–2.1)		2.0 (1.8–2.3)		

Rates were age standardized to the 2000 U.S. standard population.
*Annual percent change based on rates that were age-adjusted to the 2000 U.S. standard population using regression analysis.
†Annual percent change is statistically significantly different from zero (two-sided P<.05).
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remains much higher among persons with lower than high socioeconomic position.[27–29] Progress in reducing smoking has been slowest among the least educated.[27,30] The prevalence of obesity, hypertension, and diabetes has increased in all socioeconomic position groups in recent years.[27,30–33]

These environmental and socioeconomic factors may also have contributed to the differences in inequalities in all-cause and cause-specific mortality by race and sex. For example, the increases in death rates for cancer and heart disease among white women with <12 years of education but not among white men with <12 years of education partly reflects the later uptake of cigarette smoking among women than men. Smoking prevalence in women peaked about 20 years after it peaked in men.[34,35] The large inequality in HIV infection mortality rates between blacks and whites may reflect an increased risk of HIV infection from sexual behavior and drug use as well as lower receipt of highly active antiretroviral therapy in blacks than in whites[36,37]

Our findings are qualitatively similar to those of previous studies that analyzed temporal trends in US mortality by socioeconomic position in earlier time periods.[1,3,6] Using the 1960 National Mortality Follow Back Survey and 1986 National Health Interview Survey, Pappas et al documented that the disparity in mortality rates according to education increased from 1960 to 1986 among white and black, men and women, age 25–64 years, although the increase in disparity was less for women than men.[3] Feldman et al. reported widening of the educational disparity in death rates from 1960 to the time period 1971–1984 among white men 55 years or above, but not white women.[1] Similarly, using the National Occupational Mortality Surveillance, Steenland and colleagues reported that the differential in mortality by socioeconomic position increased from 1984 to 1997 among men age 35–64, but not in women.[6] In all of these studies, the disparity in death rates increased over time due to slower progress among those with lower than higher socioeconomic position. Our study, in contrast, finds no decrease in all cause mortality rates in the lowest educational group between 1993 and 2001. Furthermore, all-cause mortality rates among lower educated white women increased rather than decreased, with accidents, cancer, COPD, and heart disease accounting for about half of the total increase in white women with <12 years of education.

Mortality data collected after 2001 could not be analyzed using the same category of race/ethnicity. However, analysis of the 2005 mortality data by education for all races combined showed that the educational inequalities in all-cause mortality continued to be substantial.[38] Among 25–64 year olds, the all-cause mortality rate for those with <12 years of education was 3.2 times higher than that for persons with ≥13 years of education. The results of these studies illustrate the difficulty of achieving the goal of eliminating health disparities among disadvantaged subgroups of the population by 2010. Socioeconomic factors that contribute to poor nutrition, tobacco use, and physical inactivity often establish these patterns early in life[39]. Lower socioeconomic groups also have less access to preventive resources and health care. The elimination of health disparities will require addressing a broad spectrum of factors in the social and physical environment that contribute to poor health.

Table 2. Trends in age-standardized death rates (per 100,000) for selected causes of death with decreasing trend in the general population among 25–64 year old U.S. adults by race, sex, and education, 1993–2001

		Whites			Blacks		
		Rate			Rate		
Cause/Sex	Education in years	1993	2001	Annual %*	1993	2001	Annual %*
Cancer							
Men	All	127.9	110.2	−1.9†	221.1	173.5	−2.7†
	<12 Yrs	195.3	208.3	0.8	256.0	246.8	0.1
	16+ Yrs	85.6	66.4	−3.1†	125.0	85.2	−5.1†
	Rate difference (<12 vs. 16+)	109.7	141.9		131.0	161.6	
	Rate Ratio, 95% CI (<12 vs. 16+)	2.3 (2.1–2.4)	3.1(2.9–3.4)		2.0 (1.6–2.6)	2.9 (2.4–3.5)	
Women	All	111.9	98.0	−1.7†	145.1	132.1	−1.1†
	<12 Yrs	142.0	157.7	1.1†	146.4	130.7	−0.3
	16+ Yrs	87.6	72.5	−2.7†	131.0	113.1	−2.6†
	Rate difference (<12 vs. 16+)	54.5	85.2		15.4	17.6	
	Rate Ratio, 95% CI (<12 vs. 16+)	1.6 (1.5–1.7)	2.2 (2.0–2.3)		1.1 (0.9–1.4)	1.2 (1.0–1.4)	
Heart Diseases							
Men	All	129.3	100.7	−3.2†	245.8	194.9	−2.7†
	<12 Yrs	228.8	214.9	−0.6	281.7	262.9	−0.2
	16+ Yrs	72.3	51.1	−4.2†	139.3	99.2	−5.1†
	Rate difference (<12 vs. 16+)	156.5	163.8		142.4	163.7	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.2 (3.0–3.4)	4.2 (3.9–4.6)		2.0 (1.6–2.5)	2.6 (2.2–3.1)	
Women	All	44.8	37.9	−2.1†	122.0	106.1	−1.8†
	<12 Yrs	84.4	97.8	1.8†	151.4	132.9	−0.4
	16+ Yrs	20.0	16.9	−2.9†	73.1	62.8	−2.9†
	Rate difference (<12 vs. 16+)	64.4	80.9		78.3	70.1	
	Rate Ratio, 95% CI (<12 vs. 16+)	4.2 (3.9–4.6)	5.8 (5.3–6.3)		2.1 (1.7–2.6)	2.1 (1.8–2.5)	
Stroke							
Men	All	12.0	10.3	−1.9†	44.1	37.2	−2.8†
	<12 Yrs	22.4	23.9	1.0	55.3	55.8	−0.4
	16+ Yrs	6.5	5.0	−3.1†	21.4	18.8	−2.4†
	Rate difference (<12 vs. 16+)	15.9	18.9		33.9	37.0	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.5 (3.1–3.9)	4.8 (4.3–5.4)		2.6 (1.9–3.5)	3.0 (2.4–3.8)	
Women	All	9.9	8.6	−1.8†	30.2	28.0	−1.4†
	<12 Yrs	15.9	19.2	1.8†	34.4	35.4	0.4
	16+ Yrs	5.9	4.6	−3.1†	21.5	15.7	−4.4†
	Rate difference (<12 vs. 16+)	10.1	14.6		12.8	19.7	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.7 (2.4–3.1)	4.2 (3.7–4.7)		1.6 (1.2–2.1)	2.3 (1.8–2.8)	
HIV Infection							
Men	All	31.3	6.3	−23.0†	111.3	56.1	−12.1†
	<12 Yrs	28.7	15.4	−12.5†	123.1	120.9	−3.1
	16+ Yrs	31.4	3.5	−28.4†	118.2	28.9	−20.1†
	Rate difference (<12 vs. 16+)	−2.7	12.0		4.9	92.0	
	Rate Ratio, 95% CI (<12 vs. 16+)	0.9 (0.8–1.0)	4.5 (3.9–5.1)		1.0 (0.9–1.2)	4.2 (3.5–5.0)	
Women	All	1.9	0.9	−11.9†	23.1	21.7	−4.6
	<12 Yrs	5.7	5.4	−3.4	41.0	52.9	0.6
	16+ Yrs	0.8	0.1	−22.9†	8.9	5.9	−10.7†
	Rate difference (<12 vs. 16+)	4.9	5.2		32.2	47.1	
	Rate Ratio, 95% CI (<12 vs. 16+)	7.1 (5.2–9.5)	39.2 (22.4–68.6)		4.6 (3.2–6.8)	9.0 (6.3–12.9)	

Rates were age standardized to the 2000 U.S. standard population.

*Annual percent change based on rates that were age-adjusted to the 2000 U.S. standard population using regression analysis.

†Annual percent change is statistically significantly different from zero (two-sided P<.05).

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Table 3. Trends in age-standardized death rates (per 100,000) for selected leading causes of death with increasing or leveling of trend in the general population among 25–64 year old U.S. adults by race, sex, and education, 1993–2001

		Whites			Blacks		
		Rate			Rate		
Cause/Sex	Education in years	1993	2001	Annual %*	1993	2001	Annual %*
Accidents							
Men	All	40.5	46.2	1.7†	69.4	63.8	−0.6
	<12 Yrs	93.2	119.9	3.4†	95.1	112.8	3.6†
	16+ Yrs	18.9	18.7	−0.10	31.7	27.6	−2.4†
	Rate difference (<12 vs. 16+)	74.4	101.2		63.4	85.2	
	Rate Ratio, 95% CI (<12 vs. 16+)	4.9 (4.6–5.3)	6.4 (6.0–6.8)		3.0 (2.5–3.7)	4.1 (3.4–4.9)	
Women	All	13.7	17.5	2.9†	18.1	20.9	1.2†
	<12 Yrs	28.7	47.2	6.7†	26.1	35.6	3.6†
	16+ Yrs	9.2	9.0	−0.30	10.9	10.8	−3.10
	Rate difference (<12 vs. 16+)	19.4	38.2		15.2	24.8	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.1 (2.8–3.4)	5.3 (4.8–5.8)		2.4 (1.7–3.4)	3.3 (2.6–4.1)	
Diabetes							
Men	All	9.6	11.3	1.7†	27.5	29.6	0.70
	<12 Yrs	17.6	24.9	4.1†	31.1	38.4	3.2†
	16+ Yrs	4.9	5.1	0.70	17.8	16.0	−3.0†
	Rate difference (<12 vs. 16+)	12.7	19.8		13.3	22.4	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.6 (3.2–4.1)	4.9 (4.4–5.4)		1.7 (1.2–2.6)	2.4 (1.9–3.1)	
Women	All	7.4	7.7	0.40	23.4	24.3	0.10
	<12 Yrs	14.1	20.0	4.0†	30.0	32.2	1.40
	16+ Yrs	3.6	3.3	−1.50	15.5	11.0	−4.3†
	Rate difference (<12 vs. 16+)	10.5	16.7		14.5	21.2	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.9 (3.3–4.5)	6.0 (5.2–6.9)		1.9 (1.3–2.8)	2.9 (2.3–3.8)	
COPD							
Men	All	11.9	11.02	−0.70	16.9	14.5	−1.10
	<12 Yrs	26.6	34.7	3.6†	19.3	21.9	2.4†
	16+ Yrs	4.0	3.0	−3.9†	6.9	3.8	−5.7†
	Rate difference (<12 vs. 16+)	22.6	31.7		12.4	18.1	
	Rate Ratio, 95% CI (<12 vs. 16+)	6.7 (5.9–7.6)	11.7 (10.3–13.3)		2.8 (1.7–4.8)	5.8 (3.6–9.5)	
Women	All	10.1	10.4	0.50	10.6	10.8	0.40
	<12 Yrs	20.7	35.2	6.5†	12.8	15.7	2.4†
	16+ Yrs	3.6	3.1	−3.5†	4.4	5.4	1.60
	Rate difference (<12 vs. 16+)	17.1	32.1		8.4	10.3	
	Rate Ratio, 95% CI (<12 vs. 16+)	5.8 (5.0–6.8)	11.5 (10.0–13.3)		2.9 (1.7–5.0)	2.9 (1.9–4.3)	

Rates were age standardized to the 2000 U.S. standard population.
*Annual percent change based on rates that were age-adjusted to the 2000 U.S. standard population using regression analysis.
†Annual percent change is statistically significantly different from zero (two-sided P<.05).
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Strengths of our study include the use of national data that encompass 83% of the non-Hispanic white and black population in the U.S. from 1993 through 2001. The large number of deaths allows more precise statistical estimates of death rates by race and sex for specific causes of death. By limiting our analysis to broad disease categories for which death certificate data are more accurate,[40] we minimize inaccuracies in the cause of death.

Our major findings are not affected by coding changes implemented in ICD-10, beginning with the 1999 mortality data. These slightly accelerated the decline in death rates from heart disease and the increase from accidents, diabetes, and COPD (in women), and it may also have attenuated the decrease from cancer,[41] stroke, HIV infection,[42] and COPD (in men). ICD-10 allocated fewer deaths (1.5% of total) to heart disease as the underlying cause of death than ICD-9, but more deaths to the other causes. Increases in other causes in ICD-10 compared to ICD-9 ranged from 0.7% for cancer to 6.4% for HIV infection.[43] However, adjustments of rates using ICD comparability ratios for two of the leading causes most affected by the ICD changes (heart disease and HIV infection) had little effect on our findings. The annual percent decreases in heart disease death rates among white men with ≥16 years of education with and

without adjustment for the change in ICD coding rules were, respectively, −4.0% (−4.5% : −3.5%) and −4.2% (95% CI, −4.7% : −3.7%). The corresponding annual percent decreases in HIV infection mortality rates among black men with <12 years of education were −3.9% (−9,9% : 2.4%) and −3.1% (−9.2%: 3.4%). Furthermore, the unfavorable mortality trends among less-educated men and women was observed for all causes of death combined, a category that is not affected by the change in disease classification, as well as for most of the seven specific causes described here.

A limitation of our study is that death certificates capture only one indicator of socioeconomic position, educational attainment. Socioeconomic position is a multi-factorial construct that reflects a combination of individual- and geographic area-level influences. Although it is optimal to consider multiple indices of socioeconomic position in examining relationships with health outcomes,[39,44] educational attainment alone is frequently used as an indicator because of its availability, stability, and close association with other indicators of socioeconomic position for which data are not routinely available.[45]

Another limitation of our study is its reliance on years of education as reported on death certificates by next of kin. This variable has been included on the standard death certificate since 1989. Sorlie and Johnson evaluated this information in relation to self reported data from the National Longitudinal Mortality Study (NLMS) and found that education reported by proxies on the death certificate was higher than self-reported education in NLMS; 39% of adults who did not complete high school according to self-reported data were listed as high school graduates on their death certificates.[46] Although the extent of this misclassification may have varied over the study period (1993–2001), this particular source of error would have little impact on overall conclusions of our paper because the mortality trends are unfavorable in both groups of lower educated categories: 12 and fewer than 12 years of education.

Changes in autopsy rates over time could also potentially affect trends in cause-specific mortality rates because of the importance of the autopsy to the information on death certificates.[47] We cannot examine changes in autopsy rates by educational attainment for our study period (1993–2001) because NCHS stopped collecting information on whether an autopsy was performed or not in 1995 and resumed in 2003. We examined data for 1993 and 1994 and found that the percentage of deaths with autopsies were low in all groups and did not differ substantially by educational attainment. This percentage was 7%–8% among the lowest educated and 9%–10% among the most educated. In between, the rates range from 9%–11% with no discernable gradient. Data for 2003–2005 generally showed similar pattern, although the rates were slightly lower. Based on these data, changes in autopsy rates over time are unlikely to affect the all-cause mortality trend by educational attainment.

Finally, the generalizability of our findings to all age groups within the U.S. may be limited in that the educational gradient at ages 65 and above may be narrowed by universal access to health care through Medicare. However, deaths in ages 25–64 are of societal importance because they affect individuals and families most likely in the workforce, raising children and/or supporting other family members. The generalizability of our findings may also be affected slightly by exclusion of data from seven states with incomplete reporting of education on death certificates. The 3.5% of decedents with missing education information on their death certificates were excluded from the numerator, but not the denominator, of the study population (remaining 43 states and District of Colombia). The percentage of decedents with missing information on education was slightly higher in 1993 (4.7%) than in 2001 (2.8%). We assessed whether this might affect the interpretation of our trends. Analyses that measured the temporal trends without exclusion of deaths with missing education information slightly strengthened the decreasing trends for some causes and weakened the increasing mortality trends for others. However, none of these differences affected our main findings.

In conclusion, socioeconomic inequalities in mortality rates are increasing in the U.S. due to continuing reductions in death rates among the most educated white and black men and white women, but lack of progress or worsening trends in the least educated persons.

Supporting Information

Table S1 International Classification of Diseases (ICD) codes for major causes of death according to the Tenth and Ninth Revisions
Found at: doi:10.1371/journal.pone.0002181.s001 (0.03 MB XLS)

Table S2 Trends in age-standardized death rates (per 100,000) for selected causes of death with decreasing trend in the general populationamong 25–64 year old U.S. adults by race, sex, and education, 1993–2001
Found at: doi:10.1371/journal.pone.0002181.s002 (0.04 MB XLS)

Table S3 Trends in age-standardized death rates (per 100,000) for selected leading causes of death with increasing or leveling of trend in the general population among 25–64 year old U.S. adults by race, sex, and education, 1993–2001
Found at: doi:10.1371/journal.pone.0002181.s003 (0.04 MB XLS)

Table S4 The contributions of specific causes to the total increase (in less educated persons) or decrease (in most educated persons)in the all cause mortality rate (per 100,000) between 1993 and 2001 in 25–64 year old U.S. adults by race and sex
Found at: doi:10.1371/journal.pone.0002181.s004 (0.04 MB XLS)

Author Contributions

Conceived and designed the experiments: AJ. Analyzed the data: MT AJ EW TM RA. Wrote the paper: MT AJ. Other: Helped in the interpretation of data: MT RA TM. Reviewed manuscript critically: MT RA TM EW.

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Widening of Socioeconomic Inequalities in U.S. Death Rates, 1993–2001

Ahmedin Jemal[1]*, Elizabeth Ward[1], Robert N. Anderson[2], Taylor Murray[1], Michael J. Thun[1]

1 Epidemiology and Surveillance Research, American Cancer Society, Atlanta, Georgia, United States of America, 2 Division of Vital Statistics, National Center for Health Statistics, Centers for Disease Control and Prevention, Hyattsville, Maryland, United States of America

Abstract

Background: Socioeconomic inequalities in death rates from all causes combined widened from 1960 until 1990 in the U.S., largely because cardiovascular death rates decreased more slowly in lower than in higher socioeconomic groups. However, no studies have examined trends in inequalities using recent US national data.

Methodology/Principal Findings: We calculated annual age-standardized death rates from 1993–2001 for 25–64 year old non-Hispanic whites and blacks by level of education for all causes and for the seven most common causes of death using death certificate information from 43 states and Washington, D.C. Regression analysis was used to estimate annual percent change. The inequalities in all cause death rates between Americans with less than high school education and college graduates increased rapidly from 1993 to 2001 due to both significant decreases in mortality from all causes, heart disease, cancer, stroke, and other conditions in the most educated and lack of change or increases among the least educated. For white women, the all cause death rate increased significantly by 3.2 percent per year in the least educated and by 0.7 percent per year in high school graduates. The rate ratio (RR) comparing the least versus most educated increased from 2.9 (95% CI, 2.8–3.1) in 1993 to 4.4 (4.1–4.6) in 2001 among white men, from 2.1 (1.8–2.5) to 3.4 (2.9–3–9) in black men, and from 2.6 (2.4–2.7) to 3.8 (3.6–4.0) in white women.

Conclusion: Socioeconomic inequalities in mortality are increasing rapidly due to continued progress by educated white and black men and white women, and stable or worsening trends among the least educated.

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* E-mail: ajemal@cancer.org

Introduction

Socioeconomic inequalities in death rates from all causes combined have widened in the U.S.[1–7] since the early 1960s, largely because heart disease mortality has decreased more rapidly in higher than lower socioeconomic groups.[1,3] However, most of the studies that used individual-level socioeconomic measures have been based on relatively small representative samples of the U.S. population rather than on national data, precluding simultaneous stratification by race, sex, and education in examining cause-specific trends. Further, no studies published in the peer-review literature have examined the trends since 1990 using national vital statistics. Such studies are important in measuring progress towards achieving the Healthy People 2010 objective of eliminating health disparities among subgroups of the population.

In this study, we examined mortality trends for all-causes and seven leading causes of death (cancer, heart disease, stroke, accidents, human immunodeficiency virus [HIV] infection, diabetes, and chronic obstructive pulmonary disease [COPD]) in relation to educational attainment from 1993 through 2001. These seven categories account for 70% of the total deaths. Mortality trends for several conditions decreased markedly over the past 10–15 years (cancer, heart disease, stroke, HIV infection) while others increased (accidents, diabetes, COPD), in part due to changes in risk factors and, for the former, advances in treatment.[8,9] We restricted the analysis to white and black men and women, ages 25–64 years, an age range in which education is usually complete and provides a better index of socioeconomic position than at older ages.[10,11]

Methods

We obtained mortality data from 1993 through 2001 from the National Vital Statistics System (NVSS) administered by the National Center for Health Statistics. Underlying causes of death were classified according to the selection and coding rules of the Ninth Revision of the International Classification of Diseases (ICD-9)[12] for deaths recorded between 1993 and 1998, and according to the Tenth Revision of the International Classification of Diseases (ICD-10)[13] for those recorded between 1999 and 2001. The ICD-9 and ICD-10 codes for all causes and 15 leading causes included in this analysis are given on the web (Table S1).

Information on educational attainment (number of years of schooling) as a marker of socioeconomic position was obtained

from death certificates. Although this information has been included on the standard death certificate since 1989, we restricted our analyses to the time interval 1993 to 2001 for three reasons: most states did not collect death certificate information on education systematically until 1993: race/ethnicity information collected by the Current Population Survey is not consistent with that of death certificates beginning with the 2002 survey (see below): and the question about educational attainment on the death certificate changed beginning with the 2003 mortality data from a highest grade of school completed to collegiate track education, i.e., the ability to identify degree status.[14] We classified educational attainment into four categories according to total years of schooling: less than high school graduate (<12 years of education), high school graduate (12 years), some college (13–15 years), and college graduate or post graduate (≥16 years).

We restricted the analyses to deaths among non-Hispanic whites and blacks (4,257,269), because of problems with reporting other racial and ethnic subgroups.[15] We excluded 609,093 deaths that occurred in seven states (Georgia, Kentucky, New York, Oklahoma, Rhode Island, South Dakota, and West Virginia) because completeness of education on death certificate in these states was less than 80% in at least one of the nine calendar years considered in this study. Another 126,238 deaths that occurred in the remaining 43 states and the District of Colombia were excluded due to missing data on education on the death certificates. The final analysis was based on 3,521,938 deaths recorded from 1993 to 2001; these comprised 97% of the total deaths among non-Hispanic whites and blacks in the 43 states and District of Colombia.

We obtained population data (the denominators for rate calculations) for the corresponding age, sex, race/ethnicity, education, state and time intervals from the U.S. Bureau of Census based on the Current Population Survey, a nationally representative sample of U.S. households.

Death rates (per 100,000) from all causes combined and from 15 leading causes were calculated by sex, race/ethnicity, educational attainment, and calendar year. Rates within the age range 25–64 years were age-standardized using the 2000 U.S. population standard. Temporal trends from all causes and seven selected cancer sites by educational attainment were assessed by fitting a weighted least squares regression models to the log-transformed annual age-standardized rates, weighted by the inverse of the variance, using joinpoint regression program, Version 3.0 software.[16] The annual percentage change or slope of the line segment was considered statistically significant if two-sided, $P<0.05$. Similarly, we also assessed the linearity of the annual percent changes across education levels within each race-, sex-, disease-specific category by fitting a weighted least square regression model to the log-transformed coefficients of the slopes, weighted by the inverse of the variance.[16] The educational disparity was assessed by calculating the ratio of the death rate for all causes combined in the least educated group (<12 years of education) to the most educated group (college degree or more) for 1993 and 2001. We also calculated the contribution of specific conditions to the overall decrease (in the case of heart disease, cancer, stroke, and HIV infection) or increase (diabetes, COPD, accidents) in mortality rates in the general population.[8,17] This calculation was expressed as a percentage of the total change.

Results

Table 1 and Figure 1 show trends in death rates from all causes combined from 1993 through 2001 among white and black men and women, 25–64 years old, in relation to educational attainment. The all cause death rate decreased significantly during this interval among the most educated (≥16 years) men and women, with the largest decrease in black men. In contrast, the all cause death rate increased in those with less than a high school education. The annual percent increase was largest among white women with less than 12 years of education (3.2% per year), but was also statistically significant (0.7% per year) in white women who had completed high school (Table 1). Between 1993 and 2001, the ratio of the all cause death rate in persons with <12 years versus ≥16 years of education increased from 2.9 (95% CI, 2.8–3.1) to 4.4 (4.1–4.6) in white men, from 2.1 (1.8–2.5) to 3.4 (2.9–3–9) in black men, from 2.6 (2.4–2.7) to 3.8 (3.6–4.0) in white women and from 1.8 (1.5–2.1) to 2.0 (1.8–2.3) over this nine-year interval. Among black women this ratio increased, but the trend was not statistically significant.

Among men, the temporal decrease in all cause death rates became larger with each additional increment of educational attainment. For example, the annual percentage decrease among black men was 2.6% for those with 12 years of education, 4.0% in men with 13–15 years of education, and 6.4% in those with ≥16 years of education. Among women, death rates from all causes combined decreased during this time interval only in black and white women with ≥16 years of education (Table 1).

Table 2 depicts trends in death rates from 1993 through 2001 for persons with <12 years of education and for those with ≥16 years of education for four major causes of death that are known to be decreasing in the general population. For all of these conditions, death rates decreased among the most educated. In contrast, the only condition for which the death rate decreased significantly among those with <12 years of education was HIV infection among white men. For white women with <12 years of education, the death rate from cancer increased by 1.1% per year and that from heart disease and stroke increased by 1.8% annually during the same time interval. The trends in death rates and the number of deaths in 1993 and 2001 for each race, sex, disease, and education specific group are provided in Tables S2 on the web.

Table 3 shows mortality trends among the least (<12 years of education) and most (≥16 years) educated persons by race and sex for three major conditions (accidents, diabetes, and COPD) known to have stable or increased death rates in the general population. Among the least educated, death rates increased for each of these conditions except for diabetes in black men and women for whom it did not change significantly. In contrast, among the most educated group, rates significantly decreased for COPD in white and black men and white women, for diabetes in black men and women and for accidents in black men, or remained stable for the remaining sex, race, and disease categories. The increases in death rates from 1993 through 2001 were inversely related to educational attainment (Table S3 on the web). For COPD, the death rate increased significantly among the least educated while decreasing significantly among men and women who had completed college in all sub groups except for black women for whom it did not change significantly.

In persons with <12 years of education, about 40% of the total increase in all cause death rates between 1993 and 2001 in white men was due to increases from accidents, cancer, and suicide, and nearly 50% of the total increase in white women was from accidents, cancer, COPD, and heart disease (Table S4 on web). In both white men and women, accidents contributed the largest percentage. In blacks, increases from accidents and nephritis in men and from accidents, HIV, and septicemia in women were offset by decreases from heart disease and cancer.

In persons with ≥16 years of education, about 90% of the total decrease in death rates from all causes between 1993 and 2001

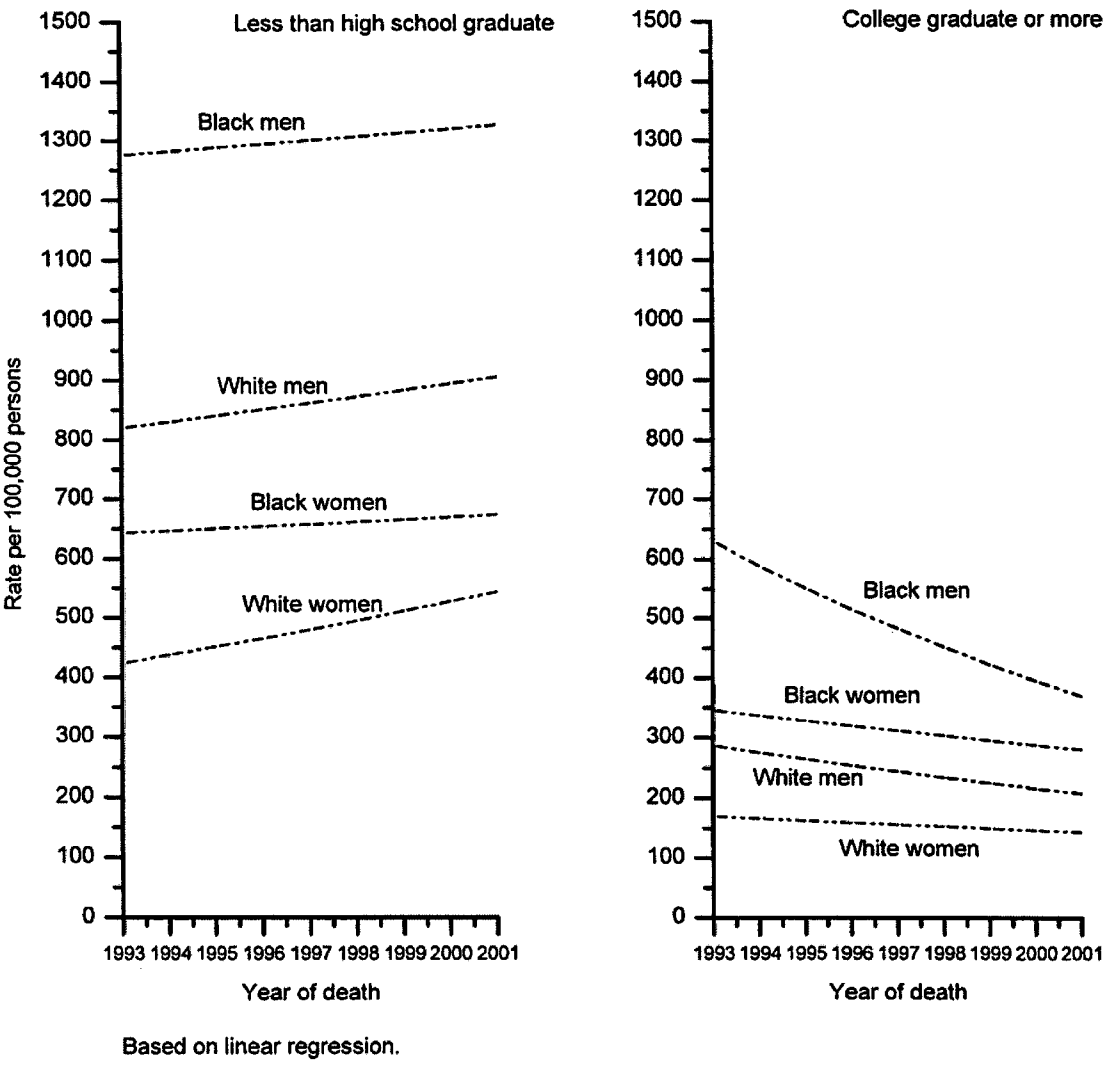

Figure 1. Temporal trends in age-standardized death rates from all causes combined among 25–64 year old U.S. adults by educational attainment, 1993–2001.
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among white men and 78% among black men were due to reduction in death rates from HIV infection, heart disease, and cancer, with HIV infection alone contributing over 50% in this age range (Table S4 on the web). In women with comparable education, the reduction in death rates from cancer, heart disease, and stroke during the corresponding time interval accounted for about 80% of the total decrease in all cause mortality rates in whites and 65% of the decrease in blacks. The reduction in death rates from cancer alone accounted for 65% and 35% of the total decrease in all-cause mortality among the most educated white and black women, respectively.

Discussion

Our principal finding is that socioeconomic inequalities in mortality continue to increase in the U.S. due to reductions in death rates among the most educated combined with lack of progress or worsening trends in the least educated. As noted, the ratio of the all cause death rate in persons with <12 years versus ≥16 years of education increased from 2.9 (95% CI, 2.8–3.1) to 4.4 (4.1–4.6) in white men, from 2.1 (1.8–2.5) to 3.4 (2.9–3–9) in black men, and from 2.6 (2.4–2.7) to 3.8 (3.6–4.0) in white women. Contributing to the inequality is the unprecedented decrease in the all-cause death rate among the most educated men (totaling 36% in black men and 25% in white men over the nine-year interval) largely due to decreases in death rates from HIV infection, cancer, and heart disease.

Lower educational attainment, a marker of socioeconomic position, is associated with a host of environmental, social and economic factors that detrimentally affect health over a life time. People with less education have fewer financial resources, less access to health insurance or stable employment, and less health literacy. Social and economic factors increase the vulnerability of low socioeconomic communities to risk factors such as smoking, obesity, physical inactivity, hypertension, and HIV infection.[18–22] People without health insurance are less likely to receive basic preventive services or standard timely treatment.[23,24] Those with lower health literacy are less likely to seek medical attention for asymptomatic conditions or to navigate the health care system effectively.[25,26] The prevalence of most major risk factors

Table 1. Trends in age-standardized death rates (per 100,000) from all causes combined among 25–64 year old U.S. adults by race, sex, and education, 1993–2001

		Whites					Blacks				
		1993		2001			1993		2001		
Sex	Education in years	No. of Deaths	Rate	No. of Deaths	Rate	Annual %*	No. of Deaths	Rate	No. of Deaths	Rate	Annual %*
Men											
	All	197085	471.5	198728	414.9	−1.9†	49922	1019.3	49566	807.8	−3.2†
	<12 Years	46187	836.8	38638	931.1	1.3	18622	1253.5	14861	1283.1	0.5
	12 Years	83895	591.6	88435	596.0	−0.4	21553	1251.7	23722	1039.7	−2.6†
	13–15 Years	33479	348.9	37255	296.2	−2.3†	6310	631.5	7249	472.7	−4.0†
	16+ Years	33524	284.7	34400	212.7	−3.9†	3437	596.2	3734	381.6	−6.4†
	P value trend					0.001					0.008
	Rate difference (<12 vs. 16+)		552.2		718.4			657.3		901.5	
	Rate ratio, 95% CI (<12 vs. 16+)	2.9 (2.8–3.1)		4.4 (4.1–4.6)			2.1 (1.8–2.5)		3.4 (2.9–3.9)		
Women											
	All	110539	255.6	122950	247.3	−0.5†	29297	501.9	34341	476.7	−0.9†
	<12 Years	24473	422.4	21711	553.4	3.2†	9888	622.6	8614	622.3	0.6
	12 Years	53250	296.1	57153	321.8	0.7†	12688	612.9	15478	634.2	−0.5
	13–15 Years	18976	184.9	24865	177.7	−0.1	4375	331.1	6612	327.3	0.1
	16+ Years	13840	165.4	19221	146.1	−2.0†	2346	350.7	3637	308.2	−2.5†
	P value trend					0.01					0.26
	Rate difference (<12 vs. 16+)		257.1		407.3			272.0		314.2	
	Rate ratio, 95% CI (<12 vs. 16+)	2.6 (2.4–2.7)		3.8 (3.6–4.0)			1.8 (1.5–2.1)		2.0 (1.8–2.3)		

Rates were age standardized to the 2000 U.S. standard population.
*Annual percent change based on rates that were age-adjusted to the 2000 U.S. standard population using regression analysis.
†Annual percent change is statistically significantly different from zero (two-sided P<.05).
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remains much higher among persons with lower than high socioeconomic position.[27–29] Progress in reducing smoking has been slowest among the least educated.[27,30] The prevalence of obesity, hypertension, and diabetes has increased in all socioeconomic position groups in recent years.[27,30–33]

These environmental and socioeconomic factors may also have contributed to the differences in inequalities in all-cause and cause-specific mortality by race and sex. For example, the increases in death rates for cancer and heart disease among white women with <12 years of education but not among white men with <12 years of education partly reflects the later uptake of cigarette smoking among women than men. Smoking prevalence in women peaked about 20 years after it peaked in men.[34,35] The large inequality in HIV infection mortality rates between blacks and whites may reflect an increased risk of HIV infection from sexual behavior and drug use as well as lower receipt of highly active antiretroviral therapy in blacks than in whites[36,37]

Our findings are qualitatively similar to those of previous studies that analyzed temporal trends in US mortality by socioeconomic position in earlier time periods.[1,3,6] Using the 1960 National Mortality Follow Back Survey and 1986 National Health Interview Survey, Pappas et al documented that the disparity in mortality rates according to education increased from 1960 to 1986 among white and black, men and women, age 25–64 years, although the increase in disparity was less for women than men.[3] Feldman et al. reported widening of the educational disparity in death rates from 1960 to the time period 1971–1984 among white men 55 years or above, but not white women.[1] Similarly, using the National Occupational Mortality Surveillance, Steenland and colleagues reported that the differential in mortality by socioeconomic position increased from 1984 to 1997 among men age 35–64, but not in women.[6] In all of these studies, the disparity in death rates increased over time due to slower progress among those with lower than higher socioeconomic position. Our study, in contrast, finds no decrease in all cause mortality rates in the lowest educational group between 1993 and 2001. Furthermore, all-cause mortality rates among lower educated white women increased rather than decreased, with accidents, cancer, COPD, and heart disease accounting for about half of the total increase in white women with <12 years of education.

Mortality data collected after 2001 could not be analyzed using the same category of race/ethnicity. However, analysis of the 2005 mortality data by education for all races combined showed that the educational inequalities in all-cause mortality continued to be substantial.[38] Among 25–64 year olds, the all-cause mortality rate for those with <12 years of education was 3.2 times higher than that for persons with ≥13 years of education. The results of these studies illustrate the difficulty of achieving the goal of eliminating health disparities among disadvantaged subgroups of the population by 2010. Socioeconomic factors that contribute to poor nutrition, tobacco use, and physical inactivity often establish these patterns early in life[39]. Lower socioeconomic groups also have less access to preventive resources and health care. The elimination of health disparities will require addressing a broad spectrum of factors in the social and physical environment that contribute to poor health.

Table 2. Trends in age-standardized death rates (per 100,000) for selected causes of death with decreasing trend in the general population among 25–64 year old U.S. adults by race, sex, and education, 1993–2001

		Whites			Blacks		
		Rate			Rate		
Cause/Sex	Education in years	1993	2001	Annual %*	1993	2001	Annual %*
Cancer							
Men	All	127.9	110.2	−1.9†	221.1	173.5	−2.7†
	<12 Yrs	195.3	208.3	0.8	256.0	246.8	0.1
	16+ Yrs	85.6	66.4	−3.1†	125.0	85.2	−5.1†
	Rate difference (<12 vs. 16+)	109.7	141.9		131.0	161.6	
	Rate Ratio, 95% CI (<12 vs. 16+)	2.3 (2.1–2.4)	3.1(2.9–3.4)		2.0 (1.6–2.6)	2.9 (2.4–3.5)	
Women	All	111.9	98.0	−1.7†	145.1	132.1	−1.1†
	<12 Yrs	142.0	157.7	1.1†	146.4	130.7	−0.3
	16+ Yrs	87.6	72.5	−2.7†	131.0	113.1	−2.6†
	Rate difference (<12 vs. 16+)	54.5	85.2		15.4	17.6	
	Rate Ratio, 95% CI (<12 vs. 16+)	1.6 (1.5–1.7)	2.2 (2.0–2.3)		1.1 (0.9–1.4)	1.2 (1.0–1.4)	
Heart Diseases							
Men	All	129.3	100.7	−3.2†	245.8	194.9	−2.7†
	<12 Yrs	228.8	214.9	−0.6	281.7	262.9	−0.2
	16+ Yrs	72.3	51.1	−4.2†	139.3	99.2	−5.1†
	Rate difference (<12 vs. 16+)	156.5	163.8		142.4	163.7	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.2 (3.0–3.4)	4.2 (3.9–4.6)		2.0 (1.6–2.5)	2.6 (2.2–3.1)	
Women	All	44.8	37.9	−2.1†	122.0	106.1	−1.8†
	<12 Yrs	84.4	97.8	1.8†	151.4	132.9	−0.4
	16+ Yrs	20.0	16.9	−2.9†	73.1	62.8	−2.9†
	Rate difference (<12 vs. 16+)	64.4	80.9		78.3	70.1	
	Rate Ratio, 95% CI (<12 vs. 16+)	4.2 (3.9–4.6)	5.8 (5.3–6.3)		2.1 (1.7–2.6)	2.1 (1.8–2.5)	
Stroke							
Men	All	12.0	10.3	−1.9†	44.1	37.2	−2.8†
	<12 Yrs	22.4	23.9	1.0	55.3	55.8	−0.4
	16+ Yrs	6.5	5.0	−3.1†	21.4	18.8	−2.4†
	Rate difference (<12 vs. 16+)	15.9	18.9		33.9	37.0	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.5 (3.1–3.9)	4.8 (4.3–5.4)		2.6 (1.9–3.5)	3.0 (2.4–3.8)	
Women	All	9.9	8.6	−1.8†	30.2	28.0	−1.4†
	<12 Yrs	15.9	19.2	1.8†	34.4	35.4	0.4
	16+ Yrs	5.9	4.6	−3.1†	21.5	15.7	−4.4†
	Rate difference (<12 vs. 16+)	10.1	14.6		12.8	19.7	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.7 (2.4–3.1)	4.2 (3.7–4.7)		1.6 (1.2–2.1)	2.3 (1.8–2.8)	
HIV Infection							
Men	All	31.3	6.3	−23.0†	111.3	56.1	−12.1†
	<12 Yrs	28.7	15.4	−12.5†	123.1	120.9	−3.1
	16+ Yrs	31.4	3.5	−28.4†	118.2	28.9	−20.1†
	Rate difference (<12 vs. 16+)	−2.7	12.0		4.9	92.0	
	Rate Ratio, 95% CI (<12 vs. 16+)	0.9 (0.8–1.0)	4.5 (3.9–5.1)		1.0 (0.9–1.2)	4.2 (3.5–5.0)	
Women	All	1.9	0.9	−11.9†	23.1	21.7	−4.6
	<12 Yrs	5.7	5.4	−3.4	41.0	52.9	0.6
	16+ Yrs	0.8	0.1	−22.9†	8.9	5.9	−10.7†
	Rate difference (<12 vs. 16+)	4.9	5.2		32.2	47.1	
	Rate Ratio, 95% CI (<12 vs. 16+)	7.1 (5.2–9.5)	39.2 (22.4–68.6)		4.6 (3.2–6.8)	9.0 (6.3–12.9)	

Rates were age standardized to the 2000 U.S. standard population.
*Annual percent change based on rates that were age-adjusted to the 2000 U.S. standard population using regression analysis.
†Annual percent change is statistically significantly different from zero (two-sided P<.05).
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Table 3. Trends in age-standardized death rates (per 100,000) for selected leading causes of death with increasing or leveling of trend in the general population among 25–64 year old U.S. adults by race, sex, and education, 1993–2001

		Whites			Blacks		
		Rate			Rate		
Cause/Sex	Education in years	1993	2001	Annual %*	1993	2001	Annual %*
Accidents							
Men	All	40.5	46.2	1.7†	69.4	63.8	−0.6
	<12 Yrs	93.2	119.9	3.4†	95.1	112.8	3.6†
	16+ Yrs	18.9	18.7	−0.10	31.7	27.6	−2.4†
	Rate difference (<12 vs. 16+)	74.4	101.2		63.4	85.2	
	Rate Ratio, 95% CI (<12 vs. 16+)	4.9 (4.6–5.3)	6.4 (6.0–6.8)		3.0 (2.5–3.7)	4.1 (3.4–4.9)	
Women	All	13.7	17.5	2.9†	18.1	20.9	1.2†
	<12 Yrs	28.7	47.2	6.7†	26.1	35.6	3.6†
	16+ Yrs	9.2	9.0	−0.30	10.9	10.8	−3.10
	Rate difference (<12 vs. 16+)	19.4	38.2		15.2	24.8	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.1 (2.8–3.4)	5.3 (4.8–5.8)		2.4 (1.7–3.4)	3.3 (2.6–4.1)	
Diabetes							
Men	All	9.6	11.3	1.7†	27.5	29.6	0.70
	<12 Yrs	17.6	24.9	4.1†	31.1	38.4	3.2†
	16+ Yrs	4.9	5.1	0.70	17.8	16.0	−3.0†
	Rate difference (<12 vs. 16+)	12.7	19.8		13.3	22.4	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.6 (3.2–4.1)	4.9 (4.4–5.4)		1.7 (1.2–2.6)	2.4 (1.9–3.1)	
Women	All	7.4	7.7	0.40	23.4	24.3	0.10
	<12 Yrs	14.1	20.0	4.0†	30.0	32.2	1.40
	16+ Yrs	3.6	3.3	−1.50	15.5	11.0	−4.3†
	Rate difference (<12 vs. 16+)	10.5	16.7		14.5	21.2	
	Rate Ratio, 95% CI (<12 vs. 16+)	3.9 (3.3–4.5)	6.0 (5.2–6.9)		1.9 (1.3–2.8)	2.9 (2.3–3.8)	
COPD							
Men	All	11.9	11.02	−0.70	16.9	14.5	−1.10
	<12 Yrs	26.6	34.7	3.6†	19.3	21.9	2.4†
	16+ Yrs	4.0	3.0	−3.9†	6.9	3.8	−5.7†
	Rate difference (<12 vs. 16+)	22.6	31.7		12.4	18.1	
	Rate Ratio, 95% CI (<12 vs. 16+)	6.7 (5.9–7.6)	11.7 (10.3–13.3)		2.8 (1.7–4.8)	5.8 (3.6–9.5)	
Women	All	10.1	10.4	0.50	10.6	10.8	0.40
	<12 Yrs	20.7	35.2	6.5†	12.8	15.7	2.4†
	16+ Yrs	3.6	3.1	−3.5†	4.4	5.4	1.60
	Rate difference (<12 vs. 16+)	17.1	32.1		8.4	10.3	
	Rate Ratio, 95% CI (<12 vs. 16+)	5.8 (5.0–6.8)	11.5 (10.0–13.3)		2.9 (1.7–5.0)	2.9 (1.9–4.3)	

Rates were age standardized to the 2000 U.S. standard population.
*Annual percent change based on rates that were age-adjusted to the 2000 U.S. standard population using regression analysis.
†Annual percent change is statistically significantly different from zero (two-sided P<.05).
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Strengths of our study include the use of national data that encompass 83% of the non-Hispanic white and black population in the U.S. from 1993 through 2001. The large number of deaths allows more precise statistical estimates of death rates by race and sex for specific causes of death. By limiting our analysis to broad disease categories for which death certificate data are more accurate,[40] we minimize inaccuracies in the cause of death.

Our major findings are not affected by coding changes implemented in ICD-10, beginning with the 1999 mortality data. These slightly accelerated the decline in death rates from heart disease and the increase from accidents, diabetes, and COPD (in women), and it may also have attenuated the decrease from cancer,[41] stroke, HIV infection,[42] and COPD (in men). ICD-10 allocated fewer deaths (1.5% of total) to heart disease as the underlying cause of death than ICD-9, but more deaths to the other causes. Increases in other causes in ICD-10 compared to ICD-9 ranged from 0.7% for cancer to 6.4% for HIV infection.[43] However, adjustments of rates using ICD comparability ratios for two of the leading causes most affected by the ICD changes (heart disease and HIV infection) had little effect on our findings. The annual percent decreases in heart disease death rates among white men with ≥16 years of education with and

without adjustment for the change in ICD coding rules were, respectively, −4.0% (−4.5% : −3.5%) and −4.2% (95% CI, −4.7% : −3.7%). The corresponding annual percent decreases in HIV infection mortality rates among black men with <12 years of education were −3.9% (−9,9% : 2.4%) and −3.1% (−9.2%: 3.4%). Furthermore, the unfavorable mortality trends among less-educated men and women was observed for all causes of death combined, a category that is not affected by the change in disease classification, as well as for most of the seven specific causes described here.

A limitation of our study is that death certificates capture only one indicator of socioeconomic position, educational attainment. Socioeconomic position is a multi-factorial construct that reflects a combination of individual- and geographic area-level influences. Although it is optimal to consider multiple indices of socioeconomic position in examining relationships with health outcomes,[39,44] educational attainment alone is frequently used as an indicator because of its availability, stability, and close association with other indicators of socioeconomic position for which data are not routinely available.[45]

Another limitation of our study is its reliance on years of education as reported on death certificates by next of kin. This variable has been included on the standard death certificate since 1989. Sorlie and Johnson evaluated this information in relation to self reported data from the National Longitudinal Mortality Study (NLMS) and found that education reported by proxies on the death certificate was higher than self-reported education in NLMS; 39% of adults who did not complete high school according to self-reported data were listed as high school graduates on their death certificates.[46] Although the extent of this misclassification may have varied over the study period (1993–2001), this particular source of error would have little impact on overall conclusions of our paper because the mortality trends are unfavorable in both groups of lower educated categories: 12 and fewer than 12 years of education.

Changes in autopsy rates over time could also potentially affect trends in cause-specific mortality rates because of the importance of the autopsy to the information on death certificates.[47] We cannot examine changes in autopsy rates by educational attainment for our study period (1993–2001) because NCHS stopped collecting information on whether an autopsy was performed or not in 1995 and resumed in 2003. We examined data for 1993 and 1994 and found that the percentage of deaths with autopsies were low in all groups and did not differ substantially by educational attainment. This percentage was 7%–8% among the lowest educated and 9%–10% among the most educated. In between, the rates range from 9%–11% with no discernable gradient. Data for 2003–2005 generally showed similar pattern, although the rates were slightly lower. Based on these data, changes in autopsy rates over time are unlikely to affect the all-cause mortality trend by educational attainment.

Finally, the generalizability of our findings to all age groups within the U.S. may be limited in that the educational gradient at ages 65 and above may be narrowed by universal access to health care through Medicare. However, deaths in ages 25–64 are of societal importance because they affect individuals and families most likely in the workforce, raising children and/or supporting other family members. The generalizability of our findings may also be affected slightly by exclusion of data from seven states with incomplete reporting of education on death certificates. The 3.5% of decedents with missing education information on their death certificates were excluded from the numerator, but not the denominator, of the study population (remaining 43 states and District of Colombia). The percentage of decedents with missing information on education was slightly higher in 1993 (4.7%) than in 2001 (2.8%). We assessed whether this might affect the interpretation of our trends. Analyses that measured the temporal trends without exclusion of deaths with missing education information slightly strengthened the decreasing trends for some causes and weakened the increasing mortality trends for others. However, none of these differences affected our main findings.

In conclusion, socioeconomic inequalities in mortality rates are increasing in the U.S. due to continuing reductions in death rates among the most educated white and black men and white women, but lack of progress or worsening trends in the least educated persons.

Supporting Information

Table S1 International Classification of Diseases (ICD) codes for major causes of death according to the Tenth and Ninth Revisions
Found at: doi:10.1371/journal.pone.0002181.s001 (0.03 MB XLS)

Table S2 Trends in age-standardized death rates (per 100,000) for selected causes of death with decreasing trend in the general populationamong 25–64 year old U.S. adults by race, sex, and education, 1993–2001
Found at: doi:10.1371/journal.pone.0002181.s002 (0.04 MB XLS)

Table S3 Trends in age-standardized death rates (per 100,000) for selected leading causes of death with increasing or leveling of trend in the general population among 25–64 year old U.S. adults by race, sex, and education, 1993–2001
Found at: doi:10.1371/journal.pone.0002181.s003 (0.04 MB XLS)

Table S4 The contributions of specific causes to the total increase (in less educated persons) or decrease (in most educated persons)in the all cause mortality rate (per 100,000) between 1993 and 2001 in 25–64 year old U.S. adults by race and sex
Found at: doi:10.1371/journal.pone.0002181.s004 (0.04 MB XLS)

Author Contributions

Conceived and designed the experiments: AJ. Analyzed the data: MT AJ EW TM RA. Wrote the paper: MT AJ. Other: Helped in the interpretation of data: MT RA TM. Reviewed manuscript critically: MT RA TM EW.

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Selecting a reperfusion strategy for acute ST elevation myocardial infarction

Authors
C Michael Gibson, MS, MD
Duane S Pinto, MD, MPH
Donald Cutlip, MD
Section Editors
Christopher P Cannon, MD
Bernard J Gersh, MB, ChB, DPhil, FRCP, MACC
James Hoekstra, MD
Deputy Editor
Gordon M Saperia, MD, FACC

Disclosures

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INTRODUCTION — Coronary artery reperfusion with either primary percutaneous coronary intervention (PCI) or fibrinolytic therapy, if performed in a timely manner, improves clinical outcomes compared to no reperfusion in nearly all groups of patients with an acute ST elevation myocardial infarction (STEMI). (See "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome", section on 'Time from hospital arrival (door-to-balloon time) on outcomes' and "Fibrinolytic therapy in acute ST elevation myocardial infarction: Initiation of therapy", section on 'Timing'.)

Occasionally a decision to not attempt to reperfuse the patient will be made due to reasons such as serious comorbidities, end of life issues, or late presentation. (See "Fibrinolytic therapy in acute ST elevation myocardial infarction: Initiation of therapy", section on 'Indications' and "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome", section on 'Introduction'.)

Primary PCI, if performed in a timely fashion, is the reperfusion therapy of choice in most patients with STEMI, including an MI with new or presumably new left bundle branch block, or a true posterior MI. However, not all facilities have the ability to perform primary PCI in a timely manner, and for many patients a decision must be made between the local administration of fibrinolytic therapy or transfer to a nearby institution for primary PCI.

The factors that must be considered before choosing one of these two reperfusion strategies in patients with STEMI will be reviewed here. The clinical-trial data supporting these conclusions, the clinical use of both primary PCI and fibrinolytic therapy, and the role of PCI after fibrinolytic are discussed in detail separately. (See "Primary percutaneous coronary intervention versus fibrinolysis in acute ST elevation myocardial infarction: Clinical trials" and "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome" and "Fibrinolytic therapy in acute ST elevation myocardial infarction: Initiation of therapy" and "Percutaneous coronary intervention after fibrinolysis for acute ST elevation myocardial infarction" and "Prehospital fibrinolysis (thrombolysis) for suspected acute ST elevation myocardial infarction".)

Our recommendations found at the end of this topic are in broad agreement with guidelines from the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) and the European

Society of Cardiology (ESC) on STEMI and PCI [1-3]. These guidelines recommended that patients with acute STEMI who present within 12 hours of symptom onset be treated with immediate reperfusion therapy.

Immediate reperfusion is not as urgent in patients with a non-ST elevation MI in whom a completely occluded infarct-related artery at presentation is much less common. (See "Coronary arteriography and revascularization for unstable angina or non-ST elevation acute myocardial infarction".)

GENERAL ISSUES — Prompt restoration of normal blood flow in the infarct-related artery is essential to myocardial salvage and mortality reduction in patients with acute ST elevation myocardial infarction (STEMI) (figure 1) [4]. This relationship is particularly important in the first few hours after symptom onset, when the amount of myocardium salvageable by reperfusion is greatest (figure 2) [5-7]. (See 'Time from symptom onset' below.)

As the benefits of reperfusion with either primary percutaneous coronary intervention (PCI) or fibrinolysis decline rapidly with time, a treatment strategy with either primary PCI or fibrinolytic therapy should be chosen and implemented as soon as possible [8]. Based upon data from randomized trials, primary PCI is preferred when performed in a timely fashion by an expert operator [8-11]. However, when a patient presents to a facility that does not have primary PCI capability, or when it is not available, the choice between primary PCI and fibrinolytic therapy can be complicated, primarily for those patients who present within three hours of symptom onset (see 'PCI-related delay' below).

Studies of successful hospitals have identified a number of organizational changes that contributed to minimizing treatment delay, two of which were performance of prehospital electrocardiograms to activate the catheterization laboratory and substantial interdisciplinary collaboration in the establishment of STEMI care protocols and continuous quality assurance. (See "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome", section on 'Hospital performance'.)

Due to the critical relationship between time-to-reperfusion and mortality reduction, this decision should be made rapidly, guided by a predetermined, institution-specific, written protocol. These protocols should be designed and customized for each institution because important predictors of outcome, including the experience of operators and the ease and speed of patient transfer, are unique to each hospital. Such protocols facilitate the delivery of standardized evidence-based care and minimize delays in implementing reperfusion therapy [12].

FACTORS DETERMINING CHOICE OF REPERFUSION STRATEGY — If timely, high-quality primary percutaneous coronary intervention (PCI) is available, it is the preferred reperfusion strategy for most patients with acute ST elevation myocardial infarction (STEMI). It is presumed that the procedure will be done expeditiously (door-to-balloon time less than 90 minutes). These issues are discussed in detail elsewhere. (See "Primary percutaneous coronary intervention versus fibrinolysis in acute ST elevation myocardial infarction: Clinical trials", section on 'Primary PCI versus fibrinolytic trials' and "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome", section on 'Early versus late presentation' and "Primary percutaneous coronary intervention in

acute ST elevation myocardial infarction: Determinants of outcome", section on 'Importance of local expertise'.)

However, there are circumstances when reperfusion with fibrinolytic therapy is a reasonable alternative. The following section discusses factors that should go into decision making regarding reperfusion [13-15].

PCI-related delay — Outcomes for both fibrinolytic therapy and primary PCI worsen as the time to treatment with either therapy increases. Similarly, as the PCI related delay (defined below) increases, the benefit from primary PCI compared to fibrinolytic therapy declines. The following terminology is used when evaluating time to treatment:

- The door-to-needle time refers to the time from presentation at a hospital (or ambulance) to the administration of fibrinolytic therapy.
- The door-to-balloon time refers to the time from presentation at a PCI center to first balloon inflation. The trial data demonstrating the importance of the door-to-balloon time on patient outcome are discussed separately. (See "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome", section on 'Time from hospital arrival (door-to-balloon time) on outcomes'.)
- The PCI-related delay is the difference between the door-to-balloon time and the door-to-needle time. The PCI-related delay overestimates the reperfusion delay for PCI somewhat, since PCI reperfusion is immediate while fibrinolytic therapy generally does not reestablish perfusion for about 30 minutes.

The impact of PCI-related delay on survival comes from both randomized trials and observational studies. In a 2003 review of 23 randomized trials of primary PCI versus fibrinolysis, which enrolled a total of 7739 patients, the magnitude of the survival benefit at four to six weeks declined as the mean PCI-related delay increased. When the PCI-related delay was more than 62 minutes there was no survival advantage to primary PCI over fibrinolysis (figure 3) [16]. In 13 trials evaluating the combined endpoint of death, reinfarction, or stroke at four to six weeks (4946 patients), every additional 10 minute delay in door-to-balloon time beyond the door-to-needle time reduced the absolute benefit of primary PCI by 1.17 percent. The two strategies became equivalent with regard to the combined endpoint after a delay of 93 minutes (figure 4).

However, in the community, door-to-balloon times and PCI-related delays are significantly longer than those in randomized clinical trials. In a 2012 study of patients enrolled in the United States National Registry of Myocardial Infarction (NRMI) -2,3, 4 and 5 (1994 to 2006) registries, the median door-to-balloon time was 161 minutes, compared to a median of 90 to 107 minutes for patients enrolled in randomized clinical trials [17-19].

Increasing PCI-related delay also worsens outcomes in patients not enrolled in clinical trials [17,20]. The following findings were noted in a 2011 report of over 19,000 propensity-score matched patients enrolled in the NRMI 2, 3, 4, and 5 registries [20]:

- Among patients who were transferred for primary PCI, delays of >90 minutes were seen in 68 percent of cases and the median door to balloon time was 161 minutes (the median door to needle time was 35 minutes).

Multivariable analysis found no mortality advantage for primary PCI over fibrinolysis in patients with a PCI related delay longer than approximately 120 minutes. For those groups of patients with PCI delay of <60 and 60 to 90 minutes, the in-hospital death rates favored PCI (2.7 versus 7.4 and 3.6 versus 5.5 percent, respectively), whereas the rates were similar for the group of patients with PCI delay of >90 minutes (5.7 versus 6.1 percent, respectively).

Interpretation of the results of these studies should consider the following issues:

- There may be confounding factors associated with both increased PCI-related delay and worse outcomes (in the observational studies), such as the experience of hospitals and operators in the relevant studies.
- When endpoints in addition to survival (eg, reinfarction and stroke) are considered, the advantage of primary PCI over fibrinolysis may be retained with slightly greater PCI-related delay [20].
- In stratified analyses based upon patient age, duration of symptoms, and infarct location, the PCI-related delay at which mortality rates with primary PCI were no better than that of fibrinolysis varied considerably depending on patient age, symptom duration, and infarct location [20]. This point is discussed in detail in the next section.

Patient related factors — Patient characteristics affect the PCI-related delay at which the mortality rates with PCI and fibrinolysis are equal (equipoise). The following observations were made in the large observational study of NRMI data discussed above [20]:

- Equipoise occurred at 71 minutes of PCI-related delay in patients <65 years and at 155 minutes in patients ≥65 years (figure 5 and table 1). This means that at any PCI-related delay greater than these values, the odds of survival with PCI was no longer higher than that with fibrinolysis. This may be secondary to the fact that fibrinolysis has a greater complication rate in elderly patients.
- Equipoise occurred at 94 minutes in patients with symptom duration ≤120 minutes and 190 minutes in patients with symptom duration >120 minutes. The later equipoise with longer symptom duration may reflect greater resistance to fibrinolysis in those presenting late (figure 2). Patients who present more than three hours after symptom onset are on the flatter portion of the survival curve for fibrinolytic therapy, where myocardial salvage and survival benefit are less time-sensitive (figure 2). In these patients, the advantages of PCI are likely to be retained with PCI-related delays much greater than 60 minutes. This issue is discussed in detail below. (See 'Time from symptom onset' below.)

- Patients with anterior infarction lost the advantage of PCI at shorter PCI related delays than did patients with non-anterior infarcts (table 1).

Because the survival benefit of primary PCI is most apparent in high-risk patients [21,22], the magnitude of PCI-related delay at which the survival benefit of PCI is lost probably also varies according to risk. (See "Primary percutaneous coronary intervention versus fibrinolysis in acute ST elevation myocardial infarction: Clinical trials", section on 'High- versus low-risk patients' and 'Very high-risk patients' below.)

Non-patient related factors — Non-patient related factors that appear to increase the PCI delay are door to door transfer times and off-hour presentation. In the NRMI study mentioned above, the median door-to-door transfer time was 120 minutes, as opposed to 30 minutes in randomized trials [17]. The relationship between the time that a patient presents and treatment delays was evaluated in a review of 68,439 patients treated for STEMI with either fibrinolytic therapy or primary PCI [23]. Among patients who presented off-hours (weekdays 5 PM to 7 AM and weekends), there was a significant increase in time to treatment with PCI (door-to-balloon time 116 versus 95 minutes with presentation during regular hours), which increased the PCI-related delay since there was no increase in time to treatment for fibrinolytic therapy (34 versus 33 minutes). (See "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome", section on 'Other factors'.)

Summary — We agree with guidelines from the American College of Cardiology Foundation/American Heart Association and the European Society of Cardiology, which recommend that the first medical contact-to-device time goal should be less than 120 minutes in STEMI patients being transferred from another institution for primary PCI [1-3]. Conversely, many patients in whom PCI-related delays longer than 120 minutes are anticipated may benefit from expeditious use of fibrinolytic therapy, followed by inter-institution transfer. These guidelines emphasize that hospital, operator, and patient factors should be taken into account in the process of choosing an optimal reperfusion strategy.

Time from symptom onset — For most patients who present with STEMI, primary PCI leads to better outcomes compared to fibrinolysis as long as it can be performed in a timely manner. (See "Primary percutaneous coronary intervention versus fibrinolysis in acute ST elevation myocardial infarction: Clinical trials", section on 'Primary PCI with stenting versus fibrinolysis'.)

However, understanding the temporal relationship between symptom onset, reperfusion, myocardial salvage, and mortality is essential to the selection of an appropriate reperfusion strategy [6,7,15]. The data related to this issue are presented elsewhere. (See "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome", section on 'Time from symptom onset on outcomes' and "Fibrinolytic therapy in acute ST elevation myocardial infarction: Initiation of therapy", section on 'Timing'.)

Presentation within three hours — Patients who present ≤3 hours from symptom onset are on the steep portion of the survival versus time-to-reperfusion curve (figure 2) [5-7]. In this early stage, there is an opportunity for substantial myocardial salvage and mortality reduction. It is in this time window that fibrinolytic therapy has the greatest likelihood of achieving patency of the infarct related artery. Thus, for

those patients who cannot receive primary PCI within 90 minutes, fibrinolytic therapy has a therapeutic advantage. (See 'PCI-related delay' above.)

The value of early reperfusion with fibrinolytic therapy in patients presenting shortly after symptom onset was established by a meta-analysis of 22 trials including 50,246 patients [5]. The absolute benefit with fibrinolytic therapy, compared to placebo or control, was greatest in patients treated within one hour of symptom onset, then fell sharply and plateaued for patients treated within one to two hours, two to three hours, and three to six hours.

When delivered in a timely manner, PCI has the advantage of restoring patency in over 90 percent of patients, while fibrinolysis achieves this outcome significantly less often. (See "Fibrinolytic (thrombolytic) agents in acute ST elevation myocardial infarction: Markers of efficacy", section on 'Markers'.) Thus, for patients who present within three hours of symptom onset, the choice between fibrinolytic therapy and primary PCI depends in large part upon the anticipated delay required for primary PCI. When the delay from initial hospital presentation at PCI capable hospital to balloon inflation will be less than 90 minutes, or when the delay between presentation at a non-PCI capable hospital to balloon inflation will be less than 120 minutes, PCI is recommended [8,13,24]. These recommendations are consistent with those made by the American College of Cardiology Foundation/American Heart Association (2013) and the European Society of Cardiology (2012) guidelines on STEMI [1-3]. (See 'PCI-related delay' above and "Primary percutaneous coronary intervention versus fibrinolysis in acute ST elevation myocardial infarction: Clinical trials".)

The best evidence comparing PCI to fibrinolysis in patients who present within three hours of symptom onset comes from the STREAM study in which 1892 patients who presented within three hours were randomly assigned to undergo either fibrinolytic therapy with bolus tenecteplase or primary PCI [25]. Patients who could undergo PCI within one hour were excluded. In the lytic group, coronary angiography was performed urgently for evidence of reperfusion failure or routinely at 6 to 24 hours. There was no difference in the primary composite end point (death, shock, congestive heart failure, or reinfarction up to 30 days) between the two groups (12.4 versus 14.3 percent, respectively; relative risk 0.86, 95% CI 0.68-1.09). The rates of intracranial hemorrhage were 1.0 and 0.2 percent before a protocol amendment allowed for a lower dose of lytic for patients ≥75 years. Limitations of the trial included protocol change, enrollment before aspiration thrombectomy became standard practice, and an older approach to the use of antithrombotic therapies. In addition, the elimination of patients who could receive PCI within 60 minutes biases the study in favor of fibrinolysis. Thus, while fibrinolysis leads to efficacy outcomes comparable to primary PCI in patients who present early, we prefer the latter due to concerns about the safety of lytic therapy.

For individuals who are treated with fibrinolytic therapy, angiography with PCI is considered for most patients. (See 'Angiography after fibrinolysis' below.)

Presentation between 3 and 12 hours — While most of the evidence regarding the efficacy of fibrinolytic therapy comes from studies of patients who present less than four to six hours after the onset

of STEMI, we believe that it is reasonable to extend their conclusions to patients who present up to 12 hours.

Approximately half of patients with STEMI present more than three to four hours after symptom onset [26]. Such patients are on a flatter portion of the survival versus time-to-reperfusion curve (figure 2). They are usually better served by the greater efficacy and reduced stroke risk of primary PCI, despite the time required for transfer. A delay to implementation of PCI related to transfer eventually erodes the benefit of PPCI over fibrinolysis is variable and depends many factors. This PCI related delay should be <90 minutes and preferably <60 minutes in most cases. The PCI-related delay is the difference between the door-to-balloon time and the door-to-needle time.

Presentation after 12 hours — Registry data suggest that 9 to 31 percent of patients with STEMI present more than 12 hours after the onset of symptoms [27,28]. Fibrinolytic therapy administered at this time is not likely to improve outcomes, as the benefit is small (but not zero) and likely outweighed by the risks. However, primary PCI may be beneficial in selected patients. Very little evidence is available to review, as most such patients were excluded from the major primary PCI trials. The following points influence our recommendations for care in these late presenting patients:

- The mortality benefit, as well as an improvement in left ventricular function from PCI likely extends beyond 12 hours, but the magnitude of this benefit is unknown. (See "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome", section on 'Late PCI to open an occluded artery'.)
- In many patients the onset of symptoms is unclear due to poor recall of the patients. Thus, for some patients, the true onset of STEMI may be shorter than the reported onset.

The possible indication for late (between 12 and 24 hours) primary PCI to open an occluded artery varies with the clinical status of the patient.

- Symptomatic or unstable patients — There are no randomized trials or observational studies from the era of aggressive antithrombotic therapy that have addressed patients who present more than 12 hours after STEMI and who continue with evidence of ischemia. However, our experts believe that in the absence of evidence, urgent diagnostic coronary arteriography and PCI, as opposed to no reperfusion of the infarct related artery, will lead to improved outcomes. Asymptomatic patients — Randomized trials of routine late PCI have shown an improvement in left ventricular function but not in hard clinical endpoints. However, these trials included many patients who presented after 24 hours; thus, the results are not directly applicable. (See "Coronary artery patency and outcome after myocardial infarction", section on 'Late PCI to open an occluded artery'.) Our experts make the following suggestions for care of asymptomatic patients who present between 12 and 24 hours after STEMI:

    - Diagnostic coronary arteriography should be performed within 24 hours.

- For patients with subtotal occlusion of the infarct related artery or a totally occluded artery with collateral flow to the distal artery, our experts prefer to perform PCI.
- In patients with total occlusion and no collateral flow or in others in whom there is uncertainty as to the optimal approach, our experts suggest performing a viability study before considering PCI.

Patients for whom PCI is usually preferred

Diagnosis in doubt — Some patients present with signs and symptoms that are suggestive but not diagnostic for STEMI. Examples include patients with non-diagnostic or borderline features of the ECG or those with an ECG suggesting STEMI but an atypical history (eg, pericarditis). In such patients the diagnosis should be confirmed with immediate echocardiography or coronary angiography, and patients at institutions that cannot perform these procedures should be transferred. Immediate PCI can then be employed as the reperfusion strategy if indicated.

High risk of fibrinolytic associated bleeding — Fibrinolytic therapy carries a greater risk of minor and major bleeding compared to primary PCI. Intracranial hemorrhage (ICH) is the most serious of these risks and occurs in approximately 0.7 percent of patients treated with fibrinolytics [13,29,30]. Patients with contraindications to fibrinolysis represent a high-risk group and, although there are no randomized data specific to this population, such patients appear to benefit from primary PCI [27]. (See "Primary percutaneous coronary intervention versus fibrinolysis in acute ST elevation myocardial infarction: Clinical trials", section on 'PCI when fibrinolysis is contraindicated'.)

Transfer for PCI is recommended by the American College of Cardiology/American Heart Association (ACC/AHA) and the European Society of Cardiology (ESC) guidelines for the following patients:

- Those with absolute contraindications to fibrinolysis (table 2) [13,24].
- Those with significant or multiple relative contraindications leading to an estimated intracranial hemorrhage risk ≥4 percent (table 3) [13].

Very high-risk patients — The benefits of primary PCI over fibrinolysis are greater in very high-risk patients and patients with cardiogenic shock (CS) [13,21,22,24,31]. (See "Primary percutaneous coronary intervention versus fibrinolysis in acute ST elevation myocardial infarction: Clinical trials", section on 'High- versus low-risk patients' and "Prognosis and treatment of cardiogenic shock complicating acute myocardial infarction", section on 'Reperfusion'.)

This point was illustrated in an analysis of 16 randomized trials that compared primary PCI to fibrinolysis [32]. In this study, an increase in baseline mortality risk from 4.4 to 12.4 percent allowed for an increase in the acceptable PCI-related delay (equipoise) from 43 to 200 minutes.

As a result, transfer for PCI is generally favored for patients with the following characteristics:

- Severe heart failure and/or pulmonary edema.

- Those deemed to be at high risk on the basis of models such as the TIMI risk score (calculator 1) [21,22].

Patients with CS represent a uniquely high-risk population. Primary percutaneous coronary intervention (PCI) is preferred to fibrinolysis for most patients with cardiogenic shock complicating acute MI. (See "Prognosis and treatment of cardiogenic shock complicating acute myocardial infarction", section on 'Reperfusion'.)

For such patients in whom primary PCI is not immediately available, such as those who present to hospitals without on-site PCI, there is some evidence that they may benefit from administration of fibrinolytics and placement of an intraaortic balloon pump (IABP) prior to transfer [33]. If the delay to primary PCI is greater than 120 minutes, fibrinolytic therapy should be given and the patient then transferred as soon as possible for possible PCI. Such treatment should not delay arrangements for urgent transfer and PCI. (See "Prognosis and treatment of cardiogenic shock complicating acute myocardial infarction".) Because of the greater mortality benefit of primary PCI over fibrinolytics in these high-risk patients, greater degrees of PCI-related delay are usually tolerated.

ANGIOGRAPHY AFTER FIBRINOLYSIS — If fibrinolytic therapy is given, subsequent angiography with percutaneous coronary intervention (PCI) is appropriate for most patients prior to discharge. The optimal timing of routine angiography and possible PCI after fibrinolytic therapy for acute ST elevation myocardial infarction (STEMI) is discussed elsewhere. (See "Percutaneous coronary intervention after fibrinolysis for acute ST elevation myocardial infarction", section on 'Adjunctive or early elective PCI'.)

There are four situations in which the evidence supports angiography followed by PCI within 24 hours of fibrinolytic therapy:

- For failed fibrinolysis or threatened reocclusion, as manifested by findings such as persistent or recurrent chest pain, ST segment elevation, or hemodynamic or electrical instability. (See "Management of failed fibrinolysis (thrombolysis) or threatened reocclusion in acute ST elevation myocardial infarction" and "Percutaneous coronary intervention after fibrinolysis for acute ST elevation myocardial infarction".)
- Patients in cardiogenic shock who present to a facility without primary PCI capability represent a situation in which PCI should be carried out as soon as possible after initial treatment with fibrinolytics. (See "Prognosis and treatment of cardiogenic shock complicating acute myocardial infarction", section on 'Reperfusion' and 'Very high-risk patients' above.)
- As part of a pharmacoinvasive strategy in which fibrinolytic therapy is followed by patient transfer to an interventional center for angiography and PCI. The delay to PCI (because of the transfer process) normally precludes a primary PCI approach, so fibrinolytic therapy is utilized to provide possible reperfusion prior to planned PCI following patient transfer. (See "Percutaneous coronary intervention after fibrinolysis for acute ST elevation myocardial infarction", section on 'Pharmacoinvasive strategy'.)

- In high-risk patients, the angiogram and PCI are completed between three and six hours.
- In low-risk patients, our experts suggest coronary angiography between 3 and 24 hours. It is also reasonable to perform coronary arteriography after 24 hours (but before discharge). For patients who do not accept a recommendation for transfer for possible PCI or those lower risk patients for whom transfer is a hardship or logistically difficult, an alternate strategy of transfer only for evidence of recurrent ischemia (including at the time of prehospital stress testing) is reasonable.

ADJUNCTIVE THERAPIES — Patients treated with either fibrinolytic therapy or primary percutaneous coronary intervention (PCI) for acute ST elevation myocardial infarction (STEMI) should also receive other therapies aimed at improving coronary perfusion. These therapies include an antithrombin (heparin, low molecular weight heparin, or bivalirudin) and aggressive antiplatelet therapy (aspirin, clopidogrel, and, in patients undergoing primary PCI, a glycoprotein IIb/IIIa inhibitor). (See "Overview of the acute management of ST elevation myocardial infarction" and "Antiplatelet agents in acute ST elevation myocardial infarction" and "Anticoagulant therapy in acute ST elevation myocardial infarction" and "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Periprocedural management", section on 'Adjunctive therapy'.)

ROLE OF CABG — Coronary artery bypass graft surgery (CABG) is infrequently performed in patients with an acute ST elevation myocardial infarction (STEMI). The main indications for emergent or urgent CABG are related to failure of fibrinolysis or percutaneous coronary interventions (PCI), cardiogenic shock, or life threatening ventricular arrhythmias in the setting of left main or three-vessel coronary artery disease [13].

The benefit of revascularization must be weighed against the increase in mortality after CABG in the first three to seven days after STEMI. Thus, if the patient can be medically stabilized, surgery should be delayed to allow myocardial recovery. Patients with critical anatomy should undergo CABG during the initial hospitalization. (See "Coronary artery bypass graft surgery after acute ST elevation myocardial infarction".)

SUMMARY AND RECOMMENDATIONS

- Coronary artery reperfusion with either primary percutaneous coronary intervention (PCI) or fibrinolytic therapy improves clinical outcomes compared to no reperfusion in nearly all groups of patients with an acute ST elevation myocardial infarction (STEMI). For STEMI patients who present between 0 and 12 hours after symptom onset, we recommend reperfusion with either primary PCI or fibrinolysis (**Grade 1A**). (See 'Introduction' above.)
- Primary PCI (when delivered in a timely manner by expert healthcare providers), compared to fibrinolysis, leads to lower rates of death and recurrent myocardial infarction, as well as smaller infarcts. (See 'Introduction' above.)
- The decision to choose fibrinolytic therapy generally results when a patient presents to a setting in which expert primary PCI is not available within the time parameters

recommended below. However, these time cut-offs are not rigid and a higher tolerance for delay in getting a patient to primary PCI may be needed for higher-risk patients or those at risk for fibrinolytic associated bleeding. (See 'Factors determining choice of reperfusion strategy' above.)

- The following recommendations apply to patients who present within 12 hours of symptom onset:

  - For patients who are transported to or arrive at a PCI-capable hospital, we recommend primary PCI, rather than fibrinolysis, as long as it can be performed with a door-to-balloon time 90 minutes or less (**Grade 1A**).
  - For patients who are transported to or arrive at a hospital not capable of immediate PCI, we recommend immediate transfer to a PCI capable hospital for primary PCI rather than fibrinolysis at the first hospital, as long as it can be performed with a first medical contact to PCI time of less than 120 minutes (**Grade 1A**).
  - For those patients in whom the decision remains unclear after consideration of the above recommendations, we believe it is reasonable to prefer primary PCI. Reasons for this suggestion include the hemorrhagic risk associated with fibrinolytic therapy, as well as the likely need for PCI after fibrinolysis. (See 'Patients for whom PCI is usually preferred' above.)
  - PCI is preferred to fibrinolysis, with less emphasis placed upon time to presentation and PCI-related delay in patients with markers of high mortality risk, such as Killip class three or four, or a TIMI risk score ≥5 (calculator 1). These patients are more likely to benefit from primary PCI than fibrinolysis. In addition, the benefits of primary PCI over fibrinolysis are probably retained at greater degrees of PCI-related delay in these patients. We recommend primary PCI for high-risk patients (**Grade 1B**). (See 'Very high-risk patients' above.)
  - While the optimal strategy for the management of patients in cardiogenic shock is unknown, the rapid restoration of blood flow improves outcomes. Primary PCI is the preferred reperfusion strategy in most of these patients, although fibrinolysis prior to transfer to an institution with on-site PCI may be of benefit. Recommendations for the use of reperfusion therapy in patients with cardiogenic shock are found separately. (See "Prognosis and treatment of cardiogenic shock complicating acute myocardial infarction", section on 'Summary and Recommendations'.)
  - For patients who have received fibrinolysis at hospital without PCI capability, we recommend expeditious transfer to a PCI capable hospital (**Grade 1A**). For patients who do not accept a recommendation for transfer for possible PCI or those lower risk patients for whom transfer is a hardship or logistically difficult, an alternate strategy of transfer only for evidence of recurrent ischemia (including at the time of prehospital stress testing) is reasonable.

The subsequent management of transferred patients, and those with threatened reocclusion, is discussed above. (See 'Angiography after fibrinolysis' above.)

- The following recommendations apply to patients who present after 12 hours of symptom onset:

  - For patients who present between 12 and 36 hours after symptom onset and have severe heart failure, hemodynamic or electrical instability, or persistent ischemic symptoms, we recommend primary PCI, as opposed to no reperfusion therapy (**Grade 1B**). (See 'Presentation after 12 hours' above.)
  - We recommend not using fibrinolytic therapy for patients who present between 12 and 36 hours, including those for whom PCI is recommended but not employed (eg, patient refusal or PCI not available) (**Grade 1B**).

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Impact of Primary Coronary Angioplasty Delay on Myocardial Salvage, Infarct Size, and Microvascular Damage in Patients With ST-Segment Elevation Myocardial Infarction

Insight From Cardiovascular Magnetic Resonance

Marco Francone, MD, PhD, MSc,* Chiara Bucciarelli-Ducci, MD,†§ Iacopo Carbone, MD,* Emanuele Canali, MD,† Raffaele Scardala, MD,† Francesca A. Calabrese, MD,* Gennaro Sardella, MD,‡ Massimo Mancone, MD,‡ Carlo Catalano, MD,* Francesco Fedele, MD,† Roberto Passariello, MD,* Jan Bogaert, MD, PhD,‖ Luciano Agati, MD†

Rome, Italy; London, United Kingdom; and Leuven, Belgium

Objectives We investigated the extent and nature of myocardial damage by using cardiovascular magnetic resonance (CMR) in relation to different time-to-reperfusion intervals.

Background Previous studies evaluating the influence of time to reperfusion on infarct size (IS) and myocardial salvage in patients with ST-segment elevation myocardial infarction (STEMI) have yielded conflicting results.

Methods Seventy patients with STEMI successfully treated with primary percutaneous coronary intervention within 12 h from symptom onset underwent CMR 3 ± 2 days after hospital admission. Patients were subcategorized into 4 time-to-reperfusion (symptom onset to balloon) quartiles: ≤90 min (group I, n = 19), >90 to 150 min (group II, n = 17), >150 to 360 min (group III, n = 17), and >360 min (group IV, n = 17). T2-weighted short tau inversion recovery and late gadolinium enhancement CMR were used to characterize reversible and irreversible myocardial injury (area at risk and IS, respectively); salvaged myocardium was defined as the normalized difference between extent of T2-weighted short tau inversion recovery and late gadolinium enhancement.

Results Shorter time-to-reperfusion (group I) was associated with smaller IS and microvascular obstruction and larger salvaged myocardium. Mean IS progressively increased overtime: 8% (group I), 11.7% (group II), 12.7% (group III), and 17.9% (group IV), p = 0.017; similarly, MVO was larger in patients reperfused later (0.5%, 1.5%, 3.7%, and 6.6%, respectively, p = 0.047). Accordingly, salvaged myocardium markedly decreased when reperfusion occurred >90 min of coronary occlusion (8.5%, 3.2%, 2.4%, and 2.1%, respectively, p = 0.004).

Conclusions In patients with STEMI treated with primary percutaneous coronary intervention, time to reperfusion determines the extent of reversible and irreversible myocardial injury assessed by CMR. In particular, salvaged myocardium is markedly reduced when reperfusion occurs >90 min of coronary occlusion. (J Am Coll Cardiol 2009;54: 2145–53) © 2009 by the American College of Cardiology Foundation

Current therapeutic strategies in patients with ST-segment elevation myocardial infarction (STEMI) aim for a timely recanalization of the infarct-related artery (IRA) to reduce the progression of the ischemic-necrotic wavefront of myocardial injury and salvage the damaged but still viable myocardium within the area at risk (1,2). In some patients microvascular obstruction (MVO) may occur within the ischemic region in addition to myocardial necrosis, and it is usually associated with greater left ventricular (LV) remodeling and a worse clinical outcome (3–5). Delays in recanalizing the occluded artery in patients with STEMI

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From the *Cardiovascular Magnetic Resonance Unit, Department of Radiology Sciences, and the †Cardiac Imaging Unit and Cardiovascular Division and ‡Catheterization Laboratory, Department of Cardiology Sciences, "Sapienza" University of Rome, Rome, Italy; §Cardiovascular Magnetic Resonance Unit, Royal Brompton Hospital, London, United Kingdom; and the ‖Department of Medical Imaging, Gasthuisberg University Hospital, Leuven, Belgium. Drs. Francone and Bucciarelli-Ducci contributed equally to this work.

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Abbreviations and Acronyms

CMR = cardiovascular magnetic resonance
IRA = infarct-related artery
IS = infarct size
LAD = left anterior descending artery
LGE = late gadolinium enhancement
LV = left ventricle/ventricular
LVEDV = left ventricular end-diastolic volume
LVEF = left ventricular ejection fraction
LVESV = left ventricular end-systolic volume
MVO = microvascular obstruction
PCI = percutaneous coronary intervention
PPCI = primary percutaneous coronary intervention
SSFP = steady-state free precession
STEMI = ST-segment elevation myocardial infarction
T2w-STIR = T2-weighted short tau inversion recovery
TE = echo time
TR = repetition time

influence the presence and extent of infarct size (IS) and of MVO (5–7), with a strong impact on the rate of cardiac mortality and morbidity (8). Cardiovascular magnetic resonance (CMR) with late gadolinium enhancement (LGE) imaging represents a well-established and reproducible diagnostic tool to assess irreversible ischemic injury and to visualize the location and transmural extent of IS and MVO within the infarcted region (5,6,9).

T2-weighted short tau inversion recovery (T2w-STIR) imaging is a sequence sensitive to increased myocardial water content, allowing the delineation of myocardial edema after an acute ischemic insult, thus representative of the myocardium at risk. The T2w-STIR hyperintense areas usually include both reversible and irreversible injured myocardium (10–12). However, by the use of a combined T2w-STIR and LGE CMR imaging protocol, salvaged myocardium can be quantified as the difference between the area of increased T2w-STIR signal (myocardium at risk) and the area of LGE (IS), as previously reported (10–14).

The authors of previous studies (1,2,6,7,15–18) evaluating the influence of primary percutaneous coronary intervention (PPCI) delays on IS and myocardial salvage in patients with STEMI reported conflicting results. The present study was designed to determine the influence of time to reperfusion on myocardial damage assessed by CMR in patients with STEMI undergoing PPCI.

Methods

Study population. Between October 2007 and May 2008, 75 consecutive patients with first STEMI undergoing PPCI within 12 h after the onset of symptoms were prospectively enrolled in the study. Creatine kinase and troponin I measurements were systematically performed at hospital admission, every 3 h for the subsequent 24 h, and then every 12 h for the following 2 days. The CMR study was carried out within 5 days from PPCI. A follow-up CMR study to assess LV remodeling was performed at 6 months. Exclusion criteria were unsuccessful PPCI, rescue percutaneous coronary intervention (PCI), facilitated PCI, contraindication to glycoprotein IIb/IIIa inhibitors, non-STEMI, previous MI, previous coronary artery bypass grafting, and contraindications to CMR. Patients with hemodynamic instability at the time of CMR also were excluded. All participants gave written informed consent to the protocol, and the study was approved by the local ethics committee.

PCI and medications. We performed PPCI and stenting of the IRA in all patients according to the clinical protocol used at our institution (3,19). Thrombolysis In Myocardial Infarction (TIMI) flow grade was semiquantitatively scored as previously described (2,19). The number of coronary vessels demonstrating significant coronary artery disease was reported. Collateral flow to the infarct zone was assessed on the initial angiogram before PCI and graded on a scale of 0 to 3 by use of Rentrop classification (20). A successful angioplasty was defined a combination of post-procedural TIMI flow grade 3 and residual stenosis <30%. Time to reperfusion was defined as the interval from the onset of symptoms to the first balloon inflation.

The CMR acquisition protocol. We performed CMR imaging in all patients by using a 1.5-T system (Magnetom Avanto, Siemens Medical Systems, Erlangen, Germany) equipped with SQ-engine gradients (amplitude: 45 mT/m; slew rate: 200 mT/m/ms) and a 12-channel phased-array cardiac coil. After obtaining scout images, cine steady-state free precession (SSFP) CMR images were acquired from patients during short breath holds in the short-axis, 2-chamber, and 4-chamber planes; on short-axis images, the left ventricle was completely encompassed from the base to the apex, from which we acquired a total of 10 to 12 images. Cine SSFP images were obtained by use of the following parameters: repetition time (TR) 51.3 ms, echo time (TE) 1.21 ms, flip angle 80°, 8-mm slice thickness, no interslice gap, matrix of 256 × 256, field of view ranging from 340 to 400 mm, and a voxel size of 1.7 × 1.7 × 8.0 mm.

For T2w-STIR imaging, a breath-hold black-blood segmented turbo spin echo technique was adopted by the use of a triple inversion recovery preparation module (TR 2 R-to-R intervals, TE 75 ms, flip angle 180°, TI 170 ms, slice thickness 8 mm, no interslice gap, field of view 340 to 400 mm, matrix 256 × 256, and a voxel size of 2.3 × 1.3 × 8 mm). Technical details of this sequence are described elsewhere (21). The T2w-STIR images were acquired on short axis planes covering the entire left ventricle during 6 to 8 consecutive breath holds. Each slice was obtained during an end-expiratory breath-hold of 12 to 15 s, depending on the patient's heart rate.

Finally, short-axis LGE images were obtained by use of a segmented inversion recovery technique and acquired 10 to 15 min after injection (Gadolinium-BOPTA, Multihance, Bracco, Milan, Italy; 0.1 mmol/kg body weight at 2 ml/s). Sequence parameters were the following: TR 700 ms, TE 4.33 ms, matrix 256 × 256, flip angle 30°, slice thickness 8.0 mm, no interslice gap, and voxel size 1.7 × 1.4 × 8 mm. The inversion time was progressively optimized to null the signal in the normal myocardium (typical values, 250 to 300 ms) to

ensure matching slice position between T2w-STIR and LGE images, same acquisition planes were adopted. Cine, T2w-STIR, and LGE images were acquired at the same short-axis slice position.

Image analysis. All CMR studies were analyzed off-line by the use of a dedicated workstation (Siemens Argus, Erlangen, Germany). Left ventricular volumes, systolic function, and mass were calculated from the short-axis SSFP cines. Infarcted myocardial mass and MVO were manually traced and calculated from the LGE short-axis images. As reported in Bondarenko et al. (22), myocardial regions was considered infarcted if the IS signal intensity was >5 SDs above the remote myocardium. The MVO was defined as a dark zone within the infarcted segments, usually located in the subendocardium. The mass of myocardial edema was traced and calculated from the T2w-STIR images by the use of a similar threshold-based approach (signal intensity >2 SDs of remote myocardium) (23). Salvaged myocardium was quantified as the difference between the area of increased T2w-STIR signal (area at risk) and the area of LGE (IS) as previously described (10–14). All measurements were normalized to LV mass.

Statistical analysis. Data were analyzed with SPSS software version 15.0 (SPSS Inc., Chicago, Illinois). The continuous variables were calculated as the average value considering the standard deviation, whereas those that were categorical were calculated as percentages. The differences between means of continuous variables at different times to reperfusion were analyzed by 1-way analysis of variance by the use of a linear trend analysis, and a post-hoc analysis with Bonferroni correction was made for differences between groups. The differences between categorical variables were analyzed with the chi-square test of Pearson. A Student *t* test for independent groups was used to assess differences in continuous variables between anterior versus nonanterior infarction, whereas a Student paired-samples *t* test was used to highlight differences in LV parameters after primary PCI and at 6-month follow-up; these tests were made without correction for multiple comparisons. A linear regression analysis was used to evaluate the relationship between time to treatment and CMR extent of MVO, IS, and salvaged myocardium. Differences were considered statistically significant at a 2-sided p value ≤0.05.

Results

Clinical and angiographic data. Seventy patients (89% men, mean age 58 ± 9 years) were studied with CMR 3 ± 2 days after PPCI. There were no differences between the 4 groups. Seventy-five patients were initially recruited, but 5 patients were excluded because of claustrophobia (n = 3) or clinical instability (n = 2). A follow-up CMR was performed in 58 patients; the remaining 12 patients declined. We performed PPCI in left anterior descending artery (LAD) in 43 patients, in the right coronary artery in 26 patients, and in the left circumflex artery in 1 patient. Mean time to reperfusion was 4.4 ± 4.7 h. No events suggesting reocclusion/stenosis were observed between PPCI and CMR examinations.

For the purpose of the study, patients were subcategorized into 4 quartiles on the basis of time from symptom onset to reperfusion: ≤90 min (group I, n = 19), >90 to 150 min (group II, n = 17), >150 to 360 min (group III, n = 17), and >360 min (group IV, n = 17). No differences on baseline clinical and angiographic characteristics were observed in the 4 groups (Table 1). In particular, no statistical differences between groups were observed in relation to incidence of LAD disease, TIMI flow grade 3 before PPCI, and significant collateral circulation.

Time to reperfusion and IS. An infarcted region on LGE images was visualized in all patients and corresponded to the territory distribution of the IRA. Mean IS among 4 groups was 12 ± 8% of LV mass. A significant increase of IS over time was found (8%, 11%, 12%, and 18%, respectively, p = 0.005) (Fig. 1A). The largest increase in IS was observed in patients with the longest time to reperfusion (group IV vs. I, p = 0.002). Time to reperfusion expressed as a continuous variable significantly correlated with IS (r = 0.60, p = 0.0001) (Fig. 2). On a separate analysis on LAD versus non-LAD infarcts, we observed that anterior infarcts were significantly larger than inferior ones. This phenomenon was consistently observed across the 4 reperfusion groups (Table 2).

Time to reperfusion, myocardial edema, and myocardial salvage. Increased signal intensity on T2w-STIR imaging (myocardial edema) was observed in 62 of 70 patients (89%); in the remaining 8 (11%) patients, T2w signal intensity was not homogeneous throughout segments because of the presence of a central hypointense core with peripheral hyperintense rim related to underlying microvascular damage. The mean size of edema among 4 groups was 16 ± 8% of LV mass. In all patients the location of T2w-STIR increased signal intensity corresponded to the territory of distribution of the IRA. The extent of myocardial edema did not changed significantly as time to reperfusion progressed (16%, 15%, 15%, and 19%, respectively, p = 0.37) (Fig. 1B). Conversely, the extent of salvaged myocardium (edematous but not necrotic myocardium) was significantly reduced overtime (8.5%, 3.2%, 2.4%, and 2.1%, respectively, p = 0.003) (Fig. 1C). In particular, a marked reduction in salvaged myocardium was observed when reperfusion occurred area after 90 min of coronary occlusion (group I vs. II, p = 0.0001; group I vs. III, p = 0.0001; group I vs. IV, p = 0.0001), whereas no significant changes were observed between groups II, III, and IV. In late reperfused patients (group IV), an almost complete absence of salvaged myocardium was observed (Fig. 1C). A significant inverse correlation was found between time and salvaged myocardium by linear regression analysis (r = −0.53, p = 0.005).

Time to reperfusion and MVO. Mean size of MVO was 2.1 ± 3.4% of LV mass. The incidence and extent of MVO

Table 1 Patient Characteristics Categorized by Time From Symptom Onset to Reperfusion

Variables	Groups (n = 70 Patients) ≤90 Min (n = 19)	>90–150 Min (n = 17)	>150–360 Min (n = 17)	>360 Min (n = 17)	p Value
Risk factors					
Age, yrs	58 ± 7.3	57 ± 10	57 ± 13	58 ± 11	0.75
Sex, male	15 (78)	13 (76)	10 (58)	9 (53)	0.42
Hypertension	5 (26)	4 (23)	7 (41)	3 (18)	0.15
Diabetes	1 (5)	3 (18)	0 (0)	1 (6)	0.34
Smoking	12 (63)	12 (70)	8 (47)	9 (53)	0.54
Dyslipidemia	4 (21)	6 (35)	4 (23)	2 (12)	0.61
Family history of CAD	5 (26)	6 (35)	3 (18)	3 (18)	0.45
Clinical data					
Time to treatment, h	1.0 ± 0.1	2.4 ± 0.4	5.0 ± 0.9	9.0 ± 3.5	0.001
CK, UI/l	1,806 ± 934	2,012 ± 1,871	2,264 ± 1,544	2,562 ± 1,134	0.34
CK-MB, UI/l	284 ± 218	302 ± 243	311 ± 234	483 ± 486	0.33
Troponin I, ng/ml	8.7 ± 9.9	10.6 ± 11.4	10.9 ± 10.1	11.8 ± 9.2	0.28
Concomitant medications, %					
ACE inhibitors/ARBs	18 (95)	15 (88)	16 (94)	17 (100)	
Beta-blockers	17 (89)	16 (94)	16 (94)	16 (94)	0.89
Statins	19 (100)	17 (100)	17 (100)	16 (94)	
Angiographic data					
Infarct-related artery					
LAD	14 (74)	10 (59)	9 (53)	10 (59)	0.44
LCx	0 (0)	0 (0)	1 (6)	0 (0)	
RCA	5 (26)	7 (41)	7 (41)	7 (41)	
Number of vessels					
1	10 (53)	7 (41)	8 (47)	8 (47)	0.26
2	6 (31)	8 (47)	6 (35)	8 (47)	
3	1 (5)	2 (12)	3 (17)	1 (6)	
TIMI flow grade 3 before PCI	3 (15)	2 (11)	3 (17)	3 (17)	0.84
Collateral flow grade 2 to 3	2 (10)	3 (17)	2 (11)	3 (17)	0.51

Values are mean ± SD or n (%).

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; CAD = coronary artery disease; CK = creatine kinase; CK-MB = creatine kinase-myocardial band; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; PCI = percutaneous coronary intervention; RCA = right coronary artery; TIMI = Thrombolysis in Myocardial Infarction.

progressively increased as time to reperfusion increased (0.5%, 1.5%, 3.7%, and 6.6%, respectively, p = 0.039) (Fig. 1D). In particular, the larger MVO area was observed in the latest reperfused group (group IV vs. I, p = 0.034); a weak but statistically significant correlation was observed between time to reperfusion and MVO (r = 0.39, p = 0.005). Furthermore, in patients with MVO, IS was significantly greater than in patients without MVO (16 ± 9.8% vs. 10 ± 6.9%, respectively, p = 0.012).

Time to reperfusion and LV function. Significant increase in LV volumes and reduction in ejection fraction over time was observed (Table 3). However, these changes were not homogeneous because both left ventricular end-diastolic volume (LVEDV) and left ventricular end-systolic volume (LVESV) increased and left ventricular ejection fraction (LVEF) reduced only in the group reperfused the latest (group IV). There were no differences in LVEF across the 4 reperfusion groups between anterior and nonanterior infarcts (Table 2).

At the 6-month follow-up, a significant reduction of LVEDV and LVESV in groups I and II and a significant increased in groups III and IV (Table 4) was observed. A significant increase in LVEF was present only in group I, whereas LVEF was significantly decreased only in group IV (Table 4).

Discussion

In this study we describe the benefits associated with early coronary reperfusion as assessed by CMR in patients with STEMI treated with PPCI. Noninvasive myocardial tissue characterization provided by CMR enabled us to differentiate reversible and irreversible myocardial injury (myocardium at risk and myocardial infarction, respectively) and consequently to determine the presence and extent of salvaged myocardium.

The main findings of this study are that: 1) patients reperfused early (≤90 min) demonstrated smaller IS and microvascular damage and larger salvaged myocardium, whereas patients reperfused later (time to reperfusion >360 min) presented larger IS and MVO and very limited, if any, salvaged myocardium; and 2) the presence and extent of salvaged myocardium markedly decreased when reperfusion occurred after >90 min of coronary occlusion. To the best

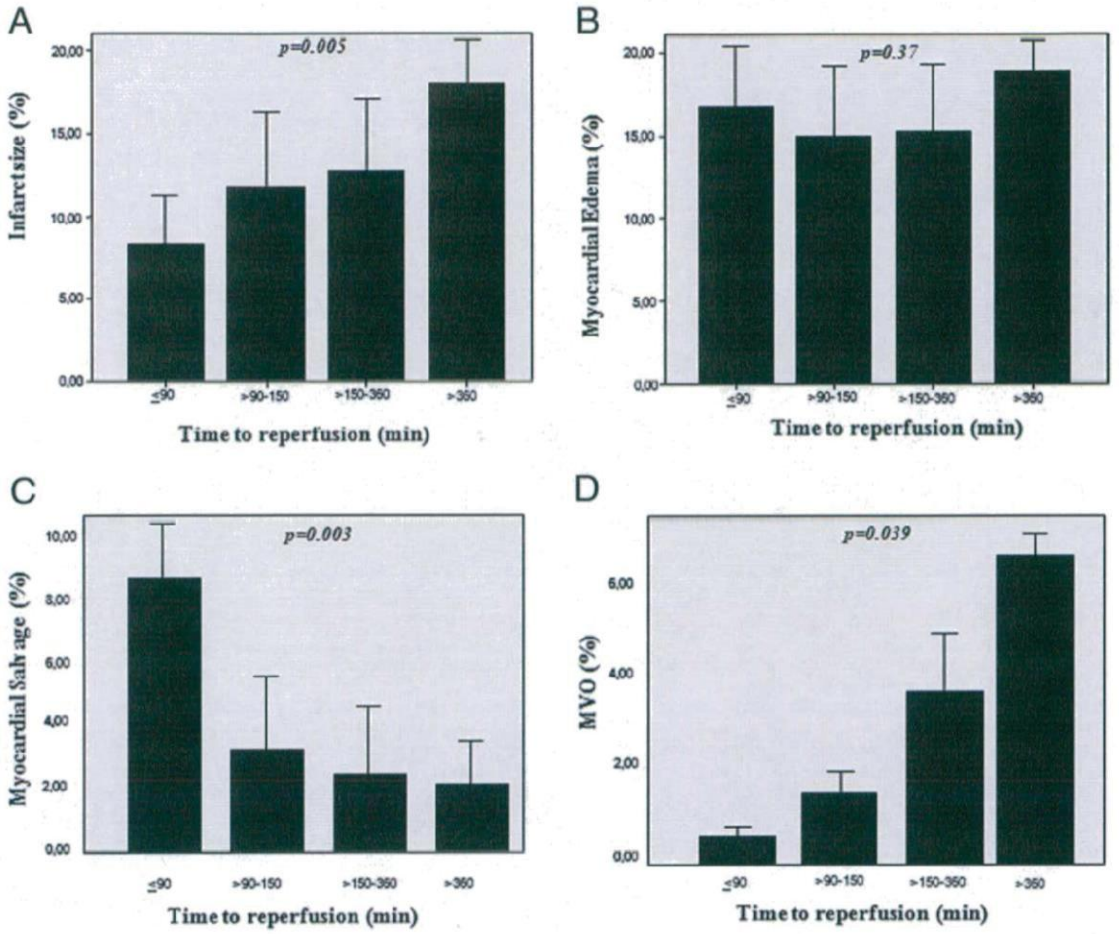

Figure 1 Time to Reperfusion and Cardiovascular Magnetic Resonance Parameters

Bar graphs show the influence of time to reperfusion on infarct size **(A)**, myocardial edema **(B)**, myocardial salvage **(C)**, and microvascular obstruction (MVO) **(D)**. Data are expressed as % left ventricular mass.

of our knowledge, this is the first in vivo, clinical, and noninvasive evaluation of the consequences of early and delayed coronary reperfusion on myocardial damage, as directly visualized by CMR.

Time to reperfusion, myocardial salvage, IS, and MVO obstruction. Reimer and Jennings (1) have demonstrated that approximately one-half of the ischemic myocardium progresses towards necrosis within 40 min of coronary occlusion, one-third of the ischemic myocardium is still salvageable at 3 h, and that the process of myocardial necrosis is complete about 6 h after the onset of coronary occlusion. After this time, the potential for salvage myocardium is considered minimal or absent (1,2). The benefits of reperfusion persist up to 12 h, but these are of decreasing magnitude over time (7–9). According to the "open artery hypothesis," most of the clinical benefits of late recanalization (>6 h) are independent from myocardial salvage and are mostly related to attenuation of LV remodeling processes and reduction of clinical instability (2,7,24).

Multiple randomized clinical trials (6–8) showed a significantly lower rate of mortality among patients achieving TIMI flow grade 3 within 90 min after the onset of STEMI (golden hour). For these reasons, the European Society of Cardiology and American College of Cardiology/American Heart Association clinical guidelines on STEMI recommend PCI within 90 min from first medical contact. Our CMR data confirm this experimental and clinical evidence by demonstrating a progressive increase over time in IS and MVO extent. However, by using CMR we were able to observe, for the first time, that salvaged myocardium consistently reduces after 90 min of coronary occlusion (Figs. 3A and 3B).

Previous studies (1,2,5–7,15–18) in which the authors evaluated the influence of time to reperfusion on IS and salvaged myocardium yielded conflicting results. As previously underlined, Reimer and Jennings (1) demonstrated in

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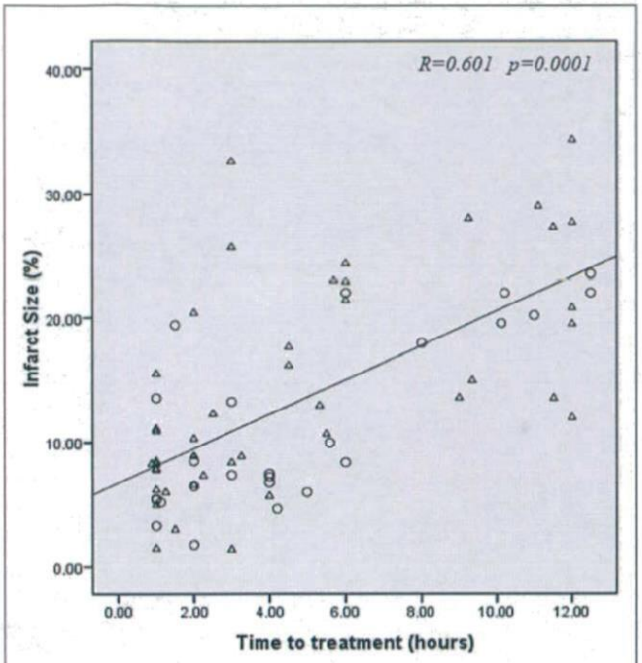

Figure 2 Relationship Between Time to Reperfusion and Infarct Size

Triangles = anterior infarct location; **circles** = nonanterior infarct location.

dogs a substantial reduction of salvaged myocardium in the first hours after coronary ligation. Whereas a reduced efficacy of lytic treatment overtime has been well documented, a recent meta-analysis by Boersma (18) suggests that time delays are largely unimportant in primary PCI. In particular, with clinical data obtained by the use of myocardial scintigraphy, Schomig et al. (16) found no significant relation between time to reperfusion and IS and a constantly high myocardial salvage index in patients treated with PCI even after 12 h from symptom onset. Conversely, by analyzing the T2W-STIR and LGE images, our CMR data support the hypothesis that myocardium potentially salvaged by reperfusion significantly reduces after 90 min of coronary occlusion even in patients treated with PPCI.

The main determinants of MVO are still unclear (3–5,15,24). In agreement with Tarantini et al. (15), we observed a progressive MVO increase over time. In particular MVO was detected only in 6 of 19 patients (31%) treated within 90 min and in 14 of 17 patients (82%) treated after 6 h. Thus, both incidence and extent of MVO are time-dependent phenomenon, as observed for IS. These results are consistent with previous experimental data hypothesizing that the extent of microvascular injury is also driven by the extent of IS (14,15,25).

Finally, the impact of time to reperfusion on LV volumes and LVEF was significantly more pronounced in patients reperfused late (group IV) compared with the other groups (I, II, and III). This finding was confirmed also in the CMR at 6 months, demonstrating a significant increase in LVEDV and LVESV in the later reperfused groups (group III, >150 to 360 min and group IV, >360 min); LVEF significantly decreased only in group IV.

Myocardium at risk and salvaged myocardium. Increased signal intensity in the T2w-STIR images is related to increased water content. In patients with STEMI this phenomenon is likely to represent post-ischemic intracellular edema either related to altered transmembrane sodium gradients or to the inflammatory response to the acute ischemic insult. The authors of recent CMR studies (10–14,24) demonstrated that the increased signal intensity on T2w-STIR images corresponds indeed to the area of myocardium at risk determined histologically. Aletras et al. (10) demonstrated in animal model of 90-min coronary occlusion followed by reperfusion that the area at risk measured by microspheres was comparable with the area of increased signal in the T2w images 2 days later. The increased signal intensity on T2w-STIR images consist of both reversibly and irreversibly injured myocardium. In addition, areas of LGE identified IS with detailed precision compared with histology (10), confirming that IS acutely is not overestimated because of the contribution of edematous areas, which are indeed characterized and quantified only by the T2w images. Therefore, on the basis of the histological evidence that myocardium at risk is identified by the T2w areas and IS by LGE areas, the amount of salvaged myocardium can be derived by subtracting the area of LGE from the T2w area.

Cury et al. (26) recently applied T2w imaging by using a double inversion-recovery with chemical fat saturation and LGE protocol to improve the accuracy in the diagnosis of acute coronary syndrome in the emergency department. The

Table 2 Relationship Among Infarct Location (LAD vs. Non-LAD) and Time to Treatment, Infarct Size, and LVEF

	Groups							
Variables	≤90 Min	p Value	>90–150 Min	p Value	>150–360 Min	p Value	>360 Min	p Value
LAD time to treatment, h	1.0 ± 0.2	0.710	2.5 ± 0.5	0.984	5.2 ± 0.9	0.335	11.5 ± 1.1	0.359
Non-LAD time to treatment, h	1.1 ± 0.2		2.4 ± 0.5		4.5 ± 0.8		10.2 ± 3.1	
LAD infarct size, %	12 ± 3.1	0.050	14 ± 10.1	0.041	16 ± 7.9	0.038	20 ± 9.8	0.002
Non-LAD infarct size, %	6.8 ± 1.5		8.9 ± 3.2		9.7 ± 6.8		10 ± 1.3	
LAD LVEF, %	47 ± 12.4	0.427	44 ± 10.1	0.220	44 ± 5.7	0.147	34 ± 6.0	0.378
Non-LAD LVEF, %	50 ± 10.7		51 ± 9.4		51 ± 7.2		39 ± 7.6	

LAD = left anterior descending artery; LVEF = left ventricular ejection fraction.

Table 3 Influence of Time to Reperfusion on Left Ventricular Function Assessed by CMR

Variables	Groups ≤90 Min (n = 19)	>90–150 Min (n = 17)	>150–360 Min (n = 17)	>360 Min (n = 17)	p Value
LVEDV, ml	128 ± 32	131 ± 37	130 ± 41	153 ± 22	0.03
LVESV, ml	62 ± 22	69 ± 30	68 ± 24	94 ± 21	0.02
LVEF, %	47 ± 10	46 ± 9	47 ± 6	38 ± 7	0.06

CMR = cardiovascular magnetic resonance; LVEDV = left ventricular end-diastolic volume; LVEF = left ventricular ejection fraction; LVESV = left ventricular end-systolic volume.

authors of previous studies (11–15) showed that areas of increased T2 signal intensity are consistently larger than the LGE areas of the irreversible injury. Similarly, in our study, the edematous zone is consistently larger than the infarcted zone but only in patients treated early and progressively reduces with delays on reperfusion evolving in irreversible myocardial damage. The amount of myocardium successfully salvaged dramatically reduces after 90 min of coronary occlusion; thus, clinical benefits of IRA reopening are after this period (2,7,18) are largely not attributable to myocardial salvage.

Milavetz et al. (27) reported the influence of time to reperfusion on myocardial salvage assessed by technetium-99m sestamibi demonstrating that in patients with first anterior MI undergoing successful reperfusion therapy (PPCI or thrombolysis) the greatest degree of myocardial salvage was achieved with an early reperfusion therapy (<2 h). Our data confirm these findings by the use of CMR as an alternative noninvasive imaging modality. The retrospective determination of myocardium at risk, IS—and consequently myocardial salvage—by CMR up to 5 days after reperfusion appears logistically very attractive as compared with the tracer injection before reperfusion therapy required by technetium-99m sestamibi (28). Finally, our study provides additional insight on the association of 4 different time-to-reperfusion intervals and the extent of reversible and irreversible damage.

Study limitations. Despite the limited study population, a relatively high percentage of our patients were treated very early (24% of patients ≤90 min from the symptom onset, 51% within 150 min), which was made possible by an integrated hospital network system activated in our city and region. For the same reason the mean IS detected in our study population was slightly smaller than previously reported. The influence of time to reperfusion on the extent of myocardial salvage IS and MVO needs to be confirmed in larger longitudinal studies.

Currently, there is no consensus on which technique can be used to perform the best MVO quantification (29). With first-pass myocardial perfusion imaging, the area of MVO is larger than using LGE imaging. In our study MVO was assessed in LGE images. Although the size of MVO may be underestimated by use of the LGE sequences, the persistence of MVO in these images is likely to reflect a more severe form of MVO (15). Finally, in this study CMR was performed as part of a research protocol and did not contribute to the care of patients.

Clinical implications. The results of our study suggest that any strategy (30–32) to shorten the delay in the reperfusion of patients with STEMI (i.e., pre-hospital lysis or a direct catheter laboratory notification bypassing the emergency department) is crucial. Although Boersma (18) hypothesizes that that time delays are less important for primary PCI, the present study demonstrated the amount of myocardial salvage reduces significantly already after 90 min of coronary occlusion. Our data might explain the unsatisfactory clinical results of myocardial protection therapy (33). Agents directed toward improving the myocardial reperfusion itself are time-limited to the period when myocardial salvage occurs. Thus, possibly only patients presenting very early after symptom onset may take advantages from cardioprotective drugs.

Finally, this work confirms and emphasizes the important diagnostic role of CMR with LGE and T2w-STIR techniques in providing in vivo characterization of myocardial tissue damage at different temporal stages of coronary reperfusion. The use of CMR can identify and quantify areas of salvaged

Table 4 Left Ventricular Function After Primary Angioplasty and at Follow-Up

Variables	Groups ≤90 Min (n = 15)	p Value	>90–150 Min (n = 14)	p Value	>150–360 Min (n = 16)	p Value	>360 Min (n = 13)	p Value
LVEDV, ml	128 ± 32	0.003	131 ± 37	0.047	130 ± 41	0.005	153 ± 22	0.002
LVEDV follow-up, ml	119 ± 22		121 ± 37		144 ± 42		167 ± 30	
LVESV, ml	62 ± 22	0.062	69 ± 30	0.001	68 ± 24	0.006	94 ± 21	0.003
LVESV follow-up, ml	58 ± 17		56 ± 28		79 ± 38		110 ± 20	
LVEF, %	47 ± 10	0.042	46 ± 9	0.117	47 ± 6	0.980	38 ± 7	0.048
LVEF follow-up, %	55 ± 6		49 ± 10		47 ± 9		34 ± 6	

Abbreviations as in Table 3.

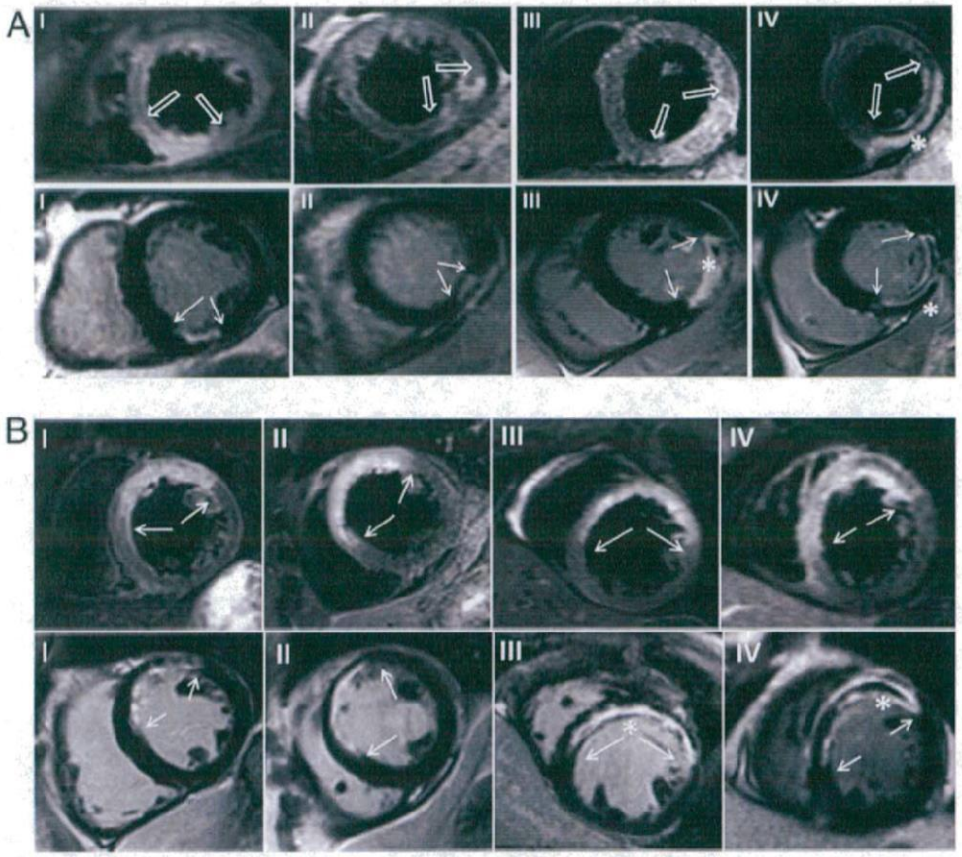

Figure 3 Influence of Time to Reperfusion on Myocardial Salvage

(A) Influence of time to reperfusion on myocardial edema and infarct size in inferior myocardial infarctions. Temporal distribution of myocardial edema and infarct size among the 4 groups in patients with inferior myocardial infarction. **(Top)** T2-weighted short tau inversion recovery (T2w-STIR) images; **(bottom)** corresponding late gadolinium enhancement (LGE) images. As time to reperfusion progresses, infarct size **(thin arrows)** and microvascular obstruction (MVO) **(*)** increase. Of note, in group I (early reperfused) the area of edema **(open arrows)** largely exceeds the area of infarct size, demonstrating presence of myocardial salvage; conversely in group IV (reperfused the latest), the area of edema almost corresponds to the infarcted area, suggesting limited myocardial salvage. **(B)** Influence of time to reperfusion on myocardial edema and infarct size in anterior myocardial infarctions. Temporal distribution of myocardial edema and infarct size among the 4 groups in patients with anterior myocardial infarction. **(Top)** T2w-STIR images; **(bottom)** corresponding LGE images. As time to reperfusion progresses, infarct size **(thin arrows)** and MVO **(*)** increase, with a parallel myocardial salvage reduction.

myocardium in patients with STEMI treated with PPCI, representing a potentially valuable tool to be used in large clinical trials assessing the efficacy of different reperfusion strategies. Large clinical trials are needed to assess the role of CMR in the risk stratification after acute myocardial infarction and possibly improve patient management.

Reprint requests and correspondence: Dr. Luciano Agati, Professor of Cardiology, Head of Cardiac Imaging Unit, Department of Cardiology, "Sapienza" University of Rome, Viale del Policlinico 155, 00161 Roma, Italy. E-mail: luciano.agati@uniroma1.it.

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Key Words: myocardial salvage ▪ myocardial infarction ▪ microvascular injury ▪ cardiovascular magnetic resonance ▪ time to reperfusion.

ORIGINAL CONTRIBUTION

System Delay and Mortality Among Patients With STEMI Treated With Primary Percutaneous Coronary Intervention

Christian Juhl Terkelsen, MD, PhD
Jacob Thorsted Sørensen, MD
Michael Maeng, MD, PhD
Lisette Okkels Jensen, MD, DmSc
Hans-Henrik Tilsted, MD
Sven Trautner, MD
Werner Vach, PhD
Søren Paaske Johnsen, MD, PhD
Leif Thuesen, MD, DmSc
Jens Flensted Lassen, MD, PhD

Context Timely reperfusion therapy is recommended for patients with ST-segment elevation myocardial infarction (STEMI), and door-to-balloon delay has been proposed as a performance measure in triaging patients for primary percutaneous coronary intervention (PCI). However, focusing on the time from first contact with the health care system to the initiation of reperfusion therapy (system delay) may be more relevant, because it constitutes the total time to reperfusion modifiable by the health care system. No previous studies have focused on the association between system delay and outcome in patients with STEMI treated with primary PCI.

Objective To evaluate the associations between system, treatment, patient, and door-to-balloon delays and mortality in patients with STEMI.

Design, Setting, and Patients Historical follow-up study based on population-based Danish medical registries of patients with STEMI transported by the emergency medical service and treated with primary PCI from January 1, 2002, to December 31, 2008, at 3 high-volume PCI centers in Western Denmark. Patients (N=6209) underwent primary PCI within 12 hours of symptom onset. The median follow-up time was 3.4 (interquartile range, 1.8-5.2) years.

Main Outcome Measures Crude and adjusted hazard ratios of mortality obtained by Cox proportional regression analysis.

Results A system delay of 0 through 60 minutes (n=347) corresponded to a long-term mortality rate of 15.4% (n=43); a delay of 61 through 120 minutes (n=2643) to a rate of 23.3% (n=380); a delay of 121 through 180 minutes (n=2092) to a rate of 28.1% (n=378); and a delay of 181 through 360 minutes (n=1127) to a rate of 30.8% (n=275) ($P<.001$). In multivariable analysis adjusted for other predictors of mortality, system delay was independently associated with mortality (adjusted hazard ratio, 1.10 [95% confidence interval, 1.04-1.16] per 1-hour delay), as was its components, prehospital system delay and door-to-balloon delay.

Conclusion System delay was associated with mortality in patients with STEMI treated with primary PCI.

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TIMELY REPERFUSION THERAPY with either fibrinolysis or primary percutaneous coronary intervention (PCI) is recommended for patients with ST-segment elevation myocardial infarction (STEMI).[1] However, agreeing on the definition of "timely" is difficult, because the benefit achieved by earlier initiation of reperfusion therapy is controversial. The only unbiased studies that have evaluated the effects of earlier reperfusion therapy on outcome are randomized controlled studies that compared prehospital and in-hospital fibrinolysis. In those studies, prehospital fibrinolysis was associated with earlier initiation (1 hour) of reperfusion therapy, resulting in an extra 15 to 21 lives saved per 1000 treated patients.[2-4] The time-dependent benefit of primary PCI has been evaluated from observational data only, and the nearly neutral relationship observed between treatment delay and mortality may lead

Author Affiliations: Departments of Cardiology (Drs Terkelsen, Sørensen, Maeng, Thuesen, and Lassen) and Clinical Epidemiology (Dr Johnsen), Aarhus University Hospital, Aarhus, Denmark; Department of Cardiology, Odense University Hospital, Odense, Denmark (Dr Jensen); Department of Cardiology, Aalborg University Hospital, Aalborg, Denmark (Dr Tilsted); Falck Emergency Medical Service, The Falck House, Copenhagen, Denmark (Dr Trautner); and Department of Clinical Epidemiology, University Medical Centre, Freiburg, Germany (Dr Vach).
Corresponding Author: Christian Juhl Terkelsen, MD, PhD, Department of Cardiology, Aarhus University Hospital, DK-8200 Aarhus N, Denmark (christian_juhl_terkelsen@hotmail.com).

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to the perception that the effect of primary PCI is less time-dependent than the effect of fibrinolysis.[5-7]

However, patients presenting early have a high mortality without reperfusion therapy and receive a large benefit from primary PCI. Conversely, those presenting late are typically low-risk patients who have already survived the prehospital phase and benefit less from reperfusion therapy.[8,9] This difference in patient characteristics may explain the lack of a clear association between treatment or patient delay and mortality, because early presenting high-risk patients who receive optimal reperfusion therapy ultimately have nearly the same mortality as those presenting late.[10,11] Moreover, determination of treatment and patient delay is based on information regarding symptom onset, which may be uncertain because of recall bias and because the onset of acute myocardial infarction (AMI) may have been preceded by hours of unstable angina. Thus, it is impossible to establish the exact time of onset of the AMI. To study the effect of delayed primary PCI therapy on mortality, it may be more relevant to focus on a parameter not hampered by recall bias and less prone to selection bias, information bias, and confounding. Several studies have focused on the association between door-to-balloon delay and outcome, whereas the total health care system delay, defined as the time from first contact with the health care system to initiation of reperfusion therapy, has received only limited attention (FIGURE 1).[12]

The present study assessed the associations between treatment, patient, system, and door-to-balloon delays and mortality in a large population-based cohort of patients with STEMI treated with primary PCI.

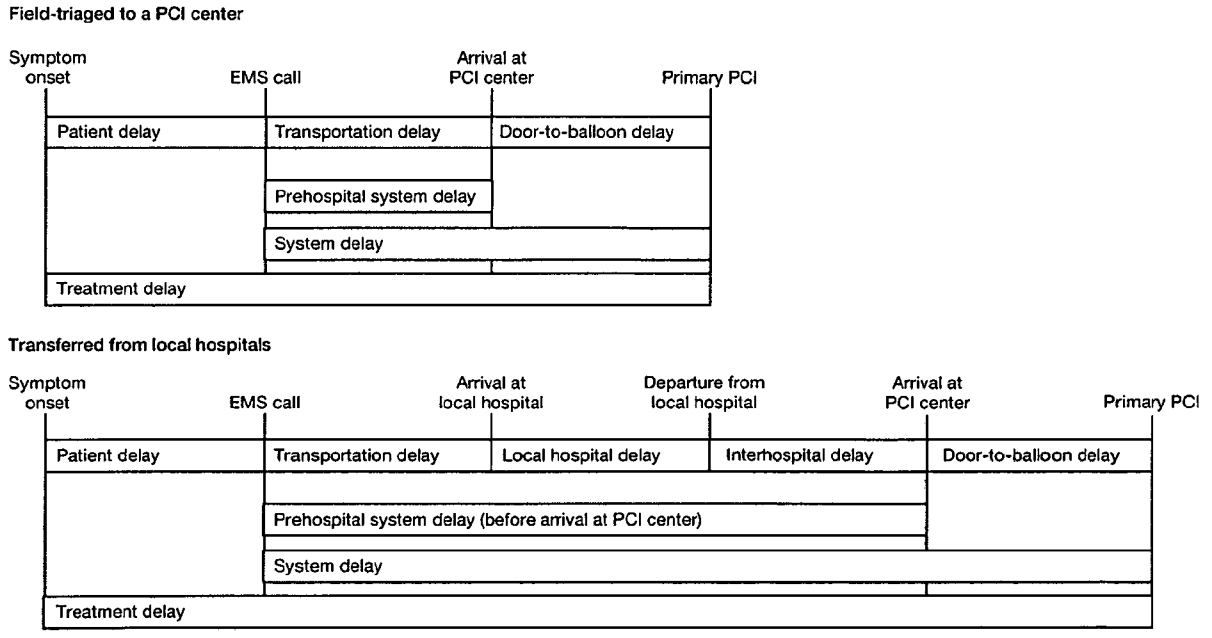
METHODS

Setting and Design

This study was based on public medical databases that cover the entire population of Western Denmark (approximately 3 million, corresponding to 55% of the Danish population). The Danish National Health Service provides tax-supported health care for all inhabitants, guaranteeing access to treatment at general practitioners and hospitals, along with emergency medical service (EMS) transportation. The EMS system in Denmark includes 5 different EMS agencies. In Western Denmark, one agency (Falck a/s) covers approximately 95% of the study region, and other EMS agencies working in Western Denmark were covered by the dispatch center operated by Falck a/s, guaranteeing access to prehospital data from these agencies also.

The EMS system is organized as a partially 1-tier and partially 2-tier system with initial dispatcher triage. All emergencies deemed in need of an ambulance result in the dispatch of a primary unit manned with 2 EMS personnel trained in basic life support and the use of a defibrillator in automated external defibrillator mode. Subject to availability and determined by either dispatcher triage or evaluation by the

Figure 1. Delays From Symptom Onset to Primary Percutaneous Coronary Intervention in Patients With ST-Segment Elevation Myocardial Infarction Transported by the Emergency Medical Service



Stratified according to prehospital triage. EMS indicates emergency medical service; PCI, percutaneous coronary intervention.

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primary unit, a physician-manned ambulance or a unit manned with a paramedic or nurse anesthetist also attend the scene. Equipment for telecommunication was gradually implemented beginning in 1999, and in 2006 all ambulances had equipment for acquisition and transmission of electrocardiographic data. The use of field triage for primary PCI gradually increased during the study period.

Throughout the study period, the catheterization laboratory was notified when the diagnosis of STEMI was established, whether in the prehospital phase or at the local hospital, and patients were admitted directly to the catheterization laboratory. Unambiguous individual-level linkage between the databases used in this study was possible using the civil registration number, a unique 10-digit personal identification number assigned to every Danish citizen at birth.[13,14] The study was approved by the Danish Data Protection Agency (J.No. 2008-41-2299).

Patients and Procedures

The study population consisted of 6209 patients with STEMI or bundle-branch block myocardial infarction admitted for primary PCI between January 1, 2002, and December 31, 2008, at the 3 Western Denmark high-volume PCI centers: Aarhus University Hospital, Skejby; Odense University Hospital, Odense; and Aalborg University Hospital, Aalborg. Patients were identified in the Western Denmark Heart Registry (WDHR), which collects baseline characteristics and patient- and procedure-specific information on all angiographies and coronary interventions performed in Western Denmark. Self-presenters and patients without EMS data were excluded.

Primary PCI has been the recommended treatment for STEMI in Denmark since the publication of the Danish Trial of Acute Myocardial Infarction 2 (DANAMI-2) in 2003.[15] Patients must meet the following criteria to be eligible for primary PCI: symptom duration of 12 hours or less and ST-segment elevation of 0.1 mV or greater in at least 2 contiguous leads (≥0.2 mV in V_1-V_3) or presumed new-onset left bundle-branch block. Pretreatment with fibrinolysis was used in 118 patients (2.0%).

Treatment, Patient, System, and Door-to-Balloon Delay

The estimates of various delays to the initiation of reperfusion therapy were based on prehospital data registered by the EMS provider (Falck a/s, Copenhagen, Denmark) and data registered

Table 1. Characteristics of Patients With ST-Segment Elevation Myocardial Infarction Transported by the Emergency Medical Service and Treated With Primary Percutaneous Coronary Intervention (N = 6209)

Characteristic	Field-Triaged Directly to PCI Center (n = 2183) No. (%)	Valid Cases	Admitted at Local Hospital and Transferred to PCI Center (n = 4026) No. (%)	Valid Cases	P Value
Demographics					
Age, median (IQR), y	64 (55-74)	2183	65 (56-74)	4026	.37
Women	548 (25)	2183	1106 (28)	4026	.04
Comorbid conditions					
Treated hypertension	481 (32)	1521	924 (30)	3053	.36
Diabetes	151 (9.7)	1564	332 (11)	3161	.39
Previous myocardial infarction	136 (9.1)	1502	337 (11)	3008	.03
Previous PCI	94 (6.3)	1500	185 (6.2)	3006	.90
Previous congestive heart failure	59 (2.9)	2014	134 (3.5)	3779	.22
Active or previous smoker	1160 (79)	1462	2316 (79)	2916	.97
Delays and transportation					
Delay, median (IQR), min[a]					
Treatment	172 (117-261)	2183	240 (175-340)	4026	<.001
Patient	74 (34-160)	1945	106 (49-210)	3548	<.001
System	97 (78-124)	2183	139 (103-180)	4026	<.001
Prehospital system	50 (37-67)	1638	89 (49-134)	3014	<.001
Door-to-balloon	39 (24-70)	1618	29 (21-72)	3008	<.001
Transportation, median (IQR), km	25 (7-46)	2183	71 (42-104)	4026	<.001
Clinical characteristics					
Body mass index, median (IQR)[b]	26 (24-29)	1157	26 (24-29)	1903	.62
Blood pressure, median (IQR), mm Hg					
Systolic	130 (115-150)	1286	126 (110-143)	2252	<.001
Diastolic	78 (65-85)	1279	75 (65-80)	2242	<.001
Killip class		2181		4023	
I	1976 (91)		3653 (91)		.87
II	108 (5.0)		189 (4.7)		
III	46 (2.1)		94 (2.3)		
IV	51 (2.3)		87 (2.2)		
Anterior STEMI or BBBMI	909 (45)	2009	1658 (46)	3624	.72
Culprit vessel		2107		3902	
Left main artery	39 (1.9)		60 (1.5)		.82
Left anterior descending artery	911 (43)		1684 (43)		
Circumflex artery	299 (14)		550 (14)		
Right coronary artery	858 (41)		1608 (41)		
Multivessel disease	917 (46)	1998	1780 (48)	3717	.16

Abbreviations: BBBMI, bundle-branch block myocardial infarction; IQR, interquartile range; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

[a] Door-to-balloon delay indicates time from arrival at PCI center to primary PCI; patient delay, time from symptom onset to contact with the health care system; prehospital system delay, time from contact with the health care system to arrival at the PCI center; system delay, time from contact with the health care system to primary PCI.

[b] Calculated as weight in kilograms divided by height in meters squared.

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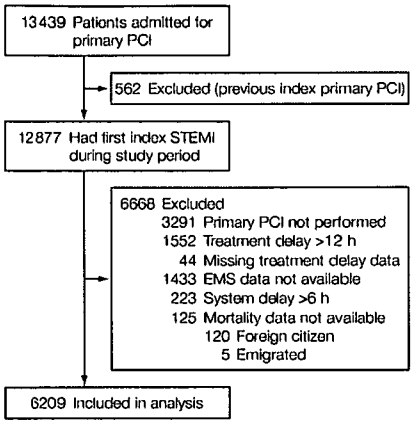
Figure 2. Flow of Patient Inclusion Into Study



System delay indicates time from contact with the health care system to time of primary percutaneous coronary intervention (PCI); treatment delay, time from symptom onset to time of primary PCI. EMS indicates emergency medical service; STEMI, ST-segment elevation myocardial infarction.

in the WDHR. Time of ambulance call was registered by a time stamp at the dispatch center, whereas time of arrival on scene, departure from scene, arrival at the local hospital, departure from the local hospital, and arrival at the PCI center were registered electronically in the ambulance by the EMS personnel by pressing a radio button. Symptom onset and time of first guiding-catheter insertion were registered in the WDHR.

Treatment delay was defined as the time from symptom onset to guiding-catheter insertion during primary PCI; patient delay as the time from symptom onset to contact with the EMS; system delay as the time from contact with the EMS to guiding-catheter insertion during primary PCI; prehospital system delay as the time from contact with the EMS to arrival at the PCI center; and door-to-balloon delay as the time from arrival at the PCI center to guiding-catheter insertion during primary PCI (Figure 1). The use of guiding-catheter insertion as a surrogate for time of intervention was chosen because time of balloon inflation was only available in a minority of patients, only a few minutes elapse from guiding-catheter insertion to first intervention, and the majority of patients achieve reperfusion before balloon inflation.[16]

Mortality and Covariates

Data on mortality were obtained from The Danish Civil Registration System, which has recorded changes in vital status of the entire Danish population since 1968.[17] Vital status is updated daily.

Baseline characteristics and other covariates (TABLE 1) were derived from the Danish Civil Registration System, the WDHR, and the National Registry of Patients.

Statistical Analysis

Dichotomous data are presented as percentages. Continuous variables are presented as medians (interquartile ranges). The Fisher exact test, χ^2 test, Mann-Whitney test, and Kruskal-Wallis test were used for comparisons of categorical and continuous variables, as appropriate. Follow-up began on the date of primary PCI and ended on the date of death, emigration, or September 24, 2009, whichever came first.

We computed Kaplan-Meier cumulative mortality curves, stratified according to intervals of system delay, and made comparisons between groups with log-rank statistics. Cox proportional hazards regression analysis was used to examine the association between the covariates and the intervals of delay to reperfusion described above and mortality. The proportional hazards assumption was checked for each categorical variable by visual inspection and by the method described by Grambsch and Therneau,[18] using the scaled Schoenfeld residuals.

For continuous variables, the linearity assumption was checked graphically using the Martingale residuals. Cox-Snell residuals were used to assess the overall model fit. Systolic and diastolic blood pressure levels were converted to categorical values, because they did not fulfill the linearity assumption.

Crude and mutually adjusted hazard ratios (HRs) with 95% confidence intervals (CIs) were computed. Variables associated with time to death in the univariable Cox regression analyses (Wald test $P<.05$) were included in multivariable Cox regression models. Missing values among covariates were replaced with their conditional means, obtained as predictions from a regression model using all nonmissing covariates for each patient.[19,20] This method for assigning missing values was also used for categorical variables without rounding the binary outcome, as previously proposed by Allison[21] when proportions are not close to 0 or 1.[21,22] Because of colinearity between infarct location and culprit vessel, only infarct location was entered in the multivariable models; because of colinearity between systolic and diastolic blood pressure, only systolic blood pressure was entered in the models. Separate models were performed considering only nonoverlapping intervals of time to reperfusion: model 1 considered treatment delay, model 2 considered patient and system delay, and model 3 considered patient, prehospital system, and door-to-balloon delay.

All statistical analyses were performed using Stata 10.0 (StataCorp, College Station, Texas).

RESULTS

A total of 13 439 patients with suspected STEMI or bundle-branch block myocardial infarction were transferred to or admitted directly to 1 of the 3 PCI centers. The first index STEMI during the study period (n=12 877 patients) was included for further analyses. Patients were excluded if primary PCI was not performed (n=3291 patients) or if they had a treatment delay greater than 12 hours (n=1552), missing treatment delay data (n=44), or a system delay greater than 6 hours (n=223). Mortality data were not available for patients who were foreign citizens (n=120) or had emigrated (n=5). In 1433 patients considered self-presenters, EMS data were not

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available. Thus, the study cohort consisted of 6209 patients (FIGURE 2), of whom 2183 (35%) were field-triaged directly to a PCI center, bypassing the local hospital. The proportion of patients field-triaged directly to the PCI centers increased from 386 of 1414 (27%) in the first 2 years of the study period to 873 of 1864 (47%) in the last 2 years ($P<.001$).

When stratifying according to whether patients were field-triaged directly to the PCI center or transferred from other hospitals, there were significant differences in several baseline characteristics and in the door-to-balloon and system delays (Table 1). For field-triaged, transferred, and all EMS-transported patients, the proportion treated with a system delay of 120 minutes or less was 72% (n=1566), 35% (n=1424), and 48% (n=2990), respectively, and among patients with available door-to-balloon time (n=4626) the proportion treated with a door-to-balloon delay of 90 minutes or less was 86% (n=1399), 80% (n=2407), and 82% (n=3806). The median time from guiding-catheter insertion to balloon inflation was 4 (interquartile range, 1-8) minutes in patients in whom time of balloon inflation was registered (n=1836). The median follow-up time was 3.4 (interquartile range, 1.8-5.2) years, with a cumulative 1-year mortality of 9.3% (n=579).

The majority of covariates were associated with mortality at follow-up in the univariable analysis (TABLE 2). According to Wald statistics, system delay had the strongest association with mortality among the covariates modifiable in the acute phase, with an HR of 1.22 (95% CI, 1.15-1.29; $P<.001$) per 1-hour increase in system delay (Table 2). When stratifying according to intervals of system delay, long-term cumulative mortality was 15.4% (n=43) in patients with system delays of 0 through 60 minutes (n=347), 23.3% (n=380) in those with delays of 61 through 120 minutes (n=2643), 28.1% (n=378) in those with delays of 121 through 180 minutes (n=2092), and 30.8% (n=275) in those with delays of 181 through 360 minutes (n=1127) ($P<.001$). Kaplan-Meier mortality curves are presented in FIGURE 3.

For the different intervals of system delay, no differences were observed in infarct location, culprit vessel, or Killip class, whereas significant differences were observed in the majority of remaining covariates (TABLE 3). In the multivariable analyses, after adjusting for other covariates, treatment delay and patient delay were not associated with mortality (TABLE 4), whereas system delay remained independently associ-

Table 2. Crude Hazard Ratios of Covariates Associated With Long-term Mortality in Univariable Cox Regression Analysis (N = 6209).

Characteristics	Valid Cases	Deaths[a]	HR (95% CI)	Wald Test	*P* Value[b]
Demographics					
Age, per 1-year increase	6209		1.074 (1.069-1.080)	666	<.001
Women	6209	364	1.46 (1.29-1.66)	35	<.001
Comorbid conditions					
Treated hypertension	4574	280	1.45 (1.25-1.69)	25	<.001
Diabetes	4725	146	2.29 (1.91-2.73)	82	<.001
Previous myocardial infarction	4510	122	1.55 (1.28-1.89)	20	<.001
Previous PCI	4506	53	1.19 (0.90-1.58)	1.5	.22
Previous congestive heart failure	5793	102	4.22 (3.43-5.17)	189	<.001
Active or previous smoker	4378	505	0.78 (0.66-0.93)	7.6	.006
Delays and transportation					
Delay, per 1-h increase[c]					
Treatment	6209		1.054 (1.029-1.080)	19	<.001
Patient	5493		1.042 (1.014-1.071)	8.8	.003
System	6209		1.22 (1.15-1.29)	51	<.001
Prehospital system	4652		1.19 (1.11-1.27)	26	<.001
Door-to-balloon	4626		1.13 (1.048-1.22)	10	.002
Transportation distance, per 1-km increase	6209		1.00 (0.999-1.002)	0.45	.50
Clinical characteristics					
Body mass index, per 1-unit increase	3060		0.94 (0.91-0.96)	25	<.001
Systolic blood pressure, mm Hg	3537	550			
<110	641	170	1 [Reference]	78	<.001
110-129	1111	161	0.49 (0.40-0.61)	42	<.001
130-144	873	101	0.40 (0.31-0.51)	54	<.001
≥145	912	118	0.45 (0.35-0.56)	46	<.001
Diastolic blood pressure, mm Hg	3521	546			
<65	812	191	1 [Reference]	69	<.001
65-74	819	119	0.55 (0.44-0.69)	26	<.001
75-84	1092	157	0.53 (0.43-0.65)	35	<.001
≥85	798	79	0.37 (0.29-0.48)	55	<.001
Killip class	6204	1073			
I	5629	811	1 [Reference]	545	<.001
II	297	97	2.63 (2.13-3.24)	81	<.001
III	140	76	5.09 (4.02-6.44)	184	<.001
IV	138	89	8.65 (6.94-10.8)	370	<.001
Anterior infarct location	5633	467	1.35 (1.19-1.54)	21	<.001
Culprit vessel LM/LAD	6009	520	1.28 (1.14-1.45)	16	<.001
Multivessel disease	5715	640	2.19 (1.92-2.49)	138	<.001

Abbreviations: CI, confidence interval; HR, hazard ratio; LAD, left anterior descending artery; LM, left main artery, PCI, percutaneous coronary intervention.
[a] Total deaths=1076.
[b] By univariable Cox regression.
[c] Door-to-balloon delay indicates time from arrival at the PCI center to primary PCI; patient delay, time from symptom onset to contact with the health care system; prehospital system delay, time from contact with the health care system to arrival at the PCI center; system delay, time from contact with the health care system to primary PCI; treatment delay, time from symptom onset to primary PCI.

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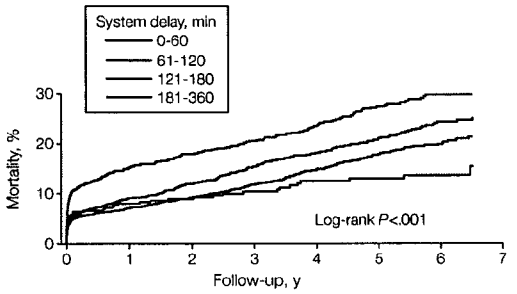
Figure 3. Kaplan-Meier Cumulative Mortality Estimates for Patients With ST-Segment Elevation Myocardial Infarction Treated With Primary Percutaneous Coronary Intervention (N=6209)



No. at risk

System delay, min							
0-60	347	311	278	230	192	138	87
61-120	2643	2339	1906	1420	1006	667	375
121-180	2092	1836	1503	1183	842	533	278
181-360	1127	923	765	647	491	332	172

Stratified according to intervals of system delay (time from contact with the health care system to the time of primary PCI). PCI indicates percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

ated with mortality, with an adjusted HR of 1.10 (95% CI, 1.04-1.16; P=.002) per 1-hour delay (Table 4). The main components of system delay were also associated with mortality: prehospital system delay had an adjusted HR of 1.10 (95% CI, 1.02-1.18; P=.02), and door-to-balloon delay had an adjusted HR of 1.14 (95% CI, 1.05-1.24; P=.001) per 1-hour delay (Table 4).

COMMENT

To our knowledge, this study is the first to evaluate the association between system delay and outcome in an unselected cohort of patients with STEMI transported by an EMS and treated with primary PCI. In contrast to treatment and patient delay, system delay was independently associated with mortality. Moreover, it was the highest ranking among the covariates studied that can be modified in the acute phase, and it comprises the total delay that is modifiable by the health care system.

The mortality benefit obtained by earlier initiation of reperfusion therapy is difficult to assess in observational studies. Previous studies have plotted mortality according to treatment delay and reported a nearly horizontal association between time to reperfusion and mortality.[6,23] However, confounding and selection bias may hamper such analyses. High-risk patients tend to present early, whereas those presenting late have already survived the early hours, ie, the period in which they are at highest risk of death. This so-called survivor-cohort effect is supported by Löwel et al.[8] In the prefibrinolytic era, they reported that 88% of patients with AMI who contacted the health care system within 1 hour of symptom onset died during the prehospital phase or in the hospital. In comparison, among patients who contacted the health care system from 1 to 24 hours after symptom onset, 43% died during the prehospital phase or in the hospital.[8,24]

This finding is consistent with those reported by Aquaro et al and Nallamothu et al, who demonstrated that early presenters had the highest risk scores[11] and the largest ST-segment elevations.[25] Without reperfusion therapy, patients presenting early have the highest mortality, but with optimal reperfusion therapy, they may attain nearly the same mortality as those presenting late.[10] This phenomenon may explain the neutral association previously observed between treatment delay and mortality.[6,23,26] Paradoxically, the phenomenon also supports a time-dependent benefit of primary PCI, because it implies that the benefit of primary PCI is more pronounced in the early hours after symptom onset and confirms that the reduction in mortality achieved by earlier reperfusion therapy is underestimated when evaluated from observational data.[10]

We were able to adjust for major risk factors in the analysis of the effect of treatment delay and patient delay and hence able to reduce the effect of confounding. Nevertheless, we found no association with mortality. This may be explained by the selection bias, which is still present. It also may be related to the fact that patient delay and treatment delay depend on the time from onset of symptoms and are affected by substantial measurement error, because patients have to recall this onset. Moreover, the biologically relevant point is the time of onset of infarction, which may not to be identical to the time of first symptoms.

Door-to-balloon delay is suggested by the D2B Alliance as "A key indicator of quality of care in STEMI patients treated with [primary] PCI."[27] Undoubtedly, this parameter is associated with mortality,[7,28,29] as is also documented in the present study. It is useful for monitoring primary PCI performance at PCI centers, and various initiatives have successfully reduced door-to-balloon delay.[30] However, door-to-balloon delay comprises only a minor part of the health care system delay. A strategy of prehospital diagnosis and rerouting patients directly to a catheterization laboratory may shorten system delay by as much as 1 hour,[31] although such a strategy may be associated with longer door-to-balloon delay, because shorter notice gives the catheterization laboratory less time to prepare for the arrival of field-triaged patients.[31] Therefore, door-to-balloon delay should be used as a performance measure at the PCI centers to ensure a focus on optimal center performance, but it may not be an ideal general health care system performance measure in patients with STEMI.

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The effects of different primary PCI delays on mortality cannot be subject to randomized assessments. Given that confounding, selection bias, and recall bias may hamper patient and treatment delays, it seems reasonable that the optimal way to evaluate the association between delayed initiation of reperfusion therapy and mortality in a nonrandomized study is to focus on system delay. Even though patient and treatment delays are theoretically applicable to all patients, data on these delays are available only in the selected cohort of patients surviving until making contact with the health care system and only if the patient is able to recall the exact time of symptom onset. Moreover, it is questionable if the exact onset of AMI can be determined, because it is based on subjective information and the AMI may have been preceded by hours of unstable angina. Accordingly, the lack of an association between patient delay and mortality may be explained by confounding, selection bias, recall bias, and measure-

Table 3. Characteristics of Patients With ST-Segment Elevation Myocardial Infarction Transported by the Emergency Medical Service and Treated With Primary Percutaneous Coronary Intervention, Stratified According to System Delay (N = 6209)

	System Delay, min								
	0-60 (n = 347)		61-120 (n = 2643)		121-180 (n = 2092)		181-360 (n = 1127)		
Variables	No. (%)	Valid Cases	No. (%)	Valid Cases	No. (%)	Valid Cases	No. (%)	Valid Cases	*P* Value[a]
Demographics									
Age, median (IQR), y	62 (54-72)	347	63 (55-73)	2643	65 (56-75)	2092	67 (58-77)	1127	<.001
Women	91 (26)	347	645 (24)	2643	584 (28)	2092	334 (30)	1127	.003
Comorbid conditions									
Treated hypertension	81 (27)	297	615 (31)	2008	449 (30)	1494	260 (34)	775	.18
Diabetes	33 (11)	300	194 (9.4)	2074	158 (10)	1537	98 (12)	814	.18
Previous myocardial infarction	16 (5.7)	283	197 (9.9)	1982	133 (9.1)	1458	127 (16)	787	<.001
Previous PCI	18 (6.4)	280	121 (6.1)	1979	77 (5.3)	1456	63 (8.0)	791	.10
Previous congestive heart failure	7 (2.1)	327	74 (3.0)	2453	59 (3.0)	1959	53 (5.0)	1054	.007
Active or previous smoker	231 (81)	287	1585 (82)	1944	1105 (78)	1414	555 (76)	733	.005
Delays, transportation, and triage									
Delay, median (IQR), min[b]									
Treatment	170 (99-265)	347	180 (125-277)	2643	221 (173-315)	2092	299 (243-378)	1127	<.001
Patient	131 (60-226)	337	99 (45-199)	2435	92 (41-188)	1827	86 (39-173)	894	<.001
Prehospital system	29 (23-35)	201	55 (41-71)	1920	101 (50-123)	1598	159 (55-193)	933	<.001
Door-to-balloon	19 (15-23)	199	28 (20-46)	1901	37 (24-92)	1593	55 (26-154)	933	<.001
Transportation, median (IQR), km	7 (4-37)	347	38 (13-59)	2643	74 (33-106)	2092	90 (47-133)	1127	<.001
Field-triaged to PCI center	153 (44)	347	1413 (54)	2643	495 (24)	2092	122 (11)	1127	<.001
Clinical characteristics									
Body mass index, median (IQR)[c]	26 (24-29)	165	26 (24-29)	1446	26 (24-29)	963	26 (24-29)	486	.97
Blood pressure, median (IQR), mm Hg									
Systolic	130 (115-149)	189	130 (115-147)	1598	125 (110-140)	1141	125 (110-140)	609	<.001
Diastolic	78 (67-85)	189	79 (68-85)	1592	75 (65-80)	1135	72 (60-80)	605	<.001
Killip class		347		2641		2090		1126	
I	316 (91)		2418 (92)		1899 (91)		996 (89)		.15
II	16 (4.6)		117 (4.4)		100 (4.8)		64 (5.7)		
III	7 (2.0)		60 (2.3)		45 (2.2)		28 (2.5)		
IV	8 (2.3)		46 (1.7)		6 (2.2)		38 (3.4)		
Anterior STEMI or BBBMI	148 (47)	312	1085 (44)	2441	868 (46)	1895	466 (47)	985	.40
Culprit vessel		327		2557		2039		1086	
Left main artery	3 (0.9)		39 (1.5)		31 (1.5)		26 (2.4)		.06
Left anterior descending artery	158 (48)		1091 (43)		888 (44)		458 (42)		
Circumflex artery	37 (11)		359 (14)		274 (13)		179 (17)		
Right coronary artery	129 (39)		1068 (42)		846 (42)		423 (39)		
Multivessel disease	140 (44)	319	1084 (45)	2419	929 (48)	1936	544 (52)	1041	<.001

Abbreviations: BBBMI, bundle-branch block myocardial infarction; IQR, interquartile range; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.
[a] By Kruskal-Wallis test.
[b] Door-to-balloon delay indicates time from arrival at PCI center to primary PCI; patient delay, time from symptom onset to contact with the health care system; prehospital system delay, time from contact with the health care system to arrival at the PCI center; system delay, time from contact with the health care system to primary PCI.
[c] Calculated as weight in kilograms divided by height in meters squared.

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ment bias, but neither this observation nor the lack of any long-lasting effect of media campaigns on patient or treatment delays should deter encouraging patients to seek medical help as soon as possible after the onset of symptoms.[32,33]

In comparison, system delay is by definition only defined in patients surviving until contact with the health care system; hence, studying the effect of system delay is not affected by selection bias from survival. It can be studied in all patients contacting the health care system, and it is an objective parameter not prone to recall bias. Most importantly, however, system delay and its components appear to be the only risk factors that can be modified in the acute phase, by optimizing prehospital and in-hospital triage.[31,34]

This study has a number of limitations. System delay may have been underestimated, because data were not available on contacts with general practitioners in the acute phase. In reviewing a sample of 130 hospital records, we found that 6% of the EMS-transported patients were not in the EMS registry, resulting in a minor underestimation of the number of patients transported by the EMS. Usually, the time of the first balloon inflation is used as the time of reperfusion, but reperfusion often takes place before balloon inflation (eg, during wiring or thrombectomy). Therefore, the time of first wiring of the vessel might be a better parameter for representing the time of reperfusion.[16] However, data on first wiring were not available, and because insertion of the guiding catheter is followed within a few minutes by the first coronary intervention, we decided to use the time of guiding-catheter insertion as the time of first intervention. Acknowledging the widespread acceptance of the door-to-balloon delay as a performance measure, we decided to use the door-to-balloon delay synonymously with the time from arrival at the PCI center to the first insertion of the guiding catheter.

We conclude that health care system delay is valuable as a performance measure when patients with STEMI are treated with primary PCI, because it is associated with mortality, it consti-

Table 4. Multivariable Cox Regression Analysis of Covariates Associated With Long-term Mortality in Patients With ST-Segment Elevation Myocardial Infarction Treated With Primary Percutaneous Coronary Intervention (N = 6209)[a]

Covariates Remaining Significant in Models[b]	Model 1		Model 2		Model 3	
	HR (95% CI)	*P* Value[c]	HR (95% CI)	*P* Value[c]	HR (95% CI)	*P* Value[c]
Demographics						
Age, per 1-y increase	1.067 (1.060-1.074)	<.001	1.066 (1.060-1.073)	<.001	1.066 (1.060-1.073)	<.001
Comorbid conditions						
Diabetes	1.97 (1.64-2.37)	<.001	1.94 (1.61-2.33)	<.001	1.95 (1.63-2.35)	<.001
Previous congestive heart failure	1.73 (1.39-2.16)	<.001	1.78 (1.43-2.22)	<.001	1.78 (1.43-2.22)	<.001
Previous or current smoking	1.24 (1.05-1.48)	.01	1.25 (1.05-1.48)	.01	1.26 (1.06-1.50)	.008
Delays, per 1-h increase[d]						
Treatment	1.00 (0.98-1.03)	.54				
Patient			1.00 (0.98-1.03)	.63	1.00 (0.98-1.03)	.64
System			1.10 (1.04-1.16)	.002		
Prehospital system					1.10 (1.02-1.18)	.02
Door-to-balloon					1.14 (1.05-1.24)	.001
Clinical characteristics						
Systolic blood pressure, mm Hg						
<110	1 [Reference]		1 [Reference]		1 [Reference]	
110-129	0.76 (0.63-0.92)	.004	0.74 (0.61-0.90)	.004	0.74 (0.61-0.89)	.001
130-144	0.66 (0.55-0.81)	<.001	0.68 (0.56-0.82)	<.001	0.66 (0.55-0.80)	<.001
≥145	0.52 (0.40-0.66)	<.001	0.53 (0.41-0.67)	<.001	0.52 (0.41-0.67)	<.001
Killip class						
I	1 [Reference]		1 [Reference]		1 [Reference]	
II	1.61 (1.29-2.01)	<.001	1.65 (1.33-2.06)	<.001	1.63 (1.31-2.03)	<.001
III	2.47 (1.92-3.18)	<.001	2.55 (1.98-3.28)	<.001	2.51 (1.95-3.23)	<.001
IV	4.73 (3.69-6.06)	<.001	4.71 (3.67-6.05)	<.001	4.57 (3.56-5.87)	<.001
Anterior STEMI or BBBMI	1.30 (1.14-1.48)	<.001	1.29 (1.13-1.47)	<.001	1.29 (1.13-1.47)	<.001
Multivessel disease	1.53 (1.34-1.76)	<.001	1.51 (1.32-1.73)	<.001	1.51 (1.31-1.73)	<.001

Abbreviations: BBBMI, bundle-branch block myocardial infarction; CI, confidence interval; HR, hazard ratio; STEMI, ST-segment elevation myocardial infarction.
[a]Adjusted for sex, body mass index, history of previous myocardial infarction, and treatment for hypertension.
[b]Nonoverlapping intervals of treatment delay were considered for inclusion in the multivariable models: model 1 considered treatment delay, model 2 considered patient and system delay, and model 3 considered patient, prehospital system, and door-to-balloon delay.
[c]By multivariable Cox regression.
[d]Door-to-balloon delay indicates time from arrival at the PCI center to primary percutaneous coronary intervention (PCI); patient delay, time from symptom onset to contact with the health care system; prehospital system delay, time from contact with the health care system to arrival at the PCI center; system delay, time from contact with the health care system to primary PCI.

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tutes the part of treatment delay modifiable by the health care system in the acute phase, and it applies to patients field-triaged directly to the PCI center as well as to patients transferred from local hospitals. Increased focus on the total health care system delay may optimize triage of patients with STEMI and may be the key to further improving survival of these patients.

Author Contributions: Dr Terkelsen had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Terkelsen, Maeng, Trautner, Thuesen, Lassen.
Acquisition of data: Terkelsen, Sørensen, Jensen, Tilsted, Trautner, Lassen.
Analysis and interpretation of data: Terkelsen, Sørensen, Maeng, Trautner, Vach, Johnsen, Lassen.
Drafting of the manuscript: Terkelsen, Sørensen, Jensen, Thuesen, Lassen.
Critical revision of the manuscript for important intellectual content: Terkelsen, Sørensen, Maeng, Jensen, Tilsted, Trautner, Vach, Johnsen, Lassen.
Statistical analysis: Terkelsen.
Obtained funding: Terkelsen, Sørensen, Lassen.
Administrative, technical, or material support: Terkelsen, Sørensen, Jensen, Trautner, Lassen.
Study supervision: Maeng, Jensen, Tilsted, Johnsen, Thuesen, Lassen.
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Effect of Door-to-Balloon Time on Mortality in Patients With ST-Segment Elevation Myocardial Infarction

Robert L. McNamara, MD, MHS,* Yongfei Wang, MS,* Jeph Herrin, PHD,* Jeptha P. Curtis, MD,* Elizabeth H. Bradley, PHD,† David J. Magid, MD, MPH,§‖ Eric D. Peterson, MD, MPH,¶ Martha Blaney, PHARMD,# Paul D. Frederick, PHD,** Harlan M. Krumholz, MD, SM,*††‡‡† for the NRMI Investigators

New Haven, Connecticut; Denver, Colorado; Durham, North Carolina; South San Francisco, California; and Seattle, Washington

OBJECTIVES We sought to determine the effect of door-to-balloon time on mortality for patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI).

BACKGROUND Studies have found conflicting results regarding this relationship.

METHODS We conducted a cohort study of 29,222 STEMI patients treated with PCI within 6 h of presentation at 395 hospitals that participated in the National Registry of Myocardial Infarction (NRMI)-3 and -4 from 1999 to 2002. We used hierarchical models to evaluate the effect of door-to-balloon time on in-hospital mortality adjusted for patient characteristics in the entire cohort and in different subgroups of patients based on symptom onset-to-door time and baseline risk status.

RESULTS Longer door-to-balloon time was associated with increased in-hospital mortality (mortality rate of 3.0%, 4.2%, 5.7%, and 7.4% for door-to-balloon times of ≤90 min, 91 to 120 min, 121 to 150 min, and >150 min, respectively; p for trend <0.01). Adjusted for patient characteristics, patients with door-to-balloon time >90 min had increased mortality (odds ratio 1.42; 95% confidence interval [CI] 1.24 to 1.62) compared with those who had door-to-balloon time ≤90 min. In subgroup analyses, increasing mortality with increasing door-to-balloon time was seen regardless of symptom onset-to-door time (≤1 h, >1 to 2 h, >2 h) and regardless of the presence or absence of high-risk factors.

CONCLUSIONS Time to primary PCI is strongly associated with mortality risk and is important regardless of time from symptom onset to presentation and regardless of baseline risk of mortality. Efforts to shorten door-to-balloon time should apply to all patients. (J Am Coll Cardiol 2006;47: 2180–6) © 2006 by the American College of Cardiology Foundation

Time to reperfusion for patients with ST-segment elevation myocardial infarction (STEMI) consistently predicts mortality for fibrinolytic therapy (1–3). In contrast, studies have found conflicting results regarding the relationship between mortality and time to reperfusion with primary percutaneous coronary intervention (PCI). Some investigators have found lower mortality for shorter symptom onset-to-reperfusion time for all patients (4) or just certain subgroups such as high-risk patients (5) or those presenting within 2 h of symptom onset (6). Other studies found no lower mortality for shorter symptom onset-to-balloon time but did find lower mortality for shorter door-to-balloon time (7,8). Finally, some studies failed to find an association between either symptom onset-to-balloon time or door-to-balloon time and mortality (9,10).

Although the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for management of patients with STEMI recommend door-to-balloon times of 90 min or less (11,12), a minority of patients are currently treated within this time period, and this pattern has not changed recently (13). The perception that time to reperfusion is less important in PCI (9,10) may contribute to the current inertia in performance. To evaluate the effect of door-to-balloon time on mortality in these patient groups, we used detailed patient-level and hospital-level longitudinal data from a national sample of patients with STEMI admitted from 1999 to 2002 from the National Registry of Myocardial Infarction (NRMI)-3 and -4 (14).

METHODS

Study design and sample. We used NRMI, a voluntary acute myocardial infarction (AMI) registry sponsored by

From the *Department of Medicine, Section of Cardiovascular Medicine, †Department of Epidemiology and Public Health, Section of Health Policy and Administration, and ‡Robert Wood Johnson Clinical Scholars Program, Yale University School of Medicine, New Haven, Connecticut; §Clinical Research Unit, Kaiser Permanente, Denver, Colorado; ‖Departments of Emergency Medicine and Preventive Medicine and Biometrics, University of Colorado Health Sciences Center, Denver, Colorado; ¶Duke Clinical Research Institute, Duke University, Durham, North Carolina; #Genentech Inc., South San Francisco, California; **Ovation Research Group, Seattle, Washington; and the ††Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, Connecticut. This research was supported by the National Heart, Lung, and Blood Institute, R01HL072575. Dr. Blaney is employed by Genentech, Inc.

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Abbreviations and Acronyms

ACC = American College of Cardiology
AHA = American Heart Association
AMI = acute myocardial infarction
CI = confidence interval
ECG = electrocardiogram
NRMI = National Registry of Myocardial Infarction
PCI = percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction

Genentech Inc. (South San Francisco, California), to define a cohort of patients with STEMI who received acute reperfusion therapy with primary PCI. The NRMI criteria (15,16) include a diagnosis of AMI according to the *International Classification of Diseases, Ninth Revision, Clinical Modification* (code 410.X1) and any one of the following criteria: total creatine kinase or creatine kinase-MB that was two or more times the upper limit of the normal range or elevations in alternative cardiac markers; electrocardiographic evidence of AMI or nuclear medicine testing, echocardiography, or autopsy evidence of AMI. During our study period of January 1, 1999, to December 31, 2002, there were 830,473 AMI admissions in NRMI. The following patients were excluded sequentially: patients transferred to or from another acute care institution (n = 341,730); with neither ST-segment elevation (2+ leads) nor left bundle branch block on the first electrocardiogram (ECG) (n = 334,013); with AMI symptom onset after the admission date and time (n = 4,305); with a nondiagnostic first ECG (e.g., the first ECG did not show ST-segment elevation or left bundle branch block; n = 14,314); with diagnostic ECG that preceded hospital presentation by more than 1 h (prehospital ECG), or with time from door-to-diagnostic ECG that was more than 6 h or missing (n = 6,467); who did not receive primary PCI (n = 92,772); with door-to-balloon times that were negative, more than 6 h, or missing (n = 925); and with unknown time of symptom onset (n = 4,804). In addition, to avoid including hospitals that performed primary PCI uncommonly, patients treated in hospitals reporting fewer than 20 PCI patients over the four-year time period (n = 1,921) were excluded. The final cohort included 29,222 patients from 395 hospitals. Mortality status at the time of discharge was known for all patients.

Data collection and measures. Our outcome was in-hospital mortality, and the principal independent variable was door-to-balloon time, which is the time from hospital arrival to balloon inflation, derived from the corresponding date/time noted in the medical record and recorded in the NRMI case report form. Patients were stratified based on their time from symptom onset-to-door time (≤1 h, >1 to 2 h, >2 h) and whether they had ACC/AHA high-risk factors (anterior/septal location, diabetes mellitus, heart rate >100 beats/min, systolic blood pressure <100 mm Hg) (11).

Other patient-level variables included age (<65 years, 65 to 79 years, ≥80 years), gender, race/ethnicity (white, black, Hispanic, other), insurance status, and clinical characteristics. Clinical characteristics consisted of medical history (current smoker, chronic renal insufficiency, previous AMI, hypertension, family history of coronary artery disease, hypercholesterolemia, congestive heart failure, previous percutaneous transluminal coronary angioplasty, previous coronary artery bypass graft surgery, chronic obstructive pulmonary disease, stroke, angina, diabetes); presentation characteristics (time from symptom onset-to-presentation, whether a prehospital ECG was performed, the admission time of day [day, evening, or night], admission day of week [weekday or weekend], chest pain at presentation, systolic blood pressure, heart rate, heart failure); and the results of the diagnostic ECG (number of leads with ST-segment elevation, AMI location, ST-segment depression, nonspecific ST/T-wave changes, Q-wave). Calendar time, measured as the number of days between January 1, 1999, and the hospital admission date, was included as an independent variable to account for any secular trends as well as for differing reporting periods by hospitals.

Statistical analysis. We first examined the bivariate association between patient characteristics and in-hospital mortality, using chi-square tests to assess for the association between categorical variables and in-hospital mortality and *t* tests or F tests to assess for the association between continuous variables and in-hospital mortality.

We then examined the bivariate association between door-to-balloon time and in-hospital mortality with door-to-balloon time as a categorical variable. We did this for the whole cohort and stratified by symptom onset-to-door time (≤1 h, >1 to 2 h, >2 h) and presence or absence of anterior/septal location, diabetes mellitus, heart rate >100 beats/min, systolic blood pressure <100 mm Hg, and any of these baseline risk factors.

For the independent effect of door-to-balloon time on in-hospital mortality, we used a multivariable logistic regression model using in-hospital death as the dependent variable. Because NRMI enrolls hospitals that then report patients, we could not assume that measurements were independent of hospital; assessment of intraclass correlations indicated that variation in both time to treatment (p = 0.1099, 95% CI 0.0916 to 0.1282) and mortality (p = 0.0084, 95% CI 0.0052 to 0.0434) was partly explained by hospital. Thus, we used hierarchical models to account for clustering of patients within hospitals. Random effects were specified for the main intercept and the coefficients of calendar time in the model. We replicated the model in all the strata of symptom onset-to-door time and baseline risk factors, as defined above; the stratification variable was not included in the corresponding subgroup model. We also estimated a final set of models using the whole cohort, each of which included the interaction between door-to-balloon time and one of these stratification variables. We performed secondary analyses that included the 2.0% of patients

Table 1. Patient Characteristics, Door-to-Balloon Time, and In-Hospital Mortality

Description	Prevalence n (%)	Door-to-Balloon Time Median, min (Quartile Range)	Door-to-Balloon Time p	Mortality n (%)	Mortality p
All	29,222 (100.00)	102 (54)		1,329 (4.55)	
Demographics					
Age			<0.0001		<0.0001
<65 yrs	17,314 (59.25)	99 (52)		356 (2.06)	
65–80 yrs	9,425 (32.25)	106 (56)		623 (6.61)	
>80 yrs	2,483 (8.50)	115 (59)		350 (14.10)	
Gender					
Male	20,712 (70.88)	100 (52)	<0.0001	739 (3.57)	<0.0001
Female	8,510 (29.12)	108 (57)		590 (6.93)	
Race			<0.0001		0.7847
White	25,082 (85.83)	101 (53)		1,147 (4.57)	
Black	1,428 (4.89)	118 (63)		58 (4.06)	
Hispanic	971 (3.32)	114 (61)		47 (4.84)	
Other	1,741 (5.96)	102 (52)		77 (4.42)	
Health insurance			<0.0001		<0.0001
Medicare only	5,218 (17.86)	107 (58)		397 (7.61)	
Medicare and (commercial or other)	5,037 (17.24)	107 (57)		381 (7.56)	
Medicare and Medicaid	473 (1.62)	113 (62)		51 (10.78)	
Commercial	13,483 (46.14)	100 (52)		313 (2.32)	
Medicaid only	751 (2.57)	104 (56)		37 (4.93)	
Veterans Administration	156 (0.53)	95 (55)		6 (3.85)	
Other	1,302 (4.46)	98 (53)		49 (3.76)	
Self	2,502 (8.56)	97 (50)		80 (3.20)	
Unknown	300 (1.03)	105 (61)		15 (5.00)	
Medical history					
Current smoker	11,320 (38.74)	99 (52)	<0.0001	282 (2.49)	<0.0001
Chronic renal insufficiency	698 (2.39)	117 (65)	<0.0001	109 (15.62)	<0.0001
Diabetes mellitus	5,440 (18.62)	110 (59)	<0.0001	380 (6.99)	<0.0001
Previous myocardial infarction	4,800 (16.43)	106 (59)	<0.0001	237 (4.94)	0.1565
Hypertension	14,218 (48.66)	105 (55)	<0.0001	749 (5.27)	<0.0001
Hypercholesterolemia	11,065 (37.87)	101 (54)	0.0124	327 (2.96)	<0.0001
Family history of coronary artery disease	8,490 (29.05)	101 (53)	0.0005	230 (2.71)	<0.0001
Congestive heart failure	913 (3.12)	118 (65)	<0.0001	126 (13.80)	<0.0001
Percutaneous coronary intervention	4,259 (14.57)	104 (57)	0.0032	150 (3.52)	0.0005
Coronary artery bypass	1,698 (5.81)	120 (65)	<0.0001	109 (6.42)	0.0001
Chronic obstructive pulmonary disease	2,319 (7.94)	107 (58)	<0.0001	152 (6.55)	<0.0001
Stroke	1,357 (4.64)	114 (65)	<0.0001	149 (10.98)	<0.0001
Angina	2,312 (7.91)	105 (58)	0.0288	123 (5.32)	0.0633
Presentation					
Prehospital 12-lead ECG	2,915 (9.98)	83 (50)	<0.0001	103 (3.53)	0.0056
Chest pain at presentation					<0.0001
No	1,527 (5.23)	123 (73)	<0.0001	336 (22.00)	
Yes	27,375 (93.68)	101 (52)	<0.0001	937 (3.42)	
Unknown	320 (1.10)	111 (61)	<0.0001	56 (17.50)	
Systolic blood pressure			<0.0001		<0.0001
<100 mm Hg	2,963 (10.14)	96 (51)		452 (15.25)	
100–180 mm Hg	23,433 (80.19)	102 (54)		786 (3.35)	
>180 mm Hg	2,724 (9.32)	112 (57)		53 (1.95)	
Unknown	102 (0.35)	117 (69)		38 (37.25)	
Heart rate			<0.0001		<0.0001
<50 beats/min	1,766 (6.04)	95 (48)		143 (8.10)	
50–100 beats/min	23,969 (82.02)	102 (53)		793 (3.31)	
>100 beats/min	3,376 (11.55)	113 (64)		355 (10.52)	
Unknown	111 (0.38)	118 (65)		38 (34.23)	
First assessment of heart failure			<0.0001		<0.0001
No congestive heart failure	25,908 (88.66)	101 (53)		722 (2.79)	
Rales/jugular venous distension	1,895 (6.48)	110 (60)		195 (10.29)	
Pulmonary edema	536 (1.83)	124 (76)		105 (19.59)	
Cardiogenic shock	883 (3.02)	105 (56)		307 (34.77)	

Continued on next page

Table 1 Continued

Description	Prevalence n (%)	Door-to-Balloon Time Median, min (Quartile Range)	p	Mortality n (%)	p
First 12-lead ECG					
Anterior/septal location	10,631 (36.38)	104 (55)	<0.0001	656 (6.17)	<0.0001
No. of leads with ST-segment elevation			<0.0001		<0.0001
Left bundle branch block	580 (1.98)	132 (84)		85 (14.66)	
2	3,174 (10.86)	118 (67)		129 (4.06)	
3 and 4	19,609 (67.10)	101 (52)		728 (3.71)	
5 and more	5,565 (19.04)	97 (48)		367 (6.59)	
Unknown	294 (1.01)	109 (62)		20 (6.80)	
First 12-lead ECG: ST-segment depression	13,758 (47.08)	99 (50)	<0.0001	584 (4.24)	0.0190
Nonspecific ST or T-wave deltas	856 (2.93)	114 (71)	<0.0001	31 (3.62)	0.1867
Q-wave (acute infarct zone)	3,565 (12.20)	106 (57)	<0.0001	196 (5.50)	0.0037
Times					
Symptom onset-to-door			<0.0001		0.0073
≤1 h	9,487 (32.47)	96 (50)		462 (4.87)	
>1–2 h	8,557 (29.28)	99 (50)		339 (3.96)	
>2 h	11,178 (38.25)	110 (61)		528 (4.72)	
Time/weekday of the admission day			<0.0001		0.3824
Weekday 8:00AM–3:59PM	10,916 (37.36)	90 (52)		492 (4.51)	
Weekday 4:00PM–11:59PM	5,690 (19.47)	105 (51)		280 (4.92)	
Weekday 12:00AM–7:59AM	4,827 (16.52)	109 (56)		198 (4.10)	
Weekend 8:00AM–3:59PM	3,639 (12.45)	110 (55)		160 (4.40)	
Weekend 4:00PM–11:59PM	2,412 (8.25)	109 (49)		120 (4.98)	
Weekend 12:00AM–7:59AM	1,738 (5.95)	119 (54)		79 (4.55)	
Calendar time			<0.0001		0.0531
First year	7,978 (27.30)	105 (57)		394 (4.94)	
Second year	7,238 (24.77)	102 (54)		344 (4.75)	
Third year	7,791 (26.66)	100 (53)		339 (4.35)	
Fourth year	6,215 (21.27)	102 (52)		252 (4.05)	

ECG = electrocardiogram.

transferred out and assumed they survived to discharge. To evaluate the potential effect of decreasing length of stay on our results, we also performed secondary analyses that evaluated mortality within 72 h. The results of both of these secondary analyses were not substantially different from the original.

Statistical analyses were performed using SAS version 9.1 (SAS Institute Inc., Cary, North Carolina), HLM 5.04 for Windows (SSI, Lincolnwood, Illinois), and Stata version 8.0 (Stata Corp., College Station, Texas). The investigators had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

RESULTS

Sample characteristics. The cohort was predominantly male (71%) and white (86%), with a mean age of 61.6 years (Table 1). A substantial proportion of patients had a prior diagnosis of coronary artery disease and/or traditional cardiac risk factors. Almost 10% received a prehospital ECG, 94% had chest pain, 11% were in overt heart failure, and 2% had left bundle branch block. A total of 62% presented within 2 h of symptom onset. There were 58% of the patients who had an ACC/AHA high-risk feature (36% with anterior/septal location, 19% with diabetes mellitus, 12% with heart rate ≥100 beats/min, and 10% with systolic blood pressure <100 mm Hg).

Association with in-hospital mortality. In unadjusted analysis, many patient characteristics were significantly associated with both door-to-balloon time and in-hospital mortality (Table 1). Notable exceptions were race/ethnicity and time/day of presentation. In hierarchical multivariable analysis, many patient characteristics continued to be significantly associated with mortality (Table 2). In particular, all four ACC/AHA high-risk factors were associated with increased mortality. In contrast, symptom onset-to-door time was not significantly associated with mortality.

Door-to-balloon time and mortality. In-hospital mortality increased significantly with increasing door-to-balloon times (Fig. 1). This relationship was seen in patients regardless of symptom onset-to-door time (Fig. 2). The association between shorter door-to-balloon times and lower mortality was seen both for patients with ACC/AHA high-risk factors and for those without these risk factors (Fig. 3). In hierarchical multivariable analysis, the odds of in-hospital mortality increased with increasing door-to-balloon time for all subgroups, whether by symptom onset-to-door time (Fig. 4A) or presence or absence of risk factors (Fig. 4B).

Table 2. Factors Independently Associated With In-Hospital Mortality in Multivariate Hierarchical Logistic Regression Model ($p < 0.01$)

Description	Odds Ratio (95% Confidence Interval)	p
Demographics		
Age		
<65 yrs	0.41 (0.36–0.47)	<0.0001
>80 yrs	1.98 (1.72–2.27)	<0.0001
Female	1.27 (1.14–1.42)	<0.0001
Medical history		
Current smoker	0.74 (0.64–0.84)	<0.0001
Chronic renal insufficiency	1.70 (1.36–2.13)	<0.0001
Diabetes	1.38 (1.22–1.57)	<0.0001
Hypercholesterolemia	0.63 (0.56–0.72)	<0.0001
Family history of coronary artery disease	0.82 (0.71–0.94)	0.0056
Percutaneous coronary intervention	0.74 (0.63–0.88)	0.0005
Coronary artery bypass	1.40 (1.14–1.72)	0.0014
Stroke	1.44 (1.20–1.74)	0.0001
Presentation		
Chest pain at presentation		
No	3.63 (3.13–4.20)	<0.0001
Unknown	3.76 (2.76–5.12)	<0.0001
Systolic blood pressure		
<100 mm Hg	3.75 (3.27–4.30)	<0.0001
>180 mm Hg	0.43 (0.33–0.55)	<0.0001
Unknown	4.59 (2.23–9.46)	<0.0001
Heart rate		
<50 beats/min	0.84 (0.69–1.03)	0.0992
>100 beats/min	2.31 (2.02–2.64)	<0.0001
Unknown	2.27 (1.08–4.75)	0.0299
First assessment of heart failure		
Rales/jugular venous distension	2.19 (1.87–2.56)	<0.0001
Pulmonary edema	3.30 (2.63–4.14)	<0.0001
Cardiogenic shock	7.25 (6.13–8.58)	<0.0001
First 12-lead electrocardiogram		
Anterior/septal location	1.81 (1.61–2.03)	<0.0001
No. of leads with ST-segment elevation		
Left bundle branch block	2.20 (1.63–2.98)	<0.0001
3 and 4	0.98 (0.81–1.18)	0.8147
5 and more	1.44 (1.18–1.77)	0.0005
Unknown	1.43 (0.86–2.38)	0.1659
Q-wave (acute infarct zone)	1.24 (1.06–1.45)	0.0065
Times		
Door-to-balloon time per 30 min	1.08 (1.05–1.11)	<0.0001

DISCUSSION

In this large observational study of patients with STEMI undergoing primary PCI, we found clear evidence of increased mortality with longer door-to-balloon times. This association was seen for patients regardless of symptom onset-to-door time and for patients with and without high-risk factors. These findings support the current guideline-based recommendations for rapid PCI and provide evidence that this recommendation is valid for all patients with STEMI and presentation within 6 h of the onset of symptoms.

Time from symptom onset to reperfusion. Shorter time from symptom onset to the administration of fibrinolytic therapy has been consistently shown to be associated with lower mortality for patients with STEMI (1–3,17,18). However, a meta-analysis of randomized trials found time from symptom onset to reperfusion related to mortality for fibrinolytic therapy in all patients, but for PCI only in those treated within 2 h (10). Large single-center observational studies have found similar results (4,6). In contrast, analysis of previous patients in NRMI-1 and -2 found no significant relationship between symptom onset-to-balloon time and mortality (7). Similarly, our study of NRMI-3 and -4 did not find improved survival for patients with decreased symptom onset-to-door time after adjusting for patient characteristics. In support of our findings, myocardial salvage has been found to be related to time from symptom onset to fibrinolytic therapy but independent of time from symptom onset to balloon (19). In addition to biological explanations, methodological issues may account for the poor relationship. First, the accuracy of the time of symptom onset is limited because of patient reporting error. Patients frequently are unsure of the exact time of symptom onset and usually give an estimate. Second, patients with less certainty of time of symptom onset may be more likely to get PCI than fibrinolytic therapy because of the increased risk of bleeding for fibrinolytic therapy. Finally, some of the deaths from STEMI may occur before hospital presentation. These patients would not be entered into the registry,

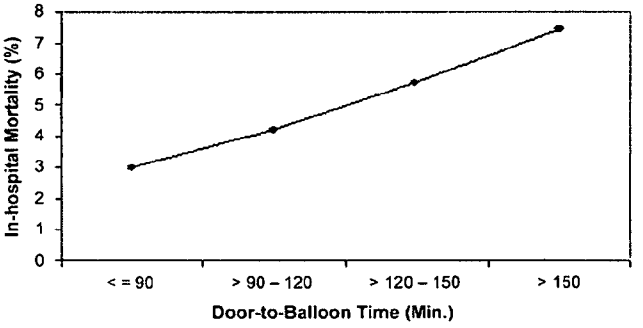

Figure 1. In-hospital mortality and door-to-balloon time; p for trend < 0.001.

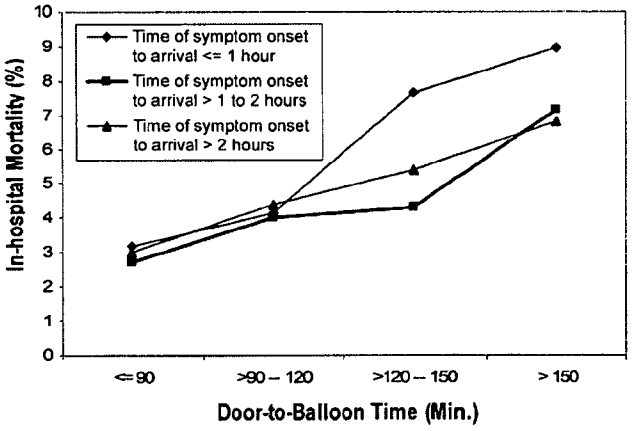

Figure 2. In-hospital mortality and door-to-balloon time in patients stratified by symptom onset-to-door time; p for trend < 0.001 for each line.

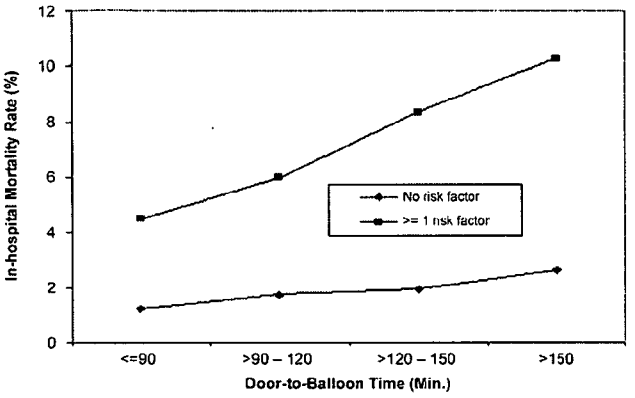

Figure 3. In-hospital mortality and door-to-balloon time in patients stratified by risk factor status; p for trend < 0.001 for each line. Risk factors include anterior/septal location, diabetes mellitus, heart rate >100 beats/min, systolic blood pressure <100 mm Hg.

and their absence likely dilutes the relationship between symptom onset-to-door time and mortality.

Door-to-balloon time. We evaluated a subset of the symptom onset-to-balloon time, the door-to-balloon time. In addition to improving the accuracy of estimate, door-to-balloon time is easier to influence because it is more under the control of individual hospitals and physicians than symptom onset-to-door time (20). As with symptom onset-to-balloon time, prior studies evaluating the association between door-to-balloon time and mortality have had mixed results. In the Global Use of Strategies to Open Occluded Arteries in Acute Coronary Syndromes (GUSTO) IIb trial, 30-day mortality rates increased progressively with time from randomization to balloon inflation, a close surrogate for door-to-balloon time (8). Analysis of patients in a prior cohort of NRMI also found increasing mortality with door-to-balloon times (7). Our study confirms this association in patients with more recent data as well as in various subgroups of patients.

In contrast, a recent study finding that symptom onset-to-balloon time was an independent predictor of mortality failed to find a similar relationship between door-to-balloon time and mortality (4). The discrepancy between these findings and those of our study may be explained by the fact that only 11% of patients in this single-center study had door-to-balloon times >90 min. In contrast, a majority of patients in the NRMI registry had door-to-balloon times in excess of 90 min. A low number of patients with times >90 min may decrease sensitivity of finding a relationship. In

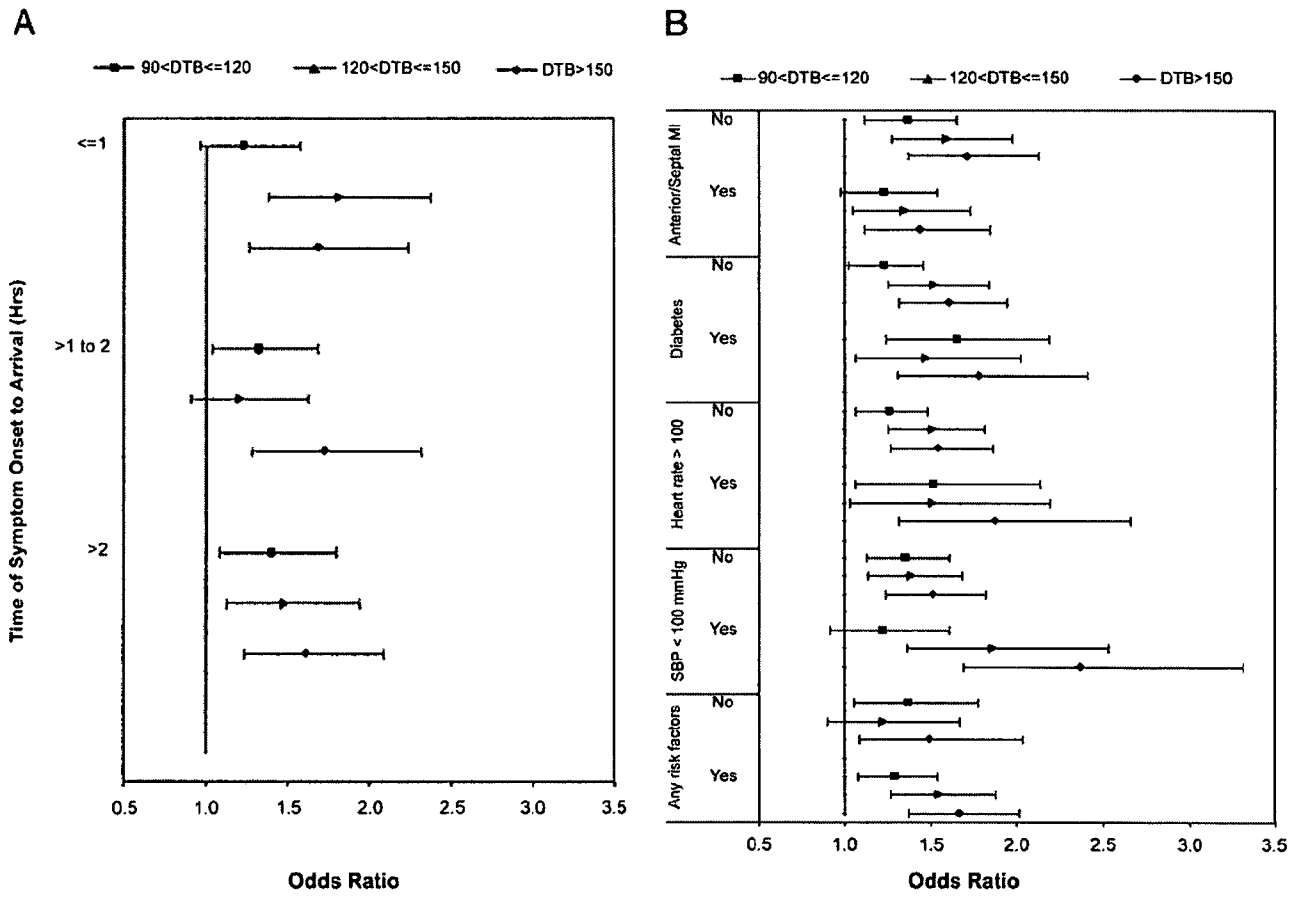

Figure 4. Independent effect of door-to-balloon time on in-hospital mortality in subgroups by **(A)** symptom onset-to-door time and **(B)** risk factor status. Reference group: door-to-balloon time <90 min. DTB = door-to-balloon; MI = myocardial infarction; SBP = systolic blood pressure.

one study, time to reperfusion was found to be important only in those at high risk (5). Our study found increasing door-to-balloon time to be related to increasing mortality for all risk groups. The magnitude of the mortality depended on the baseline risk, but the relationship with time did not differ.

Study limitations. Although this database is large and has been found to be reasonably generalizable (16), there are limitations. First, as mentioned previously, the time from symptom onset is obtained from the patient and may not be accurate. However, a more accurate time from symptom onset likely would not affect the main conclusions regarding door-to-balloon time. Second, there may be other risk factors that we did not examine that could identify a subgroup of patients in which door-to-balloon time is not important. Third, most of the patients were treated with door-to-balloon times greater than guideline recommendations. The importance of further reductions beyond 90 min has not been clarified. Fourth, these results cannot be extended to patients transferred from one hospital to another. Finally, door-to-balloon time may be a proxy for general quality of care, with the relationship with mortality reflecting unobserved quality measures.

Study implications. Efforts should continue to decrease the door-to-balloon time for all patients with STEMI undergoing primary PCI. Degree of urgency should not depend on time of symptom onset or baseline risk factors.

Reprint requests and correspondence: Dr. Harlan M. Krumholz, Yale University School of Medicine, 333 Cedar Street, PO Box 208088, New Haven, Connecticut 06520. E-mail: harlan.krumholz@yale.edu.

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BMJ

RESEARCH

Association of door-to-balloon time and mortality in patients admitted to hospital with ST elevation myocardial infarction: national cohort study

Saif S Rathore, MD/PhD student,[1] Jeptha P Curtis, assistant professor,[2] Jersey Chen, assistant professor,[2] Yongfei Wang, statistician,[3] Brahmajee K Nallamothu, assistant professor,[4] Andrew J Epstein, assistant professor,[5] Harlan M Krumholz, Harold H Hines Jr professor of medicine (cardiology) and epidemiology and public health,[2,3,6] for the National Cardiovascular Data Registry

[1]MD/PhD Program, Yale University School of Medicine, 367 Cedar Street, 316 ESH, New Haven, Connecticut 06510

[2]Section of Cardiovascular Medicine, Department of Internal Medicine, Yale University School of Medicine, 333 Cedar Street, 3 FMP, PO Box 208017, New Haven, Connecticut 06520

[3]Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, One Church Street, Suite 200, New Haven, Connecticut 06510

[4]Cardiovascular Center, CVC Cardiovascular Medicine, University of Michigan Medical School, SPC 5869, 1500 E Medical Center Drive, Ann Arbor, Michigan 48109

[5]Section of Health Policy and Administration, Yale School of Public Health, 60 College Street, Room 301, PO Box 208034, New Haven, Connecticut 06520

[6]Robert Wood Johnson Clinical Scholars Program, Yale University School of Medicine, PO Box 208088, New Haven, Connecticut 06520

Correspondence to: S S Rathore
saif.rathore@yale.edu

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ABSTRACT

Objective To evaluate the association between door-to-balloon time and mortality in hospital in patients undergoing primary percutaneous coronary intervention for ST elevation myocardial infarction to assess the incremental mortality benefit of reductions in door-to-balloon times of less than 90 minutes.

Design Prospective cohort study of patients enrolled in the American College of Cardiology National Cardiovascular Data Registry, 2005-6.

Setting Acute care hospitals.

Participants 43 801 patients with ST elevation myocardial infarction undergoing primary percutaneous coronary intervention.

Main outcome measure Mortality in hospital.

Results Median door-to-balloon time was 83 minutes (interquartile range 6-109, 57.9% treated within 90 minutes). Overall mortality in hospital was 4.6%. Multivariable logistic regression models with fractional polynomial models indicated that longer door-to-balloon times were associated with a higher adjusted risk of mortality in hospital in a continuous non-linear fashion (30 minutes=3.0%, 60 minutes=3.5%, 90 minutes=4.3%, 120 minutes=5.6%, 150 minutes=7.0%, 180 minutes =8.4%, P<0.001). A reduction in door-to-balloon time from 90 minutes to 60 minutes was associated with 0.8% lower mortality, and a reduction from 60 minutes to 30 minutes with a 0.5% lower mortality.

Conclusion Any delay in primary percutaneous coronary intervention after a patient arrives at hospital is associated with higher mortality in hospital in those admitted with ST elevation myocardial infarction. Time to treatment should be as short as possible, even in centres currently providing primary percutaneous coronary intervention within 90 minutes.

INTRODUCTION

Clinical guidelines recommend that hospitals providing primary percutaneous coronary intervention to patients with ST segment elevation myocardial infarction should treat patients within 90 minutes of contact with the medical system or admission to hospital.[1] Although most studies point to an independent association between longer time to treatment and higher mortality, the specific shape of the relation between mortality risk and time to treatment is unclear. While some studies indicate that any delay after admission is associated with higher mortality,[2-11] others suggest mortality is higher only after an initial delay in treatment of an hour or more.[12 13] In addition, it is unclear whether mortality is higher with successively longer times to treatment,[2-6 9 10 12 13] or if mortality eventually plateaus after two or more hours of delay.[7 11 14 15]

Clarifying the specific shape of the association between door-to-balloon time (that is, between arrival at hospital and treatment) and mortality is important given recent efforts to reduce delays. Current quality improvement initiatives, such as the Door-to-Balloon Alliance, seek to achieve a door-to-balloon time of 90 minutes or less among 75% or more of patients undergoing primary percutaneous coronary intervention at participating hospitals.[16] Several hospitals have shown that it is possible to push beyond this benchmark and achieve median door-to-balloon times approaching 60 minutes.[17] Relatively little data exist regarding the incremental benefit of further reductions beyond 90 minutes.

We analysed data from the American College of Cardiology National Cardiovascular Data Registry, a large national database containing detailed medical records of community patients undergoing percutaneous coronary intervention. We hypothesised that any increase in door-to-balloon time would be associated with increased mortality and that this mortality risk would persist irrespective of the length of the delay in treatment.

METHODS

National Cardiovascular Data Registry

The registry, described in detail elsewhere, is sponsored by the American College of Cardiology and contains details of patients undergoing cardiac

Table 1 | Distribution of door-to-balloon time in patients undergoing primary percutaneous coronary intervention for ST elevation myocardial infarction

Time (minutes)	Proportion of cohort (No)
≤30	3.2 (1396)
31-60	19.6 (8575)
61-90	35.1 (15 388)
91-120	23.3 (10 208)
121-150	9.8 (4283)
151-180	4.2 (1856)
181-210	2.0 (895)
211-240	1.1 (469)
≥241	1.7 (731)

catheterisation at more than 600 participating centres in the United States. Sites were encouraged to prospectively collect detailed clinical information including medical history, indications for procedure, angiographic findings, treatment, events, and procedural outcomes, from all patients undergoing cardiac catheterisation. Data quality was ensured through the use of standardised data elements and definitions, systematic data entry with common registry software, an onsite audit programme, and transmission to a central data warehouse for additional review before analysis.

Study sample

We limited our analysis to patients who, in 2005-6, presented to a participating centre within 12 hours of symptom onset with laboratory and electrocardiographic evidence of ST elevation myocardial infarction and subsequently underwent primary percutaneous coronary intervention (n=64 676). We excluded patients who were transferred from other hospitals (n=17 992) because we could not evaluate their status on admission. We also excluded patients who first received fibrinolytic therapy and were subsequently referred for primary percutaneous coronary intervention (n=3313). Patients under 18 years or over 99 years (n=9) were excluded to focus analysis on adult

Table 2 | Patients' characteristics and door-to-balloon time in patients undergoing primary percutaneous coronary intervention for ST elevation myocardial infarction. Figures are percentages of patients unless stated otherwise

		Door-to-balloon time (minutes)					
Characteristic	Overall	<60	60-89	90-119	≥120	Overall P	P for trend
No of patients	43 801	9971	15 388	10 208	8234	—	—
Demographics:							
Median age (IQR)	59 (51-70)	58 (51-68)	59 (51-69)	60 (51-71)	61 (52-73)	<0.001	<0.001
Women	27.9	24.8	25.8	29.2	34.0	<0.001	<0.001
White race	84.7	86.3	85.5	84.2	81.8	<0.001	<0.001
Medical history:							
Previous myocardial infarction	18.3	16.5	17.4	19.4	21.1	<0.001	<0.001
Previous heart failure	4.1	3.0	3.3	4.5	6.6	<0.001	<0.001
Diabetes	20.0	17.5	18.4	21.1	24.9	<0.001	<0.001
Renal failure	2.4	1.6	2.0	2.6	4.0	<0.001	<0.001
Hypertension	59.0	55.2	57.1	60.3	65.4	<0.001	<0.001
Cerebrovascular disease	6.5	5.5	5.7	7.0	8.5	<0.001	<0.001
Peripheral vascular disease	6.2	5.2	5.4	6.3	8.8	<0.001	<0.001
Current tobacco use	44.1	46.2	45.4	43.8	39.4	<0.001	<0.001
Chronic lung disease	11.5	10.7	10.8	11.8	13.5	<0.001	<0.001
Dyslipidaemia	57.3	57.4	56.8	57.4	57.9	0.083	0.38
Family history of early onset CAD	23.3	24.1	22.9	23.2	23.0	0.28	0.16
Previous PCI	19.3	18.4	18.3	20.2	20.9	<0.001	<0.001
Previous CABG	5.7	3.2	4.4	6.9	9.7	<0.001	<0.001
Admission findings:							
Admitted <6 hours after symptom onset	90.9	92.4	92.6	90.8	86.4	<0.001	<0.001
Heart failure on admission	8.4	6.8	7.2	8.7	12.1	<0.001	<0.001
Cardiogenic shock	9.5	8.6	8.9	9.6	11.7	<0.001	<0.001
NYHA class:							
I	24.2	26.3	23.5	23.4	23.8		
II	5.8	5.6	5.2	6.2	6.8		
III	15.7	14.7	15.5	16.2	16.7	<0.001	—
IV	54.3	53.4	55.9	54.2	52.6		

IQR=interquartile range, CAD=coronary artery disease, PCI=percutaneous coronary intervention, CABG=coronary artery bypass graft, NYHA=New York Heart Association.

Table 3 | Procedural characteristics and door-to-balloon time in patients undergoing primary percutaneous coronary intervention for ST elevation myocardial infarction. Figures are percentages of patients unless stated otherwise

		Door-to-balloon time (minutes)					
	Overall	<60	60-89	90-119	≥120	Overall P	P for trend
No of patients	43 801	9971	15 388	10 208	8234	—	—
Weekend procedure	28.2	17.0	28.2	34.7	33.7	<0.001	<0.001
Time of presentation:							
Weekday 0000-0759	17.0	11.2	16.7	20.5	20.2	<0.001	—
Weekday 0800-1559	32.8	52.8	31.9	21.9	23.6		
Weekday 1600-2359	22.0	19.0	23.2	22.9	22.6		
Weekend 0000-0759	6.6	3.1	6.0	9.4	8.7		
Weekend 0800-1559	12.5	8.6	12.6	14.5	14.4		
Weekend 1600-2359	9.0	5.3	9.5	10.8	10.5		
Angiographic findings							
Mean (SD) No of lesions	1.3 (0.6)	1.3 (0.6)	1.3 (0.6)	1.3 (0.6)	1.4 (0.7)	0.035	0.022
Stenosis locations:							
Left main	2.7	2.2	2.7	2.8	3.4	<0.001	<0.001
Left anterior descending	55.0	51.4	54.0	56.2	59.6	<0.001	<0.001
Circumflex	33.3	29.8	31.8	34.6	38.4	<0.001	<0.001
Right coronary artery	59.8	60.7	60.5	59.9	57.4	<0.001	<0.001
IABP used	10.8	10.0	10.4	11.0	12.4	<0.001	<0.001
Thrombin inhibitors	10.8	11.3	10.7	9.9	11.4	0.003	0.61
Non-stent device used	90.6	91.8	91.4	90.2	88.1	<0.001	<0.001
SCAI classification:							
Not reported	0.5	0.4	0.5	0.6	0.7	<0.001	—
I	16.5	14.1	15.6	17.6	19.6		
II	19.6	17.2	18.9	21.1	22.1		
III	21.2	23.3	21.8	20.0	18.8		
IV	42.2	45.0	43.2	40.6	38.7		

IABP=intra-aortic balloon pump, SCAI=Society for Cardiac Angiography and Interventions.

patients suitable for primary percutaneous coronary intervention. Finally, to minimise data coding errors, we excluded patients treated at hospitals that reported fewer than five primary percutaneous coronary interventions (n=29). A total of 18 989 patients met one or more of the above exclusion criteria, leaving 45 687 patients eligible for analysis.

Door-to-balloon time

Door-to-balloon time was defined as the time in minutes between a patient's arrival at the hospital and the first balloon inflation or device deployment as documented in the patient's medical record. For the purpose of evaluating differences in patients' characteristics associated with time to treatment we divided patients into four groups: <60, 60-89, 90-119, and ≥120 minutes. For all other analyses, we modelled door-to-balloon time as a continuous variable.

Of the 45 687 patients eligible for analysis, we excluded 503 for whom door-to-balloon time was missing. Patients with a door-to-balloon time <15 minutes (n=971) were excluded to avoid potentially incorrectly coded times. Patients with a door-to-balloon time >6 hours (n=915) were also excluded because they presumably did not receive percutaneous coronary intervention as a primary reperfusion strategy. The final study sample therefore consisted of 43 801 patients.

Statistical analysis

We first determined the mean, median, and distribution of door-to-balloon times. Differences in patients' demographic and clinical characteristics were compared across the four door-to-balloon time groups with χ^2 tests and trend analyses for categorical variables and analyses of variance for continuous variables.

We conducted logistic regression analysis using fractional polynomial modelling to determine the specific shape of the unadjusted association between door-to-balloon time and mortality in hospital. Fractional polynomial modelling compares models of different combinations of linear and non-linear transformations of door-to-balloon time to identify those models that best reflect the association of time to treatment and mortality. We identified best fitting transformations by comparison of model deviances using a χ^2 distribution with 1 degree of freedom.

We repeated analyses adjusting for patients' characteristics associated with mortality derived from the registry mortality model.[18] Variables included sex, race, age, findings at presentation (shock, renal failure, time from symptom onset to admission), medical history (diabetes, left ventricular ejection fraction, chronic

lung disease), procedural characteristics (pre-procedure intra-aortic balloon pump, use of non-stent device, use of thrombin inhibitors, time of day, weekend procedure), and angiographic findings (left main disease, proximal left anterior descending lesion, Society of Cardiac Angiography and Intervention lesion classification[19]). In addition, we adjusted for hospital characteristics, including annual primary percutaneous coronary intervention volume, teaching status, ownership, and rural location.

To assess the robustness of our findings, we repeated analyses excluding patients who arrived in shock because time to treatment might be less important for patients who do not present in shock.[20] To further reduce sample heterogeneity, we repeated analyses in the cohort of patients who presented within six hours of symptom onset.

Logistic regression models accounted for clustering of patients by hospital with Huber-White robust estimates of standard error. Statistical analyses were conducted with SAS 9.1 (SAS Institute, Cary, NC) and StataSE 9.0 (Stata Corporation, College Station, TX).

RESULTS

The median door-to-balloon time in the study cohort was 83 minutes (interquartile range 62-109 minutes), with 25 359 patients (57.9%) treated within 90 minutes of admission (table 1). A greater proportion of patients who had longer door-to-balloon times were women, non-white, and, on average, older than patients with shorter door-to-balloon times. In general, patients with longer door-to-balloon times had more comorbidities than patients with shorter door-to-balloon times, including a higher prevalence of previous myocardial infarction, heart failure, diabetes, hypertension, peripheral vascular disease, and previous revascularisation. Patients with shorter door-to-balloon times had a lower incidence of cardiogenic shock and stenoses of the left main and left anterior descending arteries, and a greater proportion had Society of Cardiac Angiography and Intervention IV lesions. A greater proportion of patients with shorter door-to-balloon times were treated on a weekday between 8 am and 4 pm and at urban hospitals (tables 2-4).

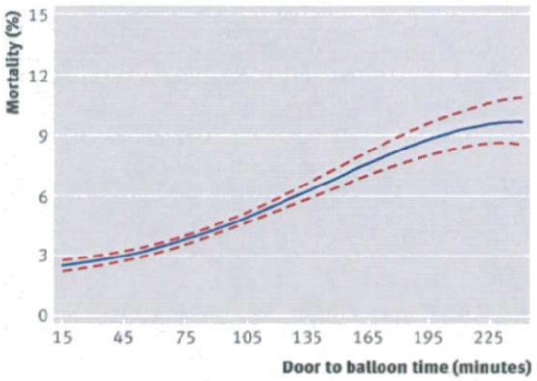

Fig 1 | Unadjusted in hospital mortality as function of door-to-balloon time (modelled as fractional polynomial) with 95% confidence intervals

Mortality in the study cohort was 4.6% (1999/43 801) overall. Patients who died in hospital had a 14 minute longer median door-to-balloon time than patients who survived (96 *v* 82 minutes, P<0.001). Patients with longer door-to-balloon time groups had higher crude mortality across the four door-to-balloon time groups (<60 minutes=3.2% (323/9971), 60-89 minutes=3.7% (568/15 388), 90-119 minutes=4.6% (473/10 208), ≥120 minutes=7.7% (635/8234), P<0.001 for trend).

Logistic regression analysis with a third degree fractional polynomial (door-to-balloon time, door-to-balloon time^2, and door-to-balloon time^3) best modelled the unadjusted association of door-to-balloon time with mortality, showing an increased risk of mortality associated with any delay in door-to-balloon time (fig 1). Estimated unadjusted mortality ranged from 2.8% for patients with door-to-balloon times of 30 minutes to 9.8% for patients with door-to-balloon times of 240 minutes (table 5).

Longer door-to-balloon times continued to be associated with increased mortality after multivariable adjustment (fig 2). A third degree fractional polynomial model continued to provide the best fit for the

Table 4 | Hospital characteristics and door-to-balloon time in patients undergoing primary percutaneous coronary intervention for ST elevation myocardial infarction. Figures are percentages of patients unless stated otherwise

		Door-to-balloon time (minutes)					
Characteristic	Overall	<60	60-89	90-119	≥120	Overall P	P for trend
No of patients	43 801	9971	15 388	10 208	8234	—	—
Median annual primary PCI volume (IQR)	144 (89-215)	145 (91-238)	146 (91-215)	143 (87-214)	135 (82-210)	<0.001	<0.001
Hospital data unavailable	3.3	3.6	3.4	3.1	3.0	0.06	0.006
Rural hospital	0.5	0.5	0.5	0.7	0.5	0.20	0.83
Teaching hospital	48.7	51.2	48.3	47.3	48.2	<0.001	<0.001
Ownership:							
Public	8.2	7.9	8.3	8.0	8.4		
Not for profit	82.2	82.2	82.6	82.3	81.4	<0.001	—
For profit	6.3	6.3	5.6	6.5	7.3		

PCI=percutaneous coronary intervention, IQR=interquartile range.

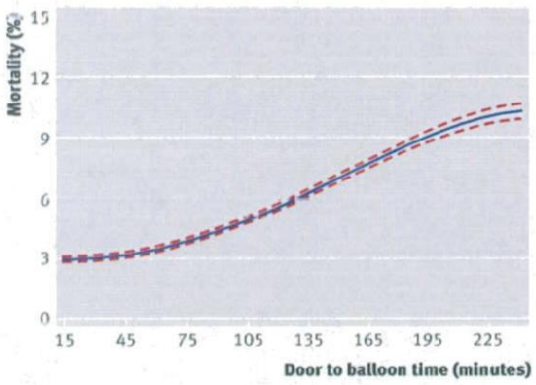

Fig 2| Adjusted in hospital mortality as function of door-to-balloon time (modelled as fractional polynomial) with 95% confidence intervals

adjusted association of door-to-balloon time with mortality, with any delay in door-to-balloon time continuing to be associated with an increased mortality risk. Estimated adjusted mortality ranged from 3.0% for patients with door-to-balloon time of 30 minutes to 10.3% for patients with door-to-balloon times of 240 minutes (table 5).

Findings were similar when we repeated analyses excluding the 4166 patients who presented in shock. In the 39 635 patients without shock, longer door-to-balloon times continued to be associated with higher crude mortality (<60 minutes=1.7% (156/9111), 60-89 minutes=1.8% (247/14 024), 90-119 minutes =2.2% (203/9226), ≥120 minutes=3.6% (262/7274), P<0.001 for trend). A third degree fractional polynomial model also provided the best fit for the adjusted association of door-to-balloon times with mortality in patients without shock, with any increase in door-to-balloon time associated with increased mortality (results not shown).

Table 5| Estimated in hospital mortality (95% confidence interval) by door-to-balloon time in patients undergoing primary percutaneous coronary intervention for ST elevation myocardial infarction

Time (minutes)	Unadjusted	Adjusted*
15	2.6 (2.3 to 2.8)	2.9 (2.8 to 3.1)
30	2.8 (2.5 to 3.0)	3.0 (2.9 to 3.2)
45	3.1 (2.8 to 3.3)	3.2 (3.1 to 3.3)
60	3.4 (3.2 to 3.7)	3.5 (3.4 to 3.6)
75	3.9 (3.7 to 4.1)	3.8 (3.7 to 4.0)
90	4.4 (4.2 to 4.6)	4.3 (4.2 to 4.4)
105	5.0 (4.8 to 5.2)	4.9 (4.8 to 5.0)
120	5.6 (5.4 to 6.0)	5.6 (5.4 to 5.7)
135	6.3 (6.0 to 6.7)	6.3 (6.1 to 6.4)
150	7.0 (6.6 to 7.5)	7.0 (6.8 to 7.2)
165	7.7 (7.2 to 8.3)	7.7 (7.5 to 8.0)
180	8.4 (7.7 to 9.1)	8.4 (8.2 to 8.7)
195	8.9 (8.2 to 9.8)	9.1 (8.8 to 9.4)
210	9.4 (8.5 to 10.3)	9.7 (9.3 to 10.0)
225	9.7 (8.7 to 10.8)	10.1 (9.7 to 10.4)
240	9.8 (8.7 to 11.0)	10.3 (10.0 to 10.7)

*Adjusted for sex, age, race, findings on presentation, medical history, procedural characteristics, angiographic findings, and hospital factors.

DISCUSSION

Any delay in door-to-balloon time for patients with ST elevation myocardial infarction undergoing primary percutaneous coronary intervention is associated with higher mortality, even among patients treated within 90 minutes of admission. The mortality risk with door-to-balloon time persists irrespective of the length of the treatment delay. Our data suggest that physicians could reduce mortality among such patients by minimising door-to-balloon time to the greatest extent possible, even among those treated within times recommended by guidelines.

Comparison with other studies

Our analysis improves on previous studies that modelled time to treatment as a categorical[4 5 7 8 10-14 20-24] or continuous linear variable.[2 3 9] Use of categorical variables might result in a loss of statistical power, which could explain why certain studies report no increased risk associated with delayed time to treatment.[20-24] Alternatively, by modelling time to treatment as a linear continuous variable, previous analyses assumed each additional delay in treatment was associated with the same additional increased risk in mortality, which is not necessarily true.[25] Neither approach accounts for the possibility that the mortality risk associated with time to treatment might vary over time. By using fractional polynomial regression, we assessed the association of door-to-balloon time and mortality using statistical modelling techniques that made no assumptions regarding the shape of the association between time to treatment and mortality.

Our principal finding of an immediate increase in mortality associated with any delay in door-to-balloon time reconciles competing reports concerning the shape of the mortality risk associated with delayed primary percutaneous coronary intervention. While some studies found that increased mortality associated with delays were present solely within the first few hours of presentation and then plateaued,[7 14] others had suggested the reverse—a risk that was initially unchanged and increased only after a few hours of delay.[12 13] Our study suggests that both reports might be correct in that the mortality risk associated with any delay in time to treatment might be present immediately after admission and persist for several hours. A closer assessment of previous studies indicates that many, in fact, suggest such a consistent trend of increased mortality with any delay in time to treatment. For instance, although Cannon and colleagues reported that mortality associated with longer door-to-balloon time manifested after two or more hours of delay, there is a clear trend towards increased mortality in patients with door-to-balloon times of 61-90 minutes and 91-120 minutes.[13] Furthermore, the few studies that have also modelled time to treatment as a continuous variable have similarly shown increases in adverse outcomes associated with any delay in

WHAT IS ALREADY KNOWN ON THIS TOPIC

Clinical guidelines recommend that hospitals providing primary percutaneous coronary intervention to patients with ST segment elevation myocardial infarction treat within 90 minutes of contact with the medical system or admission to hospital

The specific shape of the relation between mortality risk and time to treatment, and the incremental benefit of reductions in door-to-balloon times beyond 90 minutes, is unclear

WHAT THIS STUDY ADDS

Any delay in door-to-balloon time for patients with ST elevation myocardial infarction undergoing primary percutaneous coronary intervention is associated with higher mortality, even among patients treated within 90 minutes of admission

Reducing door-to-balloon time to the greatest extent possible for all patient, including those currently treated within 90 minutes of admission, might reduce mortality

treatment.[23] As such, differences in study findings concerning the specific shape of the association of door-to-balloon time and mortality largely reflect the manner in which different studies have modelled time to treatment rather than contradictory findings regarding the relation between time and outcomes.

Pathophysiology of delayed time to treatment

An increased mortality risk associated with delayed time to treatment in patients undergoing primary percutaneous coronary intervention is consistent with current pathophysiological models of myocardial infarction. Experimental models have shown that the continuous, progressive "wave front of necrosis" largely depends on the duration of ischaemia.[26-29] Thus, patients with longer door-to-balloon times will experience longer periods of vessel occlusion, resulting in more ischaemia and greater necrosis than patients with shorter times to treatment.[30] Although there might be benefits to reperfusion therapy performed after long delays, including improved ventricular remodelling and reduced susceptibility to arrhythmic events,[31] our data suggest that these benefits do not offset the underlying myocardial necrosis and attendant processes resulting from longer delays in time to treatment.[32] This hypothesis is supported by the observation that patients transferred for primary percutaneous coronary intervention achieve similar rates of normal complete antegrade perfusion (TIMI 3 flow) as patients who are not transferred but have larger infarcts and poorer myocardial salvage.[33]

Implications for practice

We believe our finding that any minute of delay in treatment is associated with an increased risk of mortality has important implications for clinical practice. Notably, our data suggest that there is no "floor" to the mortality reduction that can be achieved by reducing time to treatment. As such, further reductions in door-to-balloon times, even below the 90 minute benchmark endorsed by clinical practice guidelines, offer the potential to significantly reduce mortality. For instance, our data show that reducing average door-to-balloon times from 90 minutes to 60 minutes might reduce in hospital mortality by as much as 0.8% (from 4.3% to 3.5%). A further 30 minute reduction in door-to-balloon to an average of 30 minutes offers the potential of an additional 0.5% reduction (from 3.5% to 3.0%), underscoring the non-linear relation between time to treatment and mortality. Rather than accepting a 90 minute door-to-balloon time benchmark for primary percutaneous coronary intervention, our data support calls for an "as soon as possible" standard for patients undergoing primary percutaneous coronary intervention.[34] Such an approach, using necessary safeguards against inappropriate treatment, offers the potential for notable reductions in mortality.

Study limitations

Our study has several limitations that merit consideration. Firstly, we were unable to assess the association of time from the onset of symptoms to arrival at hospital and mortality or the association of total ischaemic time and mortality. We attempted to limit this effect by conducting a secondary analysis restricted to patients who presented within six hours of symptom onset and found our results were similar. Furthermore, robust assessment of time from onset of symptoms to hospital admission might be problematic in that these times rely on patients' reports and thus cannot be independently verified, whereas door-to-balloon times are probably more accurately recorded. Secondly, we assessed the outcome of in hospital mortality and cannot comment on the association of door-to-balloon time and mortality at later end points. Previous studies, however, have reported that the association of door-to-balloon time and mortality is comparable whether assessed during hospital admission, at 30 days, or at one year. Finally, as our analysis was based on observational data our findings might be attributable to biases introduced by unmeasured factors. We attempted to mitigate this effect through robust risk adjustment but cannot preclude the possibility of residual confounding by other non-measured patient or hospital factors associated with door-to-balloon time or mortality.

Conclusion

Door-to-balloon time is associated with mortality in patients undergoing primary percutaneous coronary intervention for ST elevation myocardial infarction. Contrary to previous studies, we found that this risk was present on admission and was not attenuated with the passage of time, indicating that any delay in door-to-balloon time in such patients is associated with an increased mortality. As such, our findings suggest a benefit from reducing door-to-balloon time for all patients undergoing primary percutaneous coronary intervention, including those currently treated within 90 minutes of hospital admission.

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ORIGINAL CONTRIBUTION

Association of Door-In to Door-Out Time With Reperfusion Delays and Outcomes Among Patients Transferred for Primary Percutaneous Coronary Intervention

Tracy Y. Wang, MD, MHS, MSc
Brahmajee K. Nallamothu, MD, MPH
Harlan M. Krumholz, MD, SM
Shuang Li, MS
Matthew T. Roe, MD, MHS
James G. Jollis, MD
Alice K. Jacobs, MD
David R. Holmes, MD
Eric D. Peterson, MD, MPH
Henry H. Ting, MD, MBA

Context Patients with ST-elevation myocardial infarction (STEMI) requiring interhospital transfer for primary percutaneous coronary intervention (PCI) often have prolonged overall door-to-balloon (DTB) times from first hospital presentation to second hospital PCI. Door-in to door-out (DIDO) time, defined as the duration of time from arrival to discharge at the first or STEMI referral hospital, is a new clinical performance measure, and a DIDO time of 30 minutes or less is recommended to expedite reperfusion care.

Objective To characterize time to reperfusion and patient outcomes associated with a DIDO time of 30 minutes or less.

Design, Setting, and Patients Retrospective cohort of 14 821 patients with STEMI transferred to 298 STEMI receiving centers for primary PCI in the ACTION Registry–Get With the Guidelines between January 2007 and March 2010.

Main Outcome Measures Factors associated with a DIDO time greater than 30 minutes, overall DTB times, and risk-adjusted in-hospital mortality.

Results Median DIDO time was 68 minutes (interquartile range, 43-120 minutes), and only 1627 patients (11%) had DIDO times of 30 minutes or less. Significant factors associated with a DIDO time greater than 30 minutes included older age, female sex, off-hours presentation, and non–emergency medical services transport to the first hospital. Patients with a DIDO time of 30 minutes or less were significantly more likely to have an overall DTB time of 90 minutes or less compared with patients with DIDO times greater than 30 minutes (60% [95% confidence interval {CI}, 57%-62%] vs 13% [95% CI, 12%-13%]; $P<.001$). Among patients with DIDO times greater than 30 minutes, only 0.6% (95% CI, 0.5%-0.8%) had an absolute contraindication to fibrinolysis. Observed in-hospital mortality was significantly higher among patients with DIDO times greater than 30 minutes vs patients with DIDO times of 30 minutes or less (5.9% [95% CI, 5.5%-6.3%] vs 2.7% [95% CI, 1.9%-3.5%]; $P<.001$; adjusted odds ratio for in-hospital mortality, 1.56 [95% CI, 1.15-2.12]).

Conclusion A DIDO time of 30 minutes or less was observed in only a small proportion of patients transferred for primary PCI but was associated with shorter reperfusion delays and lower in-hospital mortality.

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PRIMARY PERCUTANEOUS CORONARY intervention (PCI) is the preferred method of reperfusion for patients with ST-segment elevation myocardial infarction (STEMI),[1] yet approximately 75% of hospitals in the United States currently do not have acute PCI capability.[2] Patients with STEMI who present initially to these STEMI referral hospitals are frequently transferred to a STEMI receiving hospital for primary PCI. However, previous studies have highlighted the substantial delays in interhospital transfer that result in delayed reperfusion and can be associated with worse patient outcomes.[3,4]

A critical component of the interhospital transfer process is related to its initiation at the STEMI referral hospital. Most important, the duration of time from arrival to discharge at the first hospital (ie, the door-in to door-out [DIDO] time) is largely unknown.[5] Furthermore, patient characteristics related to substantial delays in DIDO time, as well as the effect of this initial delay on subsequent treatment and outcomes, are also uncertain. The DIDO measure is increasingly being advocated as an important metric of processes of care to expedite reperfusion, and a national benchmark of less than 30 minutes has been recommended by the 2008 American College of Cardiology/American Heart Association

Author Affiliations are listed at the end of this article.
Corresponding Author: Tracy Y. Wang, MD, MHS, MSc, 2400 Pratt St, Durham, NC 27705 (tracy.wang@duke.edu).

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(ACC/AHA) Clinical Performance Measures for Acute Myocardial Infarction[5] and is also a performance measure considered by the Centers for Medicare & Medicaid Services.[6]

The National Cardiovascular Data Registry (NCDR) Acute Coronary Treatment and Intervention Outcomes Network Registry–Get With the Guidelines (ACTION Registry–GWTG) provides a unique opportunity to examine DIDO times in a large national cohort of hospitals and patients. The specific objectives of this analysis were (1) to evaluate the proportion of STEMI patients who are transferred with a DIDO time of 30 minutes or less; (2) to assess the patient factors associated with delays in DIDO time; and (3) to examine the associations between a DIDO time greater than 30 minutes and overall time to reperfusion and risk-adjusted in-hospital mortality.

METHODS

Study Population

The ACTION Registry–GWTG is a voluntary quality improvement registry designed to promote evidence-based treatment of hospitalized patients with acute MI. Hospital participation is voluntary and open to all hospitals in the United States. Participation requires approval of the institutional review board at each hospital. Because patient information is collected anonymously without unique patient identifiers, institutional review boards waive the need for individual informed consent.

Between January 1, 2007, and March 30, 2010, 67 518 consecutive patients with STEMI were enrolled at PCI-capable hospitals in the ACTION Registry–GWTG. Among these, we focused on the 24 155 patients (36%) who initially presented to another hospital (STEMI referral hospital) and were subsequently transferred into an ACTION Registry–GWTG PCI facility (STEMI receiving hospital) for further treatment. Because we examined a performance measure related to timeliness of primary PCI, we excluded patients who received fibrinolytic therapy at the first hospital (ie, patients transferred for rescue PCI, facilitated PCI, or a planned pharmacoinvasive approach [n=7089]). We then excluded 2210 patients with either missing or inaccurate DIDO times. For patients with multiple admissions, we focused on the index admission (35 subsequent admissions excluded). These exclusions yielded a final analysis population of 14 821 patients with STEMI who were transferred into 298 ACTION Registry–GWTG STEMI receiving hospitals for primary PCI.

Data Collection and Definition

Hospitals participating in the ACTION Registry–GWTG collected detailed information on baseline demographic and clinical characteristics, processes of care, and in-hospital outcomes using a standardized set of data elements and definitions, as described.[7] Patient data were captured retrospectively via chart review and entered by sites into a Web-based data-collection form. Data were screened on entry, and only those meeting predetermined criteria for completeness and accuracy could be entered into the database. Each quarter, sites received a report summarizing any observed data quality issues, thus iteratively improving the overall quality of the database.

The NCDR routinely collects race/ethnicity data for quality-of-care, outcomes, and disparity research. These data were retrospectively abstracted from the medical record based on patient self-report.

Patients cannot be tracked from one hospital to the next in this registry. Patient data from the initial STEMI referral hospital (whether or not this hospital participated in the ACTION Registry–GWTG), such as time of arrival and discharge, mode of transport to the first hospital, and initial presenting features (eg, hemodynamic stability, signs of heart failure), were retrospectively abstracted into the ACTION Registry–GWTG data collection form based on medical records sent with the patient to the second STEMI receiving hospital. However, hospital characteristics of the initial STEMI referral hospital, such as size, triage process, and distance to the closest STEMI receiving hospital, are not captured in this database. DIDO time was defined as the duration of time between arrival and discharge at the STEMI referral hospital. Off-hour presentation denotes presentation to the STEMI referral hospital anytime other than 8 AM to 5 PM Monday through Friday.

Statistical Analysis

Baseline clinical characteristics, in-hospital treatment, and events were compared among patients stratified by DIDO time of 30 minutes or less vs greater than 30 minutes. Continuous variables are presented as medians with interquartile ranges (IQRs), while categorical variables are summarized as frequencies and percentages. Univariate comparisons between patients with a DIDO time of 30 minutes or less and those with a DIDO time greater than 30 minutes were performed using Wilcoxon rank sum tests for continuous variables and Mantel-Haenszel χ^2 tests for categorical variables. The Cochran-Armitage trend test was used to test the null hypothesis that the proportion of patients with a DIDO time of 30 minutes or less is the same for all months with the alternative hypothesis that the proportion of patients with a DIDO time of 30 minutes or less increases with time.

Multivariable logistic regression with generalized estimating equation (GEE) modeling was used to examine the association between DIDO status and in-hospital mortality.[8] The GEE method was used to account for within-hospital clustering because patients at the same hospital are more likely to have similar responses relative to patients in other hospitals (ie, within-center correlation for response).[9] Covariates entered into the GEE model were adapted from a previously validated mortality model in this registry[10] and included age, sex, race, body mass index, diabetes, hypertension, dyslipidemia, smoking status, prior MI,

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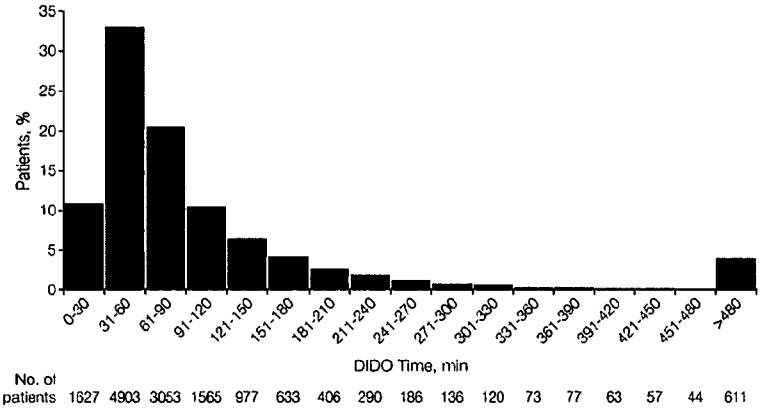
Figure 1. Distribution of DIDO Times Among 14 821 Patients With STEMI Transferred for Primary Percutaneous Coronary Intervention



Each bar represents the percentage of patients among the overall 14 821 transferred patients with ST-elevation myocardial infarction (STEMI) who had a door-in to door-out (DIDO) time within the specified time frame.

prior PCI, prior coronary artery bypass graft surgery, prior heart failure, prior stroke, dialysis, peripheral arterial disease, heart rate and systolic blood pressure at the time of first medical contact, signs of heart failure on admission, and year of presentation. In addition, GEE multivariable logistic regression was used to identify baseline patient risk characteristics and presenting features independently associated with a DIDO time greater than 30 minutes.

In a secondary analysis, we created a propensity score for DIDO time of 30 minutes or less compared with DIDO time greater than 30 minutes using all the variables with $P<.05$. Plots of the Cramer V (ϕ) measure of association for categorical variables and R^2 measure of association for continuous variables indicated good balance of all risk factors after propensity score adjustment. We then repeated the comparison between DIDO times of 30 minutes or less and greater than 30 minutes on associated mortality using inverse probability–weighted estimators.

For the main outcome variables such as in-hospital mortality, we did not have any patients with missing data. Overall door-to-balloon (DTB) time was missing in 2.4% of patients and we examined this outcome only among patients without missing data. Missing data occurred rarely (<1%) for all other reported variables. In multivariable modeling, missing values of continuous variables were imputed to the median value, while missing values of categorical variables were imputed to their most common value.

$P<.05$ was considered statistically significant for all tests. All analyses were performed using SAS software, version 9.1 (SAS Institute Inc, Cary, North Carolina).

RESULTS

Baseline Characteristics

Among 14 821 STEMI patients transferred to a STEMI receiving hospital for primary PCI, the median DIDO time was 68 minutes (IQR, 43-120 minutes). As shown in FIGURE 1, only 1627 patients (11%) had a DIDO time of 30 minutes or less. Furthermore, 56% had a DIDO time of greater than 60 minutes and 35% had a DIDO time of greater than 90 minutes. The proportion of patients with a DIDO time of 30 minutes or less showed improvement over time ($P<.001$) (FIGURE 2); median DIDO times were 90 minutes (IQR, 55-180 minutes) in January 2007 and 58 minutes (IQR, 38-103 minutes) in March 2010.

Patients with a DIDO time greater than 30 minutes were more likely to be older (median age, 61 vs 58 years; $P<.001$), female (30.6% vs 22%; $P<.001$), and more likely to have comorbidities such as hypertension, diabetes, prior heart failure, prior stroke, and chronic lung disease compared with patients with a DIDO time of 30 minutes or less (TABLE 1). Patients with a DIDO time greater than 30 minutes were more likely to have a left bundle branch block or signs of posterior MI on the presenting electrocardiogram (4.2% vs 1.0%; $P<.001$). Only a small proportion of transferred patients with prolonged DIDO times had documented contraindications to fibrinolytic therapy; among patients with DIDO times greater than 30 minutes and greater than 60 minutes, 0.6% and 0.9% had absolute contraindications to fibrinolytic therapy, respectively.

After multivariable modeling, independent patient characteristics associated with a DIDO time greater than 30 minutes include older age, female sex, off-hours presentation, and non–emergency medical services transport to the first hospital (TABLE 2). In addition, comorbid conditions (such as diabetes and prior stroke) and initial hemodynamic instability (increasing heart rates and signs of heart failure on presentation) were also associated with a higher likelihood of a DIDO time greater than 30 minutes.

Timeliness of Reperfusion

Although patients in the study cohort were transferred for primary PCI, patients with a DIDO time of 30 minutes or less were more likely to undergo primary PCI after arriving at the STEMI receiving hospital compared with patients with a DIDO time greater than 30 minutes (95.9 vs 90.5%; $P<.001$). In this transfer population, the median overall DTB time from first hospital presentation to second hospital PCI was 120 minutes (IQR, 96-159 minutes), and only

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19% of transferred patients achieved an overall DTB time of 90 minutes or less. Overall DTB time was significantly shorter for patients with a DIDO time of 30 minutes or less compared with those with a DIDO time greater than 30 minutes (median, 85 vs 127 minutes; $P<.001$). The percentage of patients with an overall DTB time of 90 minutes or less was significantly higher for patients with a DIDO time of 30 minutes or less compared with those with a DIDO time greater than 30 minutes (60% vs 13%; $P<.001$); similar results were observed for the percentage of patients achieving an overall DTB time of 120 minutes or less (91% vs 43%; $P<.001$). Second hospital arrival to balloon time was longer for patients with a DIDO time greater than 30 minutes compared with those who had a DIDO time of 30 minutes or less (median, 31 vs 26 minutes; $P<.001$).

Median length of hospitalization was similar between patients with DIDO times of 30 minutes or less and more than 30 minutes (median, 3 days; IQR, 2-5 days).

In-Hospital Mortality

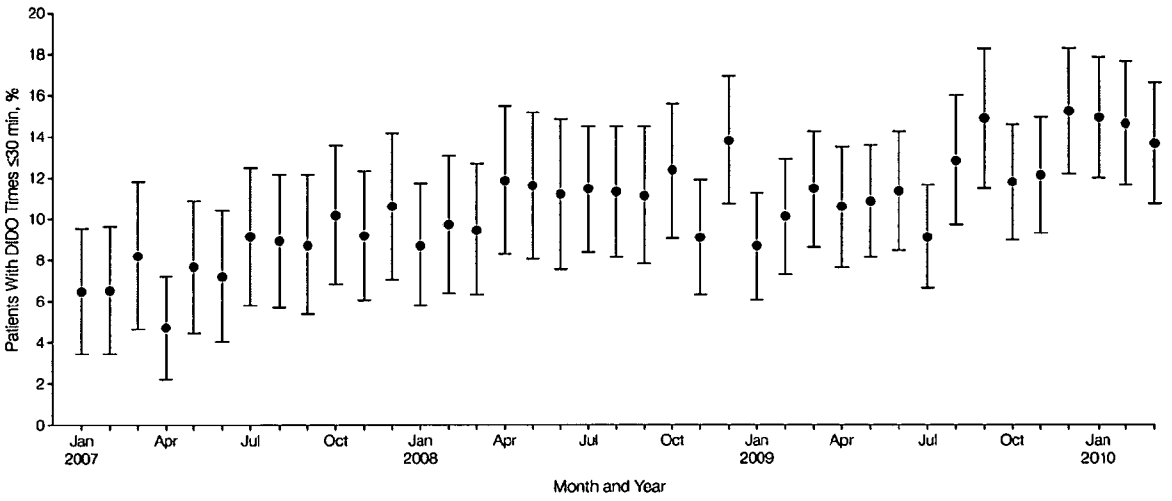
During the study period, we observed a 5.5% in-hospital mortality rate that was significantly higher among patients with a DIDO time greater than 30 minutes (5.9%) compared with patients who had a DIDO time of 30 minutes or less (2.7%; $P<.001$). This mortality difference persisted after adjusting for differences in baseline characteristics and presenting features (adjusted odds ratio [OR], 1.56; 95% confidence interval [CI], 1.15-2.21; $P=.004$), and similar results were obtained in a secondary analysis using inverse probability–weighted estimators (OR, 1.55; 95% CI, 1.06-2.26; $P=.02$). The difference in associated mortality was greater with incremental increases in DIDO time. Using patients with a DIDO time of 30 minutes or less as the reference, patients with DIDO times between 31 and 60 minutes had an adjusted OR of 1.34 (95% CI, 0.96-1.86), patients with DIDO times between 61 and 90 minutes had an adjusted OR of 1.41 (95% CI, 0.96-2.06), and patients with DIDO times greater than 90 minutes had an adjusted OR of 1.86 (95% CI, 1.36-2.54) for in-hospital mortality (FIGURE 3).

COMMENT

The timeliness of reperfusion therapy for STEMI patients transferred for primary PCI is often prolonged, with only a minority of transferred patients achieving a guideline-recommended overall DTB time of less than 90 minutes. DIDO time is a new performance measure that assesses the timeliness and quality of initial reperfusion care at the first or STEMI referral hospital, and we found that only 11% of transferred patients with STEMI met the recommended benchmark of a DIDO time of 30 minutes or less. Furthermore, patients with a DIDO time greater than 30 minutes had significantly longer overall DTB time, and the majority did not have any documented absolute contraindications to fibrinolytic therapy.

The direct relationship between total ischemic time and severity of myocardial injury and mortality has been well established for patients with STEMI[11-14] and has fueled national campaigns to reduce system delays to reperfusion. For

Figure 2. Monthly Trends in Percentage of Patients With DIDO Times of 30 Minutes or Less Among 14 821 Patients With STEMI Transferred During the Study Period, January 2007 Through March 2010



Each point represents the observed percentage of patients with door-in to door-out (DIDO) times of 30 minutes or less among all transferred patients with ST-elevation myocardial infarction (STEMI) who were treated that month. Error bars represent the approximation 95% binomial confidence interval. Sample sizes during each of these months range between 220 and 557 patients.

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patients with STEMI who directly arrive at a PCI-capable hospital, several initiatives have effected significant reductions in DTB time.[15-17] Nevertheless, with only a minority of hospitals having round-the-clock PCI capability[2,3,18] and a substantial proportion of contemporary STEMI patients requiring interhospital transfer for primary PCI, there has been a growing interest in measuring the timeliness and quality of reperfusion for transferred STEMI patients, including performance at both the STEMI referral and STEMI receiving hospitals.

The traditional measure of overall DTB time, which for transfer patients is defined as the time from presentation at the STEMI referral hospital to the time of primary PCI at the STEMI receiving hospital, relies on efficient communication and coordination of care between STEMI referral and receiving hospitals as well as emergency transport services. A previous analysis from the NCDR CathPCI Registry shows that less than 10% of transferred patients with STEMI between 2005 and 2007 met the metric of overall DTB time of less than 90 minutes.[4] Our analysis shows that overall DTB time has further improved for transferred patients with STEMI, with approximately 1 in 5 patients treated within an overall DTB time of less than 90 minutes.

To further delineate quality improvement targets for STEMI patients transferred for primary PCI, the 2008 ACC/AHA Performance Measures for STEMI designated a new performance benchmark, DIDO time, which assesses the amount of time spent at the STEMI referral hospital prior to transfer and reflects the transfer process between STEMI referral and receiving centers. Based largely on regionally designed STEMI systems of care,[19-21] a benchmark of 30 minutes or less is recommended for this measure. Our study shows that while there has been a significant downward secular trend in DIDO time, only 1 in 10 patients achieved a DIDO time of 30 minutes or less at the STEMI referral hospital. In fact, more than one-third of patients had a DIDO time greater than 90 minutes and more than 58% had a DIDO time greater than 60 minutes, rendering an overall DTB time of 90 minutes or less realistically unachievable. Moreover, the majority of patients with prolonged DIDO time did not have absolute contraindications for fibrinolytic therapy,[22,23] which is the preferred reperfusion strategy for STEMI when access to timely primary PCI is not a viable option.[24-27]

Our results underscore the importance of optimizing regional and statewide networks for STEMI systems of care. DIDO time is a performance measure that informs how efficiently the

Table 1. Baseline Patient Characteristics

Characteristics	No. (%) of Patients[a] DIDO Time ≤30 Minutes (n = 1627)	DIDO Time >30 Minutes (n = 13 194)	*P* Value
Demographics			
Age, median (IQR), y	58 (50-67)	61 (52-71)	<.001
Male	1269 (78.0)	9151 (69.4)	<.001
White race	1418 (87.2)	11 486 (87.1)	.09
Insurance status			
Private/HMO	910 (55.9)	7066 (53.6)	<.001
Medicare/Medicaid/VA	408 (25.1)	4109 (31.1)	
Self/none	299 (18.4)	1898 (14.4)	
Other/missing	10 (0.6)	121 (0.9)	
Clinical characteristics			
Hypertension	910 (55.9)	8277 (62.7)	<.001
Dyslipidemia	792 (48.7)	6673 (50.6)	.15
Previous PCI	281 (17.3)	2298 (17.4)	.89
Diabetes mellitus	271 (16.7)	3246 (24.6)	<.001
Previous myocardial infarction	263 (16.2)	2333 (17.7)	.14
Chronic lung disease	106 (9.1)	962 (11.3)	.03
Previous CABG	75 (4.6)	875 (6.6)	.002
Peripheral arterial disease	65 (4.0)	753 (5.7)	.004
Previous stroke	50 (3.1)	723 (5.5)	<.001
Previous heart failure	49 (3.0)	663 (5.0)	<.001
Contraindication to fibrinolytic therapy	4 (0.2)	83 (0.6)	.84
Presenting features			
Off-hour presentation[b]	1001 (61.5)	8720 (66.1)	<.001
EMS transport to first hospital	472 (29.0)	3589 (27.2)	.40
Prehospital ECG	615 (37.8)	5150 (39.0)	.28
ECG findings			
ST elevation	1610 (99.0)	12 632 (95.7)	<.001
LBBB	11 (0.7)	481 (3.7)	
Posterior MI	4 (0.3)	68 (0.5)	
Hypotension (SBP ≤90 mm Hg)	92 (5.7)	696 (5.3)	.53
Tachycardia (heart rate ≥100/min)	194 (11.9)	2214 (16.8)	<.001
Signs of heart failure[c]	98 (6.0)	1602 (12.1)	<.001
Signs of cardiogenic shock	102 (6.3)	942 (7.1)	.20
Creatinine clearance, median (IQR), mL/min[d]	93.8 (70.8-120.1)	86.2 (61.4-114.4)	<.001

Abbreviations: CABG, coronary artery bypass graft surgery; ECG, electrocardiogram; EMS, emergency medical services; HMO, health maintenance organization; IQR, interquartile range; LBBB, left bundle branch block; MI, myocardial infarction; PCI, percutaneous coronary intervention; SBP, systolic blood pressure; VA, veterans administration.

[a] Data are expressed as number (percentage) of patients unless otherwise indicated.

[b] Off-hours denotes presentation between 5 PM and 8 AM Monday through Friday and all day Saturday and Sunday.

[c] Signs of heart failure are dyspnea, orthopnea, paroxysmal nocturnal dyspnea, or lower-extremity edema associated with at least 1 of the following: rales of more than one-third of the lung fields, jugular venous distension, S_3 gallop, pulmonary congestion on radiography, or elevated brain natriuretic peptide levels.

[d] Creatinine clearance was calculated by the Cockroft-Gault equation among patients not receiving dialysis.

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STEMI referral hospital coordinates care and transfer, and achieving a DIDO time of 30 minutes or less was strongly associated with an overall DTB time of 90 minutes or less. Thus, DIDO can be used to inform the choice of reperfusion therapy. However, the ultimate choice of reperfusion therapy (fibrinolysis vs primary PCI) at STEMI referral hospitals should be individualized based on several factors, such as the patient's mortality and bleeding risks and duration of symptoms, in addition to the time needed to transfer to a PCI-capable hospital.[27]

Although patient-level characteristics such as age, sex, diabetes, and heart failure contributed to DIDO time, the magnitude of their contributions were small, and most baseline patient variables were not associated with prolonged DIDO times (>30 minutes). Logistics such as presentation during off-hours or failure to use emergency medical services transport to the STEMI referral hospital were significant contributors, but additional STEMI referral hospital- and system-level variables are important and likely associated with the variability in DIDO time. These factors, described in previous literature,[19,20,28] are not captured in this database but focus on early triage and treatment on the stretcher, a prespecified simple reperfusion strategy coordinated with the STEMI receiving hospital, availability of immediate transportation, use of a prehospital electrocardiogram to diagnose STEMI, and activating transport with earlier lead time. DIDO time provides a simple but useful metric for quality improvement programs that seek to design and evaluate STEMI systems of care, such as the AHA's Mission: Lifeline.[29]

Our study is the first to our knowledge to show a significantly higher mortality risk associated with a DIDO time greater than 30 minutes that persists after adjusting for many of the clinical and presenting patient features that contribute to MI mortality risk.[9] Although we cannot exclude the contribution of unmeasured patient differences, we observed a large difference in time to reperfusion (42-minute difference in median overall DTB time) between groups, which is particularly remarkable given the generalizability of the study population (18% older than 75 years, 30% women, 24% diabetic). Therefore, the association of a DIDO time of 30 minutes or less with lower mortality may potentially be mediated by the reduction in overall reperfusion delays. These results lend support to this new performance measure as a target for quality improvement interventions given its strong correlation to total system delays in primary PCI and in-hospital mortality. Compared with patients with a DIDO time of 30 minutes or less, those with DIDO times of 31 to 60 and 61 to 90 minutes were associated with a nonsignificant increase in trend for higher mortality, and patients with DIDO times greater than 90 minutes were associated with the highest mortality risk (Figure 3).

Thus, optimizing systems of care to achieve a DIDO time of 30 minutes or less for the majority of patients transferred for primary PCI is a reasonable target, particularly because this is currently achieved in only 11% of transferred STEMI patients. DIDO time is a useful performance measure attributable to STEMI referral hospitals that can be used to assess and iteratively improve effectiveness of regional STEMI networks and may further emerge as a quality benchmark to ascertain performance and accountability.

The findings in our study need to be considered in the light of some limitations. First, the ACTION Registry–GWTG captures transfer patients from the perspective of the 298 participating STEMI receiving hospitals; therefore, we have no insight into the hospital characteristics and process descriptors of the initial STEMI refer-

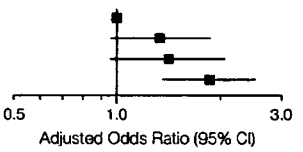
Table 2. Patient Characteristics Significantly Associated With a DIDO Time of 30 Minutes or Greater[a]

Characteristics	Adjusted OR (95% CI)	χ^2	*P* Value
Heart rate (per 10 beats/min increase)	1.08 (1.04-1.10)	28	<.001
Female	1.42 (1.22-1.65)	21	<.001
Diabetes	1.39 (1.16-1.67)	13	<.001
Off-hours presentation[b]	1.30 (1.13-1.50)	13	<.001
Signs of heart failure on admission	1.54 (1.20-1.92)	12	<.001
Non-EMS transport to first hospital	1.26 (1.08-1.4)	9	.003
Prior stroke	1.47 (1.09-2.00)	6	.01
Current/recent smoker	0.83 (0.71-0.97)	6	.02
Age (per 5-y increase)	1.03 (1.00-1.06)	5	.03

Abbreviations: CI, confidence interval; DIDO, door-in to door-out; EMS, emergency medical services; OR, odds ratio.
[a] Other nonsignificant covariates in the model include race; insurance status; prior myocardial infarction, heart failure, percutaneous coronary intervention, or coronary artery bypass graft surgery; peripheral arterial disease; hypertension; dyslipidemia; body mass index; dialysis; cardiogenic shock on initial presentation; and presenting systolic blood pressure. Model c index=0.62. The degree of freedom is 1 for each variable in the table.
[b] Off-hours denotes presentation between 5 PM and 8 AM Monday through Friday and all day Saturday and Sunday.

Figure 3. Association of DIDO Time With In-Hospital Mortality

DIDO Time, min	Mortality, No. of Patients/Total (%)	Adjusted Odds Ratio (95% CI)
≤30	43/1600 (2.7)	1.0 (Reference)
31-60	192/4841 (4.0)	1.34 (0.96-1.86)
61-90	146/3013 (4.9)	1.41 (0.96-2.06)
>90	430/5176 (8.3)	1.86 (1.36-2.54)



For each door-in to door-out (DIDO) time group, the unadjusted mortality rate is presented, as well as the adjusted odds ratio and 95% confidence interval (CI; error bars) for each group, with DIDO time greater than 90 minutes as the reference group.

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ral hospital (eg, triage process, decision to transfer, distance to closest STEMI receiving hospital), which are likely to significantly affect DIDO time. However, time of presentation as well as some of the presenting patient features at the initial hospital visit are captured in this database. Time clocks are not always standardized within and between institutions. We also do not collect data on symptom persistence or severity, which can also contribute to timeliness of transfer or selection of fibrinolytic therapy.

Second, this analysis population includes only patients transferred for primary PCI and excludes patients with STEMI who were eligible for primary PCI but were not transferred (those who did not receive any reperfusion therapy and those who died out of hospital). Because reperfusion is known to be underutilized in routine practice,[30] the proportion of patients with STEMI requiring interhospital transfer for primary PCI is likely underestimated.

Third, while the observational nature of this study permits real-world assessment of care patterns, the association between DIDO time and mortality do not necessarily prove causality. Despite multivariable adjustment, unmeasured confounding (eg, patients with a DIDO time ≤30 minutes may be healthier and easier to transport) may contribute to the lower mortality observed among patients with a DIDO time of 30 minutes or less. Future studies will need to examine the association with longitudinal outcomes because only in-hospital mortality data are collected in this database.

CONCLUSION

DIDO time is a new reperfusion performance measure for patients with STEMI who require interhospital transfer for primary PCI. Our study shows that patients with a DIDO time of 30 minutes or less are more likely to achieve an overall DTB time of less than 90 minutes and are associated with lower risk-adjusted mortality compared with patients who had a DIDO time greater than 30 minutes, thus affirming the importance of DIDO time as a metric for reperfusion quality. Significantly, the majority of transferred patients with STEMI nationwide do not meet the recommended 30-minute benchmark, suggesting that further attention and improvement of this performance measure will translate into substantial improvement in the timeliness of primary PCI and clinical outcomes for transferred STEMI patients.

Author Affiliations: Duke Clinical Research Institute, Duke University Medical Center, Durham, North Carolina (Drs Wang, Roe, Jollis and Peterson and Ms Li); VA Health Services Research and Development Center for Excellence, Department of Medicine, University of Michigan Medical School, Ann Arbor (Dr Nallamothu); Robert Wood Johnson Clinical Scholars Program, Yale University School of Medicine and Yale–New Haven Hospital Center for Outcomes Research and Evaluation, New Haven, Connecticut (Dr Krumholz); Department of Medicine, Section of Cardiology, Boston Medical Center, Boston, Massachusetts (Dr Jacobs); and Knowledge and Evaluation Research Unit (Dr Ting), Division of Cardiovascular Diseases (Dr Holmes), Mayo Clinic, Rochester, Minnesota.

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Study concept and design: Wang, Ting.
Acquisition of data: Li, Peterson.
Analysis and interpretation of data: Wang, Nallamothu, Krumholz, Li, Roe, Jollis, Jacobs, Holmes, Peterson, Ting.
Drafting of the manuscript: Wang, Nallamothu, Krumholz, Peterson, Ting.
Critical revision of the manuscript for important intellectual content: Wang, Nallamothu, Krumholz, Li, Roe, Jollis, Jacobs, Holmes, Peterson, Ting.
Statistical analysis: Li.
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Study supervision: Peterson, Ting.
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> The great business of study is to form a *mind* adapted and adequate to all times and all occasions; to which all nature is then laid open, and which may be said to possess the key of her inexhaustible riches.
>
> —Sir Joshua Reynolds (1723-1792)

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Composition of Coronary Thrombus in Acute Myocardial Infarction

Johanne Silvain, MD, PHD,* Jean-Philippe Collet, MD, PHD,* Chandrasekaran Nagaswami, MD,† Farzin Beygui, MD, PHD,* Kathryn E. Edmondson, PHD,† Anne Bellemain-Appaix, MD,* Guillaume Cayla, MD,* Ana Pena, PHD,* Delphine Brugier, PHD,* Olivier Barthelemy, MD,* Gilles Montalescot, MD, PHD,* John W. Weisel, PHD†

Paris, France; and Philadelphia, Pennsylvania

Objectives We sought to analyze the composition of coronary thrombus in vivo in ST-segment elevation myocardial infarction (STEMI) patients.

Background The dynamic process of intracoronary thrombus formation in STEMI patients is poorly understood.

Methods Intracoronary thrombi (n = 45) were obtained by thromboaspiration in 288 consecutive STEMI patients presenting for primary percutaneous intervention, and analyzed using high-definition pictures taken with a scanning electron microscope. Plasma biomarkers (TnI, CRPus, IL-6, PAI-1, sCD40 ligand, and TNF-α) and plasma fibrin clot viscoelastic properties were measured simultaneously on peripheral blood.

Results Thrombi were mainly composed of fibrin (55.9 ± 18%) with platelets (16.8 ± 18%), erythrocytes (11.5 ± 9%), cholesterol crystals (5.2 ± 8.4%), and leukocytes (1.3 ± 2.0%). The median ischemic time was 175 min (interquartile range: 140 to 297). Ischemic time impacted thrombi composition, resulting in a positive correlation with intracoronary thrombus fibrin content, $r = 0.38$, $p = 0.01$, and a negative correlation with platelet content, $r = -0.34$, $p = 0.02$. Thus, fibrin content increased with ischemic time, ranging from 48.4 ± 21% (<3 h) up to 66.9 ± 9% (>6 h) ($p = 0.02$), whereas platelet content decreased from 24.9 ± 23% (<3 h) to 9.1 ± 6% (>6 h) ($p = 0.07$). Soluble CD40 ligand was positively correlated to platelet content in the thrombus ($r = 0.40$, $p = 0.02$) and negatively correlated with fibrin content ($r = -0.36$; $p = 0.04$). Multivariate analysis indicated that ischemic time was the only predictor of thrombus composition, with a 2-fold increase of fibrin content per ischemic hour (adjusted odds ratio: 2.00 [95% confidence interval: 1.03 to 3.7]; $p = 0.01$).

Conclusions In acute STEMI, platelet and fibrin contents of the occlusive thrombus are highly dependent on ischemia time, which may have a direct impact on the efficacy of drugs or devices used for coronary reperfusion. (J Am Coll Cardiol 2011;57:1359–67) © 2011 by the American College of Cardiology Foundation

Acute coronary thrombosis resulting in total occlusion of a coronary artery leads to ST-segment elevation myocardial infarction (STEMI) (1). Exposition of the lipid-rich core after atherosclerosis plaque rupture/erosion into the arterial lumen triggers the formation of unstable platelet aggregates, which may lead to intermittent reduction in coronary flow and cause distal embolization (2). Early fibrin formation strengthens the platelet aggregate, favoring persistent flow obstruction and blood coagulation activation proximally and

From the *Institut de Cardiologie, INSERM UMRS937, Pitié-Salpêtrière Hospital (AP-HP), Université Paris 6, Paris, France; and the †Department of Cell and Developmental Biology, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania. This study was supported by grants from the "Fédération Française de Cardiologie," the "Institut de l'Athérothrombose," and NIH (HL30954, HL090774, and T32 HL07439). Dr. Silvain has received research grants from Daiichi-Sankyo, Eli Lilly, Sanofi-Aventis, INSERM, Fédération Française de Cardiologie, and Société Française de Cardiologie; consultant fees from Daiichi-Sankyo and Eli Lilly; and lecture fees from AstraZeneca, Daiichi-Sankyo, and Eli Lilly. Dr. Collet has received research grants from Boston Scientific, Bristol-Myers Squibb, Centocor, Cordis, Eli Lilly, Fédération Française de Cardiologie, Fondation de France, Guerbet Medical, INSERM, Medtronic, Sanofi-Aventis, Société Française de Cardiologie, and Stago; and consulting and lecture fees from Bristol-Myers Squibb, Eli Lilly, and Sanofi-Aventis. Dr. Beygui has received lecture fees from Roche, Sanofi-Aventis, Pfizer, and Astellas. Dr. Cayla has received research grants from Fédération Française de Cardiologie; and consulting fees from Eli Lilly, Daiichi-Sankyo, Servier, Abbott, CLS Behring, and AstraZeneca. Dr. Montalescot has received research grants from Abbott Vascular, Bristol-Myers Squibb, Boston Scientific, Centocor, Eli Lilly, Fédération Française de Cardiologie, Fondation de France, Guerbet Medical, INSERM, ITC Edison, Medtronic, Pfizer, Sanofi-Aventis, Société Française de Cardiologie, and Stago; consulting fees from AstraZeneca, Bayer, Bristol-Myers Squibb, Boehringer Ingelheim, Daiichi, Eisai, Eli Lilly, Menarini, Novartis, Pfizer, Portola, Sanofi-Aventis, Schering-Plough, and The Medicines Company; and lecture fees from Abbott Vascular, Accumetrics, AstraZeneca, Bristol-Myers Squibb, Cordis, Daiichi, Eli Lilly, GlaxoSmithKline, Menarini, Merck Sharpe & Dohme, Pfizer, Sanofi-Avenits, and Schering-Plough. All other authors have reported that they have no relationships to disclose.

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Abbreviations and Acronyms

adjOR = adjusted odds ratio
IQR = interquartile range
MBG = myocardial blush grade
MI = myocardial infarction
PCI = percutaneous coronary intervention
SEM = scanning electron microscopy
STEMI = ST-segment elevation myocardial infarction
TIMI = Thrombolysis In Myocardial Infarction
UFH = unfractionated heparin

distally to the occlusion. The resulting red thrombus is comprised of erythrocytes and inflammatory cells entrapped by the fibrin network. The layered aspect highlights the repeated episodes of thrombus growth (3,4).

It remains unclear how time affects the dynamic process of thrombus formation in the coronary arteries of STEMI patients (5). Data are also scarce on how thrombus architecture correlates with coronary reperfusion after primary percutaneous coronary intervention (PCI) or with peripheral blood biomarkers. The increased use of thromboaspiration in primary PCI for STEMI offers a unique opportunity to study thrombus composition, dynamic formation, and architecture in vivo (6–9).

Ischemic time was hypothesized to be among the strongest independent correlates of thrombus architecture. We therefore evaluated the effect of the following plausible determinants of thrombus architecture (e.g., coronary anatomy and reperfusion, patient clinical presentation, peripheral blood biomarkers, fibrin clot viscoelastic properties, and response to fibrinolysis). Our aim was to characterize the independent correlates of thrombus architecture and to assess whether thrombus architecture per se could affect myocardial reperfusion.

Methods

Study design and thrombus collection. Between January 2007 and April 2008, we prospectively screened all the STEMI patients referred to the catheterization laboratory for primary PCI associated with thromboaspiration performed by a low-profile catheter (Export 6F, Medtronic, Santa Rosa, California). Thromboaspiration was performed whenever possible (when the anatomy of the coronary artery—curve and size—allowed it) in all patients with a Thrombolysis In Myocardial Infarction (TIMI) flow grade 0 and in all patients with a visible thrombus if TIMI flow grade was 1 or more.

Collected thrombi were immediately washed with saline and fixed with 2% glutaraldehyde in 50 mmol/l Na-cacodylate buffer (pH 7.3).

Scanning electron microscope analysis. Sample fixation, dehydration, and preparation were performed according to a previously published method (10). High-definition photographs (3,000× magnification) were obtained using a Philips/FEI XL20 scanning electron microscope 4-nm resolution (FEI, Hillsboro, Oregon) (11). To control for composition heterogeneity in the analysis of the surface of thrombus, we covered several areas (at least 12 according to a grid and the size of the thrombus) for each thrombus (Fig. 1). A semiquantitative analysis and a visual approach were used for the first 10 thrombi. For the semiquantitative analysis, each picture was divided into 400 squares (Image J software, National Institutes of Health, Bethesda, Maryland), and the predominant composition (platelet, fibrin, erythrocytes, leukocytes, cholesterol crystal) of each square was noted (Fig. 1) (12). All the structures visualized were easy to identify, and crystal-like structures were characterized as cholesterol crystals (asterisks in Fig. 2B) on the basis of previous SEM images described in vitro (13,14) and the probability of their presence in the setting of a ruptured plaque exposing a lipid-rich core. The visual approach consisted of a careful observation of each pictures with a subjective evaluation of the percentage of each component. Very low interindividual variability was found in the thrombus composition analysis (<6%) between the 2 approaches; therefore. the time-consuming semiquantitative analysis was not performed for the remaining 35 thrombi (Figs. 2A and 2B). The 2 scientists performing scanning electron microscopy (SEM) and analysis were blinded to the clinical data.

Blood samples and measurement. Blood samples were drawn from the arterial sheath just after insertion and were collected in Vacutainer tubes (Becton Dickinson, Franklin Lakes, New Jersey) containing trisodium citrate 0.129 mol/l (3.2% sodium citrate) for routine blood work and for biomarkers measurements.

Soluble CD40L levels were measured using a human sCD40L ELISA bioassay (Arcus Biological, Modena, Italy). TNF-α and IL-6 levels were measured by Quantikine sandwich enzyme immunoassays (R&D Systems, Abingdon, United Kingdom) according to the manufacturer's instructions. CRP levels were quantified by commercially available ELISA kits (Zymutest, Hypen BioMed, Neuville sur Oise, France). The PAI-1 concentration was measured using an Asserachrom PAI-1 kit (Diagnostica Stago, Asnieres, France). All measures were assessed in duplicate.

Whole blood clot viscoelastic properties and lysis rates. Clots were formed in a thermostable 37°C plastic plate by recalcifying 700 μl of PPP with $CaCl_2$ (10 mmol/l final concentration) and 5 μl of purified recombinant human tissue factor (Innovin, Dade Behring, Deerfield, Illinois). To facilitate lysis, 10 μl of tissue plasminogen activator (rt-PA) (0.5 nmol/l final concentration) (Boehringer Ingelheim, Ingelheim am Rhein, Germany) was also added. Plasma clot viscoelastic properties were measured with a Hemodyne RM-2 Analyser (Hemodyne, Richmond, Virginia). Fibrinolysis was assessed by continuous monitoring of the elastic modulus and was expressed as the lysis rate (s^{-1}). The assay accuracy is reportedly similar to that of determination of the lysis front velocity (or fiber lysis rate). Clot lysis time was defined as the time needed for the maximum elastic modulus to decrease by 50%. The intra-

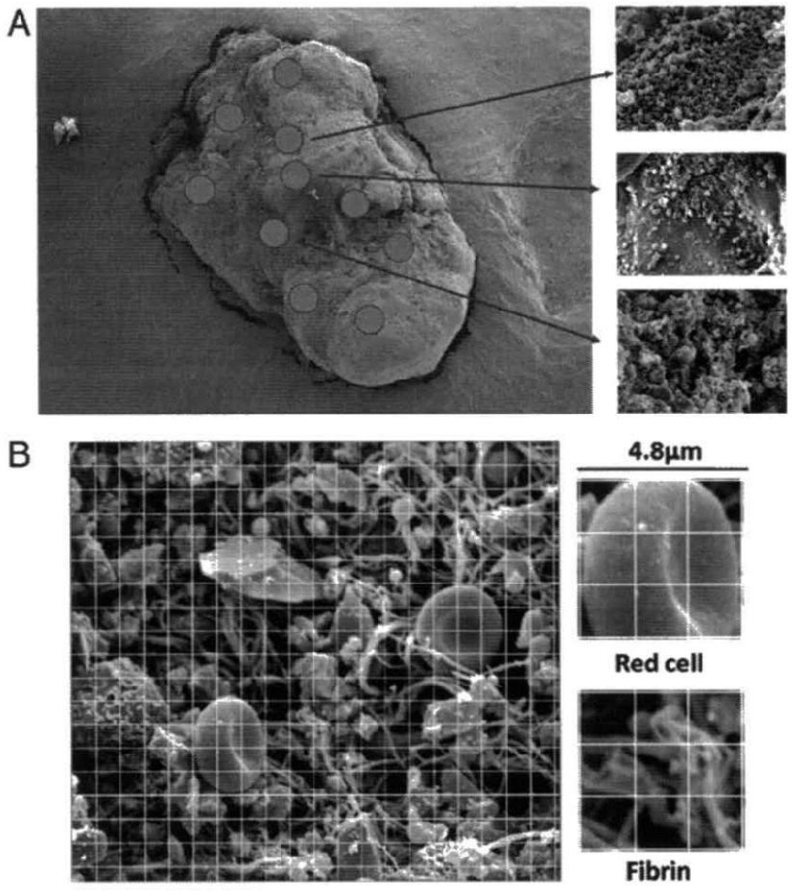

Figure 1 **Analysis of Clot Surface With 10+ Areas**

These areas (indicated by the **blue circles**) were used to average the thrombus heterogeneity **(A)** and perform semiquantitative analysis **(B)**.

individual variability of this technique was published previously (15).

Data collection. All patients entered the e-PARIS registry, a prospective web-based registry regrouping clinical and biological data on STEMI patients treated by primary PCI. Our angiographic core laboratory reviewed all angiographic films and noted the size of the infarct-related artery, corrected TIMI frame count, and myocardial blush grade (MBG), as previously described (16). Clinical and biological data were analyzed to identify predictors of thrombus composition. This study was approved by the Institutional Review Board of the Pitié-Salpêtrière Hospital in Paris (CPP), France.

Clinical follow-up. Patients were followed-up for 30 days through out-patient consultation. Physicians noted the occurrence of major cardiovascular and cerebrovascular events, including death, stroke, recurrent myocardial infarction (MI), urgent revascularization, and definite and probable stent thrombosis (Academic Research Consortium definition), as well as major and minor bleeding events. ST-segment resolution data were collected from the patient file.

Statistical analysis. Categorical variables were expressed as percentages, and continuous variables as mean ± SD or medians with the interquartile range (IQR) (25th to 75th percentiles) for time delay. Association between continuous variables was assessed by Pearson's correlation test. The variable ischemic time had an almost normal distribution. Because complementary analyses using Pearson's correlation test after log-transformation and nonparametric Spearman's test found similar results, the variable was considered normally distributed for all other analyses. Potential associations between clinical and biological parameters were tested by Student *t* test and ANOVA test with Dunnett's correction for multiple comparisons. Multivariable logistic and mixed models were used to assess the relationship between ischemic time and both qualitative and quantitative thrombus composition. Covariables (age, diabetes, renal insufficiency, admission troponin fibrinogen and platelet levels, pre-hospital abciximab use, clopidogrel pre-treatment, unfractionated heparin [UFH] versus enoxaparin use, and coronary artery reference diameter) were introduced into the models in addition to ischemic time in a stepwise fashion.

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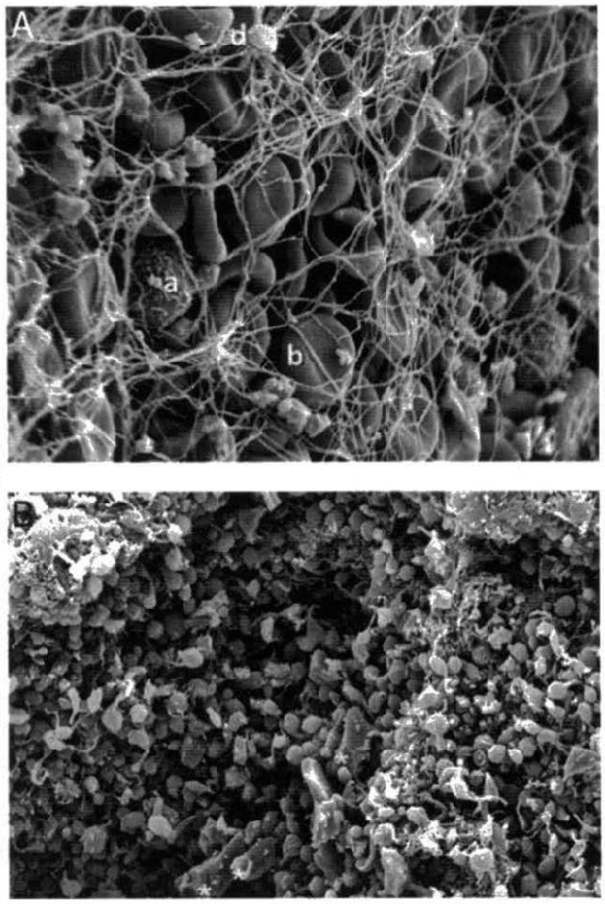

Figure 2 **Scanning Electron Micrograph at 3,000× Magnification**

(A) This portion is mainly composed of erythrocytes **(b)** trapped in a fibrin mesh **(c)** with few platelet aggregates **(d)** and rare white cells **(a)**. **(B)** This portion is mainly composed of platelet aggregates with a few cholesterol crystals **(yellow asterisks)**.

Diagnostics were systematically conducted for both logistic and mixed models to assess the normal distribution of residuals. Analyses were performed with SAS version 9.2 (SAS Institute, Cary, North Carolina).

Results

We prospectively screened 349 patients referred for primary PCI. Sixty-one late presenters were excluded because there was a time delay of >12 h from symptom onset to PCI or because symptom onset could not be characterized. Thromboaspiration was used in one-third of the early STEMI presenters (38%), and significant coronary thrombi >1 mm^3 were successfully retrieved in one-third of them (Fig. 3). The baseline characteristics of the patients are shown in Table 1. Patients were treated aggressively, with a high proportion receiving high loading doses of clopidogrel (at least 600 mg) and abciximab in addition to aspirin and low molecular weight or UFH. Median ischemic time (from symptom onset to PCI) was 175 min (IQR: 140 to 297 min). Details of procedures, angiographic findings, biomarker distributions, viscoelastic measurements, and fibrinolysis results are reported in Table 2.

Thrombus composition. Analyses were performed on 44 of the 45 thrombi collected. One thrombus was not analyzed because the SEM preparation had failed. Fibrin fibers were the major thrombus component, representing more than 60% of their composition. Platelets, erythrocytes, cholesterol crystals, and leukocytes together comprised the remaining 40% (Fig. 4). Thrombus components were easily identified in our high-definition SEM images. The 2 examples shown here are good representatives of the broad scope of thrombi components. These include a fibrin-and-erythrocyte composition typical of "old" fibrin-rich thrombi, usually found in patients with an ischemic time of >3 h (Fig. 2A) and a "fresh" platelet-rich thrombus of a patient presenting early, within the first hour following symptom onset (Fig. 2B). Remarkably, we could identify in these high-definition images an unexpected percentage (5%) of cholesterol crystals that were only described previously ex vivo (13).

Effect of time on thrombus composition. Ischemic time was found to have a high impact on thrombus composition, resulting in a positive correlation with intracoronary thrombus fibrin content, $r = 0.38$, $p = 0.01$, and a negative correlation with platelet content $r = -0.34$, $p = 0.02$. Pearson's correlation test after log-transformation and Spearman's nonparametric correlation test showed similar results ($r = 0.39$, $p = 0.01$; $r = -0.34$, $p = 0.025$; and $r = 0.36$, $p = 0.017$; $r = -0.30$, $p = 0.05$, respectively). Additionally, when ischemic time was divided into 3 categories (<3 h, 3 to 6 h, and >6 h), we observed a stepwise increase in fibrin content with respect to prolonged ischemic

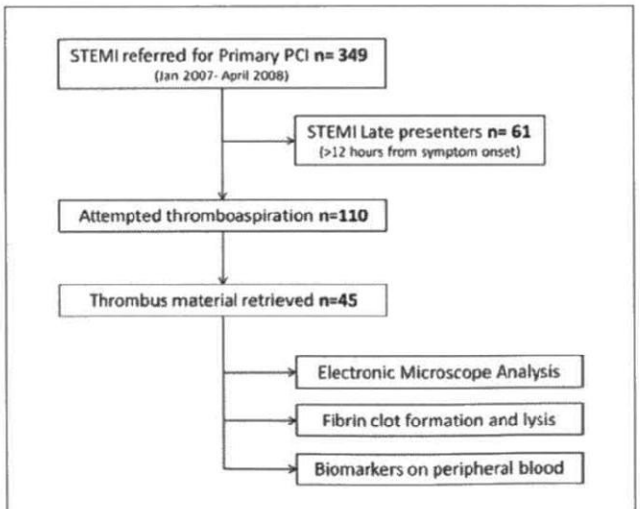

Figure 3 **Flow Chart of the Study**

Table 1 Baseline Characteristics (n = 45)

Demographics and risk factors	
Age	57.9 ± 13.2
Male	38 (84.4%)
Active smoker	21 (46.6%)
Diabetes	12(26.6%)
Hypertension	16 (35.5%)
Dyslipidemia	30 (66.6%)
BMI	26.4 ± 4.1
Past medical history of	
ACS	7 (15.5%)
Angioplasty	6 (13.3%)
CABG	1 (2.2%)
Clinical presentation	
Anterior MI	21 (46.6%)
Cardiac arrest	4 (11.1%)
TIMI risk score	3.0 ± 2.1
Killip class	1.2 ± 0.6
Cardiogenic shock	2 (4.4%)
Time delay in min	
Symptom onset to medical contact	80 [55–179]
Medical contact to catheterization laboratory	66 [55–128]
Catheterization laboratory to sheath insertion	20 [10–33]
Symptom onset to PCI	175 [140–297]
Biomarkers on admission	
Troponin I, μg/ml	5.1 ± 13.8
Negative troponin	17 (37.7%)
CK, IU/ml	447 ± 828
CRP, mg/l	13.7 ± 38
Fibrinogen, g/l	3.7 ± 1.3
Platelet, mm^3	242 ± 93
Creatinine clearance, ml/min	98 ± 33
Antithrombotic treatment	
ASA	45 (100%)
Clopidogrel	37 (83.5%)
Unfractionated heparin	17 (37.7%)
Enoxaparin	26 (62.3%)
GP IIb/IIIa inhibitor	41 (91.1%)
Pre-hospital	8 (17.7%)
Catheterization laboratory	33 (73.3%)
Thrombolysis	1 (2.2%)

Values are mean ± SD, n (%), or median [interquartile range].

ACS = acute coronary syndrome(s); ASA = acetylsalicylic acid; BMI = body mass index; CABG = coronary artery bypass grafting; CK = creatine kinase; CRP = C-reactive protein; GP = glycoprotein; MI = myocardial infarction; PCI = percutaneous intervention; TIMI = Thrombolysis in Myocardial Infarction.

time ranging 48.4 ± 21% (<3 h) to 66.9 ± 9% (>6 h) (p = 0.02). Platelet content decreased from 24.9 ± 23% (<3 h) to 9.1 ± 6% (>6 h) (p = 0.07) (Fig. 5). The evolution of each thrombus component relative to ischemic time is represented in Figure 6.

Effect of antithrombotic treatment on thrombus composition. Aspirin was administrated before thromboaspiration in 100% of patients, and abciximab was used either in a pre-hospital setting or in the catheterization laboratory in 91% of patients, limiting the analysis of their impact on thrombus composition. Clopidogrel pre-treatment was administered in 29 patients (66%) and did not induce any significant changes on platelet composition (24.1 ± 6% vs. 15.5 ± 3%; p = 0.17) when compared with patients without pre-hospital inhibition of the $P2Y_{12}$ receptor.

Biomarker distribution, viscoelastic properties, and fibrinolysis. The peripheral measure of the platelet activation marker sCD40 ligand was positively correlated with platelet content in the thrombus (r = 0.40, p = 0.02) and negatively correlated with fibrin content (r = −0.36; p = 0.04). The simultaneous measure of the more classic biomarker of myocardial infarction, namely troponin I, was a strong biomarker of ischemic time (r = 0.56, p < 0.01), but was not correlated with thrombus composition. No correlation was seen between ischemic time and inflammation biomarkers (IL-6, TNF-α, CRPus) or PAI-1, and neither platelet count nor fibrinogen level was correlated with thrombus composition (data not shown). Patients presenting after 6 h had a nonsignificant trend towards faster clotting time, stiffer

Table 2 Angiographic Results, Revascularization Procedure, and Biological Data (n = 45)

Radial approach	42 (93.3%)
Diameter of the infarct-related artery	3.15 ± 0.5
Acute stent thrombosis	5 (11.1%)
Patients with more than 1 significant lesion	13 (28.8%)
Infarct-related artery	
LAD	21 (46.6%)
RCA	17 (37.7%)
Cx	6 (13.3%)
CABG	1 (2.2%)
Successful PCI	41 (91.1%)
Ejection fraction post-MI (%)	48.9 ± 12
Markers of reperfusion	
TIMI flow grade 3 before PCI	3 (6.6%)
TIMI flow grade 3 after PCI	40 (88.8%)
cTFC before PCI	133 ± 45
cTFC after PCI	25 ± 22
TIMI MBG3 before PCI	4 (8.8%)
TIMI MBG3 after PCI	18 (40%)
ST-segment resolution >70%	25 (55.3)
Biomarkers	
CRPus, μg/ml	8.5 ± 3.9
IL-6, pg/ml	14.2 ± 34.8
PAI-1, ng/ml	70.2 ± 51.2
sCD40-ligand, ng/ml	1.2 ± 0.6
TNF-alpha, pg/ml	8.6 ± 1.1
Viscoelastic properties and response to fibrinolysis	
PCF, kdynes/s	1.4 ± 1.4
Elastic modulus max, kdynes/s	8.7 ± 8.8
Clotting time, s	691 ± 651
Clot lysis time, s	347 ± 204
Lysis rate × 10^4, s^{-1}	2.9 ± 4.1

Values are n (%) or mean ± SD.

cTFC = corrected Thrombolysis In Myocardial Infarction frame count; CRPus = ultra-sensitive C-reactive protein; Cx = circumflex coronary artery; IL = interleukin; LAD = left anterior descending coronary artery; MBG = myocardial blush grade; PAI = plasminogen activator inhibitor; PCF = platelet contractile force; RCA = right coronary artery; sCD40 = soluble CD40; TNF = tumor necrosis factor; other abbreviations as in Table 1.

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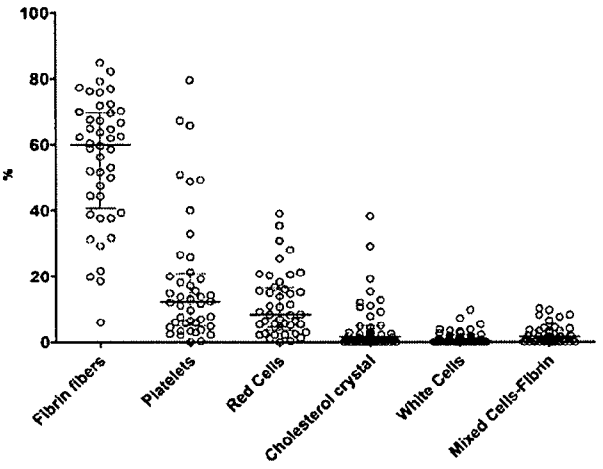

Figure 4 **Thrombi Composition in 44 STEMI Patients (Early Presenters)**

Red lines indicate median and interquartile range (25% to 75%). PCI = percutaneous intervention; STEMI = ST-segment elevation myocardial infarction.

clot (as indicated from the elastic modulus), and longer clot lysis time (Fig. 7).

Independent correlates of thrombus composition and of reperfusion. Ischemic time was the only correlate of thrombus composition in the multivariable stepwise logistic analysis. None of the other covariables met the 0.05 significance level for entering the model. Every additional ischemic hour led to a 2-fold increase in the rates of fibrin-rich thrombus—<30% platelet and >70% fibrin—(adjusted odds ratio [adjOR]: 2 [95% confidence interval (CI): 1.03 to 3.7]) and a 50% reduction in platelet content (adjOR: 0.5 [95% CI: 0.27 to 0.94]) ($p = 0.001$ for both). Similar results were obtained when the fibrin content (%) was analyzed quantitatively in a multivariable mixed model with the same covariables introduced in the model in addition to ischemic time. "Fresh" platelet-rich thrombus was defined as >30% platelet and <70% fibrin, and "old" fibrin-rich thrombi as <30% platelet and >70% fibrin. No differences in reperfusion were seen between "fresh" platelet-rich thrombi and "old" fibrin-rich thrombi assessed by ST-segment resolution and TIMI MBG. Independent correlates of successful reperfusion (ST-segment resolution of >70%) included a low plasma fibrinogen level (adjOR: 0.33 [95% CI: 0.12 to 0.91] [per g/l], $p = 0.003$) and the use of enoxaparin versus UFH (adjOR: 10.3 [95% CI: 1.7 to 62], $p = 0.02$). High and low counts for plasma fibrinogen level were 8 and 1.8 g/l, respectively.

Discussion

Thrombus aspiration is a newly recommended technique that facilitates thrombus removal from the culprit coronary artery in myocardial infarction. The method reportedly improves mortality in STEMI patients presenting within 12 h of symptoms onset when used in conjunction with primary PCI (7,8). This life-saving technique allowed us to study prospectively the composition of occlusive thrombi in STEMI patients admitted for mechanical coronary reperfusion.

We report the results of a new analysis method for intracoronary thrombi obtained in vivo that allows the determination of their precise composition using SEM, associated here with an analysis of cardiac biomarkers, fibrin clot viscoelastic properties, and fibrinolysis obtained simultaneously from patients' peripheral blood. The analysis of high-definition SEM images that we produced with respect to ischemic time (from symptom onset to thrombus retrieval) revealed that the dynamic formation of the thrombus during an acute coronary occlusion is a fast-evolving process. The platelet and fibrin fiber components of the thrombus, which are both therapeutic targets, changed rapidly with respect to ischemic time. These observations of thrombus structure and formation in vivo demonstrate the relationship between thrombus composition and ischemic time, which was found to be the only major predictors of thrombus composition. Our results also demonstrate that thrombus composition is an indicator of coronary occlusion time and, therefore, of the beginning of myocardial damage.

Our findings add to the body of knowledge on thrombus formation in acute MI. First, they confirm, at the pathophysiological level, the generally accepted pathogenesis of clot formation in vivo in STEMI patients. "Fresh" thrombi have the highest proportion of platelets, whereas the proportion of fibrin fibers increases over time, as the level of thrombin increases, leading to "older" fibrin-rich thrombi. These results confirm previous in vivo animal studies showing the very early stage of thrombus formation, just after endothelial injury, when the initial thrombus is primarily composed of activated platelets, rapidly stabilized by fibrin

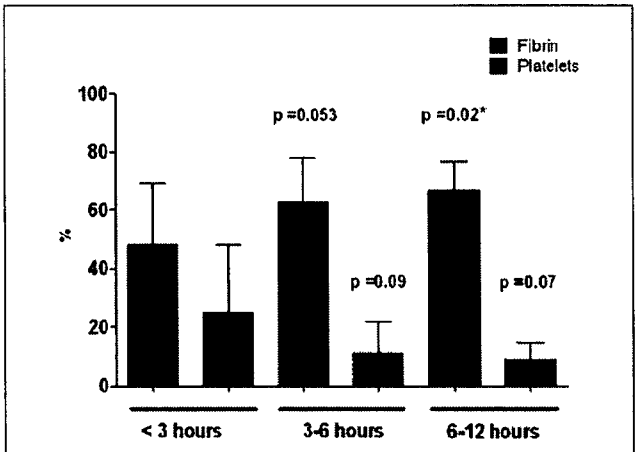

Figure 5 **Impact of Time on Thrombus Composition**

The p values are given for comparison with the group <3 h as a reference with multiple Student *t* test. *$p < 0.05$. Multiple comparisons were done with the Dunnett's test, resulting in a $p = 0.044$ for fibrin and nonsignificant for platelet content.

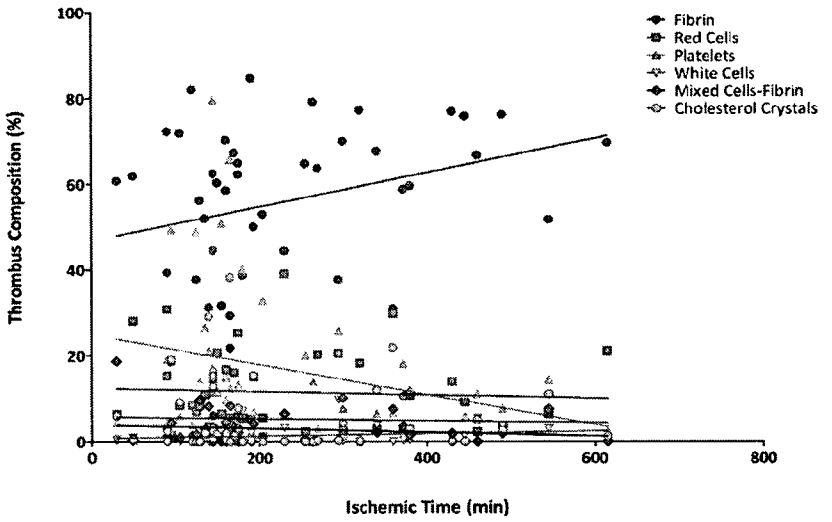

Figure 6 **Evolution of the Percentage Thrombus Composition for Each Component**

The components in percentages (y-axis) are shown relative to ischemic times in minutes (x-axis). **Lines** represent linear regression for correlation with ischemic time.

fibers, with a decreasing proportion of platelets over time (17–19). At a clinical level, our results are along the same lines as those reported by Kramer et al. (20), who showed that the thrombus composition itself seems to be a prognostic marker and is linked to short- and long-term mortality in a large study in STEMI. In this previous study, thrombus composition was evaluated by classical light microscopy showing 2 types of thrombi, "fresh thrombi" (<1 day) composed of layered patterns of fibrin and intact platelets, erythrocytes, and granulocytes, and "older thrombi" (>1 day) comprised of lytic and/or organized areas. Our own analysis differs from this previous classification by the age of clots (earlier period), the method used (scanning electronic microscope), the structure analyzed (we studied the thrombus surface, which reflects more the latter layers of thrombus formation), and the results reported (focused on the proportion of each component). The high-resolution imaging facilitated the detailed characterization of all structures present in the thrombi, despite the difficulties of this task, because of their remarkable heterogeneity. This allowed us, for example, to identify cholesterol crystals that were most likely released by the ruptured plaque. It should also be noted that fibrin is a major component of the thrombus even at the relatively early stages studied here. Additionally, simultaneous measurements of biomarkers allow us to confirm the role of sCD40 ligand on platelet accumulation in the intracoronary thrombus at the early phase of formation.

Our findings also help interpret results obtained from previous clinical trials. Indeed, fibrinolysis treatment has been demonstrated to have a narrow therapeutic time window and seems to be most efficient during the first 3 h of STEMI (21,22). According to our study, this represents a period when the clot has a small and accessible amount of fibrin fibers and when fibrinolysis has not yet been overcome by the intense fibrin formation. Furthermore, the fast accumulation of fibrin fibers in the thrombus followed by its stabilization by FXIII cross-linking is likely to increase clot stiffness, resulting in resistance to fibrinolysis as shown in vitro (15,23). Regarding antiplatelet agents, even though glycoprotein (GP) IIb/IIIa inhibitors, such as abciximab, have been shown to reduce mortality in primary PCI (vs. placebo), the potential benefit is mostly observed with an early administration (24–29). In contrast, negative studies with GP IIb/IIa inhibitors seem to relate to late presentation of patients (30,31). These clinical results suggest a time limit under which these molecules are efficient, and correspond according to our study to the time when the occlusive thrombus contains a high proportion of platelets, shortly before it evolves into a compact, fibrin-rich structure.

In our study, the effect of antithrombotic pretreatment by aspirin and abciximab was initially included in the analysis, but due to the fact that almost all patients received these 2 fast-acting agents before thromboaspiration, we could not demonstrate any potential effect of such drugs on thrombus composition. We believe that the impact of pre-hospital $P2Y_{12}$ inhibition on platelet composition should be studied in a dedicated study.

Study limitations. First, although erythrocytes were the second most common cell identified in our thrombi, we were surprised not to find an increased percentage of erythrocytes with time. Erythrocytes in clots were the origin of the word "red" thrombi for old thrombi as opposed to recent platelet-rich "white" thrombi. Erythrocytes may contribute more to thrombus composition at later stages and

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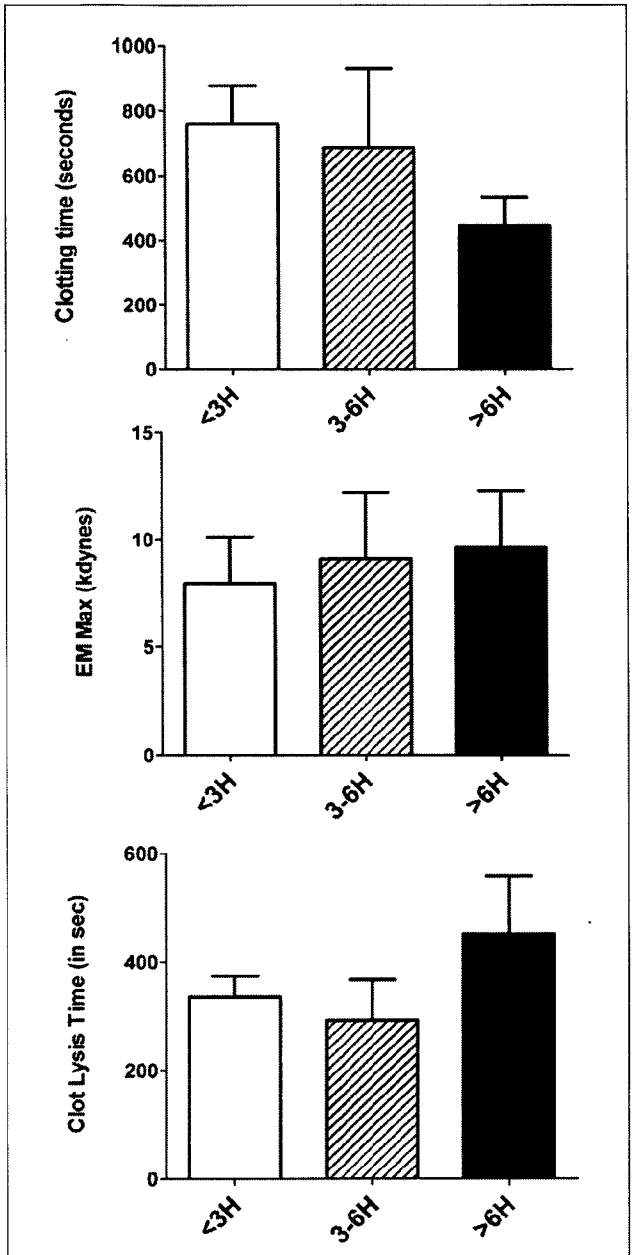

Figure 7 **Results of Fibrin Clot Viscoelastic Properties and Response to Fibrinolysis According to Ischemic Time**

No significant differences were found between groups with the Dunnett's test. EM Max = maximum elastic modulus.

not in the time window of acute reperfusion of STEMI. The role of erythrocytes in thrombi remains to be studied more extensively, since they also appear to mediate the formation of thicker fibrin fibers and influence clot viscoelasticity by increasing the viscous component of the sample relative to the elastic component (32). Second, due to the in vivo nature of our study, the analysis was performed on the main aspirated piece of the thrombus and did not include the total volume of retrieved fragments or the distal embolic debris. Because the retrieval of the thrombus is done by aspiration through the catheter lumen, the high-definition analysis, made by scanning the surface of the piece of thrombus, can correspond, in fact, to any part of the thrombus (head or tail, surface or core, luminal or abluminal), turning this potential limitation into a major strength of this approach. To our knowledge, there is no known technique (beside surgical removal or postmortem autopsy) that can analyze the whole thrombus, including the part of the thrombus that might have embolized, or allows analyzing the 3-dimensional structure of a thrombus. Additionally, the number of thrombi retrieved, and the random localization of the pictures that were analyzed, should guarantee an unbiased measurement, and control for composition heterogeneity in the pieces of thrombi that were obtained. Third, potential distortion of the samples might have occurred during thromboaspiration. However, we believe that damage was limited, knowing that thrombi are stiffer than in vitro clots and that fibrin fibers and clots bear outstanding elastic properties (33,34). The preserved appearance of cells and fibrin fibers in the microscopy images confirmed that distortion was minimal. Fourth, the choice of SEM can be criticized since material cannot be stained as in histopathologic analysis, but was motivated by its ability to provide high-resolution images of thrombi in humans who had had MI (5). Fifth, the aspirated thrombus may be older than expected from the duration of the ischemic time, and younger thrombus could be superimposed onto an older thrombus, thereby potentially confusing our observations (20). Finally, even if thrombi were retrieved randomly in a subset of patients representative of our STEMI population, the absence of successful thromboaspiration in all STEMI presenters could have biased our results. A methodological limitation also needs to be underlined, as the multivariable analysis should be considered as only exploratory, because the model is not parsimonious.

Our work helps characterize thoroughly the components of coronary thrombi in STEMI and thereby contributes to the current understanding of coronary thrombus formation, which is relevant to the efficacy of various reperfusion treatments. The composition of the aspirated thrombus could also be a potential surrogate end point in clinical trials assessing the benefit of a new antithrombotic regimen (new drugs or new combination of drugs). Ongoing research should elucidate the mechanistic relationships between thrombus composition, myocardial perfusion, and microvascular obstruction.

Conclusions

Thrombus aspiration, an integral component of mechanical reperfusion of acute MI, allowed us to describe in detail the composition of the occlusive thrombus and its changes over

time. Our study shows that the platelet and fibrin contents of the occlusive thrombi of acute STEMI evolve rapidly. Even within a population of patients treated with aggressive antithrombotic regimens, ischemic time is a key determinant of thrombus composition.

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Reprint requests and correspondence: Dr. Gilles Montalescot, Bureau 236, Institut de Cardiologie, Pitié-Salpêtrière University Hospital, 47-83 boulevard de l'Hôpital, 75013 Paris, France. E-mail: gilles.montalescot@psl.aphp.fr.

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Universal Definition of Myocardial Infarction

Kristian Thygesen, Joseph S. Alpert, Harvey D. White, TASK FORCE MEMBERS: Chairpersons: Kristian Thygesen (Denmark), Joseph S. Alpert (USA) , Harvey D. White (New Zealand), Biomarker Group: Allan S. Jaffe, Coordinator (USA), Fred S. Apple (USA), Marcello Galvani (Italy), Hugo A. Katus (Germany), L. Kristin Newby (USA), Jan Ravkilde (Denmark), ECG Group: Bernard Chaitman, Co-ordinator (USA), Peter M. Clemmensen (Denmark), Mikael Dellborg (Sweden), Hanoch Hod (Israel), Pekka Porela (Finland), Imaging Group: Richard Underwood, Coordinator (UK), Jeroen J. Bax (The Netherlands), George A. Beller (USA), Robert Bonow (USA), Ernst E. Van Der Wall (The Netherlands), Intervention Group: Jean-Pierre Bassand, Co-ordinator (France), William Wijns, Coordinator (Belgium), T. Bruce Ferguson (USA), Philippe G. Steg (France), Barry F. Uretsky (USA), David O. Williams (USA), Clinical Investigation Group: Paul W. Armstrong, Coordinator (Canada), Elliott M. Antman (USA), Keith A. Fox (UK), Christian W. Hamm (Germany), E. Magnus Ohman (USA), Maarten L. Simoons (The Netherlands), Global Perspective Group: Philip A. Poole-Wilson, Coordinator (UK), Enrique P. Gurfinkel (Argentina), José-Luis Lopez-Sendon (Spain), Prem Pais (India), Shanti Mendis (Switzerland), Jun-Ren Zhu (China), Implementation Group: Lars C. Wallentin Coordinator (Sweden), Francisco Fernández-Avilés (Spain), Kim M. Fox (UK), Alexander N. Parkhomenko (Ukraine), Silvia G. Priori (Italy), Michal Tendera (Poland), Liisa-Maria Voipio-Pulkki (Finland), ESC COMMITTEE FOR PRACTICE GUIDELINES, Alec Vahanian, Chair (France), A. John Camm (UK), Raffaele De Caterina (Italy), Veronica Dean (France), Kenneth Dickstein (Norway), Gerasimos Filippatos (Greece), Christian Funck-Brentano (France), Irene Hellemans (The Netherlands), Steen Dalby Kristensen (Denmark), Keith McGregor (France), Udo Sechtem (Germany), Sigmund Silber (Germany), Michal Tendera (Poland), Petr Widimsky (Czech Republic), José Luis Zamorano (Spain), DOCUMENT REVIEWERS and Joao Morais, Review Coordinator (Portugal), Sorin Brener (USA), Robert Harrington (USA), David Morrow (USA), Udo Sechtem (Germany), Michael Lim (Singapore), Marco A. Martinez-Rios (Mexico), Steve Steinhubl (USA), Glen N. Levine (USA), W. Brian Gibler (USA), David Goff (USA), Marco Tubaro (Italy), Darek Dudek (Poland), Nawwar Al-Attar (France)

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Expert Consensus Document

Universal Definition of Myocardial Infarction

Kristian Thygesen; Joseph S. Alpert; Harvey D. White;
on behalf of the Joint ESC/ACCF/AHA/WHF Task Force
for the Redefinition of Myocardial Infarction

TASK FORCE MEMBERS

Chairpersons: Kristian Thygesen (Denmark)*, Joseph S. Alpert (USA)*, Harvey D. White (New Zealand)*
Biomarker Group: Allan S. Jaffe, Coordinator (USA), Fred S. Apple (USA), Marcello Galvani (Italy), Hugo A. Katus (Germany), L. Kristin Newby (USA), Jan Ravkilde (Denmark) ECG Group: Bernard Chaitman, Co-ordinator (USA), Peter M. Clemmensen (Denmark), Mikael Dellborg (Sweden), Hanoch Hod (Israel), Pekka Porela (Finland) Imaging Group: Richard Underwood, Coordinator (UK), Jeroen J. Bax (The Netherlands), George A. Beller (USA), Robert Bonow (USA), Ernst E. Van Der Wall (The Netherlands) Intervention Group: Jean-Pierre Bassand, Co-ordinator (France), William Wijns, Coordinator (Belgium), T. Bruce Ferguson (USA), Philippe G. Steg (France), Barry F. Uretsky (USA), David O. Williams (USA) Clinical Investigation Group: Paul W. Armstrong, Coordinator (Canada), Elliott M. Antman (USA), Keith A. Fox (UK), Christian W. Hamm (Germany), E. Magnus Ohman (USA), Maarten L. Simoons (The Netherlands) Global Perspective Group: Philip A. Poole-Wilson, Coordinator (UK), Enrique P. Gurfinkel (Argentina), José-Luis Lopez-Sendon (Spain), Prem Pais (India), Shanti Mendis† (Switzerland), Jun-Ren Zhu (China) Implementation Group: Lars C. Wallentin Coordinator (Sweden), Francisco Fernández-Avilés (Spain), Kim M. Fox (UK), Alexander N. Parkhomenko (Ukraine), Silvia G. Priori (Italy), Michal Tendera (Poland), Liisa-Maria Voipio-Pulkki (Finland)

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Joao Morais, Review Coordinator (Portugal), Sorin Brener (USA), Robert Harrington (USA), David Morrow (USA), Udo Sechtem (Germany), Michael Lim (Singapore), Marco A. Martinez-Rios (Mexico), Steve Steinhubl (USA), Glen N. Levine (USA), W. Brian Gibler (USA), David Goff (USA), Marco Tubaro (Italy), Darek Dudek (Poland), Nawwar Al-Attar (France)

The recommendations set forth in this report are those of the Task Force Members and do not necessarily reflect the official position of the American College of Cardiology.

*Co-chairpersons.

†Dr Shanti Mendis of the World Health Organization participated in the task force in her personal capacity, but this does not represent WHO approval of this document at the present time.

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Definition of myocardial infarction

Criteria for acute myocardial infarction

The term myocardial infarction should be used when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischaemia. Under these conditions any one of the following criteria meets the diagnosis for myocardial infarction:

- Detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit (URL) together with evidence of myocardial ischaemia with at least one of the following:
  - Symptoms of ischaemia;
  - ECG changes indicative of new ischaemia [new ST-T changes or new left bundle branch block (LBBB)];
  - Development of pathological Q waves in the ECG;
  - Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.
- Sudden, unexpected cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischaemia, and accompanied by presumably new ST elevation, or new LBBB, and/or evidence of fresh thrombus by coronary angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood.
- For percutaneous coronary interventions (PCI) in patients with normal baseline troponin values, elevations of cardiac biomarkers above the 99th percentile URL are indicative of peri-procedural myocardial necrosis. By convention, increases of biomarkers greater than 3 x 99th percentile URL have been designated as defining PCI-related myocardial infarction. A subtype related to a documented stent thrombosis is recognized.
- For coronary artery bypass grafting (CABG) in patients with normal baseline troponin values, elevations of cardiac biomarkers above the 99th percentile URL are indicative of peri-procedural myocardial necrosis. By convention, increases of biomarkers greater than 5 x 99th percentile URL plus either new pathological Q waves or new LBBB, or angiographically documented new graft or native coronary artery occlusion, or imaging evidence of new loss of viable myocardium have been designated as defining CABG-related myocardial infarction.
- Pathological findings of an acute myocardial infarction.

Criteria for prior myocardial infarction

Any one of the following criteria meets the diagnosis for prior myocardial infarction:

- Development of new pathological Q waves with or without symptoms.
- Imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischaemic cause.
- Pathological findings of a healed or healing myocardial infarction.

Introduction

Myocardial infarction is a major cause of death and disability worldwide. Coronary atherosclerosis is a chronic disease with stable and unstable periods. During unstable periods with activated inflammation in the vascular wall, patients may develop a myocardial infarction. Myocardial infarction may be a minor event in a lifelong chronic disease, it may even go undetected, but it may also be a major catastrophic event leading to sudden death or severe hemodynamic deterioration. A myocardial infarction may be the first manifestation of coronary artery disease, or it may occur, repeatedly, in patients with established disease. Information on myocardial infarction attack rates can provide useful data regarding the burden of coronary artery disease within and across populations, especially if standardized data are collected in a manner that demonstrates the distinction between incident and recurrent events. From the epidemiological point of view, the incidence of myocardial infarction in a population can be used as a proxy for the prevalence of coronary artery disease in that population. Furthermore, the term myocardial infarction has major psychological and legal implications for the individual and society. It is an indicator of one of the leading health problems in the world, and it is an outcome measure

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in clinical trials and observational studies. With these perspectives, myocardial infarction may be defined from a number of different clinical, electrocardiographic, biochemical, imaging, and pathological characteristics.

In the past, a general consensus existed for the clinical syndrome designated as myocardial infarction. In studies of disease prevalence, the World Health Organization (WHO) defined myocardial infarction from symptoms, ECG abnormalities, and enzymes. However, the development of more sensitive and specific serological biomarkers and precise imaging techniques allows detection of ever smaller amounts of myocardial necrosis. Accordingly, current clinical practice, health care delivery systems, as well as epidemiology and clinical trials all require a more precise definition of myocardial infarction and a re-evaluation of previous definitions of this condition.

It should be appreciated that over the years, while more specific biomarkers of myocardial necrosis became available, the accuracy of detecting myocardial infarction has changed. Such changes occurred when glutamine-oxaloacetic transaminase (GOT) was replaced by lactate dehydrogenase (LDH) and later by creatine kinase (CK) and the MB fraction of CK, i.e. CKMB activity and CKMB mass. Current, more specific, and sensitive biomarkers and imaging methods to detect myocardial infarction are further refinements in this evolution.

In response to the issues posed by an alteration in our ability to identify myocardial infarction, the European Society of Cardiology (ESC) and the American College of Cardiology (ACC) convened a consensus conference in 1999 in order to re-examine jointly the definition of myocardial infarction (published in the year 2000 in the *European Heart Journal* and *Journal of the American College of Cardiology*[1]). The scientific and societal implications of an altered definition for myocardial infarction were examined from seven points of view: pathological, biochemical, electro-cardiographic, imaging, clinical trials, epidemiological, and public policy. It became apparent from the deliberations of the former consensus committee that the term myocardial infarction should not be used without further qualifications, whether in clinical practice, in the description of patient cohorts, or in population studies. Such qualifications should refer to the amount of myocardial cell loss (infarct size), to the circumstances leading to the infarct (e.g. spontaneous or procedure related), and to the timing of the myocardial necrosis relative to the time of the observation (evolving, healing, or healed myocardial infarction).[1]

Following the 1999 ESC/ACC consensus conference, a group of cardiovascular epidemiologists met to address the specific needs of population surveillance. This international meeting, representing several national and international organizations, published recommendations in Circulation 2003.[2] These recommendations addressed the needs of researchers engaged in long-term population trend analysis in the context of changing diagnostic tools using retrospective medical record abstraction. Also considered was surveillance in developing countries and out-of-hospital death, both situations with limited and/or missing data. These recommendations continue to form the basis for epidemiological research.

Given the considerable advances in the diagnosis and management of myocardial infarction since the original document was published, the leadership of the ESC, the ACC, and the American Heart Association (AHA) convened, together with the World Heart Federation (WHF), a Global Task Force to update the 2000 consensus document.[1] As with the previous consensus committee, the Global Task Force was composed of a number of working groups in order to refine the ESC/ACC criteria for the diagnosis of myocardial infarction from various perspectives. With this goal in mind, the working groups were composed of experts within the field of biomarkers, ECG, imaging, interventions, clinical investigations, global perspectives, and implications. During several Task Force meetings, the recommendations of the working groups were coordinated, resulting in the present updated consensus document.

The Task Force recognizes that the definition of myocardial infarction will be subject to a variety of changes in the future as a result of scientific advance. Therefore, this document is not the final word on this issue for all time. Further refinement of the present definition will doubtless occur in the future.

Clinical Features of Ischemia

The term myocardial infarction reflects cell death of cardiac myocytes caused by ischemia, which is the result of a perfusion imbalance between supply and demand. Ischemia in a clinical setting most often can be identified from the patient's history and from the ECG. Possible ischemic symptoms include various combinations of chest, upper extremity, jaw, or epigastric discomfort with exertion or at rest. The discomfort associated with acute myocardial infarction usually lasts at least 20 min. Often, the discomfort is diffuse, not localized, not positional, not affected by movement of the region, and it may be accompanied by dyspnea, diaphoresis, nausea, or syncope.

These symptoms are not specific to myocardial ischemia and can be misdiagnosed and thus attributed to gastrointestinal, neurological, pulmonary, or musculoskeletal disorders. Myocardial infarction may occur with atypical symptoms, or even without symptoms, being detected only by ECG, biomarker elevations, or cardiac imaging.

Pathology

Myocardial infarction is defined by pathology as myocardial cell death due to prolonged ischemia. Cell death is categorized pathologically as coagulation and/or contraction band necrosis, which usually evolves through oncosis, but can result to a lesser degree from apoptosis. Careful analysis of histological sections by an experienced observer is essential to distinguish these entities.[1]

After the onset of myocardial ischemia, cell death is not immediate but takes a finite period to develop (as little as 20 min or less in some animal models). It takes several hours before myocardial necrosis can be identified by macroscopic or microscopic post-mortem examination. Complete necrosis of all myocardial cells at risk requires at least 2–4 h or longer depending on the presence of collateral circulation to the ischemic zone, persistent or intermittent coronary arterial

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occlusion, the sensitivity of the myocytes to ischemia, preconditioning, and/or, finally, individual demand for myocardial oxygen and nutrients. Myocardial infarctions are usually classified by size: microscopic (focal necrosis), small [<10% of the left ventricular (LV) myocardium], moderate (10–30% of the LV myocardium), and large (>30% of the LV myocardium), and by location. The pathological identification of myocardial necrosis is made without reference to morphological changes in the coronary arterial tree or to the clinical history.[1]

Myocardial infarction can be defined pathologically as acute, healing, or healed. Acute myocardial infarction is characterized by the presence of polymorphonuclear leukocytes. If the time interval between the onset of the infarction and death is quite brief, e.g. 6 h, minimal or no polymorphonuclear leukocytes may be seen. The presence of mononuclear cells and fibroblasts, and the absence of polymorphonuclear leukocytes characterize healing infarction. Healed infarction is manifested as scar tissue without cellular infiltration. The entire process leading to a healed infarction usually takes at least 5–6 weeks. Reperfusion may alter the macroscopic and microscopic appearance of the necrotic zone by producing myocytes with contraction bands and large quantities of extravasated erythrocytes. Myocardial infarctions can be classified temporally from clinical and other features, as well as according to the pathological appearance, as evolving (<6 h), acute (6 h–7 days), healing (7–28 days), and healed (29 days and beyond). It should be emphasized that the clinical and electrocardiographic timing of the onset of an acute infarction may not correspond exactly with the pathological timing. For example, the ECG may still demonstrate evolving ST-T changes and cardiac biomarkers may still be elevated (implying a recent infarct) at a time when pathologically the infarction is in the healing phase.[1]

Patients who suffer sudden cardiac death with or without ECG changes suggestive of ischemia represent a challenging diagnostic group. Since these individuals die before pathological changes can develop in the myocardium, it is difficult to say with certainty whether these patients succumbed to a myocardial infarction or to an ischemic event that led to a fatal arrhythmia. The mode of death in these cases is sudden, but the etiology remains uncertain unless the individual reported previous symptoms of ischemic heart disease prior to the cardiac arrest. Some patients with or without a history of coronary disease may develop clinical evidence of ischemia, including prolonged and profound chest pain, diaphoresis and/or shortness of breath, and sudden collapse. These individuals may die before blood samples for biomarkers can be obtained, or these individuals may be in the lag phase before cardiac biomarkers can be identified in the blood. These patients may have suffered an evolving, fatal, acute myocardial infarction. If these patients present with presumably new ECG changes, for example ST elevation, and often with symptoms of ischemia, they should be classified as having had a fatal myocardial infarction even if cardiac biomarker evidence of infarction is lacking. Also, patients with evidence of fresh thrombus by coronary angiography (if performed) and/or at autopsy should be classified as having undergone sudden death as a result of myocardial infarction.

Table 1 Clinical classification of different types of myocardial infarction

Type 1
Spontaneous myocardial infarction related to ischaemia due to a primary coronary event such as plaque erosion and/or rupture, fissuring, or dissection
Type 2
Myocardial infarction secondary to ischaemia due to either increased oxygen demand or decreased supply, e.g. coronary artery spasm, coronary embolism, anaemia, arrhythmias, hypertension, or hypotension
Type 3
Sudden unexpected cardiac death, including cardiac arrest, often with symptoms suggestive of myocardial ischaemia, accompanied by presumably new ST elevation, or new LBBB, or evidence of fresh thrombus in a coronary artery by angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood
Type 4a
Myocardial infarction associated with PCI
Type 4b
Myocardial infarction associated with stent thrombosis as documented by angiography or at autopsy
Type 5
Myocardial infarction associated with CABG

Clinical Classification of Myocardial Infarction

Clinically the various types of myocardial infarction can be classified as shown in Table 1.

On occasion, patients may manifest more than one type of myocardial infarction simultaneously or sequentially. It should also be noted that the term myocardial infarction does not include myocardial cell death associated with mechanical injury from coronary artery bypass grafting (CABG), for example ventricular venting, or manipulation of the heart; nor does it include myocardial necrosis due to miscellaneous causes, e.g. renal failure, heart failure, cardioversion, electrophysiological ablation, sepsis, myocarditis, cardiac toxins, or infiltrative diseases.

Biomarker Evaluation

Myocardial cell death can be recognized by the appearance in the blood of different proteins released into the circulation from the damaged myocytes: myoglobin, cardiac troponin T and I, CK, LDH, as well as many others.[3] Myocardial infarction is diagnosed when blood levels of sensitive and specific biomarkers such as cardiac troponin or CKMB are increased in the clinical setting of acute myocardial ischemia.[1] Although elevations in these biomarkers reflect myocardial necrosis, they do not indicate its mechanism.[3,4] Thus, an elevated value of cardiac troponin in the absence of clinical evidence of ischemia should prompt a search for other etiologies of myocardial necrosis, such as myocarditis, aortic dissection, pulmonary embolism, congestive heart failure, renal failure, and other examples indicated in Table 2.

The preferred biomarker for myocardial necrosis is cardiac troponin (I or T), which has nearly absolute myocardial tissue specificity as well as high clinical sensitivity, thereby reflect-

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Table 2 Elevations of troponin in the absence of overt ischemic heart disease

Cardiac contusion, or other trauma including surgery, ablation, pacing, etc.
Congestive heart failure—acute and chronic
Aortic dissection
Aortic valve disease
Hypertrophic cardiomyopathy
Tachy- or bradyarrhythmias, or heart block
Apical ballooning syndrome
Rhabdomyolysis with cardiac injury
Pulmonary embolism, severe pulmonary hypertension
Renal failure
Acute neurological disease, including stroke or subarachnoid haemorrhage
Infiltrative diseases, e.g. amyloidosis, haemochromatosis, sarcoidosis, and scleroderma
Inflammatory diseases, e.g. myocarditis or myocardial extension of endo-/pericarditis
Drug toxicity or toxins
Critically ill patients, especially with respiratory failure or sepsis
Burns, especially if affecting >30% of body surface area
Extreme exertion

Modified from Jaffe *et al.*,[4] and French and White.[5]

ing even microscopic zones of myocardial necrosis.[3] An increased value for cardiac troponin is defined as a measurement exceeding the 99th percentile of a normal reference population (URL = upper reference limit). Detection of a rise and/or fall of the measurements is essential to the diagnosis of acute myocardial infarction.[6] The above-mentioned discriminatory percentile is designated as the decision level for the diagnosis of myocardial infarction, and must be determined for each specific assay with appropriate quality control.[7–9] Optimal precision [coefficient of variation (CV)] at the 99th percentile URL for each assay should be defined as ≤10%. Better precision (CV≤10%) allows for more sensitive assays.[10,11] The use of assays that do not have independent validation of optimal precision (CV≤10%) is not recommended. The values for the 99th percentile can be found on the International Federation for Clinical Chemistry website http://www.ifcc.org/index.php?option=com_remository&Itemid=120&func=fileinfo&id=7.

Blood samples for the measurement of troponin should be drawn on first assessment (often some hours after the onset of symptoms) and 6–9 h later.[12] An occasional patient may require an additional sample between 12 and 24 h if the earlier measurements were not elevated and the clinical suspicion of myocardial infarction is high.[12] To establish the diagnosis of myocardial infarction, one elevated value above the decision level is required. The demonstration of a rising and/or falling pattern is needed to distinguish background elevated troponin levels, e.g. patients with chronic renal failure (Table 2), from elevations in the same patients which are indicative of myocardial infarction.[6] However, this pattern is not absolutely required to make the diagnosis of myocardial infarction if the patient presents >24 h after the onset of symptoms. Troponin values may remain elevated for 7–14 days following the onset of infarction.[4]

If troponin assays are not available, the best alternative is CKMB (measured by mass assay). As with troponin, an increased CKMB value is defined as a measurement above the 99th percentile URL, which is designated as the decision level for the diagnosis of myocardial infarction.[9] Gender-specific values should be employed.[9] The CKMB measurements should be recorded at the time of the first assessment of the patient and 6–9 h later in order to demonstrate the rise and/or fall exceeding the 99th percentile URL for the diagnosis of myocardial infarction. An occasional patient may require an additional diagnostic sample between 12 and 24 h if the earlier CKMB measurements were not elevated and the clinical suspicion of myocardial infarction is high.

Measurement of total CK is not recommended for the diagnosis of myocardial infarction, because of the large skeletal muscle distribution and the lack of specificity of this enzyme.

Reinfarction

Traditionally, CKMB has been used to detect reinfarction. However, recent data suggest that troponin values provide similar information.[13] In patients where recurrent myocardial infarction is suspected from clinical signs or symptoms following the initial infarction, an immediate measurement of the employed cardiac marker is recommended. A second sample should be obtained 3–6 h later. Recurrent infarction is diagnosed if there is a ≥20% increase of the value in the second sample. Analytical values are considered to be different if they are different by >3 SDs of the variance of the measures.[14] For troponin, this value is 5–7% for most assays at the levels involved with reinfarction. Thus, a 20% change should be considered significant, i.e. over that expected from analytical variability itself. This value should also exceed the 99th percentile URL.

Electrocardiographic Detection of Myocardial Infarction

The ECG is an integral part of the diagnostic work-up of patients with suspected myocardial infarction.[1,2,15,16] The acute or evolving changes in the ST-T waveforms and the Q-waves when present potentially allow the clinician to date the event, to suggest the infarct-related artery, and to estimate the amount of myocardium at risk. Coronary artery dominance, size and distribution of arterial segments, collateral vessels, and location, extent, and severity of coronary stenoses can also impact ECG manifestations of myocardial ischemia.[17] The ECG by itself is often insufficient to diagnose acute myocardial ischemia or infarction since ST deviation may be observed in other conditions such as acute pericarditis, LV hypertrophy, LBBB, Brugada syndrome, and early repolarization patterns.[18] Also Q-waves may occur due to myocardial fibrosis in the absence of coronary artery disease, as in, for example, cardiomyopathy.

ECG Abnormalities of Myocardial Ischemia That May Evolve to Myocardial Infarction

ECG abnormalities of myocardial ischemia or infarction may be inscribed in the PR segment, the QRS complex, and the ST segment or T-waves. The earliest manifestations of myocar-

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Table 3 ECG manifestations of acute myocardial ischaemia (in absence of LVH and LBBB)

ST elevation
New ST elevation at the J-point in two contiguous leads with the cut-off points: ≥0.2 mV in men or ≥0.15 mV in women in leads V_2-V_3 and/or ≥0.1 mV in other leads
ST depression and T-wave changes
New horizontal or down-sloping ST depression ≥0.05 mV in two contiguous leads; and/or T inversion ≥0.1 mV in two contiguous leads with prominent R-wave or R/S ratio >1

Table 4 ECG changes associated with prior myocardial infarction

Any Q-wave in leads V_2-V_3 ≥0.02 s or QS complex in leads V_2 and V_3
Q-wave ≥0.03 s and ≥0.1 mV deep or QS complex in leads I, II, aVL, aVF, or V_4-V_6 in any two leads of a contiguous lead grouping (I, aVL,V_6; V_4-V_6; II, III, and aVF)[a]
R-wave ≥0.04 s in V_1-V_2 and R/S ≥1 with a concordant positive T-wave in the absence of a conduction defect

[a]The same criteria are used for supplemental leads V_7-V_9, and for the Cabrera frontal plane lead grouping.

dial ischemia are typical T-waves and ST segment changes.[19,20] Increased hyper-acute T-wave amplitude with prominent symmetrical T-waves in at least two contiguous leads is an early sign that may precede the elevation of the ST segment. Increased R-wave amplitude and width (giant R-wave with S-wave diminution) are often seen in leads exhibiting ST elevation, and tall T-waves reflecting conduction delay in the ischemic myocardium.[21] Transient Q-waves may be observed during an episode of acute ischemia or rarely during acute myocardial infarction with successful reperfusion.[22]

Table 3 lists ECG criteria for the diagnosis of acute myocardial ischemia that may lead to infarction. The J-point is used to determine the magnitude of the ST elevation. J-point elevation in men decreases with increasing age; however, that is not observed in women, in whom J-point elevation is less than in men.[23]

Contiguous leads means lead groups such as anterior leads (V_1-V_6), inferior leads (II, III, and aVF), or lateral/apical leads (I and aVL). More accurate spatial contiguity in the frontal plane can be established by the Cabrera display: aVL, I, aVR, II, aVF, and III.[24] Supplemental leads such as V_3R and V_4R reflect the free wall of the right ventricle.

Although the criteria in Table 3 require that the ST shift be present in two or more contiguous leads, it should be noted that occasionally acute myocardial ischemia may create sufficient ST segment shift to meet the criteria in one lead but have slightly less than the required ST shift in an adjacent contiguous lead. Lesser degrees of ST displacement or T-wave inversion in leads without prominent R-wave amplitude do not exclude acute myocardial ischemia or evolving myocardial infarction.

ST elevation or diagnostic Q-waves in regional lead groups are more specific than ST depression in localizing the site of myocardial ischemia or necrosis.[25,26] However, ST depression in leads V_1-V_3 suggests myocardial ischemia, especially when the terminal T-wave is positive (ST elevation equivalent), and may be confirmed by concomitant ST elevation ≥0.1 mV recorded in leads V_7-V_9.[27,28] The term 'posterior' to reflect the basal part of the LV wall that lies on the diaphragm is no longer recommended. It is preferable to refer to this territory as inferobasal.[29] In patients with inferior myocardial infarction it is advisable to record right precordial leads (V_3R and V_4R) seeking ST elevation in order to identify concomitant right ventricular infarction.[30]

During an acute episode of chest discomfort, pseudonormalization of previously inverted T-waves may indicate acute myocardial ischemia. Pulmonary embolism, intracranial processes, or peri-/myocarditis may also result in ST-T abnormalities and should be considered (false positives) in the differential diagnosis.

The diagnosis of myocardial infarction is difficult in the presence of LBBB even when marked ST-T abnormalities or ST elevation are present that exceed standard criteria.[31,32] A previous ECG may be helpful to determine the presence of acute myocardial infarction in this setting. In patients with right bundle branch block (RBBB), ST-T abnormalities in leads V_1-V_3 are common, making it difficult to assess the presence of ischemia in these leads; however, when ST elevation or Q-waves are found, myocardial ischemia or infarction should be considered. Some patients present with ST elevation or new LBBB, and suffer sudden cardiac death before cardiac biomarkers become abnormal or pathological signs of myocardial necrosis become evident at autopsy. These patients should be classified as having had a fatal myocardial infarction.

Prior Myocardial Infarction

As shown in Table 4, Q-waves or QS complexes in the absence of QRS confounders are usually pathognomonic of a prior myocardial infarction.[33–35] The specificity of the ECG diagnosis for myocardial infarction is greatest when Q-waves occur in several leads or lead groupings. ST deviations or T-waves alone are non-specific findings for myocardial necrosis. However, when these abnormalities occur in the same leads as the Q-waves, the likelihood of myocardial infarction is increased. For example, minor Q-waves ≥0.02 and <0.03 s that are ≥0.1 mV deep are suggestive of prior infarction if accompanied by inverted T-waves in the same lead group.

Other validated myocardial infarction-coding algorithms, such as the Minnesota code, Novacode, and WHO MONICA, define Q-wave depth on the basis of depth, width, and ratio of R-wave amplitude, such as Q-wave depth at least one-third or one-fifth of R-wave amplitude, and have been used extensively in epidemiological studies and clinical trials.[36,37]

Conditions That Confound the ECG Diagnosis of Myocardial Infarction

A QS complex in lead V_1 is normal. A Q-wave <0.03 s and <1/4 of the R-wave amplitude in lead III is normal if the frontal QRS axis is between 30 and 0°. The Q-wave may also be normal in aVL if the frontal QRS axis is between 60 and

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Table 5 Common ECG pitfalls in diagnosing myocardial infarction

False positives
Benign early repolarization
LBBB
Pre-excitation
Brugada syndrome
Peri-/myocarditis
Pulmonary embolism
Subarachnoid haemorrhage
Metabolic disturbances such as hyperkalaemia
Failure to recognize normal limits for J-point displacement
Lead transposition or use of modified Mason-Likar configuration[24]
Cholecystitis
False negatives
Prior myocardial infarction with Q-waves and/or persistent ST elevation
Paced rhythm
LBBB

90°. Septal Q-waves are small non-pathological Q-waves <0.03 s and <1/4 of the R-wave amplitude in leads I, aVL, aVF, and V_4-V_6. Pre-excitation, obstructive or dilated cardiomyopathy, LBBB, RBBB, left anterior hemi-block, left and right ventricular hypertrophy, myocarditis, acute cor pulmonale, or hyperkaliemia may be associated with Q/QS complexes in the absence of myocardial infarction. ECG abnormalities that simulate myocardial ischemia or infarction are presented in Table 5.

Reinfarction

The ECG diagnosis of reinfarction following the initial infarction may be confounded by the initial evolutionary ECG changes. Reinfarction should be considered when ST elevation ≥0.1 mV reoccurs in a patient having a lesser degree of ST elevation or new pathognomonic Q waves, in at least two contiguous leads, particularly when associated with ischemic symptoms for 20 min or longer. The re-elevation of the ST segment can, however, also be seen in threatening myocardial rupture and should lead to additional diagnostic work-up. ST depression or LBBB on their own should not be considered valid criteria for myocardial infarction.

Coronary Revascularization

ECG abnormalities during or after percutaneous coronary intervention (PCI) are similar to those seen during spontaneous myocardial infarction. In patients who have undergone CABG, new ST-T abnormalities are common but not necessarily diagnostic of myocardial ischemia.[38] However, when new pathological Q waves (Table 4) appear in territories other than those identified before surgery, myocardial infarction should be considered, particularly if associated with elevated biomarkers, new wall motion abnormalities, or hemodynamic instability.

Imaging Techniques

Non-invasive imaging plays many roles in patients with known or suspected myocardial infarction, but this section concerns only its role in the diagnosis and characterization of infarction. The underlying rationale is that regional myocardial hypoperfusion and ischemia lead to a cascade of events including myocardial dysfunction, cell death, and healing by fibrosis. Important imaging parameters are therefore perfusion, myocyte viability, myocardial thickness, thickening, and motion, and the effects of fibrosis on the kinetics of radiolabeled and paramagnetic contrast agents.

Commonly used imaging techniques in acute and chronic infarction are echocardiography, radionuclide ventriculography, myocardial perfusion scintigraphy (MPS), and magnetic resonance imaging (MRI). Positron emission tomography (PET) and X-ray computed tomography (CT) are less common. There is considerable overlap in their capabilities, but only the radionuclide techniques provide a direct assessment of myocardial viability because of the properties of the tracers used. Other techniques provide indirect assessments of myocardial viability, such as myocardial function from echocardiography or myocardial fibrosis from MRI.

Echocardiography

Echocardiography is an excellent real-time imaging technique with moderate spatial and temporal resolution. Its strength is the assessment of myocardial thickness, thickening, and motion at rest. This can be aided by tissue Doppler imaging. Echocardiographic contrast agents can improve endocardial visualization, but contrast studies are not yet fully validated for the detection of myocardial necrosis, although early work is encouraging.[39]

Radionuclide Imaging

Several radionuclide tracers allow viable myocytes to be imaged directly, including thallium-201, technetium-99m MIBI, tetrofosmin, and [^{18}F]2-fluorodeoxyglucose (FDG).[40–42] The strength of the techniques are that they are the only commonly available direct methods of assessing viability, although the relatively low resolution of the images disadvantages them for detecting small areas of infarction.[43] The common single photon-emitting radio-pharmaceuticals are also tracers of myocardial perfusion and so the techniques readily detect areas of infarction and inducible perfusion abnormalities. ECG-gated imaging provides a reliable assessment of myocardial motion, thickening, and global function.[44,45]

Magnetic Resonance Imaging

Cardiovascular MRI has high spatial resolution and moderate temporal resolution. It is a well-validated standard for the assessment of myocardial function and has, in theory, similar capability to echocardiography in suspected acute infarction. It is, however, more cumbersome in an acute setting and is not commonly used. Paramagnetic contrast agents can be used to assess myocardial perfusion and the increase in extracellular space associated with the fibrosis of chronic infarction. The former is not yet fully validated in clinical practice, but the latter is well validated and can play an important role in the detection of infarction.[46,47]

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X-Ray Computed Tomography

Infarcted myocardium is initially visible to CT as a focal area of decreased LV enhancement, but later imaging shows hyperenhancement as with late gadolinium imaging by MRI.[48,49] This finding is clinically relevant because contrast-enhanced CT may be performed for suspected embolism and aortic dissection, conditions with clinical features that overlap with those of acute myocardial infarction.

Application in the Acute Phase of Myocardial Infarction

Imaging techniques can be useful in the diagnosis of myocardial infarction because of the ability to detect wall motion abnormalities in the presence of elevated cardiac bio-markers. If for some reason biomarkers have not been measured or may have normalized, demonstration of new loss of myocardial viability alone in the absence of non-ischemic causes meets the criteria for myocardial infarction. However, if biomarkers have been measured at appropriate times and are normal, the determinations of these take precedence over the imaging criteria.

Echocardiography provides assessment of many non-ischemic causes of acute chest pain such as peri-myocarditis, valvular heart disease, cardiomyopathy, pulmonary embolism, or aortic dissection. Echocardiography is the imaging technique of choice for detecting complications of acute infarction including myocardial free wall rupture, acute ventricular septal defect, and mitral regurgitation secondary to papillary muscle rupture or ischemia. However, echocardiography cannot distinguish regional wall motion abnormalities due to myocardial ischemia from infarction.

Radionuclide assessment of perfusion at the time of patient presentation can be performed with immediate tracer injection and imaging that can be delayed for up to several hours. The technique is interpreter dependent, although objective quantitative analysis is available. ECG gating provides simultaneous information on LV function.

An important role of acute echocardiography or radionuclide imaging is in patients with suspected myocardial infarction and a non-diagnostic ECG. A normal echocardiogram or resting ECG-gated scintigram has a 95–98% negative predictive value for excluding acute infarction.[50–54] Thus, imaging techniques are useful for early triage and discharge of patients with suspected myocardial infarction.[55,56]

A regional myocardial wall motion abnormality or loss of normal thickening may be caused by acute myocardial infarction or by one or more of several other ischemic conditions including old infarction, acute ischemia, stunning, or hibernation. Non-ischemic conditions such as cardiomyopathy and inflammatory or infiltrative diseases can also lead to regional loss of viable myocardium or functional abnormality, and so the positive predictive value of imaging techniques is not high unless these conditions can be excluded and unless a new abnormality is detected or can be presumed to have arisen in the setting of other features of acute myocardial infarction.

Application in the Healing or Healed Phase of Myocardial Infarction

Imaging techniques are useful in myocardial infarction for analysis of LV function, both at rest and during dynamic exercise or pharmacological stress, to provide an assessment of remote inducible ischemia. Echocardiography and radionuclide techniques, in conjunction with exercise or pharmacological stress, can identify ischemia and myocardial viability. Non-invasive imaging techniques can diagnose healing or healed infarction by demonstrating regional wall motion, thinning, or scar in the absence of other causes.

The high resolution of contrast-enhanced MRI means that areas of late enhancement correlate well with areas of fibrosis and thereby enable differentiation between transmural and subendocardial scarring.[57] The technique is therefore potentially valuable in assessing LV function and areas of viable and hence potentially hibernating myocardium.

Myocardial Infarction Associated With Revascularization Procedures

Peri-procedural myocardial infarction is different from spontaneous infarction, because the former is associated with the instrumentation of the heart that is required during mechanical revascularization procedures by either PCI or CABG. Multiple events that can lead to myocardial necrosis are taking place, often in combination, during both types of intervention.[58–61] While some loss of myocardial tissue may be unavoidable during procedures, it is likely that limitation of such damage is beneficial to the patient and their prognosis.[62]

During PCI, myocardial necrosis may result from recognizable peri-procedural events, alone or in combination, such as side-branch occlusion, disruption of collateral flow, distal embolization, coronary dissection, slow flow or no-reflow phenomenon, and microvascular plugging. Embolization of intracoronary thrombus or atherosclerotic particulate debris cannot be entirely prevented despite current antithrombotic and antiplatelet adjunctive therapy or protection devices. Such events induce extensive inflammation of non-infarcted myocardium surrounding small islets of myocardium necrosis.[63–67] New areas of myocardial necrosis have been demonstrated by MRI following PCI.[68] A separate subcategory of myocardial infarction is related to stent thrombosis as documented by angiography and/or autopsy.

During CABG, numerous additional factors can lead to peri-procedural necrosis. These include direct myocardial trauma from sewing needles or manipulation of the heart, coronary dissection, global or regional ischemia related to inadequate cardiac protection, microvascular events related to reperfusion, myocardial damage induced by oxygen free radical generation, or failure to reperfuse areas of the myocardium that are not subtended by graftable vessels.[69–71] MRI studies suggest that most necrosis in this setting is not focal, but diffuse and localized to the sub-endocardium.[72] Some clinicians and clinical investigators have preferred using CKMB for the diagnosis of peri-procedural infarction because of a substantial amount of data relating CKMB elevations to prognosis.[73,74] However, an increasing number of studies using troponins in that respect have emerged.[59,75]

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Diagnostic Criteria for Myocardial Infarction With PCI

In the setting of PCI, the balloon inflation during a procedure almost always results in ischemia whether or not accompanied by ST-T changes. The occurrence of procedure-related cell necrosis can be detected by measurement of cardiac biomarkers before or immediately after the procedure, and again at 6–12 and 18–24 h.[76,77] Elevations of biomarkers above the 99th percentile URL after PCI, assuming a normal baseline troponin value, are indicative of post-procedural myocardial necrosis. There is currently no solid scientific basis for defining a biomarker threshold for the diagnosis of peri-procedural myocardial infarction. Pending further data, and by arbitrary convention, it is suggested to designate increases more than three times the 99th percentile URL as PCI-related myocardial infarction (type 4a).

If cardiac troponin is elevated before the procedure and not stable for at least two samples 6 h apart, there are insufficient data to recommend biomarker criteria for the diagnosis of peri-procedural myocardial infarction.[77] If the values are stable or falling, criteria for reinfarction by further measurement of biomarkers together with the features of the ECG or imaging can be applied.

A separate subcategory of myocardial infarction (type 4b) is related to stent thrombosis as documented by angiography and/or autopsy. Although iatrogenic, myocardial infarction type 4b with verified stent thrombosis must meet the criteria for spontaneous myocardial infarction as well.

Diagnostic Criteria for Myocardial Infarction With CABG

Any increase of cardiac biomarkers after CABG indicates myocyte necrosis, implying that an increasing magnitude of biomarker is likely to be related to an impaired outcome. This has been demonstrated in clinical studies employing CKMB where elevations five, 10 and 20 times the upper limit of normal after CABG were associated with worsened prognosis.[73,78,79] Likewise, the increase of troponin levels after CABG indicates necrosis of myocardial cells, which predicts a poor outcome, in particular when elevated to the highest quartile or quintile of the troponin measurements.[59,75]

Unlike the prognosis, scant literature exists concerning the use of biomarkers for defining myocardial infarction in the setting of CABG. Therefore, biomarkers cannot stand alone in diagnosing myocardial infarction (type 5). In view of the adverse impact on survival observed in patients with significant biomarker elevations, this Task Force suggests, by arbitrary convention, that biomarker values more than five times the 99th percentile of the normal reference range during the first 72 h following CABG, when associated with the appearance of new pathological Q-waves or new LBBB, or angiographically documented new graft or native coronary artery occlusion, or imaging evidence of new loss of viable myocardium, should be considered as diagnostic of a CABG-related myocardial infarction (type 5 myocardial infarction).

Definition of Myocardial Infarction in Clinical Investigations

A universal definition for myocardial infarction would be of great benefit to future clinical studies in this area since it will allow for trial-to-trial comparisons as well as accurate meta-analyses involving multiple investigations. In clinical trials, myocardial infarction may be an entry criterion or an end-point. The definition of myocardial infarction employed in these trials will thus determine the characteristics of patients entering the studies as well as the number of outcome events. In recent investigations, different infarct definitions have been employed, thereby hampering comparison and generalization among these trials.

Consistency among investigators and regulatory authorities with regard to the definition of myocardial infarction used in clinical investigations is essential. The Task Force strongly encourages trialists to employ the definition described in this document. Furthermore, investigators should ensure that a trial provides comprehensive data for the various types of myocardial infarction (e.g. spontaneous, peri-procedural) and includes the employed decision limits for myocardial infarction of the cardiac bio-markers in question. All data should be made available to interested individuals in published format or on a website. Data concerning infarctions should be available in a form consistent with the current revised definitions of myocardial infarction. This does not necessarily restrict trialists to a narrow end-point definition, but rather ensures that across all future trials access to comparable data exists, thereby facilitating cross-study analyses. The recommendations put forward in this section are not detailed and should be supplemented by careful protocol planning and implementation in any clinical trial.

The Task Force strongly endorses the concept of the same decision limit for each biomarker employed for myocardial infarction types 1 and 2, and, likewise, the same higher three- and five-fold decision limits in the setting of myocardial infarction types 4a and 5, respectively[78–80] (Tables 6 and 7). In clinical trials, as in clinical practice, measurement of cardiac troponin T or I is preferred over measurement of CKMB or other biomarkers for the diagnosis of myocardial infarction. Assessment of the quantity of myocardial damage (infarct size) is also an important trial end-point. Although the specific measurements vary depending on the assay and whether cardiac troponin T or I is used, in most studies troponin values correlate better with radionuclide-and MRI-determined infarct size than do CK and CKMB.[81–83]

The use of cardiac troponins will undoubtedly increase the number of events recorded in a particular investigation because of increased sensitivity for detecting infarction.[84–87] Ideally, data should be presented so that future clinical investigations or registries can translate the myocardial infarction end-point chosen in one study into the end-point of another study. Thus, measurements should be presented in a uniform manner to allow independent judgment and comparison of the clinical end-points. Furthermore, this Task Force suggests that data be reported as multiples of the 99th percentile URL of the applied biomarker, enabling comparisons between various classes and severity of the different types of myocardial infarction as indicated in Tables 6 and 7.

It is recommended that within a clinical trial all investigators whenever possible should employ the same assay in order to reduce the inter-assay variability, and, even better,

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Table 6 Classification of the different types of myocardial infarction according to multiples of the 99th percentile URL of the applied cardiac biomarker

Multiples × 99%	MI type 1 (spontaneous)	MI type 2 (secondary)	MI type 3* (sudden death)	MI type 4a** (PCI)	MI type 4b (stent thrombosis)	MI type 5** (CABG)	Total number
1-2 ×							
2-3×							
3-5 ×							
5-10 ×							
>10 ×							
Total number							

*Biomarkers are not available for this type of myocardial infarction since the patients expired before biomarker determination could be performed.

**For the sake of completeness, the total distribution of biomarker values should be reported. The dark grey areas represent biomarker elevations below the decision limit used for these types of myocardial infarction.

Irrespective of the specific end-point definition chosen in a clinical trial, all data should be provided. All boxes in the table should be completed, including the shaded areas.

the latter could be reduced to zero by application of a core laboratory using the same assay for all measurements.

In the design of a study, investigators should specify the expected effect of the new treatment under investigation. Factors that should be considered include:

- Assessment of the incidence of spontaneous myocardial infarction (type 1) and infarction related to myocardial oxygen supplies and demand (type 2) in treated patients vs. control subjects.
- Assessment of the incidence of sudden death related to myocardial infarction when applying the suggested criteria (type 3).
- Assessment of the incidence of procedure-related myocardial infarctions and biomarker elevations (PCI, types 4a and 4b; and CABG, type 5).

Public Policy Implications of Redefinition of Myocardial Infarction

Evolution of the definition of a specific diagnosis such as myocardial infarction has a number of implications for individual citizens as well as for society at large. The process of assigning a specific diagnosis to a patient should be associated with a specific value for the patient. The resources spent on recording and tracking a particular diagnosis must also have a specific value to society in order to justify the effort. A tentative or final diagnosis is the basis for advice about further diagnostic testing, treatment, lifestyle changes, and prognosis for the patient. The aggregate of patients with a particular diagnosis is the basis for health care planning and policy, and resource allocation.

Table 7 Sample clinical trial tabulation of randomized patients by types of myocardial infarction

Types of MI	Treatment A Number of patients	Treatment B Number of patients
MI type 1		
MI type 2		
MI type 3		
MI type 4a		
MI type 4b		
MI type 5		
Total number		

One of the goals of good clinical practice is to reach a definitive and specific diagnosis, which is supported by current scientific knowledge. The approach to the definition of myocardial infarction outlined in this document meets this goal. In general, the conceptual meaning of the term myocardial infarction has not changed, although new sensitive diagnostic methods have been developed to diagnose this entity. Thus, the current diagnosis of acute myocardial infarction is a clinical diagnosis based on patient symptoms, ECG changes, and highly sensitive biochemical markers, as well as information gleaned from various imaging techniques. However, it is important to characterize the extent of the infarct as well as residual LV function and the severity of coronary artery disease, rather than merely making a diagnosis of myocardial infarction. The information conveyed about the patient's prognosis and ability to work requires more than just the mere statement that the patient has suffered an infarct. The multiple other factors just mentioned are also required so that appropriate social, family, and employment decisions can be made. A number of risk scores have been developed predicting post-infarction prognosis. The classification of the various other prognostic entities associated with myocardial necrosis should lead to a reconsideration of the clinical coding entities currently employed for patients with the myriad conditions that can lead to myocardial necrosis with consequent elevation of biomarkers.

Many patients with myocardial infarction die suddenly. Difficulties in definition of sudden and out-of-hospital death make attribution of the cause of death variable among physicians, regions, and countries. For example, out-of-hospital death is generally ascribed to ischemic heart disease in the USA but to stroke in Japan. These arbitrary and cultural criteria need re-examination.

It is important that any revised criteria for the definition of myocardial infarction involve comparability of this definition

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over time so that adequate trend data can be obtained. Furthermore, it is essential to ensure widespread availability and standard application of the measures in order to ensure comparability of data from various geographic regions. Shift in criteria resulting in a substantial increase or decrease in case identification will have significant health resource and cost implications.[86,87] Moreover, an increase in sensitivity of the criteria for myocardial infarction might entail negative consequences for some patients who are not currently labeled as having had an infarction. On the other hand, increasing diagnostic sensitivity for myocardial infarction can have a positive impact for a society:

- Increasing the sensitivity of diagnostic criteria for myocardial infarction will result in more cases identified in a society, thereby allowing appropriate secondary prevention.
- Increasing the specificity of diagnostic criteria for myocardial infarction will result in more accurate diagnosis but will not exclude the presence of coronary artery disease, the cases of which may benefit from secondary prevention.

It should be appreciated that the agreed modification of the definition of myocardial infarction may be associated with consequences for the patients and their families with respect to psychological status, life insurance, professional career, as well as driving and pilot licenses. Also the diagnosis is associated with societal implications as to diagnosis-related coding, hospital reimbursement, mortality statistics, sick leave, and disability attestation.

In order to meet this challenge, physicians must be adequately informed of the altered diagnostic criteria. Educational materials will need to be created and treatment guidelines must be appropriately adapted. Professional societies should take steps to facilitate the rapid dissemination of the revised definition to physicians, other health care professionals, administrators, and the general public.

Global Perspectives of the Redefinition of Myocardial Infarction

Cardiovascular disease is a global health problem. Approximately one-third of persons in the world die of cardiovascular disease, largely coronary artery disease and stroke, and 80% of these deaths from cardiovascular disease occur in developing countries. The greater proportion of deaths is due to heart disease and specifically coronary heart disease, of which myocardial infarction is a major manifestation. Since it is difficult to measure the prevalence of coronary artery disease in a population, the incidence of myocardial infarction may be used as a proxy, provided that a consistent definition is used when different populations, countries, or continents are being compared.

The changes in the definition of myocardial infarction have critical consequences for less developed and developing countries. In many countries, the resources to apply the new definition may not be available in all hospitals. However, many developing countries already do have medical facilities capable of or currently employing the proposed definition of myocardial infarction. In the context of the overall cost for a patient with myocardial infarction, the expense associated with a troponin assay would not be excessive and should be economically affordable in many hospitals in developing countries, particularly those where infarcts are frequent events. The necessary equipment, staff training, and running costs may be lacking in some regions, but certainly not in others. In less advantaged hospitals, the diagnosis of myocardial infarction may depend mostly on clinical signs and symptoms coupled with less sophisticated biomarker analyses. Some of these institutions may only have access to CK and its isoenzymes at the present time. The redefinition arises from and is compatible with the latest scientific knowledge and with advances in technology, particularly with regard to the use of bio-markers, high quality electrocardiography, and imaging techniques. The definition can and should be used by developed countries immediately, and by developing countries as quickly as resources become available.

The change in the definition of myocardial infarction will have a substantial impact on the identification, prevention, and treatment of cardiovascular disease throughout the world. The new definition will impact epidemiological data from developing countries relating to prevalence and incidence. The simultaneous and continuing use of the older WHO definition for some years would allow a comparison between data obtained in the past and data to be acquired in the future employing the newer biomarker approach. Cultural, financial, structural, and organizational problems in the different countries of the world in diagnosis and therapy of acute myocardial infarction will require ongoing investigation. It is essential that the gap between therapeutic and diagnostic advances be addressed in this expanding area of cardiovascular disease.

Conflicts of Interest

The members of the Task Force established by the ESC, the ACCF, AHA and the WHF have participated independently in the preparation of this document, drawing on their academic and clinical experience and applying an objective and critical examination of all available literature. Most have undertaken and are undertaking work in collaboration with industry and governmental or private health providers (research studies, teaching conferences, consultation), but all believe such activities have not influenced their judgment. The best guarantee of their independence is in the quality of their past and current scientific work. However, to ensure openness, their relations with industry, government and private health providers are reported in the ESC and European Heart Journal websites (www.escardio.org and www.eurheartj.org). Expenses for the Task Force/Writing Committee and preparation of this document were provided entirely by the above mentioned joint associations.

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Name	Research contracts (such as grants, etc.)	Consulting/advising	Employment in industry	Stockholder of a healthcare company	Owner of a healthcare company (or partnership)	Others
Writers						
Joseph S. Alpert	None	Sanofi-Aventis Exeter Continuing Medical Education Company Novartis	None	None	None	None
Elliott M. Antman	Sanofi-Aventis (via TIMI Study Group) Eli-Lilly (via TIMI Study Group)	Sanofi-Aventis	None	None	None	None
Fred S. Apple	Abbott Ortho Clinical Diagnostics Biosite Beckman Bayer DPC Roche BioMerieux MKI	Abbott Ortho Clinical Diagnostics Sensera	None	None	None	None
Paul W. Armstrong	Hoffman LaRoche Canada Sanofi-Aventis Proctor & Gamble/Alexion Schering Plough Research Institute Boerhringer Ingelheim	Abbott Laboratories TaregGen Medicure	None	None	None	None
Jean-Pierre Bassand	None	None	None	None	None	None
Joeren J. Bax	GE BMS Guidant Medtronic	None	None	None	None	None
George A. Beller	None	None	None	None	None	None
Robert Bonow	None	None	None	None	None	None
Bernard Chaitman	CV Therapeutics Pfizer	CV Therapeutics Pfizer Merck Sanofi-Aventis	None	None	None	None
Peter M. Clemmensen	Medtronic	Medtronic	None	None	None	None
Mikael Dellborg	None	None	None	None	None	None
T. Bruce Ferguson, Jr.	None	None	None	None	None	None
Francisco Fernández-Avilés	None	None	None			
Keith A. Fox	Sanofi BMS GSK	Sanofi BMS GSK	None	None	None	None
Kim M. Fox	Servier Labs	Servier Labs	None	None	None	None
Marcello Galvani	None	None	None	None	None	None
Enrique P. Gurfinkel	Shering Plough Sanofi-Aventis	Sanofi-Aventis	None	None	None	None
Christian W. Hamm	Abbott Roche	Abbott	None	None	None	None
Hanoch Hod	None	None	None	None	None	None
Allan S. Jaffe	Dade-Behring	Dade-Behring Beckman-Coulter Ortho Diagnostics Pfizer Bayer GSK	None	None	None	None

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Hugo A. Katus	None	None	None	None	None	I have invented the troponin T assay and hold a patent jointly with Roche Diagnostics.
Jose-Luis Lopez-Sendon	Bristol Meyer Squibb Eli Lilly Servier CVT AstraZeneca Amgen Schering Plough Novartis Bayer Solvay Merck	Medtronic	None	None	None	None
Shanthi Mendis	None	None	None	None	None	None
L. Kristin Newby	Schering Plough Inverness Medical, Inc. Roche Diagnostics BMS-Sanofi BG Medicine	Adolor Tethys Proctor and Gamble J&J/Scios Biosite Atherogenics	None	None	None	None
E. Magnus Ohman	Bristol-Myers Squibb† Sanofi-Aventis† Schering-Plough† Millennium Pharmaceuticals† Eli Lilly† Berlex†	Invoise† Savacor† Liposcience Response Biomedical The Medicines Company Dataxcope Abiomed		Invoise† Savacor† Medtronic†		Speaker's bureau: CV Therapeutics† Schering Plough†
Prem Pais	Boehringer Ingelheim AstraZeneca Cadila Limited	None	None	None	None	None
Alexander N. Parkhomenko	Servier Sanofi-Aventis GSK	GSK	None	None	None	None
Philip A. Poole-Wilson	Roche	None	None	None	None	Bayer MSD Menarini
Pekka Porela	None	None	None	None	None	None
Silvia G. Priori	Medtronic Guidant	Lundbeck	None	None	None	Speaker's bureau: Medtronic Guidant
Jan Ravkilde	Abbott Diagnostics Dade-Behring Diagnostics Roche Diagnostics	None	None	None	None	None
Maarten L. Simoons	Servier	Servier	None	None	None	None
Philippe Gabriel Steg	Sanofi-Aventis	Sanofi-Aventis Takeda Nycomed The Medicines Company Servier	None	None	None	Speaker's bureau: Boehringer-Ingelheim BMS GSK Nycomed Sanofi-Aventis Servier ZLB-Behring
Michal Tendera	Servier Bayer Amgen	Servier Bayer Amgen	None	None	None	None
Kristian Thygesen	None	None	None	None	None	None
Richard Underwood	None	CV Therapeutics, Inc. GE Healthcare	None	None	None	None
Barry F. Uretsky	None	None	None	None	None	None
Ernst E. Van Der Wall	None	None	None	None	None	None
Liisa-Maria Voipio-Pulkki	None	None	None	None	None	None

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Lars C. Wallentin	Boerhringer Ingelheim AstraZeneca Bristol Myers Squibb Eli Lilly GSK Schering Plough Sanofi	None	None	None	None	None
Harvey D. White	Alexion Sanofi-Aventis Eli Lilly Merck Sharpe & Dohme The Medicines Company Neuren Pharmaceuticals NIH Glaxo Smith Kline Pfizer Roche Fournier Laboratories Johnson & Johnson Proctor & Gamble Schering Plough Janssen Cilag	The Medicines Company Neuren Pharmaceuticals Glaxo Smith Kline Medicure				Speaker's honorarium: Sanofi-Aventis The Medicines Company
William Wijns	Biotronik Medtronic Biotronic Conor Medsystems Cordis Abbott Terumo Cordis Johnson & Johnson Therabel Pharma GSK					
David O. Williams	Cordis, a Johnson & Johnson Company Abbott Vascular	Cordis, a Johnson & Johnson Company Abbott Vascular	None	None	None	None
Jun-Ren Zhu	None	None	None	None	None	None
Reviewers						
Nawwar Al-Attar	None	None	None	None	None	None
Sorin Brener	None	None	None	None	None	None
Darek Dudek	Eli Lilly Schering Balton Biotronic Nycomed Sanofi Eurocor Boehringer Ingelheim Pfizer Volcano	Boston Abbott Cordis Invatec Medtronic				
W. Brian Gibler	Abbott POC i-STAT	None	None	None	None	Education grants to EMCREG-International: Biosite Schering-Plough Sanofi-Aventis
David Goff	None	GSK	None	None	None	None
Robert Harrington*	Abbott Vasc-Devices Acorn Cardiovascular Actelion Acushphere, Inc. Advanced CV Syst Advanced Stent Technologies, Inc. Agilent Ajinomoto Alexion** Alsius Allergan	Bristol Myers Squibb				Educational Activities generate activity for Duke Univ.: Portola Pharmaceutical† Schering-Plough Merck/Schering-Plough Venture† Sanofi-Aventis

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	Berlex					
	Biocompatibles, Ltd.					
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	Biosense Webster, Inc.					
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	CardioKinetix, Inc.					
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	Conor Medsystems, Inc.					
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	Critical Therapeutics, Inc.					
	CryoVascular System, Inc.					
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	Echosens, Inc.					
	Elipse Surg Tech					
	Edwards Lifesciences					
	Eisai					
	Enzon Pharmaceutical					
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Glen N. Levine	None	None	None	None	None	None
Michael Lim	None	None	None	Singapore Heart, Stroke and Cancer Centre	None	None
Marco A. Martinez-Rios	None	None	None	None	None	None
Joao Morais	None	AstraZeneca	None	None	None	None
David Morrow	Bayer Diagnostics Biosite Inc. Beckman Coulter Dade-Behring Roche Diagnostics	Beckman Coulter	None	None	None	Honoraria for educational presentations: Bayer Diagnostics
Udo Sechtem	Bosch	Pfizer Novartis				
Steve Steinhubl	The Medicines Company Eli Lily	Sanofi-Aventis The Medicines Company AstraZeneca Eli Lilly	None	None	None	None
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Clinical and Angiographic Predictors and Prognostic Value of Failed Thrombus Aspiration in Primary Percutaneous Coronary Intervention

Maarten A. Vink, MD,*† Miranda C. Kramer, MD,* Xiaofei Li, MD,*
Peter Damman, MD,* Saskia Z. Rittersma, MD, PhD,‡ Karel T. Koch, MD, PhD,*
Allard C. van der Wal, MD, PhD,* Jan G. P. Tijssen, PhD,*
Robbert J. de Winter, MD, PhD*

Amsterdam and Zwolle, the Netherlands

Objectives This study sought to investigate which factors are associated with failure of thrombus aspiration (TA) and if this has prognostic implications.

Background The pathophysiological mechanism and clinical benefit of TA during primary percutaneous coronary intervention for acute ST-segment elevation myocardial infarction is still in debate.

Methods Between August 2001 and October 2007, TA was attempted in 1,399 patients. Failure of TA was defined as the inability to reach and/or cross the occlusion with the aspiration catheter for effective thrombus removal. In addition, we analyzed patients in which no material could be obtained. We examined baseline clinical and angiographic variables related to failure of TA or to the lack of aspirate. Follow-up on vital status was obtained at 1 year.

Results In 144 (10.3%) patients, the aspiration catheter failed to cross the lesion. After multivariable adjustment, marked proximal tortuosity (odds ratio [OR]: 2.88, 95% confidence interval [CI]: 1.92 to 4.31, $p < 0.001$), the presence of a calcified lesion (OR: 2.70, 95% CI: 1.77 to 4.13, $p < 0.001$), and a bifurcation lesion (OR: 1.97, 95% CI: 1.15 to 3.37, $p = 0.013$) were independent predictors of failed TA. Age over 60 years and the circumflex as infarct-related artery were associated with the lack of aspirate. Mortality rates at 1 year were 6.2% in patients with failed TA and 6.4% with successful TA (hazard ratio: 0.98, 95% CI: 0.49 to 1.95, $p = 0.95$).

Conclusions The presence of marked proximal tortuosity of the infarct-related artery, a calcified lesion, and a bifurcation lesion are independent predictors of failure of thrombus aspiration. We found that unsuccessful TA did not affect 1-year mortality. (J Am Coll Cardiol Intv 2011;4:634–42)
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From the *Department of Cardiology, Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands; †Department of Cardiology, Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands; and the ‡Department of Cardiology, Isala Klinieken, Zwolle, the Netherlands. The authors have reported that they have no relationships to disclose.

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Reperfusion therapy by primary percutaneous coronary intervention (PPCI) with stenting has proven the optimal approach to reduce morbidity and mortality in acute ST-segment elevation myocardial infarction (STEMI). In PPCI, the presence of coronary thrombus has been linked to distal embolization and microvascular obstruction, reflected by lower post-procedure myocardial blush grade (MBG) and no-reflow, which is associated with an increased infarct size and worse outcome (1–3). Various devices designed to remove thrombus before stenting have been tested in small- to moderate-sized randomized controlled trials. Meta-analyses of adjunctive thrombectomy trials have reported an inconsistent effect of the device-based removal of thrombus from the infarct-related artery on reperfusion surrogate and clinical endpoints, with a difference between mechanical and manual devices in favor of manual aspiration (4–8).

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These previous reports on thrombectomy in the setting of PPCI did not provide information on the factors associated with failure to remove thrombus with the various manual thrombus aspiration (TA) devices and potential prognostic implications. The reported proportion of unsuccessful employment varies from 4% to 11%, mainly because of the inability to cross the lesion (9–11). Even though a retrospective study described the failure of the X-Sizer (ev3 Inc., Plymouth, Minnesota) mechanical thrombectomy device in 24% of cases (12), it is not known which factors are associated with failure of the currently used TA catheters and whether this is associated with worse outcomes. We sought to determine predictive factors as well as the prognostic value of failure of the TA catheter to reach the infarct-related lesion in PPCI in a large all-comer acute STEMI population. In addition, we evaluated which factors were associated with the inability to retrieve material after successful positioning of the TA catheter.

Methods

Procedures and medication. We analyzed data from acute STEMI patients who underwent PPCI with TA at the Academic Medical Center, University of Amsterdam between August 2001 and October 2007. Patients were eligible for PPCI when they presented with acute STEMI (≥2-mm ST-segment elevation in ≥2 contiguous leads) with symptom duration of ≤12 h. All interventions were done according to existing practice guidelines for PCI. Baseline clinical, angiographic, and procedural variables were collected prospectively in a dedicated database and included statements on possible failure of deployment of the TA device used. All patients received aspirin 300 mg and unfractionated heparin 5,000 to 10,000 IU at the start of the procedure. The use of glycoprotein IIb/IIIa inhibitors was at the discretion of the operator. Subsequently, patients were prescribed aspirin 100 mg once daily for life. Clopidogrel was administered at a loading dose of 300 or 600 mg before or immediately after the procedure, followed by 75 mg once daily for 1 month in patients treated with bare-metal stents, and 6 months in patients treated with drug-eluting stents.

TA cohort. In our institution, TA has been available for use as an adjunct to PPCI since August 2001. In these first years, TA was not a proven or formally recommended therapy and its use was at the discretion of the operator. The study cohort consists of all patients for whom a TA device was used in adjunct to the standard procedure. Device selection was at the discretion of the operator. The devices used were the 7-F Rescue catheter (Boston Scientific/Scimed, Inc., Maple Grove, Minnesota), which became available in August 2001 and was mainly used until the end of 2004; the 6-F Export aspiration catheter (Medtronic Vascular Inc., Santa Rosa, California), which became available in August 2004 and currently is still in use; and the 6-/7-F Proxis embolic protection device (St. Jude Medical, St. Paul, Minnesota), which became available in February 2004 and combines aspiration with distal embolic protection. During the study period, PPCI was performed via the femoral artery only, with the standard use of 7-F guiding catheters. After 6-F–compatible Export catheters became available at the end of 2006, both 6-F and 7-F catheters were used for this device. A total of 1,399 patients were identified in which a TA device was used during PPCI. We classified patients into 2 groups based on the success of the aspiration catheter to reach and/or cross through the lesion without pre-dilation (or with device-required pre-dilation in case of the Proxis device). We compared baseline clinical and angiographic variables of both patient groups to determine factors associated with unsuccessful crossing of the TA device. In addition, we analyzed all patients in which the catheter had successfully crossed the lesion, but no thrombotic material could be obtained, and compared them with patients in which aspirate was retrieved.

Abbreviations and Acronyms

CI = confidence interval
HR = hazard ratio
IQR = interquartile range
MBG = myocardial blush grade
OR = odds ratio
PCI = percutaneous coronary intervention
PPCI = primary percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction
TA = thrombus aspiration
TIMI = Thrombolysis In Myocardial Infarction

We obtained information on 1-year vital status from the institutional follow-up database of PCI patients. Patients were surveyed 1 year after PCI by means of a mailed, self-administered questionnaire. Follow-up information was synchronized with computerized mortality records from the

National Death Index and local authorities, which were updated until August 2010.

Statistical analysis. Data are presented as mean ± SD for normally distributed, continuous variables, or median (interquartile range [IQR]), and as frequencies (percentages) for categorical variables. Differences between patient groups were tested with Student *t* test or the Mann-Whitney *U* statistic test as appropriate. Categorical variables were compared by chi-square test. All tests were 2-tailed, and a value of $p < 0.05$ was considered statistically significant. Cumulative event rates of all-cause mortality were estimated by the Kaplan-Meier method, and the timing of death is illustrated by Kaplan-Meier plots. Follow-up was censored at 1 year. The association between clinical and angiographic variables and failure to cross the lesion, or to obtain material in the case of successful passage, were assessed using logistic regression analysis in both crude models and multivariable-adjusted models for variables that showed a univariable association with failure of TA ($p \leq 0.1$). Variables were entered en bloc and the results were expressed as odds ratios (ORs) with 95% confidence intervals (CIs). Statistical analysis was performed with SPSS software (SPSS, version 18.0 for Windows, SPSS Inc., Chicago, Illinois).

Results

Failure of thrombus aspiration. The study flow chart is displayed in Figure 1. In 144 patients (10.3%) of the 1,399 patients for whom TA was attempted, the TA catheter failed to cross the lesion. Baseline clinical and angiographic characteristics are summarized in Table 1. At a mean age of 63 ± 13 years versus 60 ± 13 years, patients in the failed TA group were older than patients in the successful TA group ($p = 0.009$). In addition, these patients more often had multivessel coronary artery disease (40% vs. 27%, $p = 0.001$). As expected, some differences in the presence of certain angiographic variables were seen. A calcified lesion was more often seen in the group in which TA had failed, at 33.3% versus 14.8% in the successful TA group ($p < 0.001$). Likewise, marked proximal coronary tortuosity was significantly more frequent at 67.9% versus 32.1% in the failed TA group and successful TA group, respectively ($p < 0.001$). The circumflex artery was more often the infarct-related artery in patients with failed TA (20.1%) than it was in the patients with successful TA (10.0%), $p = 0.002$.

None of the clinical variables was predictive of failure of TA (Table 2). Marked proximal tortuosity of the coronary artery, the presence of a calcified lesion, and a bifurcation

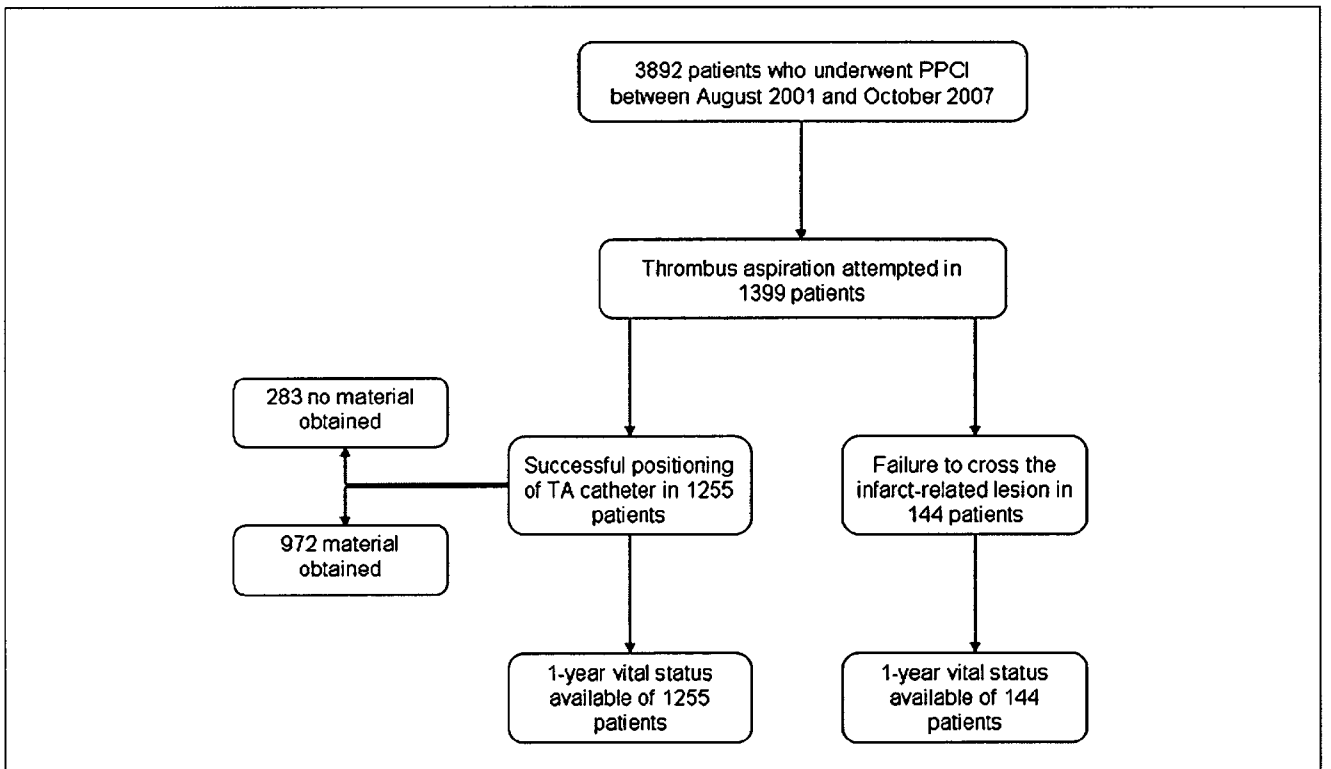

Figure 1. Study Flow Chart

All patients in whom thrombus aspiration (TA) was attempted were identified. They were divided into 2 groups (successful TA vs. failed TA). Subsequently, patients with successful TA were divided by the presence or absence of thrombotic material. PPCI = primary percutaneous coronary intervention.

Table 1. Baseline Clinical and Angiographic Characteristics

				Successful Aspiration		
	Failed Aspiration (n = 144)	Successful Aspiration (n = 1,255)	p Value	No Material (n = 283)	Material (n = 972)	p Value
Age, yrs	63 ± 13	60 ± 13	0.009	60 ± 13	61 ± 12	0.03
Male	98 (68)	919 (73)	0.20	207 (73)	712 (73)	0.97
Diabetes mellitus	17 (12)	122 (10)	0.46	25 (9)	97 (10)	0.57
Hypertension	54 (38)	359 (32)	0.16	87 (31)	308 (32)	0.76
Hypercholesterolemia	34 (24)	260 (21)	0.45	59 (21)	201 (21)	0.95
History of smoking	91 (63)	771 (61)	0.72	156 (55)	615 (63)	0.013
Family history of CAD	66 (46)	531 (42)	0.43	110 (39)	421 (43)	0.18
Previous PCI	10 (7)	83 (7)	0.86	22 (8)	61 (6)	0.37
Previous CABG	3 (2)	19 (2)	0.49	4 (1)	15 (2)	0.88
Previous MI	15 (10)	118 (9)	0.65	33 (12)	85 (9)	0.14
Symptom-to-balloon, h	3.0 (2.3–4.3)	3.0 (2.2–4.5)	0.65	3.2 (2.2–4.6)	3.0 (2.1–4.4)	0.35
Shock	4 (3)	82 (7)	0.10	22 (8)	60 (6)	0.34
Multivessel disease	58 (40)	341 (27)	0.001	79 (28)	262 (27)	0.75
Infarct-related artery			0.02			0.003
LM	0 (0)	4 (0)		3 (1)	1 (0)	
LAD	47 (33)	552 (44)		125 (44)	427 (44)	
RCA	67 (44)	558 (45)		111 (39)	447 (46)	
Cx	29 (20)	125 (10)		41 (15)	84 (9)	
SVG	1 (1)	16 (1)		3 (1)	13 (1)	
TIMI flow grade 0 or 1	114 (79)	1,063 (85)	0.09	240 (85)	823 (85)	0.96
Bifurcation lesion	21 (15)	120 (10)	0.08	29 (10)	91 (9)	0.64
Ostial lesion	9 (6)	84 (7)	1.00	16 (6)	68 (7)	0.43
Distal major branch	19 (13)	117 (9)	0.14	23 (8)	94 (10)	0.43
Side branch	11 (8)	51 (4)	0.06	16 (6)	35 (4)	0.12
Calcified lesion	48 (33)	186 (15)	<0.001	48 (17)	138 (14)	0.24
Proximal tortuosity	91 (68)	462 (40)	<0.001	107 (42)	355 (40)	0.61
>45° lesion angle	39 (29)	292 (26)	0.40	65 (25)	227 (26)	0.95
Lesion length, mm	15.6 ± 5.3	16.4 ± 5.6	0.10	15.9 ± 6.1	16.5 ± 5.5	0.47
ACC/AHA type C lesion	57 (43)	434 (37)	0.19	95 (38)	339 (37)	0.63

Values are mean ± SD, n (%), or median (interquartile range).

ACC/AHA = American College of Cardiology/American Heart Association; CAD = coronary artery disease; CABG = coronary artery bypass grafting; Cx = circumflex artery; LAD = left anterior descending artery; LM = left main; MI = myocardial infarction; PCI = percutaneous coronary intervention; RCA = right coronary artery; SVG = saphenous vein graft; TIMI = Thrombolysis In Myocardial Infarction

lesion as infarct-related lesion were independent predictors of unsuccessful passage of the catheter across the lesion at ORs of 2.88 for proximal tortuosity (95% CI: 1.92 to 4.31, $p < 0.001$), 2.70 for the presence of a calcified lesion (95% CI: 1.77 to 4.13, $p < 0.001$), and 1.97 for a bifurcation lesion (95% CI: 1.15 to 3.37, $p = 0.013$).

The procedural characteristics are stated in Table 3. Most patients received a stent (93.0% in both groups, $p = 1.00$), whereas direct stenting was performed less often after failure of TA, at 9.0% versus 30.0% ($p < 0.001$). Post-procedural TIMI (Thrombolysis In Myocardial Infarction) flow grade <3 was observed in 13.9% in the failed TA group and 9.5% in the successful TA group ($p = 0.11$). The average peak creatine kinase-myocardial band values were comparable in both groups (280 μg/l, IQR: 122 to 495 μg/l, vs. 263 μg/l, IQR: 127 to 445 μg/l; $p = 0.32$). Note that these values were available only in patients who were not transferred to the referring hospitals immediately after PPCI (81 patients with failed TA and 818 patients with successful TA).

Absence of thrombotic aspirate. In 283 (27.3%) of 1,255 patients in whom the aspiration catheter successfully crossed the lesion, no material could be retrieved. The baseline clinical and angiographic characteristics are stated in Table 1. These patients were slightly older at 61 ± 12 years versus 60 ± 13 years for the patients in which thrombotic material could be obtained ($p = 0.03$). Furthermore, at 55% versus 63%, they less often had a history of smoking ($p = 0.013$). Except for the difference in the incidence of the right coronary or circumflex artery as the infarct-related artery, other baseline and angiographic characteristics were comparable in both groups. Patient age over 60 years and the circumflex

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JUNE 2011:634–42

Table 2. Univariable and Multivariable-Adjusted Logistic Regression Analysis of the Association of the Presence of a Clinical or Angiographic Feature and the Likelihood of Failure of TA

			Univariable Analysis			Multivariable-Adjusted Analysis		
Variable	Present	Absent	OR	95% CI	p Value	OR	95% CI	p Value
Age >60 yrs	85/673 (12.6)	59/726 (8.1)	1.63	1.15–2.32	0.006	1.27	0.86–1.88	0.23
Male	98/1,017 (9.6)	46/382 (12.0)	0.78	0.54–1.13	0.19			
Diabetes mellitus	17/139 (12.2)	127/1,260 (10.1)	1.24	0.73–2.13	0.43			
Hypertension	54/449 (12.0)	90/950 (9.5)	1.31	0.91–1.87	0.14			
Hypercholesterolemia	34/294 (11.6)	110/1,105 (10.0)	1.18	0.79–1.78	0.42			
History of smoking	91/862 (10.6)	53/537 (9.9)	1.08	0.75–1.54	0.68			
Family history of CAD	66/597 (11.1)	78/802 (9.7)	1.15	0.82–1.63	0.42			
Previous PCI	10/93 (10.8)	134/1,306 (10.3)	1.05	0.53–2.08	0.88			
Previous CABG	3/22 (13.6)	141/1,236 (10.2)	1.38	0.41–4.74	0.61			
Previous MI	15/133 (11.3)	129/1,266 (10.2)	1.12	0.64–1.98	0.69			
Shock	4/86 (4.7)	140/1,313 (10.7)	0.41	0.15–1.13	0.09	0.47	0.17–1.34	0.16
Multivessel disease	58/399 (14.5)	86/1,000 (8.6)	1.81	1.27–2.58	<0.001	1.35	0.91–2.00	0.13
IRA Cx	29/154 (18.8)	115/1,245 (9.2)	2.28	1.46–3.57	<0.001	1.67	0.95–2.95	0.077
TIMI flow grade 0 or 1	114/1,177 (9.7)	30/222 (13.5)	0.69	0.45–1.06	0.087	0.64	0.40–1.03	0.064
Bifurcation lesion	21/141 (14.9)	123/1,257 (9.8)	1.61	0.98–2.66	0.061	1.97	1.15–3.37	0.013
Ostial lesion	9/93 (9.7)	135/1,305 (10.3)	0.93	0.46–1.89	0.84			
Distal lesion	19/136 (14.0)	125/1,263 (9.9)	1.48	0.88–2.48	0.14			
Side branch	11/62 (17.7)	133/1,337 (9.9)	1.95	0.99–3.84	0.052	1.03	0.45–2.33	0.95
Calcified lesion	48/234 (20.5)	96/1,164 (8.2)	2.87	1.96–4.20	<0.001	2.70	1.77–4.13	<0.001
Proximal tortuosity	91/553 (16.5)	43/724 (5.9)	3.12	2.13–4.57	<0.001	2.88	1.92–4.31	<0.001
>45° lesion angle	39/331 (11.8)	95/946 (10.0)	1.20	0.81–1.78	0.37			
ACC/AHA type C lesion	57/491 (11.6)	75/814 (9.2)	1.29	0.90–1.86	0.17			

Values are number of patients with failed TA/total number of patients (%).
CI = confidence interval; IRA = infarct-related artery; OR = odds ratio; TA = thrombus aspiration; other abbreviations as in Table 1.

coronary artery as infarct-related artery were independent predictors for the absence of aspirate, at ORs of 1.37 (95% CI: 1.04 to 1.80, p = 0.025) and 1.84 (95% CI: 1.23 to 1.75, p = 0.003), respectively (Table 4).

Clinical outcome. Follow-up information on all-cause mortality was available for all patients. Death rates at 1 year were 6.2% in patients with failed TA, as compared to 6.4% in patients with successful TA (hazard ratio [HR]: 0.98, 95% CI: 0.49 to 1.95, p = 0.95). In the case of successful crossing of the lesion, the mortality rate was 6.7% in patients without aspirate, as compared to 6.3% in patients with aspirated material (HR: 1.08, 95% CI: 0.64 to 1.80, p = 0.78). Figure 2 shows the Kaplan-Meier curves for all-cause mortality of the 3 different groups.

Table 3. Procedural Characteristics

				Successful Aspiration		
	Failed Aspiration (n = 144)	Successful Aspiration (n = 1,255)	p Value	No Material (n = 283)	Material (n = 972)	p Value
Stenting	131 (93)	1,157 (93)	1.00	251 (92)	906 (93)	0.23
Direct stenting	13 (9)	376 (30)	<0.001	63 (22)	313 (32)	0.001
Stent length	19.3 ± 5.8	19.0 ± 5.0	0.96	18.4 ± 4.6	19.1 ± 5.1	0.06
Stent diameter	3.4 ± 0.6	3.5 ± 0.5	0.004	3.5 ± 0.5	3.6 ± 0.5	0.001
GP IIb/IIIa inhibitor	65 (45)	499 (40)	0.24	110 (39)	389 (40)	0.73
Distal embolization	18 (13)	163 (13)	1.00	27 (10)	136 (14)	0.05
Post-procedural TIMI flow grade <3	29 (14)	119 (10)	0.11	27 (10)	92 (10)	0.96
IABP inserted	7 (5)	106 (8)	0.15	30 (11)	76 (8)	0.14
Peak CK-MB	280 (144–495)	263 (127–445)	0.32	224 (95–384)	268 (136–462)	0.007

Values are n (%), mean ± SD, or median (interquartile range).
CK-MB = creatine kinase-myocardial band; GP = glycoprotein; IABP = intra-aortic balloon pump; TIMI = Thrombolysis In Myocardial Infarction.

Table 4. Univariable and Multivariable-Adjusted Logistic Regression Analysis for the Association of Clinical and Angiographic Variables and the Lack of Aspirate

			Univariable Analysis			Multivariable-Adjusted Analysis		
Variable	Present	Absent	OR	95% CI	p Value	OR	95% CI	p Value
Age >60 yrs	152/588 (25.9)	131/667 (19.6)	1.43	1.09–1.86	0.009	1.37	1.04–1.80	0.025
Male	207/919 (22.5)	76/336 (22.6)	1.00	0.74–1.34	0.97			
Diabetes mellitus	25/122 (20.5)	258/1,133 (22.8)	0.87	0.55–1.39	0.57			
Hypertension	87/395 (22.0)	296/860 (22.8)	0.96	0.72–1.27	0.76			
Hypercholesterolemia	59/260 (22.7)	224/995 (22.5)	1.01	0.73–1.40	0.95			
History of smoking	156/771 (20.2)	127/484 (26.2)	0.71	0.55–0.93	0.013	0.76	0.58–1.01	0.054
Family history of CAD	110/531 (20.7)	173/724 (23.9)	0.83	0.64–1.09	0.18			
Previous PCI	22/83 (26.5)	261/1,172 (22.3)	1.26	0.76–2.09	0.37			
Previous CABG	4/19 (21.1)	279/1,236 (22.6)	0.92	0.30–2.78	0.88			
Previous MI	33/118 (28.0)	250/1,137 (22.0)	1.38	0.90–2.11	0.14			
Shock	22/82 (26.8)	261/1,173 (22.3)	1.28	0.77–2.13	0.34			
Multivessel disease	79/341 (23.2)	204/914 (22.3)	1.05	0.78–1.41	0.75			
IRA Cx	42/125 (32.8)	242/1,130 (21.4)	1.79	1.20–2.67	0.004	1.84	1.23–2.75	0.003
TIMI flow grade 0 or 1	240/1,063 (22.6)	43/192 (22.4)	1.01	0.70–1.46	0.96			
Bifurcation lesion	29/120 (24.2)	253/1,134 (22.3)	1.11	0.71–1.72	0.64			
Ostial lesion	16/84 (19.0)	266/1,170 (22.7)	0.80	0.46–1.40	0.44			
Distal lesion	23/117 (19.7)	260/1,138 (22.8)	0.83	0.51–1.33	0.43			
Side branch	16/51 (31.4)	267/1,204 (22.4)	1.60	0.87–2.94	0.13			
Calcified lesion	48/186 (25.8)	234/1,068 (21.9)	1.24	0.87–1.78	0.24			
Proximal tortuosity	107/462 (23.2)	149/681 (21.9)	1.08	0.81–1.43	0.61			
>45° lesion angle	55/292 (22.3)	191/851 (22.4)	0.99	0.72–1.36	0.95			
ACC/AHA type C lesion	95/434 (21.9)	153/734 (20.7)	1.07	0.80–1.43	0.63			

Values are number of patients without aspirate/total number of patients with successful TA (%).
Abbreviations as in Tables 1 and 2.

Discussion

Success of thrombus aspiration. The present analysis of a large dataset of unselected acute STEMI patients demonstrates that manual TA failed in a considerable number of procedures where TA was attempted. Our data show that the presence of a calcified lesion, marked tortuosity of the infarct-related artery, and a bifurcation lesion are independent predictors of failure of the aspiration catheter to reach and/or cross through the infarct-related lesion. In addition, when the segment could successfully be engaged and crossed with the thrombectomy catheter, no thrombotic material was obtained in a substantial part of procedures. Our analyses show that restoration of coronary flow was not influenced by failure of TA or whether thrombotic aspirate was retrieved and, importantly, no difference in 1-year mortality was observed.

In the past years, several randomized controlled trials examining the potential benefit of adjunctive TA during PPCI have been published (9–11,13–15). Information on the occurrence of failure of successful application of the different TA devices is lacking in most of these reports. The largest trial comparing the Rescue catheter with conventional PPCI did report failure to cross the lesion in 11% of cases despite pre-dilation (9). The TAPAS (Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction) trial is the largest trial comparing the adjunctive use of the Medtronic aspiration catheter with conventional PPCI (13). In this study, patients with lesions that were judged by the operator to be too tortuous or too small for delivery of the aspiration catheter were crossed over to the conventional treatment group. No details are available for the treatment success rates of the actual patients in which TA was attempted. Likewise, the authors of the EXPIRA (Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention) trial, which is a smaller trial investigating the use of the Medtronic aspiration catheter compared with conventional PPCI, did not describe in what proportion TA had failed (14). The recently published PREPARE (Proximal Embolic Protection in Acute MI and Resolution of ST-Elevation) trial is the only randomized controlled trial in which the Proxis system was investigated (15). In 6% of patients, the system could not be satisfactorily positioned, although only patients with lesions presumably suitable for

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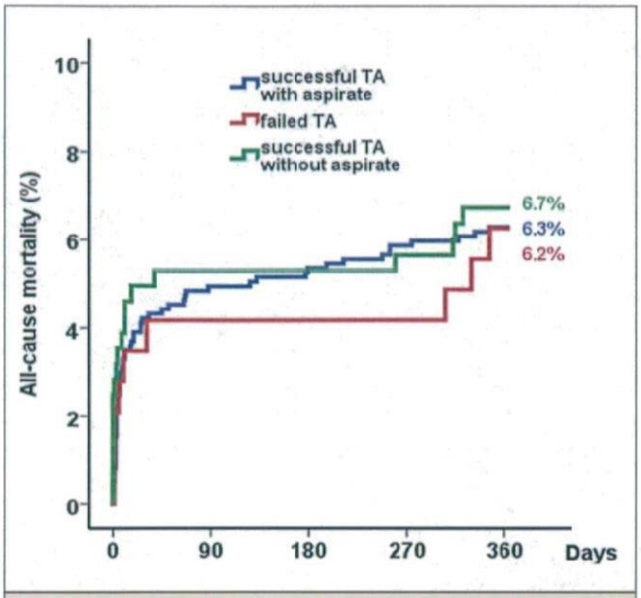

Figure 2. Kaplan-Meier Curves

Cumulative incidence of all-cause mortality in patients with successful thrombus aspiration (TA) with aspirate, patients with failed TA, and patients with successful TA without aspirate.

treatment with the device were included. At an incidence of 10.3%, the proportion of failure observed in our analysis is comparable to that described by Kaltoft et al. (9).

Predictors of failure of thrombus aspiration. In the current study, predictors of failure of TA were generally lesion-specific rather than patient-dependent. Previously, the presence of marked tortuosity and coronary calcification have been identified to be predictors of failure of intravascular ultrasound imaging, at a rate of 23% failed procedures described in a prospective cohort of patients with stable or unstable angina (16). The difference in flexibility of the catheters used for intravascular ultrasound with those currently used for TA and the dissimilar patient characteristics may explain the lower failure rate we observed. Additionally, the presence of a type C lesion was not an independent predictor of failure of TA. The American College of Cardiology/American Heart Association lesion morphology was originally introduced to provide a tool for estimation of the difficulty of a procedure and its probability of angiographic success (17). This concept of lesion morphology classification is not well defined for STEMI patients presenting with an acutely occluded vessel, which may explain the lack of correlation with TA failure in our observation.

After successful passage of the aspiration catheter through the lesion, no material could be identified in 27.3% of the patients in our cohort. This proportion is comparable with that reported in the TAPAS trial, in which no material was obtained in 27.1% of the procedures where TA was performed. The potency of endogenous fibrinolysis, enhanced by pharmacological therapy administered promptly after diagnosis before arrival at the catheterization laboratory, probably is a major contributor to this finding (18). The diversity in the morphology of the vulnerable plaque in acute myocardial infarction implies the possibility of a nonthrombotic lesion (19), whereas distal embolization could have occurred before treatment, either spontaneously or because of manipulation by the guidewire. Furthermore, the aspiration capacity of the devices used at our institution may not be sufficient to remove large thrombus load, as opposed to mechanical thrombectomy (20). During the study period, we did not use mechanical devices in the absence of beneficiary evidence in literature.

Survival. Interestingly, we found that survival at 1 year was not influenced by failure of the TA catheter to reach and/or cross the infarct-related lesion or, in the case of successful catheter passage, if thrombotic material could be retrieved. In previous reported investigations, removal of thrombus from the infarct-related artery reduced no-reflow by limiting the embolization of thrombotic material and was associated with improved TIMI flow and MBG, with an inconsistent effect on clinical outcome (4–7). It proved to be difficult to translate the benefit in surrogate endpoints in better clinical outcome. The TAPAS trial was the first trial to report better clinical outcome after routine manual TA compared with conventional PPCI (21). The occurrence of distal embolization, however, was not influenced by TA (22). The deterioration in coronary perfusion, as seen frequently in PPCI, is a complex condition related to multiple factors as endothelial dysfunction, microvascular obstruction, and reperfusion injury (23). These are unlikely to be affected simultaneously by TA alone. Thus, in the case of prompt restoration of coronary flow after wiring the coronary artery, the additional effect of TA on prognosis probably is modest. However, TA commonly allows for direct stenting, which was reported to be associated with reduced microvascular injury (24). In the present analysis, the final TIMI flow grade was not affected by failure of TA, which could explain, to some extent, the lack of a prognostic association of successful TA on 1-year mortality (25). In addition, the prognosis of these unselected acute STEMI patients may have been influenced by unidentified confounders or comorbidities associated with worse outcomes (26).

Study limitations. First, in our institution, TA is executed on the judgment of the interventional cardiologist, which could have resulted in selection bias. However, we studied patients in whom TA was attempted, where the operator considered the infarct-related lesion as suitable for TA. Second, the available data on surrogate outcomes are limited. The effect of TA on MBG could not be determined because the appropriate images to assess MBG were not collected routinely as part of daily practice. In addition, because patients were transferred to the referring hospitals

within hours after the procedure, infarct size could not be determined accurately as information on serial serum markers or left ventricular function was not available. Still, peak creatine kinase-myocardial band values were available in a considerable proportion of patients and were comparable in both groups. Furthermore, follow-up information was limited to vital status alone; therefore, a possible cardiac cause of death could not be identified.

Conclusions

Our findings demonstrate that in a considerable proportion of patients presenting with STEMI, the successful completion of TA during PPCI is limited either by the inability to reach and/or cross the infarct-related lesion, or by the lack of aspirate retrieved from the lesion. Marked proximal tortuosity of the infarct-related artery, the presence of a calcified lesion, and the presence of a bifurcation lesion are independent predictors of unsuccessful catheter passage through the lesion. Failure of TA limits the ability of direct stenting but has no influence on restoration of coronary flow as compared to successful TA. Age above 60 years and the circumflex artery as infarct-related artery were independently associated with the absence of aspirated material after successful passage of the infarct-related lesion. In our analysis of 1,399 unselected acute STEMI patients in whom TA was attempted in adjunct to PPCI, compared with successful TA, the failure to reach and/or cross the lesion and the absence of aspirate did not affect 1-year all-cause mortality.

Reprint requests and correspondence: Dr. Robbert J. de Winter, Department of Cardiology, Cardiac Catheterization Laboratory B2-137, Academic Medical Center, University of Amsterdam, Meibergdreef 9, Amsterdam 1105 AZ, the Netherlands. E-mail: r.j.dewinter@amc.uva.nl.

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Key Words: acute myocardial infarction ■ primary percutaneous coronary intervention ■ thrombus aspiration.

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Long distance transport for primary angioplasty vs immediate thrombolysis in acute myocardial infarction

Final results of the randomized national multicentre trial—PRAGUE-2

P. Widimský†, T. Buděšínský, D. Voráč, L. Groch, M. Želízko, M. Aschermann, M. Branny, J. Št'ásek, P. Formánek, on behalf of the 'PRAGUE' Study Group Investigators*

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KEYWORDS
Acute myocardial infarction;
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long distance transport;
coronary intervention;
coronary angioplasty;
stent

Background Primary percutaneous coronary intervention (PCI) is shown to be the most effective reperfusion strategy in acute myocardial infarction. The aim of this multicentre national randomized mortality trial was to test whether the nationwide change in treatment guidelines (transportation of all patients to PCI centres) was warranted.
Methods The PRAGUE-2 study randomized 850 patients with acute ST elevation myocardial infarction presenting within <12 h to the nearest community hospital without a catheter laboratory to either thrombolysis in this hospital (TL group, n = 421) or immediate transport for primary percutaneous coronary intervention (PCI group, n = 429). The primary end-point was 30-day mortality. Secondary end-points were: death/reinfarction/stroke at 30 days (combined end-point) and 30-day mortality among patients treated within 0–3 h and 3–12 h after symptom onset. Maximum transport distance was 120 km.
Results Five complications (1.2%) occurred during the transport. Randomization–balloon time in the PCI group was 97±27 min, and randomization–needle time in the TL group was 12±10 min. Mortality at 30 days was 10.0% in the TL group compared to 6.8% mortality in the PCI group ($P = 0.12$, intention-to-treat analysis). Mortality of 380 patients who actually underwent PCI was 6.0% vs 10.4% mortality in 424 patients who finally received TL ($P<0.05$). Among 299 patients randomized >3 h after the onset of symptoms, the mortality of the TL group reached 15.3% compared to 6% in the PCI group ($P<0.02$). Patients randomized within <3 h of symptom onset (n = 551) had no difference in mortality whether treated by TL (7.4%) or transferred to PCI (7.3%). A combined end-point occurred in 15.2% of the TL group vs 8.4% of the PCI group ($P<0.003$).
Conclusions Long distance transport from a community hospital to a tertiary PCI centre in the acute phase of AMI is safe. This strategy markedly decreases mortality in patients presenting >3 h after symptom onset. For patients presenting within <3 h of symptoms, TL results are similar results to long distance transport for PCI.
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† *Correspondence:* Petr Widimský, MD., PhD., FESC., Cardiocenter Vinohardy, Šrobárova 50, 100 34 Prague 10, Czech Republic.
* Appendix lists the investigators.

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Introduction

Direct coronary angioplasty as the primary reperfusion therapy for acute myocardial infarction was first described by Meyer[1] and Hartzler[2] in 1982–3. Ten years later three randomized studies showed the superiority of primary angioplasty over thrombolysis when used within the same period after onset of symptoms.[3–5] This was also confirmed by a meta-analysis of additional trials.[6] Currently there is no doubt that primary percutaneous coronary intervention (primary PCI) results in markedly lower in-hospital mortality[7–9] and decreased risk of reinfarction and stroke.[3–10] However, the use of primary PCI as the treatment of choice for all patients with acute myocardial infarction and ST segment elevations has not become routine. The explanation is complex: difficulties in the logistics of such an approach, large variation in PCI results between high- vs low-volume centres[9,11] and the possible deleterious effects of substantial treatment delay on myocardial salvage and resulting left ventricular function.[12–14]

The safety and feasibility of interhospital transportation of patients with acute myocardial infarction presenting initially to smaller hospitals without PCI facilities to the tertiary PCI centres was investigated by the LIMI study in the Netherlands[15] and by the PRAGUE-1 study in the Czech Republic.[16] Both these studies clearly proved the safety and feasibility of the transport and both had the same direction of results: transport for primary PCI was superior to immediate thrombolysis in the first hospital, and the combination strategy (thrombolysis during transport) was intermediate (inferior to transport alone, superior to thrombolysis alone). Transportation decreased the incidence of the combined clinical end-point (death/reinfarction/stroke at 30 days). Thus, immediately after the PRAGUE-1 study we started preparing for a much larger nationwide trial, with 30-day mortality as the only primary end-point: the PRAGUE-2 trial. The aim was to compare intravenous streptokinase vs immediate transport for primary PCI in patients with ST elevation myocardial infarction, admitted to hospitals without PCI facilities in the Czech Republic, where distance between primary hospitals and tertiary PCI centres does not exceed 120 km.

Methods

The study protocol has been approved by the local ethical committees of all participating centres. The local ethical committee of the coordinating centre expressed concerns about the safety of long distance transport (i.e. not performing immediate thrombolysis) specifically in patients presenting within the initial 3 h after symptom onset. Thus, the committee required repeat interim reports about mortality to ensure that whenever a significant difference in favour of any group occurred the study would be stopped prematurely.

Infrastructure

The coordinating site was at the Cardiocenter, University Hospital Vinohrady, Prague, which was also one of the seven participating PCI centres. For at least 6 months before the start of the study in all seven PCI centres primary PCI was the only reperfusion strategy used in all patients presenting from their respective primary care region (these PCI centres had completely stopped using thrombolysis in their routine treatment of patients with acute myocardial infarction). Forty-one community hospitals without catheterization facilities were the primary sites. Patients were enrolled here into the study immediately after their initial ECG and after obtaining informed consent (Fig. 1).

Randomization and the treatment arms

Patients were randomized by telephone into one of the two arms (Table 1). The anti-thrombotic treatment prescribed by the protocol is also presented in Table 1 The attending physicians were allowed to change the strategy whenever they considered this to be of help for the patient. Specifically, intravenous use of GP IIb/IIIa inhibitors (abciximab or eptifibatide) was allowed in the PCI group and discouraged in the TL group (during the initial 24 h after streptokinase). No patient received GP IIb/IIIa blockers before the intervention. In four patients (1%) randomized to the PCI group the transport was cancelled due to rapid haemodynamic deterioration into profound cardiogenic shock soon after randomization. The four patients received thrombolysis, but they are analysed as the part of the PCI group, based on the intention-to-treat principle. For precise information a second (post-hoc) analysis was performed with respect to the final treatment (whether patients indeed received PCI or TL).

Patients

During the study period (23 September 1999–7 January 2002) a total of 4853 patients with any acute myocardial infarction presented to the emergency departments of 41 participating community

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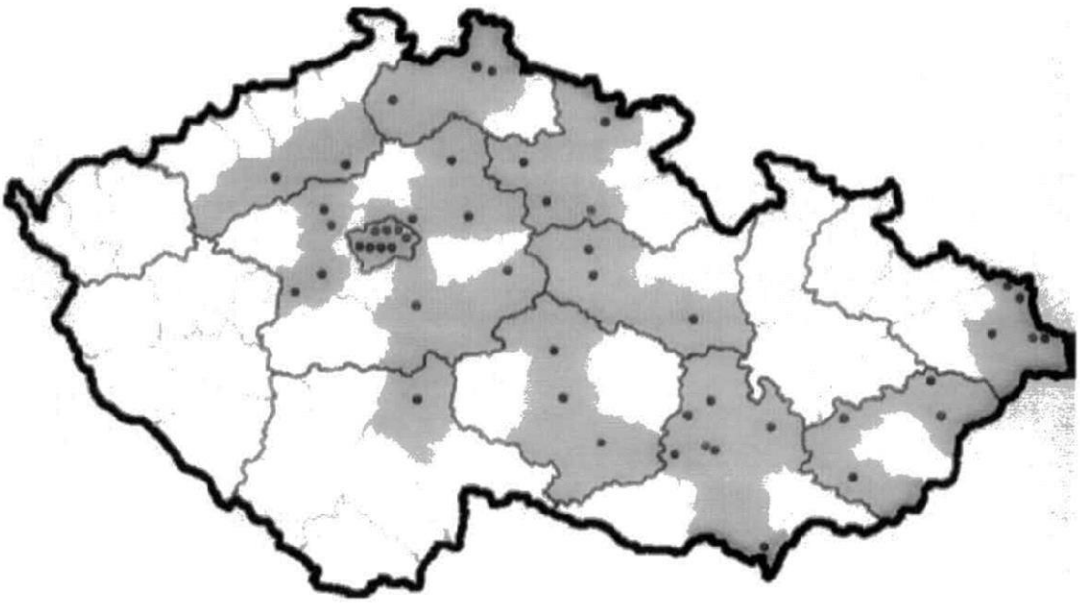

Figure 1 The map of the Czech Republic showing the geographic distribution of primary (community) hospitals/ tertiary cardiac centres (black points) along with their respective service areas-districts (grey). Thirty-three out of 77 districts (geographically 43% of the Czech districts) were participating in the study. The population of these districts however represents 5.7 million, i.e. 54% of the total country population. The situation in the country improved substantially during the study period. Thus, in 2002 additional 9 PCI centres were either newly opened or started 24-h service for primary PCI in acute myocardial infarction. Thus, at the end of study period, 95% of the Czech population had access to primary PCI at a distance <100 km from their homes.

Table 1 Treatment arms (reperfusion strategies)

Group TL (thrombolysis in the first hospital)	Group PCI (transportation to the tertiary PCI centre for primary PCI)
Patient stays in the primary hospital (transport allowed for rescue PCI or for recurrent ischaemia)	Transport to PCI centre immediately after randomization
Aspirin (Aspegic®) 500 mg iv.	Aspirin (Aspegic®) 500 mg iv.
	Heparin 200 U/kg iv.
Streptokinase 1.5 mil. U iv/45 min	PCI
Clopidogrel 75 mg for 1 month	Clopidogrel 75 mg for 1 month
Fraxiparin 0.8 ml sc. for 3 days	Fraxiparin 0.8 ml sc. for 3 days

hospitals without a catheterization laboratory. Eight hundred and fifty of them (who fulfilled the entry/exclusion criteria) have been randomized into one of the two treatment arms (Table 2). The remaining 4003 patients, who were not randomized, represent a mixture of non-ST elevation infarctions, late presenting Q-wave infarctions, contraindication for thrombolysis, refusal to sign informed consent and thrombolytic therapy or transport for primary PCI without randomization from various reasons. The only possible bias was that some physicians occasionally decided not to randomize some patients with anterior infarction and tended to send them for primary PCI without randomization. This is reflected by the some-what lower rate of anterior infarcts (40%). Another 2985 patients with ST elevation myocardial infarction presented during the same period directly (primary admissions) to the seven participating PCI centres. They were not randomized and have been treated routinely with immediate primary PCI and are not part of this study. (Information about the routine workload and results of the PCI centres are briefly described in Table 3 .) The inclusion criteria for the PRAGUE-2 study were: acute myocardial infarction (ST elevations > 1 mm in at least two leads or a new bundle branch block on initial ECG), within <12 h from the onset of symptoms, distance to PCI centre <120 km, feasibility to begin transport within 30 min after randomization, signed written

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Table 2 Patients baseline characteristics

	TL group	PCI group
Number of randomized patients	421	429
Males (%)	71	70
Mean age (years)	64	65
Anterior infarction (%)	39	41
Previous infarction (%)	11	14
Diabetes mellitus (%)	23	25
Hypertension (%)	47	49
Previous CABG (%)	1.7	0.5
Previous PCI (%)	0.2	0.9
Heart Failure (Killip II–III) at the time of randomization (%)	16	16
Cardiogenic shock (Killip IV) at the time of randomization (%)*	1	2

TL = thrombolysis; PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft. All differences in the characteristics between groups are not significant.

*After randomization (at any time during the hospital stay) cardiogenic shock developed in 11% of the TL group and 9% of the PCI group.

Table 3 Routine primary PCI results in the participating PCI centres during the study period (primary admissions, non-transported patients, are not part of the study population)

1 October 1999–7 January 2002	Primary/rescue PCI for AMI (n=)	Morphologic success rate-TIMI 2–3 (%)	In-hospital mortality (%)
Centre no. 1	621	91	8.2
Centre no. 2	331	87	7.3
Centre no. 3	387	94	4.6
Centre no. 4	718	96	5.6
Centre no. 5	163	na	4.9
Centre no. 6	532	97	2.8
Centre no. 7	287	91	9.1
Total	2985	93%	5.9%

informed consent. Exclusion criteria were: contraindication to thrombolysis (ischaemic stroke within previous 12 months, haemorrhagic stroke at any time, intracranial tumour, active internal bleeding, aortic dissection) and absence of bilateral femoral artery pulsations.

Coronary interventional procedure

Coronary angiography was performed via the femoral artery. The procedure was started by visualization of the 'non-infarct-related' coronary artery with a diagnostic 5–6F catheter and immediately thereafter the guiding catheter 6F was used for diagnostic visualization of the 'infarct-related' artery and for subsequent PCI. According to the protocol, PCI should be performed in all patients with TIMI flow 0–2 in the 'infarct-related' artery. When TIMI flow 3 was revealed on the acute coronary angiogram, it was left to the decision of the operator whether an intervention was to be performed in the acute phase, or later or not performed at all. A stent was implanted whenever anatomically suitable (vessel ≥3.0 mm in diameter, no extreme tortuosity), or when there was a suboptimal result (as assessed by the operator) after balloon angioplasty. Non-infarct-related arteries were not treated during the same procedure. Rescue PCI was defined as a percutaneous coronary intervention performed for continuing clinical and electrocardiographic signs of ischaemia after completion of the streptokinase infusion. The recommended policy was to decide within 30 min of the end of the streptokinase infusion whether to perform rescue PCI if ST elevations and chest pain continued.

Examinations and follow-up

Complete clinical examination with ECG was performed on days 1, 2, 3, at discharge and on day 30. Echocardiography was performed at discharge and

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Table 4 The time delays to treatment (min)

	TL group	PCI group
Pain onset–randomization	173±119	183±162
Randomization–start of thrombolysis	12±10	na
Randomization–start of transport	na	20±9
Transport duration	na	48±20
Door–balloon time in the PCI centre	na	26±11
Randomization–reperfusion	na (cca 60–90')	97±28

on day 30. Coronary angiography was performed in the PCI group immediately on arrival at the PCI centre. In the TL group (as well as any repeat angiography in the PCI group) it was performed according to routine clinical indication: postinfarction angina pectoris, reinfarction, rescue PTCA after failed thrombolysis. Further 1-year follow-up is under way, but is not the subject of this paper.

Study end-points and definition

The primary end-point was mortality at 30 days. It was defined as death from any cause within 30 days after randomization. The secondary end-point was the presence of any serious clinical event (death/non-fatal reinfarction/non-fatal stroke) at 30 days. Furthermore, according to the suggestion of the ethical committee (see above), the 30-day mortality among subgroups of patients treated within 0–3 h and 3–12 h after symptom onset was added as a secondary end-point.

Stroke was defined as any new neurologic deficit lasting >24 h. Reinfarction was defined as recurrent symptoms of ischemia with new electrocardiographic changes and a rise in CK-MB. Optimal procedural success was defined as TIMI-3 flow and <30% stenosis after the intervention. Partial success (suboptimal result) was defined as TIMI-2 flow and/or >30% residual stenosis.

Statistic assessment

The calculated sample size was based on the expected mortality rates, similar to those in the PRAGUE-1 study. The target sample size was thus planned for 1200 patients. Microsoft Excel and Systat software were used for the database and chi-square was used for the statistical analyses of the differences between the two groups.

Results

Study termination

The study was stopped prematurely by the ethical committee. The reason was 2.5-fold excess mortality in the TL group among patients treated after >3 h from symptom onset. The committee considered thrombolytic treatment without transportation to the PCI centre no longer justified in this subset of patients (i.e. those treated between 3–12 h after symptom onset). There was also an increasing reluctance in the primary community hospitals to randomize the patients into the thrombolytic arm. These hospitals were increasingly asking for routine transportation of all patients with ST elevations during the study period.

Complications during transport

Four hundred and twenty-five patients (99%) in the PCI group were transported immediately after randomization to the PCI centre. The remaining four patients (1%) were not transported due to rapid haemodynamic deterioration into profound cardiogenic shock soon after randomization. All four patients were resuscitated and received thrombolysis, three of them died within the initial 24 h. They are analysed within the PCI group, based on the intention-to-treat principle. The distances between primary hospitals and PCI centres varied between 5–120 km. There were two deaths and three ventricular fibrillations (successfully treated with defibrillation in the emergency ambulance car, their further course was uneventful) during the transport (i.e. complications during the transport occurred in 1.2%).

The time delays and hospital stay

The treatment delays and transport time intervals are listed in Table 4 and Fig. 2 . The mean hospital stay duration in the TL group was 13±5 days and in the PCI group 11±4 days ($P<0.05$).

Coronary angiographic findings and PCI results

The infarct-related artery was left anterior descending in 158 patients, left circumflex in 55 patients, right coronary artery in 188 patients, left

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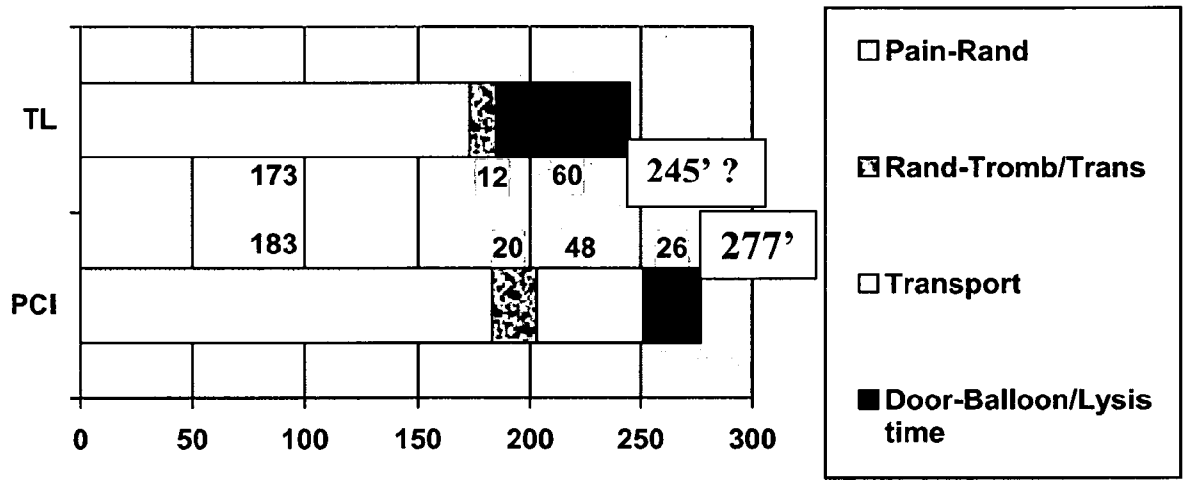

Figure 2 Time delays from the onset of symptoms to (presumed in TL) reperfusion. Patients were randomized after 173 and 183 min of symptoms respectively. The delay between randomization and thrombolysis start was 12 min and between randomization and transport start 20 min. Transport duration was 48 min. Door-to-balloon time was 26 min. To compare approximate reperfusion times, the presumed needle-reperfusion time of 60 min was added to the thrombolysis group. Thus the known total ischemia time in the PCI group was 277 min and the approximate ischaemic-reperfusion time in the thrombolysis group was 245 min.

main coronary artery in five patients and venous bypass graft in one patient. No angiography was performed in seven PCI group patients (four who finally were not transported, two who died during transport and one who received thrombolysis at the PCI centre due to technical problems in the catheter laboratory). The infarct-related artery was not defined in three patients. No significant coronary stenosis was found in 12 patients. TIMI-3 flow on the initial angiogram (pre-PCI) and immediately after PCI is shown in Fig. 3 . PCI was performed in 89% of all patients randomized to the PCI group. The full technical success rate of the interventions was 88%. There was a suboptimal result (TIMI-2 flow and/or residual diameter stenosis >30%) in 6% and the intervention was not successful in another 6% (TIMI flow 0–1 after PCI). Stents were implanted in 63% of all acute interventions. PCI success rates varied among the seven PCI centres between 85–90% (optimal success, TIMI 3 flow), and 92–100% (optimal + suboptimal success, TIMI 2–3 flow). In-hospital mortality among PCI centres varied between 2.6–9.4%. PCI was not performed in 49 PCI group patients (11%) for the following reasons: TIMI-3 flow and no pain at the time of angiography (20 patients), no significant stenosis at coronary angiography (12 patients), thrombolysis applied in the primary hospital (five patients), emergent coronary bypass surgery (three patients), chronic total coronary occlusion (two patients), death before PCI (two patients), miscellaneous (seven patients). Rescue PCI was performed in 27 TL group patients (i.e. 6.4% of streptokinase-treated patients).

Primary end-point

The 30-day mortality was 10.0% in the TL group (42 of 421 patients) vs 6.8% (29 of 429 patients) in the PCI group ($P = 0.12$).

Secondary end-points

Among 299 patients randomized after >3 h (mean 5 h and 6 min) from symptom onset, the mortality was 15.3% in the TL group vs 6.0% in the PCI group ($P<0.02$). Among 551 patients randomized within <3 h (mean 1 h and 41 min) of symptom onset, the mortality was similar in both groups (7.4% in the TL group vs 7.3% in the PCI group) (Fig. 4). The combined clinical end-point (death/reinfarction/stroke) occurred in 64 TL group patients (=15.2%) vs 36 PCI group patients (=8.4%, $P<0.003$). There were 13 (=3.1%) non-fatal reinfarctions in the TL group vs six (=1.4%) in the PCI group (ns). Non-fatal stroke occurred in nine (=2.1%) TL patients vs one (=0.2%) PCI patient ($P<0.03$).

Analysis based on the actually used treatment

Primary PCI was performed in 380 patients (89%) of the PCI group. Their 30-day mortality was 6.0%.

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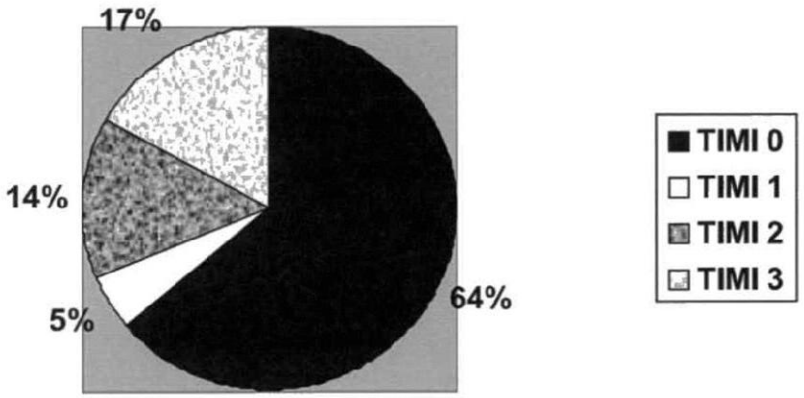
Pre-PCI:



Post PCI:

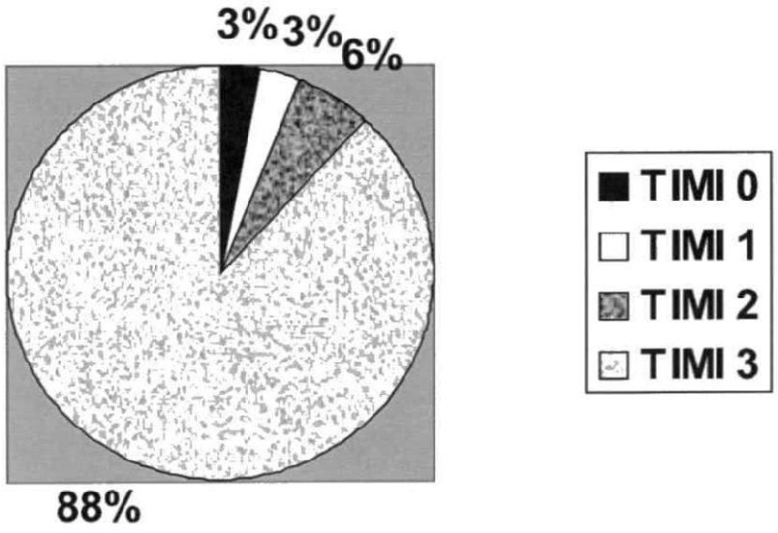


Figure 3 TIMI-flow before and after PCI.

Thrombolysis was used in 419 TL group patients and also in five PCI group patients (instead of PCI). The 30-day mortality of thrombolysed patients was 10.4% ($P<0.05$).

Left ventricular function

The mean echocardiographic left ventricular ejection fraction at 30 days was 51±9% in the TL group vs 50±8% in the PCI group (ns).

Discussion

Thirty-day mortality in the PCI group was almost exactly as expected based on the PRAGUE-1 study results (7%). However, mortality in the TL group was lower than expected 13%. Thus, the overall difference did not reach statistical significance. Nevertheless, the trend in favour of PCI strategy is clear. These data show a trend similar to that of DANAMI-2,[30] where the mortality difference was

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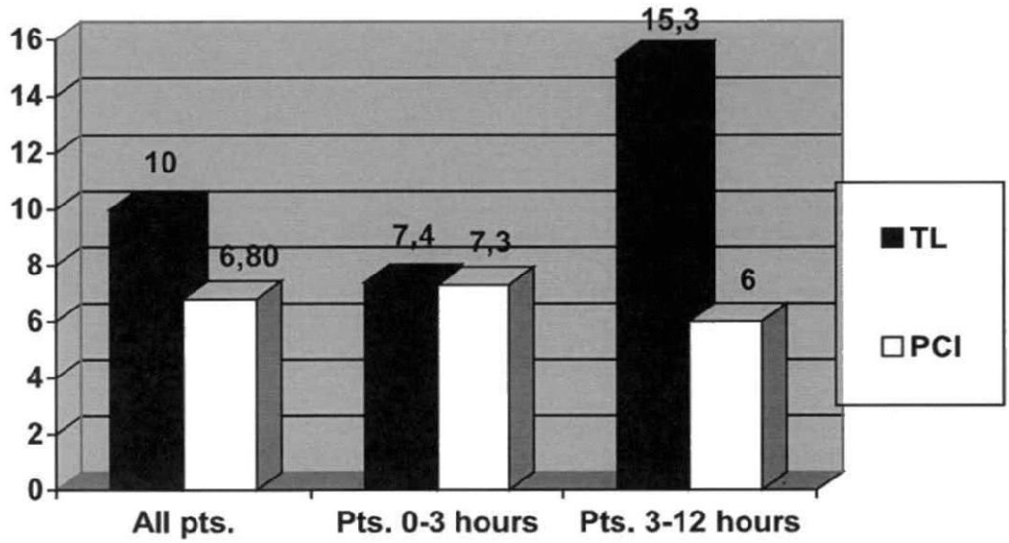

Figure 4 Thirty-day mortality (%) among all patients and among early vs late 'presenters'.

smaller, possibly due to use of t-PA instead of streptokinase.

The first 3 h of myocardial infarction

The results showed no harm from transport-related delays in the subgroup of 'early presenters' but did show a 2.5-fold increase in mortality among late presenters treated by thrombolysis. This is similar to the PCAT meta-analysis.[17] These studies support the strategy of primary PCI for every patient for whom PCI is available with only a short delay, compared to thrombolysis (i.e. short transport distances or primary admissions to PCI centres) and for every patient (even with a need for long transport distance) presenting after >3 h from symptom onset. Thrombolysis should be reserved only for those patients presenting within <3 h from symptom onset, with long, timely access to primary PCI. The study results do not show a difference between thrombolysis and PCI among patients with a presentation time <3 h, but this is not a statistical proof of equivalence; it would require a much larger study.

Patients presenting between 3–12 h after the onset of symptoms

The high mortality among TL group patients presenting after >3 h confirms the previous experience,[14,27] that thrombolysis is much less effective in these late presenters, while the effectivity of primary PCI is equal to the early presenters. The German MITRA/MIR registries showed no significant difference in mortality rates between primary angioplasty and thrombolysis for prehospital delays of <3 h. However, when pre-hospital delay was >3 h, thrombolysis was independently associated with a higher mortality rate compared with primary angioplasty.[18] Thus, the results of these studies support the change in the strategy for the late presenters—routine transfer for primary PCI should be the first choice. This is in accordance with the recent meta-analysis PCAT.[17]

Safety of transport in the acute phase of myocardial infarction

Several non-randomized observational reports[19–22] and two mentioned randomized trials[15,16] confirmed the feasibility and safety of transporting patients with acute myocardial infarction to tertiary centres for primary (or rescue) coronary angioplasty. There is a little doubt now, that the interhospital transport of patients with ST elevation acute myocardial infarction does not present any additional risk for the patient. What is the maximal distance for transport, for which the benefit of primary PCI will be offset by such an extensive time delay, that on-site thrombolysis will remain the preferable strategy? The published data are controversial in this respect. There is enough evidence that ischaemic time is related to infarct size and clinical outcome.[23–26] However, while delayed thrombolysis offers only very limited potential benefit to the patient,[28] primary PCI performed later (i.e. between 3–12 h from the onset of

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symptoms) has a similar success rate and similar clinical outcome as in patients presenting within <3 h.[27–29]

Role of centreloperator experience

The variation among seven PCI centres was 87–97% for success rate and 2.8%–9.1% for in-hospital mortality among non-study patients. This reflects mainly the differences in routine decision making: the centres with lower mortality tended to exclude some really terminally ill cardiogenic shock patients or some elderly patients, while the centres with higher mortality rates do perform primary PCI in every patient without any age or terminal phase limits. However, the variation was relatively small and the results of all seven centres were similar among the study patients (where these differences could not have any influence, because the patients were randomized in other hospital). This is different from our previous experience[16] and reflects the increasing workload of the PCI centres in the Czech Republic during the last 5 years, when primary PCI became more frequent than thrombolysis as reperfusion therapy in the entire country.

Pharmacologic treatment before/after primary PCI

Another limitation of this study is that the thrombolytic arm was represented by streptokinase rather than more potent thrombolytic agents. Streptokinase was used because it is the routine treatment of myocardial infarction in the Czech Republic. However, the use of a more potent thrombolytic would probably not substantially affect the main results of the study (the difference between tPA and streptokinase could be hardly expected in a population of 421 patients in the TL group). In the recently presented DANAMI-2 trial tPA was used and the study was also terminated prematurely due to the convincing clinical benefit in the PCI group.[30]

Implications for the current practice

The data favouring primary PCI as the best available reperfusion strategy for patients with acute myocardial infarction are sound. The change in clinical practice should be considered in three directions: (1) Patients with ST elevations in areas with PCI availability within 20–30 min of transport time should always be transported directly from the emergency car/helicopter to the catheterization laboratory (avoiding delays in the small hospitals or emergency departments of the large hospitals). (2) When PCI cannot be started within 60 min of the ECG diagnosis, thrombolysis should be used—but only for patients presenting within <3 h of symptom onset. The usefulness of immediate angiography/intervention routinely after thrombolysis in these patients remains to be established. And finally (3) all patients presenting between 3–12 h from symptom onset should be transported for primary PCI and thrombolysis should not be used in this subset of patients. The data from this study together with data from other randomized trials and myocardial infarction registries should be brought together and a modification of guidelines may be considered.

Acknowledgements

The authors express thanks to the physicians, nurses and technicians of participating catheterization laboratories, coronary care units, community hospitals and regional emergency medical services.

Appendix

The complete list of investigators

PCI centres (number of patients randomized to the PCI group in the respective cooperating primary community hospitals): Investigators

Cardiocenter, University Hospital Vinohrady, Prague (110 patients): Petr Widimský, MD., DrSc., FESC., (principal investigator of the study). Tomáš Buděšínský, MD., *David Voráč, MD. (Junior research coordinator of the study),* Jaroslav Dvořák, MD., Jiří Krupička, MD., Libor Lisa, MD, Radovan Jirmář, MD., Pavel Gregor, MD., DrSc., FESC., Rudolf Špaček, MD., PhD, Zbynek Straka, MD, PhD.

Cardiovascular Department I, University Hospital St. Anne, Brno (147 patients): Ladislav Groch, MD., Ivan Horňáček, MD., Ota Hlinomaz, MD., Jan Sitar, MD., Libor Nechvátal, MD.

Cardiocenter, Hospital Podlesí, Třinec (72 patients): Marian Branny, MD., Igor Nykl, MD., Ivo Varvařovský, MD., Jindřich Černý, MD., Marek Richter, MD.

Cardiology Clinic IKEM, Prague (45 patients): Michal Želízko, MD., PhD., Bronislav Janek, MD., PhD., Jiří Kettner, MD., PhD., Vladimír Karmazín, MD.

Cardiocenter, University Hospital Hradec Králové (35 patients): Josef Šťásek, MD., Pavel Červinka, MD., Dušan Černohorský, MD., Miroslav Brtko, MD., Vladimír Rozsíval MD., PhD., Aleš Herman, MD., PhD.

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Cardiology Department, Hospital Na Homolce, Prague (15 patients): Pavel Formánek, MD., Petr Kmoníček, MD., Ondřej Aschermann, MD.

Medical Department II, General University Hospital, Prague (5 patients): Michal Aschermann, MD., DrSc., Stanislav Šimek, MD., Aleš Linhart, MD., PhD., František Holm, MD., Jan Bělohlávek, MD.

Community hospitals (with total randomized patients) and investigators (all are MD)

Třebíč (62 patients): Josef Štumar, Jiří Carda, Ondřej Toman, Pavel Růžička, Petr Konečný. *Vyškov (59 patients)*: Josef Veselý, Oldřich Synek, František Adamec, Vladimír Foret, Jiří Pinka. *Nymburk (57 patients)*: Arnošt Václavíček, David Vencour, Michal Hudcovic, Pavel Frič, Radka Sytarová, Hana Širová, Václav Hulínský. *Havířov (57 patients)*: Miloslav Durčák, Eva Pederzoliová. *Ivančice (49 patients)*: Petr Valeš, Miroslav Čech. *Kutná Hora (42 patients)*: Venuše Šmejkalová, Alena Kadlečková, Dana Ryšavá. *Slaný (42 patients)*: Gabriel Marcínek, Ondřej Čermák, Jan Mácha. *Mladá Boleslav (38 patients)*: Jiří Kotouš, Tomáš Kubíček, Zbyněk Košek. *Valašské Meziříčí (37 patients)*: Pavel Prodělal, Marie Líčeníková, Richard Wiesner. *Vsetín (34 patients)*: Jaroslav Doubravský, Jiří Ludva, Petr Palacký, Radmila Boháčová. *Tišnov (29 patients)*: Jaroslav Vykouřil, Jaroslav Svoboda. *Havlíčkův Brod (24 patients)*: Josef Málek, JiříŠtefánek. *Kroměříž (24 patients)*: Lumír Francek, Pavel Třeštík. *Chrudim (23 patients)*: Josef Tuhý, Dalibor Kašík, Michal Wysocki. *Vysočany (22 patients)*: Eva Kosová, Jan Kaufman. *Uherské Hradiště (21 patients)*: Vladimír Okénka, Vladimír Klapal. *Svitavy (20 patients)*: Ivana Kellnerová, Emilie Smrčková. *Benešov (19 patients)*: Václav Havlik, Martin Otava. *Hořovice (17 patients)*: Eduard Kroupa. *Pardubice (16 patients)*: Marek Sychra. *Roudnice nad Labem (14 patients)*: Ilona Kašíková. *Břeclav (14 patients)*: Jitka Siegelová. *Boskovice (14 patients)*: Marie Lýčková. *Frýdek–Místek (14 patients)*: Tomáš Gistinger. *Brandýs nad Labem (13 patients)*: Richard Kobza. *Tábor (12 patients)*: Jindřich Charouzek. *Louny (9 patients)*: Jan Semrád. *Jičín (nine patients)*: Soňa Zajíčková. *Liberec (7 patients)*: Jiří Koťátko. *Beroun (7 patients)*: Karel Sochor. *Karviná (6 patients)*: Jan Bolek. *Nový Bydžov (6 patients)*: Luděk Beran. *Jihlava (6 patients)*: Zdeněk Klimsa. *Na Františku (6 patients)*: Ivo Jokl. *Turnov (5 patients)*: Oldřich Honců. *Military Hospital Brno (5 patients)*: Tomáš Brabec. *Military Hospital Prague–Střešovice (5 patients)*: David Ručka. *Česká Lípa (3 patients)*: Zdeněk Holý. *Na Žižkové (1 patient)*: Zdeněk Felix. *Kladno (1 patient)*: Jiří Povolný. *Třinec–Sosna (1 patient)*: Jan Boháč.

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Articles

Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials

Ellen C Keeley, Judith A Boura, Cindy L Grines

Summary

Background Many trials have been done to compare primary percutaneous transluminal coronary angioplasty (PTCA) with thrombolytic therapy for acute ST-segment elevation myocardial infarction (AMI). Our aim was to look at the combined results of these trials and to ascertain which reperfusion therapy is most effective.

Methods We did a search of published work and identified 23 trials, which together randomly assigned 7739 thrombolytic-eligible patients with ST-segment elevation AMI to primary PTCA (n=3872) or thrombolytic therapy (n=3867). Streptokinase was used in eight trials (n=1837), and fibrin-specific agents in 15 (n=5902). Most patients who received thrombolytic therapy (76%, n=2939) received a fibrin-specific agent. Stents were used in 12 trials, and platelet glycoprotein IIb/IIIa inhibitors were used in eight. We identified short-term and long-term clinical outcomes of death, non-fatal reinfarction, and stroke, and did subgroup analyses to assess the effect of type of thrombolytic agent used and the strategy of emergent hospital transfer for primary PTCA. All analyses were done with and without inclusion of the SHOCK trial data.

Findings Primary PTCA was better than thrombolytic therapy at reducing overall short-term death (7% [n=270] *vs* 9% [360]; p=0·0002), death excluding the SHOCK trial data (5% [199] *vs* 7% [276]; p=0·0003), non-fatal reinfarction (3% [80] *vs* 7% [222]; p<0·0001), stroke (1% [30] *vs* 2% [64]; p=0·0004), and the combined endpoint of death, non-fatal reinfarction, and stroke (8% [253] *vs* 14% [442]; p<0·0001). The results seen with primary PTCA remained better than those seen with thrombolytic therapy during long-term follow-up, and were independent of both the type of thrombolytic agent used, and whether or not the patient was transferred for primary PTCA.

Interpretation Primary PTCA is more effective than thrombolytic therapy for the treatment of ST-segment elevation AMI.

Lancet 2003; **361:** 13–20

Department of Internal Medicine, Division of Cardiology, University of Texas Southwestern Medical Center, Dallas, TX, USA (E C Keeley MD); **and William Beaumont Hospital, Royal Oak, MI** (J A Boura MS, C L Grines MD)

Correspondence to: Dr Ellen C Keeley, University of Texas Southwestern Medical Center, Division of Cardiology, 5323 Harry Hines Boulevard, Dallas, TX 75390, USA (e-mail: Ellen.Keeley@UTSouthwestern.edu)

Introduction

In the mid-1970s, acute myocardial infarction (AMI) was identified, in nearly all cases, as being the result of a ruptured atherosclerotic plaque, causing thrombosis and occlusion of the coronary artery.[1] Subsequently, the reperfusion era was ushered in with the realisation that an occlusive thrombus in a coronary artery could be managed by use of a combination of a guidewire to mechanically initiate coronary blood flow and the intracoronary infusion of streptokinase.[2] The recognition that the prompt restoration of flow salvages myocardium, reduces infarct size, and prolongs life has been the driving force behind a large number of clinical trials, assessing thrombolytic therapy for AMI. The results of these trials, done in the early 1980s and involving tens of thousands of patients, unequivocally showed that thrombolytic therapy resulted in preserved left-ventricular function and decreased mortality in patients with AMI.[3]

Primary percutaneous transluminal coronary angioplasty (PTCA), defined as balloon angioplasty undertaken as the primary reperfusion strategy for AMI without previous or concomitant thrombolytic therapy, was initially compared with intracoronary thrombolytic therapy.[4] Over the next decade, ten trials, comparing primary PTCA with intravenous thrombolytic therapy for ST-segment elevation AMI were undertaken. In 1995[5] and in 1997,[6] systematic reviews of this topic were published, with the later analysis of 2606 patients, showing improved short-term clinical outcomes, including death, with primary PTCA compared with thrombolytic therapy. Since this quantitative review, however, 13 new trials, comparing these two reperfusion modalities, have been done, more than doubling the number of randomised trials, and tripling the number of patients studied. Moreover, long-term clinical outcomes are now available for many of these trials. Our aim was, therefore, to provide an updated quantitative analysis of the results of the randomised trials of primary PTCA versus thrombolytic therapy.

Methods

Protocol

We identified all randomised trials done to date, published and unpublished, comparing primary PTCA with thrombolytic therapy for the treatment of acute ST-segment AMI, by searching the Medline database. We also searched scientific sessions abstracts in the *New England Journal of Medicine*, *Journal of the American College of Cardiology*, *Circulation*, *European Heart Journal*, *Heart*, and *Clinical Cardiology*, and questioned the principal investigators of most trials to ensure validity of the data, obtain additional unpublished data, and to verify that the study was randomised in design.

Our primary aim was to ascertain which reperfusion therapy, intravenous thrombolytic therapy or primary PTCA, is most effective for treatment of patients with

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	Patients' characteristics	Symptom duration (h)	Number randomised to PTCA (n=3872)	Numer randomised to thrombolysis (n=3867)	Stents used	Glycoprotein IIb/IIIa antagonists used	Thrombolytic agent used, administration time	Time to treatment (min)	
								PTCA	Thrombolytic therapy
Streptokinase trials (n=1837)									
Zijlstra[8]	Age ≤75 years, ST↑	<6	152	149	No	No	1·5 million U SK, 1h	62*	30*
Riberio[9]	Age <75 years, ST↑	<6	50	50	No	No	1·2 million U SK, 1h	238	179
Grinfeld[10]	ST↑	<12	54	58	No	No	1·5 million U SK, 1h	63†	18†
Zijlstra[11]	ST↑, low risk	<6	47	53	No	No	1·5 million U SK, 1h	68*	30*
Akhras[12]	ST↑	<12	42	45	No	No	1·5 million U SK, 1h	NA	NA
Widimsky[13]**	ST↑, LBBB	<6	101	99	Yes	No	1·5 million U SK, 1h	80†	70†
de Boer[14]	Age ≥76 years; ST↑	<6	46	41	Yes	No	1·5 million U SK, 1h	59*	31*
Widimsky[15]	ST↑	<12	429	421	Yes	Yes	1·5 million U SK, 1h	277‡§	245‡§
Fibrin-specific trials (n=5902)									
DeWood[16]	Age ≤76 years; ST↑	<12	46	44	No	No	Duteplase, 4h	126*	84*
Grines[17]	ST↑	<12	195	200	No	No	t-PA, 3h	60†	32†
Gibbons[18]	Age <80 years; ST↑	<12	47	56	No	No	Duteplase, 4h	45†	20†
Ribichini[19,20]	Age <80 years; inferior MI, anterior ST↓	<6	55	55	No	No	Accelerated t-PA	40†	33†
Garcia[21,22]	anterior MI	5	95	94	No	No	Accelerated t-PA	84*	69*
GUSTO IIb[23]	ST↑, LBBB	<12	565	573	No	No	Accelerated t-PA	114†	72†
Le May[24]	ST↑, LBBB	<12	62	61	Yes	Yes	Accelerated t-PA	77†¶	15†
Bonnefoy[25]	ST↑	<6	421	419	Yes	Yes	Accelerated t-PA	190†	130†
Schomig[26]	ST↑	<12	71	69	Yes	Yes	Accelerated t-PA	65*¶	30*¶
Vermeer[27]**	Age <80 years; ST↑	<6	75	75	Yes	No	Accelerated t-PA	100†	85†
Andersen[28]	ST↑	<12	790	782	Yes	NA	Accelerated t-PA	NA	NA
Kastrati[29]	ST↑, LBBB	<12	81	81	Yes	Yes	Accelerated t-PA	75*¶	35*¶
Aversano[30]	ST↑	<12	225	226	Yes	Yes	Accelerated t-PA	102*¶	46*¶
Grines[31]	ST↑	<12	71	66	Yes	Yes	Accelerated t-PA	155*	51*
Hochman[7]	Cardiogenic shock	<36	152	150	Yes	Yes	Accelerated t-PA	75†¶	6168†¶‖

LBBB=left bundle branch block; MI=myocardial infarction; NA=data not available; SK=streptokinase; ST↑=elevation; ST↓=depression; t-PA=tissue-type plasminogen activator; accelerated t-PA[32]=15 mg intravenous bolus, followed by an infusion of 0·75 mg/kg bodyweight over 30 min (maximum 50 mg) and then 0·50 mg/kg bodyweight over 60 min (maximum 35 mg) for a maximum dose of 100 mg. 68% of patients in the Grines Study[31] and 70% of patients in the Hochman study[7] received accelerated t-PA. *From admission. †From randomisation. ‡Average time. §From symptom onset to reperfusion. ¶Median time. ‖Time to the permitted delayed revascularisation procedure (percutaneous or surgical) in the initial medical stabilisation group. **Both the PRAGUE[13] and the LIMI[27] trials included a third group of individuals, who had thrombolytic therapy followed by transfer for subsequent PTCA (n=100 and n=74 patients, respectively); these 174 patients were excluded from our analyses.

Table 1: **Summary of the 23 randomised trials of primary angioplasty versus thrombolytic therapy**

AMI. The definition of eligible patients differed between studies, but typically required ischaemic symptoms and ST segment elevation of at least 1 mm in two contiguous leads or a left bundle branch block, and no contraindications for the use of thrombolytic therapy. We analysed the data of all trials together, and in the absence of data from the SHOCK trial.[7] We assessed the effect on clinical outcomes of the thrombolytic regimen used (streptokinase or fibrin-specific), and the strategy of emergent hospital transfer for primary PTCA compared with on-site thrombolysis.

We compared the following outcomes: total mortality, reinfarction (defined as recurrent ischaemic chest pain associated with new ST-segment changes and a re-elevation of cardiac enzymes), recurrent ischaemia, total stroke, haemorrhagic stroke, major bleeding (defined as intracranial haemorrhage or bleeding that caused haemodynamic compromise or blood transfusion, or both), and the combined endpoint of death, reinfarction, and disabling stroke. Outcomes as defined by each individual trial were used. Because case-specific event rates were not available for every study at the same time points, we defined short-term as 4–6 weeks and long-term as 6–18 months, when available, as the primary timepoints of interest.

Statistical analysis

We combined study results by use of the actual counts for each outcome within each trial, and obtained a combined outcome for all studies together. All comparisons were based on an intention-to-treat analysis, according to randomised groups. The odds ratios, 95% CI, and p values were calculated with exact tests for categorical data. We did χ^2 tests or, when appropriate, Fisher's exact tests to compare PTCA with thrombolytic therapy for all outcomes to assess differences between proportions with calculations of odds ratios and exact 95% CI. A p value of

	Crossover data available	Crossover from PTCA to thrombolysis Number (%)	Crossover from thrombolysis to PTCA Number (%)
Streptokinase trials			
Zijlstra[8]	Yes	0/152	14/149 (9%)
Riberio[9]	Yes	0/50	5/50 (10%)
Grinfeld[10]	No	NA	NA
Zijlstra[11]	No	NA	NA
Akhras[12]	No	NA	NA
Widimsky[13]	No	NA	NA
de Boer[14]	No	NA	NA
Widimsky[15]	Yes	4/429 (1%)	0/421
Fibrin-specific trials			
DeWood[16]	No	NA	NA
Grines[17]	Yes	0/195	14/200 (7%)
Gibbons[18]	Yes	0/47	5/56 (9%)
Ribichini[19,20]	Yes	0/55	2/55 (4%)
Garcia[21,22]	No	NA	NA
GUSTO IIb[23]	Yes	0/565	8/573 (1%)
Le May[24]	Yes	1/62 (2%)	0/61
Bonnefoy[25]	Yes	2/421 (0·5%)	5/419 (1%)
Schomig[26]	No	NA	NA
Vermeer[27]	Yes	2/75 (3%)	0/75
Andersen[28]	No	NA	NA
Kastrati[29]	Yes	0/81	5/81 (6%)
Aversano[30]	Yes	7/225 (3%)	2/226 (1%)
Grines[31]	No	NA	NA
Hochman[7]	Yes	0/152	4/150 (3%)
Total	..	16/2509 (0·6%)	64/2516 (3%)

NA=not available.

Table 2: **Available crossover data**

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	Death Number (%)		Non-fatal reinfarction Number (%)		Total stroke Number (%)		Haemorrhagic stroke Number (%)		Death, reinfarction, stroke Number (%)	
	PTCA	Thrombolytic therapy	PTCA	Thrombolytic therapy	PTCA	Thrombolytic therapy	PTCA	Thrombolytic therapy	PTCA	Thrombolytic therapy
Streptokinase trials (n=1837)										
Zijlstra[4]	2/152 (1%)	11/149 (7%)	1/152 (1%)	18/149 (12%)	1/152 (0·7%)	3/149 (2%)	1/152 (1%)	2/149 (1%)	..	..
Riberio[9]	3/50 (6%)	1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50	0/50	0/50	0/50	..	..
Grinfeld[10]	5/54 (9%)	8/58 (14%)	1/54 (2%)	2/58 (3%)	..	..	..	..	..	..
Zijlstra[11]	1/47 (2%)	1/53 (2%)	0/47	7/53 (13%)	1/47 (2%)	2/53 (4%)	0/47	0/53	2/47 (4%)	10/53 (19%)
Akhras[12]	0/42	4/45 (9%)	0/42	5/45 (11%)	..	..	..	..	..	..
Widimsky[13]	7/101 (7%)	14/99 (14%)	1/101 (0·01%)	10/99 (10%)	0/101	1/99 (1%)	..	..	8/101 (8%)	23/99 (23%)
de Boer[14]	3/46 (7%)	9/41 (22%)	1/46 (2%)	6/41 (15%)	1/46 (2%)	3/41 (7%)	..	..	4/46 (9%)	12/41 (29%)
Widimsky[15]	29/429 (7%)	42/421 (10%)	..	..	..	..	..	..	36/429 (8%)	64/421 (15%)
All	50/921 (5%)	90/916 (10%)	6/492 (1%)	49/495 (10%)	3/396 (1%)	9/392 (2%)	1/249 (0·4%)	2/252 (0·8%)	50/623 (8%)	109/614 (18%)
OR (95% CI)	0·53 (0·37–0·75)		0·11 (0·05–0·26)		0·32 (0·09–1·21)		0·50 (0·05–5·59)		0·40 (0·28–0·58)	
Fibrin-specific trials (n=5902)										
DeWood[16]	3/46 (7%)	2/44 (5%)	..	..	..	..	..	..	..	..
Grines[17]	5/195 (3%)	13/200 (7%)	5/195 (3%)	14/200 (7%)	0/195	7/200 (4%)	0/195	4/200 (1%)	10/195 (5%)	32/200 (16%)
Gibbons[18]	2/47 (4%)	2/56 (4%)	1/47 (2%)	3/56 (5%)	0/47	0/56	0/47	0/56	..	..
Ribichini[19,20]	1/55 (2%)	3/55 (6%)	1/55 (2%)	6/55 (11%)	0/55	0/55	0/55	0/55	..	..
Garcia[21,22]	3/95 (3%)	10/94 (11%)	4/95 (4%)	5/94 (5%)	..	..	..	..	..	..
GUSTO IIb[23]	32/565 (6%)	40/573 (7%)	25/565 (4%)	37/573 (7%)	6/565 (1%)	11/573 (2%)	0/565	8/573 (1%)	54/565 (10%)	78/573 (14%)
Le May[24]	3/62 (5%)	2/61 (3%)	3/62 (5%)	8/61 (13%)	1/62 (2%)	2/61 (3%)	..	..	7/62 (11%)	10/61 (16%)
Bonnefoy[25]	20/421 (5%)	16/419 (4%)	7/421 (2%)	15/419 (4%)	0/421	4/419 (1%)	0/421	2/419 (1%)	26/421 (6%)	34/419 (8%)
Schomig[26]	3/71 (4%)	5/69 (7%)	2/71 (3%)	4/69 (6%)	..	..	..		5/71 (7%)	9/69 (13%)
Vermeer[27]	5/75 (7%)	5/75 (7%)	1/75 (1%)	7/75 (9%)	2/75 (3%)	2/75 (3%)	0/75	1/75 (1%)	8/75 (11%)	14/75 (19%)
Andersen[28]	52/790 (7%)	59/782 (8%)	13/790 (2%)	49/782 (6%)	9/790 (1%)	16/782 (2%)	..		63/790 (8%)	107/782 (14%)
Kastrati[29]	2/81 (3%)	5/81 (6%)	0/81	4/81 (5%)	1/81 (1%)	1/81 (1%)	..	..	..	..
Aversano[30]	12/225 (5%)	16/226 (7%)	11/225 (5%)	20/226 (9%)	3/225 (1%)	8/226 (4%)	..	..	24/225 (11%)	40/226 (18%)
Grines[31]	6/71 (8%)	8/66 (12%)	1/71 (1%)	0/66	0/71	3/66 (5%)	0/71	2/66 (3%)	6/71 (9%)	9/66 (14%)
Hochman[7]	71/152 (47%)	84/150 (56%)	..	..	5/152 (3%)	1/150 (1%)	0/152 (0%)	2/150 (1%)	..	..
All	220/2951 (8%)	270/2951 (9%)	74/2753 (3%)	172/2757 (6%)	27/2739 (1%)	55/2744 (2%)	0/1581	19/1594 (1%)	203/2475 (8%)	333/2471 (14%)
OR (95% CI)	0·80 (0·66–0·96) 0·79 (0·63–0·99)*		0·42 (0·31–0·55) ..		0·49 (0·31–0·77) ..		.. ..		0·57 (0·48–0·69) ..	
Combined results for all trials	270/3872 (7%)	360/3867 (9%)	80/3245 (3%)	222/3252 (7%)	30/3135 (1%)	64/3136 (2%)	1/1830 (0·05%)	21/1846 (1%)	253/3098 (8%)	442/3085 (14%)
	199/3720 (5%)*	276/3717 (7%)*	..	..	..	..	..	..	..	..
OR (95% CI)	0·73 (0·62–0·86) 0·70 (0·58–0·85)*		0·35 (0·27–0·45) ..		0·46 (0·30–0·72) ..		0·05 (0·006–0·35) ..		0·53 (0·45–0·63) ..	

OR=odds ratio. *Without SHOCK trial data.

Table 3: **Short-term clinical outcomes**

less than 0·05 was judged significant. Short-term and long-term outcomes for all trials were analysed, if available.

The SHOCK trial enrolled a high-risk group of patients in cardiogenic shock and compared a direct invasive strategy with an initial medical stabilisation strategy (thrombolysis and intra-aortic balloon pump). Of those randomised to a direct invasive strategy, 87% underwent an invasive procedure and, in the initial medical stabilisation group, 63% received thrombolytic therapy. Due to the distinctive characteristics of this trial compared with the other trials, the endpoint of mortality was analysed both with and without these patients.

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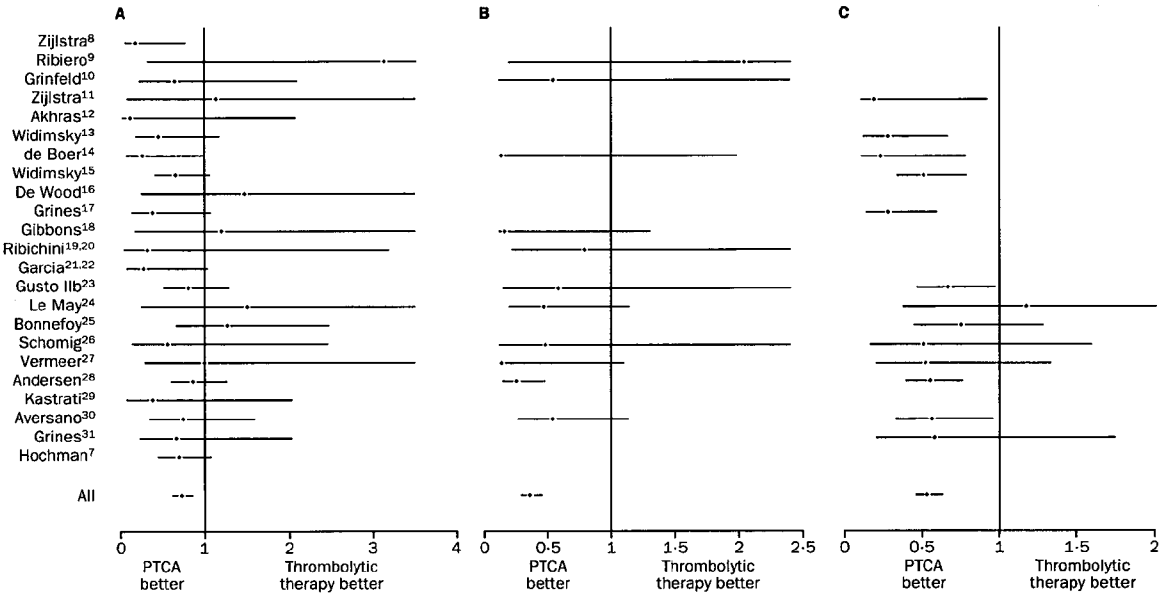

Figure 1: **Odds ratios (95% CI) of short-term death (A), non-fatal reinfarction (B), and combined endpoint of death, non-fatal reinfarction, and stroke (C) for individuals treated with primary PTCA or thrombolytic therapy**
Not all endpoints were reported in all trials.

We examined the odds ratios for each outcome for each study for heterogeneity with the Mantel-Haenszel odds ratio (Biostat, version 1). A Mantel-Haenszel p value of 0·05 was judged significant. The p values were as follows: death 0·56, reinfarction 0·19, total stroke 0·85, haemorrhagic stroke 0·75, the combined endpoint of death, stroke, and reinfarction 0·35, and the combined endpoint of death and reinfarction 0·03. Because the p value for the combined endpoint of death and reinfarction was 0·03, showing significant heterogeneity, this endpoint was not included in the analysis.

Results

Table 1 shows a summary of the features of the 23 trials we assessed.[7-31] In total, 7739 patients were randomly assigned either PTCA or thrombolytic therapy. There were eight trials of primary PTCA versus streptokinase (n=1837), and 15 of primary PTCA versus fibrin-specific agents (n=5902). Of the 3867 patients randomly assigned thrombolytic therapy, most (76%, n=2939) received a fibrin-specific agent (tissue-type plasminogen activator, t-PA). Stents were used in 12 trials, and platelet glycoprotein IIb/IIIa inhibitors in eight. The criterion for time to treatment was 6 h or less in nine of the trials, 12 h in 13 trials, and up to 36 h in the SHOCK trial.[7] Crossover data was available in 13 of the trials (table 2). Of the patients randomised to primary PTCA, 0·6% crossed over to thrombolytic therapy, and 3% to primary PTCA (table 2).

Table 3 and figures 1 and 2 show the short-term and long-term clinical outcomes for the 23 trials. Overall, patients assigned to primary PTCA were less likely to die (figure 1A), have a non-fatal reinfarction (figure 1B), or fall within the group who had a combined endpoint of death, non-fatal reinfarction, and stroke (figure 1C), than those assigned thrombolytic therapy. These outcomes were significantly decreased not only in the short-term, but also over long-term follow-up (figure 2). Major bleed was the only endpoint for which individuals were at greater risk when treated with primary PTCA rather than thrombolysis (7% [n=161] *vs* 5% [127], p=0·032; odds ratio 1·30, 95% CI 1·02–1·65).

We calculated the odds ratios and corresponding CIs for the primary endpoints, according to the type of thrombolytic regimen received (table 3, figure 3). Compared with streptokinase treatment, primary PTCA resulted in significant decreases in short-term death (p=0·0004), non-fatal reinfarction (p<0·0001), and the combined endpoint (p<0·0001). There was no significant difference between primary PTCA and streptokinase therapy for total stroke (p=0·078) and haemorrhagic stroke (p=1·0; table 3). Since there were fairly few cases of stroke in the streptokinase trials, there might not have been sufficient power to detect a significant difference in this subgroup. Compared with treatment with fibrin-specific thrombolytic agents, primary PTCA resulted in a significant reduction in short-term overall death (p=0·018), death excluding the SHOCK trial (p=0·038), non-fatal reinfarction (p<0·0001), total stroke (p=0·0019), haemorrhagic stroke (p<0·0001), and the combined endpoint (p<0·0001; table 3, figure 3).

We also calculated the odds ratios and corresponding CI for the five trials[13,15,27,28,31] that compared emergent hospital transfer for primary PTCA to on-site thrombolysis (figure 4). Combined data from these five trials indicate that, despite the delay inherent in transfer (average 39 min), primary PTCA was associated with significant reductions in non-fatal reinfarction, total stroke, and the combined endpoint when compared with on-site thrombolysis. Primary PTCA was non-significantly associated with decreased death compared with thrombolytic therapy. There was no significant difference between the two groups for haemorrhagic stroke. Overall, events arising during transfer occurred infrequently: 0·5% risk of death (reported in one study only[15]), 0·7% to 1·4% risk of ventricular arrhythmias,[13,15,27,28] and a 2% risk of second-degree or third-degree heart block (reported in one study only[28]).

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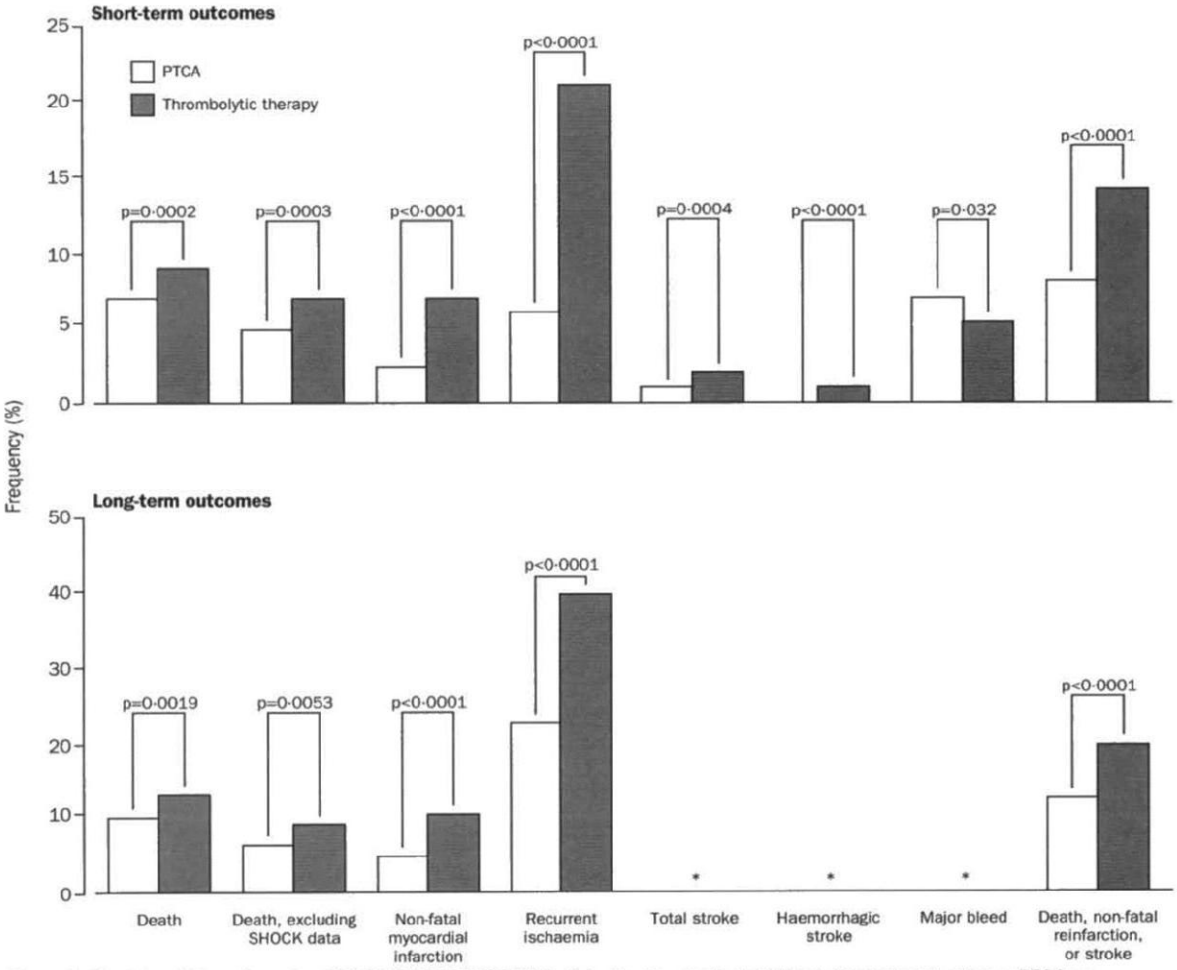

Figure 2: **Short-term[7-31] and long-term[7-9,11,12,14,17,18,20,22-24,26,27,29,30,33-36] clinical outcomes in individuals treated with primary PTCA or thrombolytic therapy**
*Data not available.

Finally, we compared results from the first ten trials done[6,11,16-23] with those of the last 13 (figure 5).[7,12-15,24-31] The results were nearly identical, showing better outcomes with primary PTCA for the endpoints of death, total stroke, and haemorrhagic stroke. The combined endpoint of death and non-fatal reinfarction was not analysed because of significant heterogeneity among studies.

Discussion

Our findings indicate that primary PTCA is better than thrombolytic therapy at reducing short-term major adverse cardiac events, including death in individuals with ST-segment elevation AMI. Furthermore, these favourable results are sustained during long-term follow-up. Primary PTCA was associated with better clinical outcomes than thrombolytic therapy irrespective of the type of thrombolytic regimen used, and even when reperfusion was delayed because of transfer for primary PTCA.

Since the previous systematic review of this topic was published in 1997,[6] several new trials comparing primary PTCA with thrombolytic therapy have been undertaken, significantly increasing the total number of patients studied. These new trials reflect the rapid evolution of

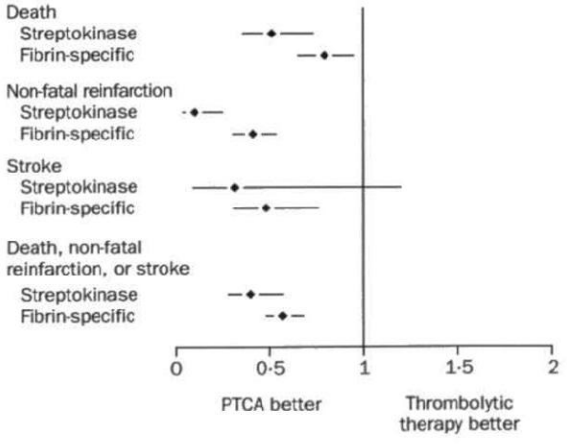

Figure 3: **Short-term clinical outcomes[7-31] in individuals treated with primary PTCA or thrombolytic therapy, according to type of thrombolytic agent used**
Odds ratios and 95% CI are shown.

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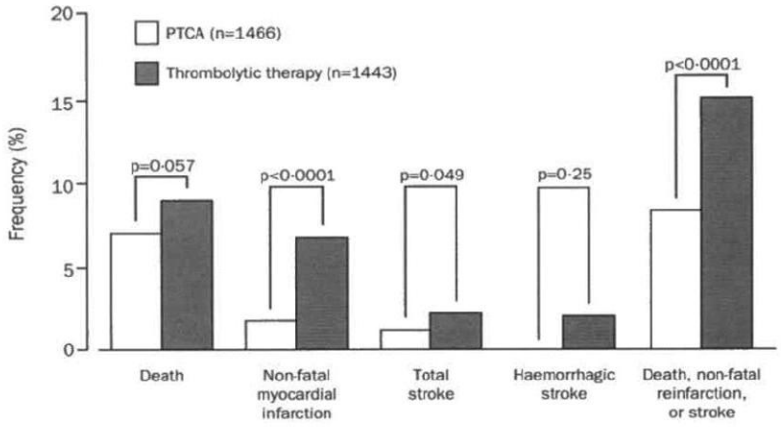

Figure 4: **Short-term clinical outcomes in individuals treated with on-site thrombolysis or after emergent transfer for primary PTCA**[13,15,27,28,31]

There are several other aspects unique to our systematic review that strengthen our findings. Variation in individual operator experience and hospital volume of primary PTCA implies that this procedure is applicable in a wide range of hospitals undertaking these procedures. Inclusion of several large trials with similar or greater numbers of patients than the GUSTO IIb trial statistically strengthens our analysis. Long-term follow-up (primarily 6 months) was available for many of the patients, affording us an opportunity to assess the durability of primary PTCA over time. High-risk patients, including elderly individuals and those in cardiogenic shock, were included in our analysis, making the results applicable to a diverse group of patients with AMI. Finally, not only has primary PTCA been shown to be better than thrombolytic therapy in hospitals that do primary PTCA without on-site surgical back-up, but emergent hospital transfer has been shown to be feasible, safe, and associated with improved clinical outcomes when compared with on-site thrombolytic therapy.

percutaneous technology and medical therapy and its effect on care of patients. For example, of the 13 new trials, nine used fibrin-specific thrombolytic agents,[7,24,31] 12 used stents,[7,13,15,24,31] and eight allowed use of platelet glycoprotein IIb/IIIa inhibitors.[7,15,24,26,29,31] Additionally, the more recent trials included in this review address important questions with respect to the safety and efficacy of emergent hospital transfer for primary PTCA,[13,15,27,28,31] primary PTCA done in high risk subgroups (such as elderly individuals[14] and patients with cardiogenic shock[7]), primary PTCA undertaken in hospitals without surgical capabilities,[30] and prehospital thrombolysis.[25]

Our results are strengthened by the fact that they concur with those of a previous review;[6] primary PTCA remains the best treatment option, despite changes in patients' care over time between the earlier ten trials and the subsequent 13 trials. Consistent with the previous analysis, we noted that the beneficial effect of primary PTCA was similar irrespective of the thrombolytic regimen used (streptokinase or fibrin-specific). This finding is particularly important in our review, since t-PA was associated with a 1% decrease in mortality compared with streptokinase in one study.[23] As a result, a large proportion of the new trials (69%, n=1929) used fibrin-specific-based regimens rather than streptokinase-based regimens (31%, 606), clearly indicating present standard of care for patients presenting with an ST-segment elevation AMI.

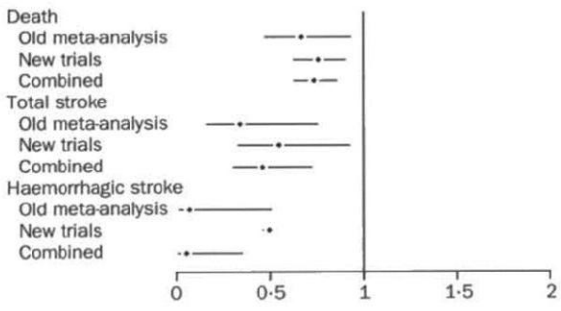

Figure 5: **Occurrence of short-term clinical outcomes based on data from the first ten trials**[8-11,16-23] **and from the subsequent 13 trials**[7,12-15,24-31] **of primary PTCA versus thrombolytic therapy**
Odds ratios and 95% CI are shown.

Primary PTCA has several limitations. Major bleeding was significantly more frequent in the group who had primary PTCA than in those receiving thrombolytic therapy. However, overall major bleeding complications were fewer in our study than in a previous review.[6] Since most of these bleeds were localised to the access site, lower doses of intravenous heparin, smaller sheath sizes, and improved operator technique used during primary PTCA in the 13 most recent trials probably contributed to the overall improved bleeding risk. Additional reported side-effects of PTCA included the need for vascular repair (0·4–2% of patients)[17,30] and development of acute renal failure (0·5–13%).[7,17] It is noteworthy that acute renal failure developed in 13% of patients randomised to a direct invasive strategy in the SHOCK trial, whereas the complication arose in 24% of those randomised to initial medical stabilisation.

Another potential limitation with primary PTCA is the inherent delay in transferring patients to the cardiac catheterisation laboratory. In a prospective survey[39] of 10 484 patients, the median time from arrival in the emergency room to administration of thrombolytic therapy was 40 min, whereas that to first balloon inflation was 93 min. The issue of time delay and its effect on clinical outcomes has been addressed previously;[36] Zijlstra and colleagues noted that patients randomised to primary PTCA had fewer adverse events than did those who received thrombolytic therapy, irrespective of whether they presented within 2 h, between 2 h and 4 h, or more than 4 h after initiation of symptoms. Results of another trial[28] indicated that patients who presented within 3 h of onset of symptoms had better outcomes with primary PTCA than with thrombolytic therapy, whereas in the PRAGUE-2 trial[15] better outcomes with primary PTCA than with thrombolytic therapy were seen only in patients treated later than 3 h after onset of symptoms. Furthermore, Bonnefoy and colleagues[25] reported that primary PTCA was no better than prehospital thrombolytic therapy in patients who presented within 6 h of an ST-segment elevation AMI (although rescue PTCA was done in 26% of the patients randomised to

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thrombolysis). Studies of combination therapy (thrombolytic therapy with low molecular weight heparin, and platelet glycoprotein IIb/IIIa inhibitors) and facilitated percutaneous transluminal coronary intervention (low-dose thrombolytics, platelet glycoprotein IIb/IIIa inhibitors, or a combination of both before primary PTCA) are continuing. The favourable results with primary PTCA are only applicable to hospitals with well-established primary PTCA programmes, and dedicated and experienced teams of operators.[40,41]

Our study has several limitations. Although we contacted the principal investigators of most studies to clarify inconsistencies in data, issues of time delay, and stent and platelet glycoprotein IIb/IIIa inhibitor use, we did not contact all the principal investigators directly for verification of the published data, which could have affected our results. Furthermore, there are differences among the trials; some are single-centred studies whereas others are multicentre and multinational trials, and some trials concentrate on specific subgroups—eg, elderly individuals and those in cardiogenic shock—and their findings might not be applicable to a wider range of patients. Although tests for heterogeneity of treatment effect for each outcome analysed were negative, these tests might not be powered sufficiently to detect such differences. Finally, earlier hospital discharge in PTCA patients can underestimate the adverse events associated with primary PTCA. However, the long-term follow-up data now available for many of the studies enabled us to show consistency of these findings in favour of primary PTCA.

Contributors

E C Keeley and C L Grines both participated in study design, data gathering, verification, and management, planning of statistical analyses, and interpretation of the results. C L Grines was responsible for the original study idea and design. E C Keeley wrote the first draft of the manuscript. J A Boura was responsible for data management, statistical analyses, and interpretation of results. All three authors participated in multiple revisions of the manuscript.

Conflict of interest statement

C L Grines has unrestricted research grants from Boston Scientific, Guidant, and Scimed companies, and has served as a consultant for Aventis and Guidant.

Acknowledgments

There was no specific funding source for this study.

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Clinical picture

Medial longitudinal fascicles

Mario Manfredi, Luigi Bozzao, Maurizio Inghilleri

A 30-year-old man was admitted with diplopia of 15 days duration. Neurological examination showed bilateral internuclear ophthalmoplegia, with paresis of the medial recti and nystagmus of the abducted eye on both lateral gaze directions. Vertical eye movements, convergence, accommodation, and light reflexes were normal. Cerebrospinal fluid analysis showed 18 lymphocytes/mL (NR: 0–5/mL) and a protein content of 0·54 g/L (0·1–0·45 g/L). There were no oligoclonal bands. Visual evoked potentials, somatosensory evoked potentials and motor evoked potentials in the four limbs were normal. Cerebral magnetic resonance imaging showed an isolated lesion involving the medial longitudinal fascicles, the classical seat of internuclear ophthalmoplegia. The lesion is displayed in a T-2 weighted median sagittal section (arrow, figure). No other lesions were visible in the brain or spinal cord. A 5-day course of intravenous methylprednisolone at 1 g a day was started with lansoprazole for gastric protection. Diplopia and gaze abnormalities subsided within 10 days, and repeat magnetic resonance imaging obtained after gadolinium administration showed no enhancement. We suspected an early manifestation of multiple sclerosis. However, we then had two reasons to rejoice: the patient promptly recovered and the medial longitudinal fascicles are really in the right place.

Department of Neurological Sciences, University of Rome "La Sapienza" 00185 Roma, Italia (Prof M Manfredi MD, Prof L Bozzao MD, M Inghilleri MD)

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EXHIBIT 11

THE PLAINFIELD TOWN HALL

PLAINFIELD - CENTRAL VILLAGE - MOOSUP - WAUREGAN

Town Hall
8 Community Avenue
Plainfield, CT 06374

Telephone (860) 230-3001
Fax (860) 230-3033

SELECTMAN'S OFFICE

SEP 2 1 2015

September 17, 2015

David A. Whitehead
President
The William W. Backus Hospital
326 Washington St., Norwich, Connecticut, 06360

Dear Mr. Whitehead,
Please accept this letter of support for the development of a Primary and Elective Percutaneous Cardiac Intervention (PCI) program at The William W. Backus Hospital. Although I am not a healthcare expert, I do know that timing is everything when it comes to a cardiac emergency, and residents in my community deserve to have timely access to PCI.

From what I understand, residents of this region are currently unable to access a PCI-capable facility within a 30-minute drive time. This lack of access should not exist- our families, friends and neighbors should not be at a disadvantage when it comes to their health, just because of where they live. Having this service available at Backus Hospital would improve quality of life, make our region a more attractive place to live and, most importantly, save lives.

Please accept this letter of support- Backus should be applauded for its commitment to offering Percutaneous Cardiac Intervention, close to home for patients.

Sincerely,

Paul E. Sweet
First Selectman

835

Office of the Mayor

SEP 21 2015

Deberey A. Hinchey

September 18, 2015

David A. Whitehead
President
William W. Backus Hospital
326 Washington Street
Norwich, CT 06360

Dear Mr. Whitehead,

Please accept this letter of support for the development of a Primary and Elective Percutaneous Cardiac Intervention (PCI) program at William W. Backus Hospital.

Although I am not a healthcare expert, I do know that timing is everything when it comes to a cardiac emergency, and residents in my community deserve to have timely access to PCI. From what I understand, residents of this region are currently unable to access a PCI-capable facility within a 30-minute drive time. This lack of access should not exist – our families, friends and neighbors should not be at a disadvantage when it comes to their health, just because of where they live.

Having this service available at Backus Hospital would improve quality of life, make our region a more attractive place to live and, most importantly, save lives.

Please accept this letter of support. Backus should be applauded for its commitment to offering Percutaneous Cardiac Intervention, close to home for patients.

Sincerely,

Deberey A. Hinchey

Mayor Deb Hinchey
City of Norwich

City of Norwich Mayor's Office
100 Broadway, Room 330 • Norwich, CT 06360
Phone: (860) 823-3743 • Cell (860) 334-2549 • Fax: (860) 885-2914
dhinchey@cityofnorwich.org • www.norwichct.org

Town of Colchester, Connecticut

127 Norwich Avenue, Colchester, Connecticut 06415

Stan Soby, First Selectman

SEP 2 4 2015

September 19, 2015

David A. Whitehead, President
The William W. Backus Hospital
326 Washington Street, Norwich, Connecticut, 06360

Dear Mr. Whitehead,

Please accept this letter of support for the development of a Primary and Elective Percutaneous Cardiac Intervention (PCI) program at The William W. Backus Hospital.

Although I am not a healthcare expert, I do know that timing is everything when it comes to a cardiac emergency, and residents in my community deserve to have timely access to PCI.

From what I understand, residents of this region are currently unable to access a PCI-capable facility within a 30-minute drive time. This lack of access puts our families, friends and neighbors at a disadvantage when it comes to their health at a critical point in their lives, just because of where they live.

Having this service available at Backus Hospital would improve quality of life, make our region a more attractive place to live and, most importantly, save lives.

Please accept this letter of support – Backus should be applauded for its commitment to offering Percutaneous Cardiac Intervention, close to home for patients.

Sincerely,

Stan Soby
First Selectman

Hartford Hospital
A Hartford HealthCare Partner

September 10, 2015

David A. Whitehead,
President, The William W. Backus Hospital
326 Washington Street, Norwich, CT, 06360
Mr. Whitehead:

Please accept this letter of support for the development of a Primary and Elective Percutaneous Cardiac Intervention (PCI) program at The William W. Backus Hospital. This letter is also a commitment to participate in the necessary clinical and administrative support for the William W. Backus Hospital's proposed PCI program.

We are in support of providing this resource to enable patients in Norwich and North Eastern Connecticut to have timely access to PCI. Many residents of this region are currently unable to access a PCI-capable facility within a 30 minute drive time, or within their local communities. This lack of access creates barriers to receiving this standard of care for a life-limiting condition.

Our expertise in the field of interventional cardiology will be leveraged to provide exceptional delivery of care, close to home, for the residents of these communities. Having the clinical and technological infrastructure available at Backus Hospital, coupled with its strong relationship with Hartford Hospital, will greatly improve the care that we are able to offer our patients. We believe in the investment Backus is making in Interventional Cardiology will promote optimal patient care.

Please accept this letter of support and intent on behalf of Hartford Cardiac Laboratory, PC. As an interventional cardiology group affiliated with Hartford HealthCare, we fully support the development of a PCI program at this facility.

Sincerely,

Francis J. Kiernan MD, FACC, FSCAI
Director, Interventional Cardiology Fellowship
Associate Clinical Professor of Medicine, University Of Connecticut School of Medicine
Director, Cardiac Laboratory
Hartford Hospital
80 Seymour Street
Hartford, CT 06102-5037
860-972-2975
francis.kiernan@hhchealth.org

David A. Whitehead
President,
The William W. Backus Hospital
326 Washington Street, Norwich, Connecticut, 06360

09/09/2015

I am writing this letter to support the development of a Primary and Elective Percutaneous Coronary Intervention (PCI) program at the William W. Backus Hospital. The hospital is equipped to perform diagnostic cardiac catheterization, and I am one of two interventional cardiologists performing cardiac catheterization at this hospital.

At present, patients undergoing diagnostic cardiac catheterization found to have significant disease are transferred to a PCI-capable facility, or are scheduled to have PCI performed at a later date. This inevitably requires repeat arterial access upon arrival at the PCI-capable facility, or keeping the original arterial sheath in place. Both situations increase the risk of peripheral arterial complications and infections. In certain instances, the risk of delayed PCI is substantial. During a recent procedure, thrombus was found in the left anterior descending coronary artery. Rather than immediately addressing the problem, the patient was transferred another facility, during which time the thrombus could potentially have propagated and completely occluded the vessel.

It may be argued that patients with a high probability of having obstructive coronary artery disease should undergo diagnostic cardiac catheterization at a PCI-capable hospital. However, many patients express a strong preference for being evaluated at Backus Hospital, with plans for transfer to another facility depending on their findings. Additionally, many patients admitted to Backus Hospital for entirely different reasons and are incidentally found to have obstructive disease.

For the reasons above, the availability of PCI capability at William W. Backus Hospital would greatly enhance patient care in the northern New London and Windham counties, enabling Eastern Connecticut residents to have timely access to PCI. Many residents of this region are currently unable to access a PCI-capable facility within their local communities or even within a 30-minute drive. Having the clinical and technological infrastructure available at Backus Hospital, coupled with its strong relationship with Hartford Hospital, will greatly improve the care that we are able to offer our patients.

As an interventional cardiologist affiliated with Backus Hospital, I fully support the development of a PCI program at this facility.

Sincerely,

John Michael Chua Chiaco, MD
General / Interventional Cardiology
Norwich Cardiac Medicine

Hartford HealthCare
Medical Group
Cardiology

September 22, 2015

Dave Whitehead
Regional President
William W. Backus Hospital
326 Washington Street
Norwich, Connecticut 06360

Dear Mr. Whitehead,

In 1999 I moved to CT and have been a practicing cardiologist at Backus Hospital since. It has been my pleasure to provide cardiology care to patients in Southeastern Connecticut, where I call home. When I first moved to Norwich, Backus hospital patients had to travel to New London for diagnostic catheterizations. I worked during the time when cardiac catheterization, as a diagnostic procedure, was felt to be safe only at a tertiary care hospital. With the approval of stand-alone diagnostic catheterization labs, access for patients improved dramatically. Still, patients with disease requiring interventions were believed to be stented safely only at a tertiary care hospital.

Soon after I came to Norwich, Backus submitted and received approval from OCHA to have a diagnostic-only catheterization lab on the model of Lawrence and Memorial Hospital in New London. Both hospitals continued to grow robust programs and improved access to safe and expert diagnostic angiography. The development of the diagnostic suite at Backus dramatically improved services to patients in the Backus catchment area. As Backus' program grew, so did L&M's.

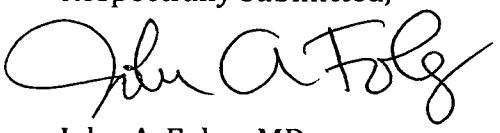
The impediment to moving from diagnostic angiography to percutaneous Intervention was the requirement to have backup cardiac surgery. I remember as a fellow that surgical back-up meant an open OR and surgical team literally standing by to provide surgical back-up. As thousands of interventions occurred safely, ORs and operative teams no longer stood readily available. The data for the life-saving impact of stenting in acute MI broke down the barrier of hospitals' needing to offer CABG back-up to provide interventional care. L&M made such an application and like many other programs, has operated safely. Years later, their application for elective PCI was approved by OCHA. They continue to run a safe and effective program.

The news for those patients in the Backus Hospital service area is far from equal to that for patients in Lawrence and Memorial's area. Patients in the Backus area are older, have more cardiac risk factors and are of a lower socio-economic status. They are limited in their ability to access and their comfort with travelling into large cities, such as Hartford, for care. Therefore, these patients do not have access to the same high quality care available to residents of the shoreline. Door to balloon times and door in door out (DIDO) times are unacceptably long for patients in the Backus Hospital catchment area. The saying "time is myocardium" is all too true.

Backus is submitting its CON for both emergent and elective angioplasty. The population's need is abundant, the access to care is limited, and the system both in Hartford HealthCare and Backus Hospital fully supports the move to a full interventional program at Backus Hospital.

I look forward to the day that I no longer have to look into the face of a patient or family member who is frightened by the prospect of travelling a long distance to be cared for by doctors and nurses they don't know. In the fifteen years I have lived and practiced in the Norwich area, I have witnessed OCHA's willingness to adapt their rules in order to benefit patients and their families. The record for safe, timely, and expert emergent and elective angioplasty in southeastern Connecticut has been firmly established. I wholeheartedly support this application for Backus Hospital's interventional program as a way to advance valuable, necessary care and improve access to that for patients in the Backus Hospital area.

Respectfully submitted,



John A. Foley, MD
Interim Medical Director Specialty Care Services
Hartford Healthcare Medical Group, East Region
Director, Cardiovascular Services
Hartford Healthcare Systems, East Region
Chief of Cardiology
The William Backus Hospital & Windham Hospital

DKH DAY KIMBALL HEALTHCARE

September 24, 2015

Dave Whitehead
President & CEO
The William W. Backus Hospital
326 Washington Street
Norwich, CT 06360

Dear Mr. Whitehead:

This letter is written in support of The William W. Backus Hospital proposal to build and operate a Percutaneous Coronary Intervention Program in Norwich.

Your proposal to provide percutaneous coronary intervention would improve patient safety as it is a service that we lack in our region of the state, and routinely requires patients to be taken over our state's border to receive this necessary service. We all know that time is of the essence when emergency situations arise, and travel time is a key factor. The addition of a Backus Hospital Percutaneous Coronary Intervention Program would work to reduce the travel time for a large number of patients.

Backus Hospital increasingly is looked to by our region as a site of specialty services. Its investment in this service continues to reflect its commitment to improve the health of the communities in Eastern Connecticut.

We support this proposal, and look forward to the project's approval and completion.

Sincerely,

Robert E. Smanik, FACHE
President & Chief Executive Officer

320 Pomfret Street | Putnam, CT 06260 | (860) 928-6541 | (860) 774-3366 ■ daykimball.org

SCOTLAND VOLUNTEER FIRE DEPARTMENT, INC.

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Anthony Kasacek Jr.
Chief

Raymond J. Arnott Jr.
President

August 30, 2015

SEP - 8 2015

David Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

RE: Percutaneous Coronary Intervention

Dear Mr. Whitehead

We at the Scotland Vol. Fire Dept. are in support of The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is a much needed one. Although many of our residents utilize both Windham and Backus Hospital healthcare services, many cardiac and stroke emergencies require transport to a more distant facilities. Our ambulance would be back in service and our personnel freed up much quicker with the facilities being that much closer. The families of these patients will appreciate these services being closer to home as well.

Your proposal to provide Percutaneous Coronary Intervention would improve recovery time and a safer patient environment which would make our EMS network more efficient as a whole. This is a service that is lacking and that everybody deserves. Time is of the essence when emergencies arise. The Percutaneous Coronary Intervention program proposal would be a major plus to the area.

Sincerely,

Tony Kasacek

Tony Kasacek
Chief

HAMPTON-CHAPLIN AMBULANCE CORPS

August 31, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Ben Brockett - Chief

190 West Old Route 6
P.O. Box 98
Hampton, CT 06247

PHONE (860) 455-9660
FAX (860) 516-0235
EMAIL hcambulance@netzero.com

WILLIMANTIC FIRE DEPARTMENT

MARC A. SCRIVENER
Chief
860-465-3120 • Fax: 860-423-7304
mscrivener@windhamct.com

August 31, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich. We would also be pleased to support a similar unit at Windham Hospital, should the opportunity arise.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Marc A. Scrivener
Fire Chief

SEP - 8 2015

Atwood Hose Fire Company
24 Wauregan Road
Wauregan, CT

Serving the Citizens of Wauregan Since 1896

August 31, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

The Atwood Hose Fire Company is pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. Our agency provides emergency medical services to the most northern distant region of the WW Backus medical control area. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

Representing an agency of emergency medical personnel in the field we believe this proposal will improve the health of the communities in Eastern Connecticut by providing early definitive cardiac treatment, which research and clinical outcomes have proven is essential. We are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Robert F Duval
Chief
Atwood Hose Fire Company
Wauregan, CT

Mohegan Fire Company

2029 Norwich / NL Turnpike
PO Box 467 • Uncasville, CT 06382
Phone: (860) 848-3004 • Fax (860) 848-9038
chiefgiangrasso@live.com

01 September, 2015

SEP - 8 2015

Mr. David Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

The Mohegan Fire Company (Town of Montville) fully supports and encourages The William W. Backus Hospital's proposal to build and operate a Percutaneous Coronary Intervention program in Norwich, CT.

This is a much needed investment in the community. Currently many of our residents and neighbors utilize Backus Hospital healthcare services; however, in the event of an acute cardiac emergency our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety, reduce transport times, improve patient outcomes, and make our EMS system as a whole much more efficient. It is a service that we lack in our community, and that our residents, our customers and your customers, deserve to have. We all know that time is of the essence when emergency situations arise, time is muscle, and at this time area our residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Joseph Giangrasso, Fire Chief
Mohegan Fire Company, Inc.

SEP 11 2015

September 1, 2015

Dave Whitehead, President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

The Mohegan Tribal Fire Department is pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our Casino patrons, employees and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulances and Paramedics must transport patients suffering from life-threatening conditions out of our response area to more distant facilities. This distance means our EMS personnel and emergency vehicles can be placed out of service for an extended amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS system much more efficient. It is a service that we lack in our community, and that our patients deserve to have. Time is of the essence when emergency situations arise, and at this time our patients are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would greatly improve the systems of care closer to home.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Joseph Grenier, Jr.
Fire Chief

THE MOHEGAN TRIBE

13 Crow Hill Road • Uncasville, CT 06382 • Telephone (860) 862-6100

SEP 10 2015

September 3, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

The Mashantucket Pequot Department of Fire and Emergency Services is pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is essential. Many of our tribal members and guests at Foxwoods currently utilize Backus Hospital's services, but many cardiac emergency situations require that patients suffering from life-threatening conditions be transported to distant facilities. This distance means a transport/transfer can tie up an ambulance or air-ambulance for a significant amount of time, rendering them unavailable for additional emergency calls.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents and guests deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Chief Richard Tougas
Mashantucket Pequot Department of Fire & Emergency Services

Department of Fire and
Emergency Medical Services

September 3, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

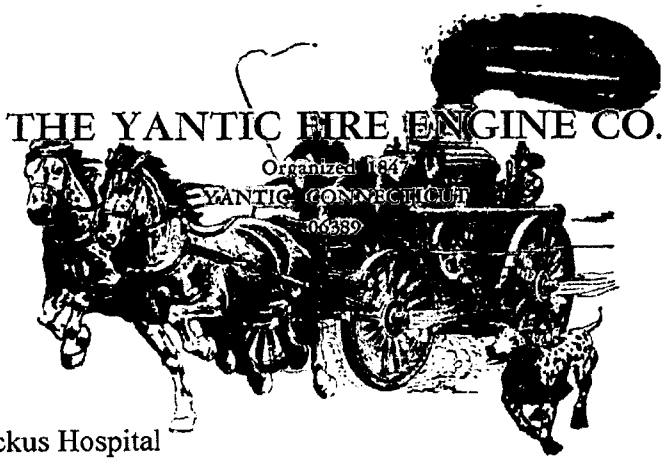
We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Walt Cox

Walter Cox
Fire/EMS Chief

52 Old Hartford Road Colchester, CT 06415 ● (860)537-2512 ● Fax (860)531-9393



9-3-2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Frank Blanchard- Chief
Yantic Fire Engine Co #1

9/3/2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Brian Theriault,
Chief, Moosup Fire Department
Moosup, CT

Oakdale Fire Company Inc.
444 Chapel Hill Rd
Oakdale, Connecticut
06370

SEP 1 0 2015

09-03-2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Gary M. Murphy
Fire Chief
860-608-4644

Baltic Fire Engine Company # 1

P.O. Box 314

Baltic, Ct. 06330

Baltic Fire Dept.

Sept. 3, 2015

Dave Whitehead, President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

SEP - 8 2015

Dear Mr. Whitehead:

The Baltic Fire Engine Co. #1 is pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Leslie L. Shull Jr. Fire Chief

Sept 3, 2015

SEP 14 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Robert Hanson
Chief of the Jewett City Fire Dept.

Office of the Fire Chief/Fire Marshal

389 Route 2
Preston Ct. 06365

September 3, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Chief Thomas Casey
Preston Fire & Emergency Services

SEP 10 2015

September 5, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

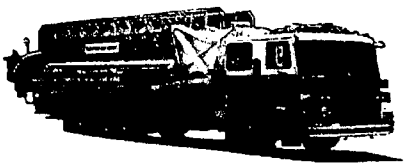
This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Roland Allard

Roland Allard
Chief
American Legion Ambulance
Fund Inc.



Plainfield Fire Company No. 1, Inc.

620 Norwich Road
Plainfield, Connecticut 06374

September 05, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our local ambulance companies and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Ralph Wells
Chief, Plainfield Fire

MARK A. ROBINSON
CHIEF
860-234-7134

LISBON FIRE DEPT

JOHN CINGRANELLI
DEPUTY CHIEF
860-501-8417

THE FIRST RAILROAD TUNNEL IN AMERICA

7 NEWENT ROAD, LISBON, CONNECTICUT 06351
VOICE 860.376.2558 FAX 860.376.0493

September 9, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

On behalf of the Officers and Members of the Lisbon Fire Department &Ambulance we are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Respectfully,

Mark A. Robinson
Chief

AMERICAN AMBULANCE SERVICE, INC.

861

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

September 10, 2015

SEP 14 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Gregory B. Allard
Vice President

Dedicated, Professional People Committed to Excellence, Caring for You.

Gardner Lake Volunteer Fire Co.

429 Old Colchester Road
Salem, Connecticut 06420
(860) 859-1743

SEP 1 6 2015

September 10, 2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Stephanie Philopena
EMS Captain
Gardner Lake Volunteer Fire Company

City of Norwich Fire Dept.
10 North Thames Street
Norwich, Connecticut 06360

Kenneth J. Scandariato
Fire Chief
(860) 892-6080
Fax (860) 886-2555

September 15, 2015

Dave Whitehead, President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are pleased to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. We all know that time is of the essence when emergency situations arise, and at this time area residents are at a distinct disadvantage in this regard. Adding a Backus Percutaneous Coronary Intervention program would change that.

This proposal is yet another example of Backus Hospital's commitment to improve the health of the communities it serves in Eastern Connecticut, and we are grateful that Percutaneous Coronary Intervention is part of your plans.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Kenneth J. Scandariato, EFO CFEI
Fire Chief/Fire Marshal

EXHIBIT 12

ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update

American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, American Society of Nuclear Cardiology, Society of Cardiovascular Computed Tomography, American Society of Echocardiography, Heart Rhythm Society, Manesh R. Patel, Gregory J. Dehmer, John W. Hirshfeld, Peter K. Smith, and John A. Spertus

J. Am. Coll. Cardiol. published online Jan 30, 2012;
doi:10.1016/j.jacc.2011.12.001

This information is current as of April 13, 2012

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://content.onlinejacc.org/cgi/content/full/j.jacc.2011.12.001v1

JACC

JOURNAL *of the* AMERICAN COLLEGE *of* CARDIOLOGY

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ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, American Society of Nuclear Cardiology, and the Society of Cardiovascular Computed Tomography

Endorsed by the American Society of Echocardiography and the Heart Rhythm Society

Coronary Revascularization Writing Group

Manesh R. Patel, MD, FACC, *Chair*
Gregory J. Dehmer, MD, FACC, FACP, FSCAI, FAHA*
John W. Hirshfeld, MD†
Peter K. Smith, MD, FACC‡
John A. Spertus, MD, MPH, FACC†

*Society for Cardiovascular Angiography and Interventions Representative; †American College of Cardiology Foundation Representative; ‡Society of Thoracic Surgeons

Technical Panel

Frederick A. Masoudi, MD, MSPH, FACC, FAHA, *Moderator*
Gregory J. Dehmer, MD, FACC, FACP, FSCAI, FAHA, *Writing Group Liaison**
Manesh R. Patel, MD, FACC, *Writing Group Liaison*
Peter K. Smith, MD, FACC, *Writing Group Liaison*‡
Charles E. Chambers, MD, FACC, FSCAI*
T. Bruce Ferguson Jr, MD, FACC, FAHA§
Mario J. Garcia, MD, FACC‖
Frederick L. Grover, MD, FACC§
David R. Holmes Jr, MD, FACC, FSCAI†
Lloyd W. Klein, MD, FACC, FSCAI, FAHA†
Marian C. Limacher, MD, FACC, FACP, FAHA†
Michael J. Mack, MD, FACC§
David J. Malenka, MD, FACC, FAHA†
Myung H. Park, MD, FACC¶
Michael Ragosta III, MD, FACC, FSCAI*
James L. Ritchie, MD, FACC, FAHA†
Geoffrey A. Rose, MD, FACC, FASE#
Alan B. Rosenberg, MD†
Andrea M. Russo, MD, FACC, FHRS**
Richard J. Shemin, MD, FACC, FAHA§
William S. Weintraub, MD, FACC, FAHA††

§American Association for Thoracic Surgery/Society of Thoracic Surgeons Representative; ‖Society of Cardiovascular Computed Tomography Representative; ¶Heart Failure Society of America Representative; #American Society of Echocardiography Representative; **Heart Rhythm Society Representative; ††American Heart Association Representative

This document was approved by the American College of Cardiology Foundation Board of Trustees in November 2011.

The American College of Cardiology Foundation requests that this document be cited as follows: Patel MR, Dehmer GJ, Hirshfeld JW, Smith PK, Spertus JA. ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 appropriate use criteria for coronary revascularization focused update: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, American Society of Nuclear Cardiology, and the Society of Cardiovascular Computed Tomography. J Am Coll Cardiol 2012;59:XXX–XX.

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ARTICLE IN PRESS

Appropriate Use Criteria Task Force

Michael J. Wolk, MD, MACC, *Chair*

Steven R. Bailey, MD, FACC, FSCAI, FAHA
Pamela S. Douglas, MD, MACC, FAHA
Robert C. Hendel, MD, FACC, FAHA, FASNC
Christopher M. Kramer, MD, FACC, FAHA
James K. Min, MD, FACC
Manesh R. Patel, MD, FACC
Leslee Shaw, PhD, FACC, FASNC
Raymond F. Stainback, MD, FACC, FASE
Joseph M. Allen, MA

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Abstract

The American College of Cardiology Foundation (ACCF), Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, and the American Association for Thoracic Surgery, along with key specialty and subspecialty societies, conducted an update of the appropriate use criteria (AUC) for coronary revascularization frequently considered. In the initial document, 180 clinical scenarios were developed to mimic patient presentations encountered in everyday practice and included information on symptom status, extent of medical therapy, risk level as assessed by noninvasive testing, and coronary anatomy. This update provides a reassessment of clinical scenarios the writing group felt to be affected by significant changes in the medical literature or gaps from prior criteria. The methodology used in this update is similar to the initial document, and the definition of appropriateness was unchanged. The technical panel scored the clinical scenarios on a scale of 1 to 9. Scores of 7 to 9 indicate that revascularization is considered appropriate and likely to improve patients' health outcomes or survival. Scores of 1 to 3 indicate revascularization is

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considered inappropriate and unlikely to improve health outcomes or survival. Scores in the mid-range (4 to 6) indicate a clinical scenario for which the likelihood that coronary revascularization will improve health outcomes or survival is uncertain.

In general, as seen with the prior AUC, the use of coronary revascularization for patients with acute coronary syndromes and combinations of significant symptoms and/or ischemia is appropriate. In contrast, revascularization of asymptomatic patients or patients with low-risk findings on noninvasive testing and minimal medical therapy are viewed less favorably. The technical panel felt that based on recent studies, coronary artery bypass grafting remains an appropriate method of revascularization for patients with high burden of coronary artery disease (CAD). Additionally, percutaneous coronary intervention may have a role in revascularization of patients with high burden of CAD. The primary objective of the appropriate use criteria is to improve physician decision making and patient education regarding expected benefits from revascularization and to guide future research.

Preface

The American College of Cardiology Foundation (ACCF), in collaboration with the Society for Cardiovascular Angiography and Interventions (SCAI), the Society of Thoracic Surgeons (STS), the American Association for Thoracic Surgery (AATS), and other societies, developed and published in 2009 appropriate use criteria (AUC) for certain clinical scenarios in which coronary revascularization could be used in an effort to address the rational use of coronary revascularization in the delivery of high-quality care. This document is the first focused update of the original document and includes new literature published since the original document and gaps noted during implementation.

The publication of AUC reflects one of several ongoing efforts by the ACCF and its partners to assist clinicians caring for patients with cardiovascular diseases and in support of high-quality cardiovascular care. The ACCF/American Heart Association (AHA) clinical practice guidelines provide a foundation for summarizing evidence-based cardiovascular care and, when evidence is lacking, provide expert consensus opinion that is approved in review by the ACCF and AHA. However, in many areas, variability remains in the use of cardiovascular procedures, raising questions of over- or underuse. The AUC provide a practical standard upon which to assess and better understand variability.

We are grateful to the technical panel and its chair, Frederick A. Masoudi, MD, MSPH, FACC, FAHA, a professional group with a wide range of skills and insights, for their thoughtful and thorough deliberation of the merits of coronary revascularization for various clinical scenarios. We would also like to thank the parent AUC Task Force and the ACCF staff, Joseph M. Allen and Lea Binder, for their exceptionally skilled support in the generation of this document.

Manesh R. Patel, MD, FACC
Chair, Coronary Revascularization Writing Group

Michael J. Wolk, MD, MACC
Chair, Appropriate Use Criteria Task Force

Introduction

This report is a focused update of the AUC for coronary revascularization published in 2009 (1). The increasing prevalence of coronary artery disease (CAD), continued advances in surgical and percutaneous techniques for revascularization and concomitant medical therapy for CAD, and the costs of revascularization have resulted in heightened interest regarding the appropriate use of coronary revascularization. Clinicians, payers, and patients are interested in the specific benefits of revascularization. Inappropriate revascularization may be harmful to patients and generate unwarranted costs to the healthcare system, whereas appropriate revascularization procedures can improve patients' clinical outcomes.

As in the original AUC document, the same classification scheme with ratings of appropriate, uncertain, and inappropriate was used. The uncertain category can cause confusion in the interpretation of the AUC and can imply several meanings within its definition. First, the rating of uncertain is used when pertinent literature is either not available or when true discrepancies exist. Second, it is impossible to include every relevant piece of clinical information (e.g., age, sex, diabetes) in the individual clinical scenarios. Attempting to do that may result in an unmanageable number of clinical scenarios and thus compromise the usefulness of the AUC in daily practice. The practice of medicine is full of uncertainties that require a thoughtful clinician to use his or her best judgment about each patient to reach decisions about management. Therefore, a rating of uncertain may be assigned by members of the technical panel if clinical information not provided might affect their individual rating, causing a shift into either the appropriate or inappropriate category.

A rating of uncertain means simply what the name implies, and depending on additional factors, it can be appropriate or inappropriate to perform revascularization. The writing group emphasizes that uncertain indications are not inappropriate. Rather, they reflect clinical scenarios that are reasonable for performing revascularization, but additional clinical factors should be considered or further research is needed to more definitively define the benefits of treatment for patients.

All prior AUC publications have reflected an ongoing effort to critically and systematically create, review, and categorize the appropriateness of certain cardiovascular

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diagnostic tests, whereas the AUC for coronary revascularization remains the only document addressing treatment. The writing group and technical panel members for this update are identical to the initial AUC (with only 1 exception) and comprised of members from relevant professional societies including both practicing interventional cardiologists and a cardiothoracic surgeon.

For the majority of clinical scenarios, the technical panel only considered the appropriate use of revascularization irrespective of whether this was accomplished by percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG). However, in a select subgroup of clinical scenarios in which revascularization is generally considered appropriate, the appropriateness of PCI and CABG, individually, was considered. In this subgroup, it was recognized that a focused update could be necessary following publication of the SYNTAX (Synergy Between PCI With TAXUS and Cardiac Surgery) trial (2). Therefore, in this update, the writing group identified 4 indications possibly affected by results of the SYNTAX trial for reexamination. The writing group also split 2 of the indications to represent levels of disease burden, recognizing, however, that the ability to reproducibly quantify the SYNTAX score in routine clinical practice has challenges. Also in this subgroup, the variables of diabetes and depressed left ventricular function were included in the initial AUC, but these were combined for the update because all indications with these variables were rated the same in the previous scores by the technical panel.

In addition, since the publication of the original document, efforts to implement data collection protocols related to the AUC indications identified a gap in the clinical scenarios related to lower-risk unstable angina/non–ST-segment elevation myocardial infarction (UA/NSTEMI) patients and asymptomatic patients with 1- or 2-vessel CAD not involving the proximal left anterior descending artery (LAD) in whom no noninvasive testing had been performed. Although limited new evidence is available for these patient populations since publication, the writing group developed indications to address these previous omissions.

Methods

A detailed description of the methods used for rating the selected clinical indications is found in a previous publication, "ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging" (3). Briefly, this process combines evidence-based medicine and practice experience by engaging a technical panel in a modified Delphi exercise. The technical panel is created from nominations given by multiple relevant professional societies and provider-led organizations as well as from health policy and payer communities. To preserve objectivity, technical panels are created so as to not include a majority of individuals whose livelihood is tied to the technology under evaluation.

In making its appropriate use determinations, the technical panel is provided with summaries of the relevant evidence from the medical literature and practice guidelines. Panelists are first asked individually, and then collectively, to assess the benefits and risks of a test or procedure in the context of the potential benefits to patients' outcomes and an implicit understanding of the associated resource use and costs. After the rating process, the final appropriate use ratings are summarized using an established rigorous methodology (4).

Indication Development

Appropriate use criteria are based on current understanding of the technical capabilities and potential patient benefits of the procedures examined. The AUC are also developed to identify common clinical scenarios—but they cannot possibly include every conceivable patient presentation. The term *indication* is used interchangeably with *clinical scenario* in the document for brevity and does not imply that a procedure should necessarily be performed. Some patients seen in clinical practice are not represented in these appropriate use criteria or have additional extenuating features that would alter the appropriateness of treatment as compared with the clinical scenarios presented. Additionally, although AUC indications and ratings are shaped by the guidelines, the AUC often contain more detailed clinical scenarios than the more generalized situations covered in clinical practice guidelines, and thus, subtle differences between these 2 guidance tools may be possible. To minimize this possibility, the coronary revascularization criteria were updated in conjunction with members of the ACCF/AHA PCI and CABG revascularization guideline committees.

Appropriate use criteria are intended to assist patients and clinicians, but are not intended to diminish the acknowledged difficulty or uncertainty of clinical decision making and cannot act as substitutes for sound clinical judgment and practice experience. Rather, the aim of these criteria is to allow assessment of utilization patterns for a test or procedure. Comparing utilization patterns across a large subset of provider's patients can allow for an assessment of a provider's management strategies with those of his/her peers. The ACCF and its collaborators believe that an ongoing review of one's practice using these criteria will help guide a more effective, efficient, and equitable allocation of healthcare resources, and ultimately, better patient outcomes.

The indications went through external review by multisociety and specialty representation for the 2009 document. Because of the narrow focus, the indications were not sent for external review for this update.

Scope of Indications

As previously described, the indications for coronary revascularization were developed considering the following common variables:

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a. The clinical presentation (e.g., acute coronary syndrome, stable angina);
b. Severity of angina (asymptomatic, Canadian Cardiovascular Society [CCS] Class I, II, III, or IV);
c. Extent of ischemia on noninvasive testing and the presence or absence of other prognostic factors, such as congestive heart failure, depressed left ventricular function, or diabetes;
d. Extent of medical therapy; and
e. Extent of anatomic disease (1-, 2-, 3-vessel disease, with or without proximal LAD or left main coronary disease).

The clinical scenarios developed include coronary anatomy, as this is the focus of much of the previous literature on coronary revascularization. However, the writing group recognizes that for everyday patient care, symptom status, ischemic burden, and level of medical therapy often play a critical role in decision making even before the coronary anatomy has been defined by angiography. It is important to note that the indications focus on revascularization, percutaneous or surgical, and do not address diagnostic catheterization or coronary angiography; these criteria are currently under development.

Technical Panel Selection

Stakeholders were given the opportunity to participate in the AUC process by submitting nominees from their organizations through a call for nominations announced in the summer of 2006. From this list of nominees, the AUC Task Force and writing group selected technical panel members to ensure an appropriate balance with respect to expertise. The 17-member technical panel was composed of 4 interventional cardiologists, 4 cardiovascular surgeons, 8 members representing noninterventional cardiologists, other physicians who treat patients with cardiovascular disease, health outcome researchers, and 1 medical officer from a health plan. For the update of the AUC for coronary revascularization, the same technical panelists (with 1 exception) from the original document published in 2009 were reconvened to rerate the 15 clinical scenarios included in the focused update.

Rating Process and Scoring

The technical panel members first rated indications independently. Then, the technical panel participated in 2 conferences calls for a discussion of each indication. After the discussion, panelists independently provided their final scores for each indication. Each panelist had equal weight in producing the final result for the indications and was not forced into consensus. For each indication, the median numerical score was determined and then assigned to an appropriate use category.

For the conference calls, each technical panelist received a personalized rating form that indicated his/her rating for each indication and the distribution of de-identified ratings of other members of the panel. In addition, the moderator received a summary rating form with similar information (including panelist identification), along with other statistics reflecting the level of agreement among technical panel members. The level of agreement among panelists, as defined by RAND, was analyzed for each indication based on the BIOMED rule for a panel of 14 to 16 (a simplified RAND method for determining disagreement) (4). Per the BIOMED definition, agreement was defined as an indication where 4 or fewer panelists' ratings fell outside the 3-point region containing the median score. Disagreement was defined as a situation where at least 5 panelists' ratings fell in both the appropriate and the inappropriate categories. Because the technical panel had 17 representatives, which exceeded the 16 addressed in this rule, an additional level of agreement analysis as described by RAND was performed that examined the interpercentile range compared with interpercentile range adjusted for symmetry (4). This information was used by the moderator to guide the technical panel's discussion by highlighting areas of differences among the panelists.

In developing these appropriate use criteria for coronary revascularization, the technical panel was asked to assess whether coronary revascularization for each indication was appropriate, uncertain, or inappropriate using the following definition of appropriate use:

Coronary revascularization is appropriate when the expected benefits, in terms of survival or health outcomes (symptoms, functional status, and/or quality of life) exceed the expected negative consequences of the procedure.

The technical panel scored each indication on a scale from 1 to 9 as follows:

Median Score 7 to 9

Appropriate procedure for specific indication (procedure **is** generally acceptable and **is** a reasonable approach for the indication).

Median Score 4 to 6

Uncertain for specific indication (procedure **may** be generally acceptable and **may** be a reasonable approach for the indication). Uncertainty implies that more research and/or patient information is needed to classify the indication definitively.

Median Score 1 to 3

Inappropriate procedure for that indication (procedure **is not** generally acceptable and **is not** a reasonable approach for the indication).

The division of these scores into 3 levels of appropriateness is somewhat arbitrary, and the numeric designations should be viewed as a continuum. Further, there is diversity in clinical opinion for particular clinical scenarios, such that scores in the intermediate level of appropriateness should be labeled uncertain, because critical patient or research data may be lacking or discordant. This designation serves as a prompt to the field to carry out definitive research investigations whenever possible. It is anticipated that the AUC reports will continue to be revised as further data are

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generated and information from the implementation of the criteria is accumulated.

To prevent bias in the scoring process, care was taken in providing objective, nonbiased information, including guidelines and key references, to the technical panel.

General Assumptions

Specific assumptions are provided that were considered by the technical panel in rating the relevant clinical scenarios for the appropriate use of revascularization:

1. Each clinical scenario includes the patient's clinical status/symptom complex, ischemic burden by noninvasive functional testing when presented, burden of coronary atherosclerosis as determined by angiography, and intensity of medical therapy in the determination of the appropriate use of coronary revascularization.
2. Assume coronary angiography has been performed when these findings are presented in the indications. The technical panel should rate the appropriateness of revascularization based upon the clinical features and coronary findings, and not the appropriateness of diagnostic coronary angiography.
3. Assume left main coronary artery stenosis (greater than or equal to 50% luminal diameter narrowing) or proximal LAD stenosis (greater than or equal to 70% luminal diameter narrowing) is not present unless specifically noted. Assume no other significant coronary artery stenoses are present except those noted in the clinical scenario.
4. The clinical scenarios should be rated based on the published literature regarding the risks and benefits of percutaneous and surgical coronary revascularization. Note that specific patient groups not well represented in the literature are not presented in the current clinical scenarios. However, the writing group recognizes that decisions about coronary artery revascularization in such patients are frequently required. Examples of such patients include those with end-stage renal disease or advanced age.
5. Clinical outcome is related to the extent of coronary artery disease (Table A1) (5). Based on this observation and clinical guideline recommendations regarding "borderline" angiographic stenosis (50% to 60%) in epicardial (non-left main) locations, a significant coronary stenosis for the purpose of the clinical scenarios is defined as:
   - Greater than or equal to 70% luminal diameter narrowing, by visual assessment, of an epicardial stenosis measured in the "worst view" angiographic projection.
   - Greater than or equal to 50% luminal diameter narrowing, by visual assessment, of a left main stenosis measured in the "worst view" angiographic projection.

Table A1. CAD Prognostic Index

Extent of CAD	Prognostic Weight (0–100)	5-Year Survival Rate (%)*
1-vessel disease, 75%	23	93
>1-vessel disease, 50% to 74%	23	93
1-vessel disease, ≥95%	32	91
2-vessel disease	37	88
2-vessel disease, both ≥95%	42	86
1-vessel disease, ≥95% proximal LAD	48	83
2-vessel disease, ≥95% LAD	48	83
2-vessel disease, ≥95% proximal LAD	56	79
3-vessel disease	56	79
3-vessel disease, ≥95% in at least 1	63	73
3-vessel disease, 75% proximal LAD	67	67
3-vessel disease, ≥95% proximal LAD	74	59

*Assuming medical treatment only. Reprinted with permission from Califf et al. (5).
CAD = coronary artery disease; LAD = left anterior descending coronary artery.

6. All patients are receiving standard care, including guideline-based risk factor modification for primary or secondary prevention in cardiovascular patients unless specifically noted (6–10).
7. Despite the best efforts of the clinician, all patients may not achieve target goals for risk factor modification. However, a plan of care to address risk factors is assumed to be occurring in patients represented in the indications. For patients with chronic stable angina, the writing group recognizes that there is a wide variance in the medical therapy for angina. The specific definition of maximal anti-ischemic medical therapy is presented in the definition section and includes the use of 2 or more antianginal medications.
8. Operators performing percutaneous or surgical revascularization have appropriate clinical training and experience and have satisfactory outcomes as assessed by quality assurance monitoring (11–13).
9. Revascularization by either percutaneous or surgical methods is performed in a manner consistent with established standards of care (11–13).
10. In the clinical scenarios, no unusual extenuating circumstances exist (such as inability to comply with antiplatelet agents, do not resuscitate status, patient unwilling to consider revascularization, technically not feasible to perform revascularization, or comorbidities likely to markedly increase procedural risk substantially) unless specifically noted.

Definitions

A complete set of definitions of terms used throughout the clinical scenarios is listed in Appendix A. These definitions were provided to and discussed with the technical panel prior to the rating of indications.

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Maximal Anti-Ischemic Medical Therapy

As previously stated, the indications assume that patients are receiving risk factor modification according to guideline-based recommendations. For the purposes of the clinical scenarios presented, **maximal antianginal medical therapy is defined as the use of at least 2 classes of therapies to reduce anginal symptoms.**

Stress Testing and Risk of Findings on Noninvasive Testing

Stress testing is commonly used for both diagnosis and risk stratification of patients with coronary artery disease. Using criteria defined for traditional exercise stress tests (14):

Low-risk stress test findings: associated with a cardiac mortality of less than 1% per year

Intermediate-risk stress test findings: associated with a 1% to 3% per year cardiac mortality

High-risk stress test findings: associated with a greater than 3% per year cardiac mortality

Examples of findings from noninvasive studies and their associated level of risk for cardiac mortality are presented in Table A2 (13). As noted in the footnote to this table, for certain low-risk findings, there may be additional findings that alter the assessment of risk, but these relationships have not been well studied. Implicit in these risk definitions is a measure of the amount of myocardium at risk, or ischemic myocardium. For the purpose of the indications for coronary revascularization, stress test findings are presented by these risk criteria. For patients without stress test findings, please refer to the note below on invasive methods of determining hemodynamic significance. Assume that when prior testing (including an imaging procedure) is referenced in an indication, the testing was performed correctly and with sufficient quality so as to produce a meaningful and accurate result within the limits of the test performance.

For the purposes of the clinical scenarios in this document, patients with both typical and atypical angina are classified by the feature of the CCS grading system presented below. Patients with noncardiac chest pain should be considered to be asymptomatic.

Grading of Angina Pectoris by the Canadian Cardiovascular Society Classification System (15)

Class I: Ordinary physical activity does not cause angina, such as walking, climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.

Class II: Slight limitation of ordinary activity. Angina occurs on walking more than 2 blocks on the level and climbing more than 1 flight of ordinary stairs at a normal pace and in normal condition.

Class III: Marked limitations of ordinary physical activity. Angina occurs on walking 1 or 2 blocks on the level and climbing 1 flight of stairs in normal conditions and at a normal pace.

Class IV: Inability to carry on any physical activity without discomfort—anginal symptoms may be present at rest.

High-Risk Features for Short-Term Risk of Death or Nonfatal MI for UA/NSTEMI (16)

At least 1 of the following:

- History—accelerating tempo of ischemic symptoms in preceding 48 hours
- Character of pain—prolonged ongoing (greater than 20 minutes) rest pain
- Clinical findings
  - Pulmonary edema, most likely due to ischemia
  - New or worsening mitral regurgitation murmur
  - S_3 or new/worsening rales
  - Hypotension, bradycardia, tachycardia
  - Age greater than 75 years
- Electrocardiogram
  - Angina at rest with transient ST-segment changes greater than 0.5 mm
  - Bundle-branch block, new or presumed new
  - Sustained ventricular tachycardia
- Cardiac marker
  - Elevated cardiac TnT, TnI, or CK-MB (e.g., TnT or TnI greater than 0.1 ng per mL)

TIMI Risk Score—for Patients With Suspected ACS (17)

Variables (1 point each)

- Age ≥65 years
- ≥3 risk factors (hypertension, diabetes mellitus, family history, lipids, smoking)
- Known CAD (stenosis ≥50%)
- Aspirin use in past 7 days
- Severe angina (≥2 episodes within 24 hours)
- ST-segment deviation ≥0.5 mm
- Elevated cardiac markers

Risk of death or ischemic event through 14 days

- Low: 0–2 (<8.3% event rate)
- Intermediate: 3–4 (<19.3% event rate)
- High: 5–7 (41% event rate)

Abbreviations

CABG = coronary artery bypass grafting
CAD = coronary artery disease
CCS = Canadian Cardiovascular Society
CTO = chronic total occlusion
FFR = fractional flow reserve
HF = heart failure

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Table A. Focused Update: New or Revised Indications

Indication		Appropriate Use Score (1–9)	
Patients With Acute Coronary Syndromes			
9.	• UA/NSTEMI and low-risk features (e.g., TIMI score ≤2) for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	U (6)	
10.	• UA/NSTEMI and intermediate-risk features (e.g., TIMI score 3–4) for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	A (8)	
Patients Without Prior Bypass Surgery Asymptomatic			
20.	• One- or 2-vessel CAD without involvement of proximal LAD • No noninvasive testing performed	I (3)	
Method of Revascularization: Multivessel CAD, CCS Angina Greater Than or Equal to Class III, and/or Evidence of Intermediate- to High-Risk Findings on Noninvasive Testing			
		PCI	CABG
62.	• Two-vessel CAD with proximal LAD stenosis	A (7)	A (8)
63.	• Three-vessel CAD with low CAD burden (i.e., 3 focal stenoses, low SYNTAX score)	A (7)	A (9)
64.	• Three-vessel CAD with intermediate to high CAD burden (i.e., multiple diffuse lesions, presence of CTO, or high SYNTAX score)	U (4)	A (9)
65.	• Isolated left main stenosis	U (6)	A (9)
66.	• Left main stenosis and additional CAD with low CAD burden (i.e., 1- to 2-vessel additional involvement, low SYNTAX score)	U (5)	A (9)
67.	• Left main stenosis and additional CAD with intermediate to high CAD burden (i.e., 3-vessel involvement, presence of CTO, or high SYNTAX score)	I (3)	A (9)

A = appropriate; CAD = coronary artery disease; CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; I = inappropriate; LAD = left anterior descending coronary artery; MI = myocardial infarction; SYNTAX = Synergy Between PCI With TAXUS and Cardiac Surgery; TIMI = Thrombolysis In Myocardial Infarction; U = uncertain; UA/NSTEMI = unstable angina/non–ST-segment elevation myocardial infarction.

IVUS = intravascular ultrasound
LAD = left anterior descending artery
LIMA = left internal mammary artery
LV = left ventricular
LVEF = left ventricular ejection fraction
MI = myocardial infarction
PCI = percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction
TIMI = Thrombolysis In Myocardial Infarction
UA/NSTEMI = unstable angina/non–ST-segment elevation myocardial infarction

Results of Updated Ratings

The writing group evaluated the previous 180 clinical scenarios and identified those where reevaluation, expansion, or consolidation was felt necessary (Table A). Nine of the 15 updated indications met the definition of agreement as described above. There were no ratings where the technical panel held such opposing viewpoints that the technical panel's votes were determined to be in "disagreement" as defined by the strict RAND definitions and described previously in the Methods section.

As the majority of the original clinical scenarios and ratings were not rerated in this update, Table A represents the focused update indications. In addition, the entire list of 171 clinical scenarios and their appropriateness scores are shown below in Tables 1, 2, 3, and 4. Figures 1, 2, 3, 4, and 5 demonstrate gradients in appropriate use rating by increasingly severe symptom status and ischemic risk, and by the method of revascularization. These are also presented in a format similar to the original document. In addition to the changes reflected in Table A, the fractional flow reserve (FFR) cut point was updated from 0.75 to 0.80 in indication 22 to reflect new literature since the publication of the original document and to maintain consistency with guidelines (18).

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Coronary Revascularization Appropriate Use Criteria (by Indication)

Table 1. Patients With Acute Coronary Syndromes

Indication		Appropriate Use Score (1–9)
1.	• STEMI • Less than or equal to 12 hours from onset of symptoms • Revascularization of the culprit artery	A (9)
2.	• STEMI • Onset of symptoms within the prior 12 to 24 hours • Severe HF, persistent ischemic symptoms, or hemodynamic or electrical instability present	A (9)
3.	• STEMI • Greater than 12 hours from symptom onset • Asymptomatic; no hemodynamic instability and no electrical instability	I (3)
4.	• STEMI with presumed successful treatment with fibrinolysis • Evidence of HF, recurrent ischemia, or unstable ventricular arrhythmias present • One-vessel CAD presumed to be the culprit artery	A (9)
5.	• STEMI with presumed successful treatment with fibrinolysis • Asymptomatic; no HF or no recurrent ischemic symptoms, or no unstable ventricular arrhythmias • Normal LVEF • One-vessel CAD presumed to be the culprit artery	U (5)
6.	• STEMI with presumed successful treatment with fibrinolysis • Asymptomatic; no HF, no recurrent ischemic symptoms, or no unstable ventricular arrhythmias at time of presentation • Depressed LVEF • Three-vessel CAD • Elective/semielective revascularization	A (8)
7.	• STEMI with successful treatment of the culprit artery by primary PCI or fibrinolysis • Asymptomatic; no HF, no evidence of recurrent or provokable ischemia, or no unstable ventricular arrhythmias during index hospitalization • Normal LVEF • Revascularization of a non-infarct-related artery during index hospitalization	I (2)
8.	• STEMI or NSTEMI and successful PCI of culprit artery during index hospitalization • Symptoms of recurrent myocardial ischemia and/or high-risk findings on noninvasive stress testing performed after index hospitalization • Revascularization of ≥1 additional coronary arteries	A (8)
9.	• UA/NSTEMI and low-risk features (e.g., TIMI score ≤2) for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	U (6)
10.	• UA/NSTEMI and intermediate-risk features (e.g., TIMI score 3–4) for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	A (8)
11.	• UA/NSTEMI and high-risk features for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	A (9)
12.	• UA/NSTEMI and high-risk features for short-term risk of death or nonfatal MI • Revascularization of multiple coronary arteries when the culprit artery cannot clearly be determined	A (9)
13.	• Patients with acute myocardial infarction (STEMI or NSTEMI) • Evidence of cardiogenic shock • Revascularization of ≥1 coronary arteries	A (8)

New and updated indications are shaded blue.

A = appropriate; CAD = coronary artery disease; HF = heart failure; I = inappropriate; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NSTEMI = non–ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI =ST-segment elevation myocardial infarction; TIMI = Thrombolysis In Myocardial Infarction; U = uncertain; UA = unstable angina.

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Table 2. Patients Without Prior Bypass Surgery

Indication		Appropriate Use Score (1–9)		
	CCS Angina Class	Asymptomatic	I or II	III or IV
14.	• One- or 2-vessel CAD without involvement of proximal LAD • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (1)	I (2)	U (5)
15.	• One- or 2-vessel CAD without involvement of proximal LAD • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	I (2)	U (5)	A (7)
16.	• One- or 2-vessel CAD without involvement of proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (3)	U (5)	U (6)
17.	• One- or 2-vessel CAD without involvement of proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (4)	A (7)	A (8)
18.	• One- or 2-vessel CAD without involvement of proximal LAD • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (6)	A (7)	A (8)
19.	• One- or 2-vessel CAD without involvement of proximal LAD • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (7)	A (8)	A (9)
20.	• One- or 2-vessel CAD without involvement of proximal LAD • No noninvasive testing performed	I (3)	U (5)	A (7)
21.	• One- or 2-vessel CAD with borderline stenosis "50% to 60%" • No noninvasive testing performed • No further invasive evaluation performed (i.e., FFR, IVUS)	Not rated	I (2)	I (3)
22.	• One- or 2-vessel CAD with borderline stenosis "50% to 60%" • No noninvasive testing performed or equivocal test results present • FFR less than or equal to 0.80* and/or IVUS with significant reduction in cross-sectional area	I (3)	U (6)	A (7)
23.	• One- or 2-vessel CAD with borderline stenosis "50% to 60%" • No noninvasive testing performed or equivocal test results present • FFR or IVUS findings do not meet criteria for significant stenosis	I (1)	I (2)	I (2)
24.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (1)	I (2)	I (3)
25.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	I (1)	U (4)	U (6)
26.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (3)	U (4)	U (6)
27.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Intermediate-risk criteria on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (4)	U (5)	A (7)
28.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (5)	A (7)
29.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • High-risk criteria on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (5)	A (7)	A (8)
30.	• One-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (5)	A (7)

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Table 2. Continued

Indication		Appropriate Use Score (1–9)		
	CCS Angina Class	Asymptomatic	I or II	III or IV
31.	• One-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving maximal anti-ischemic medical therapy	U (4)	A (7)	A (8)
32.	• One-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (6)	A (7)
33.	• One-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving maximal anti-ischemic medical therapy	U (5)	A (8)	A (9)
34.	• One-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	A (7)	A (8)	A (9)
35.	• One-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving maximal anti-ischemic medical therapy	A (7)	A (9)	A (9)
36.	• Two-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (6)	A (7)
37.	• Two-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (5)	A (7)	A (8)
38.	• Two-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (5)	A (7)	A (8)
39.	• Two-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (6)	A (7)	A (9)
40.	• Two-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	A (7)	A (8)	A (9)
41.	• Two-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (8)	A (9)	A (9)
42.	• Three-vessel CAD (no left main) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving no or minimal anti-ischemic medical therapy	U (5)	U (6)	A (7)
43.	• Three-vessel CAD (no left main) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving a course of maximal anti-ischemic medical therapy	U (5)	A (7)	A (8)
44.	• Three-vessel CAD (no left main) • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	A (7)	A (7)	A (8)
45.	• Three-vessel CAD (no left main) • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (7)	A (8)	A (9)
46.	• Three-vessel CAD (no left main) • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	A (7)	A (8)	A (9)
47.	• Three-vessel CAD (no left main) • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (8)	A (9)	A (9)
48.	• Three-vessel CAD (no left main) • Abnormal LV systolic function	A (8)	A (9)	A (9)
49.	• Left main stenosis	A (9)	A (9)	A (9)

New and updated indications are shaded blue. *FFR cut point updated from 0.75 to 0.80 to reflect new literature since publication of the original document and to maintain consistency with guidelines (18).

A = appropriate; CAD = coronary artery disease; CCS = Canadian Cardiovascular Society; I = inappropriate; LAD = left anterior descending coronary artery; LV = left ventricular; LVEF = left ventricular ejection fraction; U = uncertain.

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Table 3. Patients With Prior Bypass Surgery (Without Acute Coronary Syndrome)

Indication		Appropriate Use Score (1–9)		
	CCS Angina Class	Asymptomatic	I or II	III or IV
50.	• One or more stenoses in saphenous vein graft(s) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving no or minimal anti-ischemic medical therapy	I (3)	U (4)	U (6)
51.	• One or more stenoses in saphenous vein graft(s) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving a course of maximal anti-ischemic medical therapy	U (4)	U (6)	A (7)
52.	• One or more stenoses in saphenous vein graft(s) • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (6)	A (7)
53.	• One or more stenoses in saphenous vein graft(s) • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (4)	A (7)	A (8)
54.	• One or more stenoses in saphenous vein graft(s) • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (6)	A (7)	A (7)
55.	• One or more stenoses in saphenous vein graft(s) • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (7)	A (8)	A (9)
56.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving no or minimal anti-ischemic medical therapy	Not rated	I (3)	U (6)
57.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving a course of maximal anti-ischemic medical therapy	I (3)	U (5)	A (7)
58.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (3)	U (5)	A (7)
59.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (4)	U (6)	A (8)
60.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (6)	A (7)	A (8)
61.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (5)	A (8)	A (9)

A = appropriate; CCS = Canadian Cardiovascular Society; I = inappropriate; LV = left ventricular; U = uncertain.

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Table 4. Method of Revascularization: Multivessel CAD, CCS Angina Greater Than or Equal to Class III, and/or Evidence of Intermediate- to High-Risk Findings on Noninvasive Testing*

Indication		Appropriate Use Score (1–9)	
		PCI	CABG
62.	• Two-vessel CAD with proximal LAD stenosis	A (7)	A (8)
63.	• Three-vessel CAD with low CAD burden (i.e., 3 focal stenoses, low SYNTAX score)	A (7)	A (9)
64.	• Three-vessel CAD with intermediate to high CAD burden (i.e., multiple diffuse lesions, presence of CTO, or high SYNTAX score)	U (4)	A (9)
65.	• Isolated left main stenosis	U (6)	A (9)
66.	• Left main stenosis and additional CAD with low CAD burden (i.e., 1- to 2-vessel additional involvement, low SYNTAX score)	U (5)	A (9)
67.	• Left main stenosis and additional CAD with intermediate to high CAD burden (i.e., 3-vessel involvement, presence of CTO, or high SYNTAX score)	I (3)	A (9)
68.	• Prior bypass surgery with native 3-vessel disease and failure of multiple bypass grafts • LIMA remains patent to a native coronary artery • Depressed LVEF	U (6)	A (7)
69.	• Prior bypass surgery with native 3-vessel disease and failure of multiple bypass grafts • LIMA was used as a graft but is no longer functional • Depressed LVEF	A (8)	U (6)

New and updated indications are shaded blue. *The 2009 appropriate use criteria (1) separated out diabetes and normal or depressed LVEF for the indications in this table, but they were combined for the focused update because these clinical variables did not affect the ratings.

A = appropriate; CABG = coronary artery bypass graft; CAD = coronary artery disease; CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; I = inappropriate; LAD = left anterior descending coronary artery; LIMA = left internal mammary artery; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; SYNTAX = Synergy Between PCI With TAXUS and Cardiac Surgery; U = uncertain.

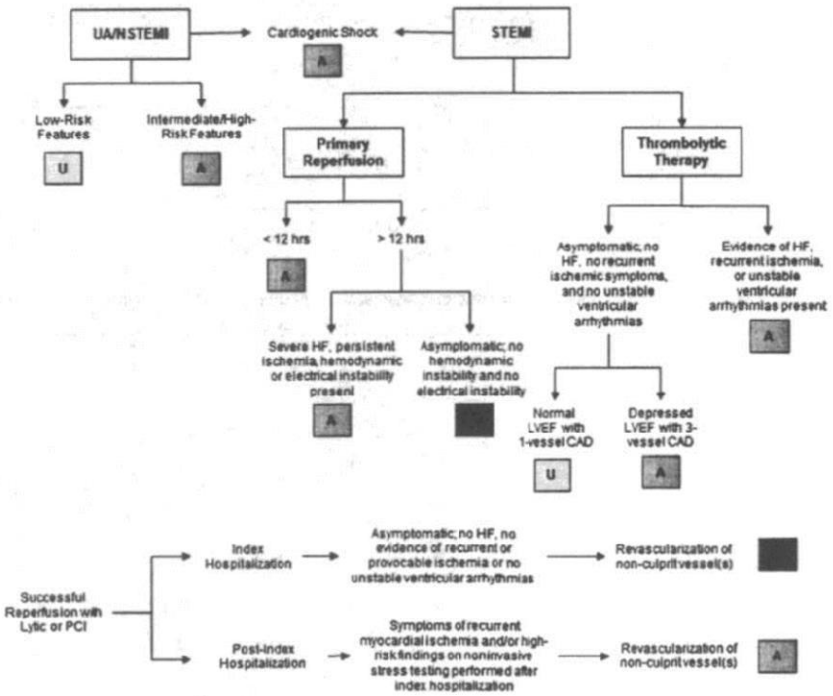

Figure 1. Appropriate Use Ratings for Revascularization in Acute Coronary Syndromes*

*The fact that the use of coronary revascularization for a particular condition is listed in this figure (appropriate, uncertain, inappropriate) does not preclude the use of other therapeutic modalities that may be equally effective. See the most current ACCF/AHA UA/NSTEMI and STEMI guidelines (16,23). A = appropriate; CAD = coronary artery disease; HF = heart failure; I = inappropriate; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction; U = uncertain; UA/NSTEMI = unstable angina/non–ST-elevation myocardial infarction.

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Low-Risk Findings on Noninvasive Study						Asymptomatic					
Symptoms Med. Rx						Stress Test Med. Rx					
Class III or IV Max Rx	U	A	A	A	A	High Risk Max Rx	U	A	A	A	A
Class I or II Max Rx	U	U	A	A	A	High Risk No/min Rx	U	U	A	A	A
Asymptomatic Max Rx			U	U	U	Int. Risk Max Rx	U	U	U	U	A
Class III or IV No/min Rx		U	A	A	A	Int. Risk No/min Rx			U	U	A
Class I or II No/min Rx			U	U	U	Low Risk Max Rx			U	U	U
Asymptomatic No/min Rx			U	U	U	Low Risk No/min Rx			U	U	U
Coronary Anatomy	CTO of 1-vz.; no other disease	1-2-vz. disease; no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease; no left main	Coronary Anatomy	CTO of 1-vz.; no other disease	1-2-vz. disease; no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease; no left main

Figure 2. Appropriate Use Ratings by Low-Risk Findings on Noninvasive Imaging Study and Asymptomatic (Patients Without Prior Bypass Surgery)

A = appropriate; CTO = chronic total occlusion; I = inappropriate; Int. = intermediate; Max = maximum; min = minimal; Med. = medical; prox. LAD = proximal left anterior descending artery; Rx = treatment; U = uncertain; vz. = vessel.

Intermediate Risk Findings on Noninvasive Study						CCS Class I or II Angina					
Symptoms Med. Rx						Stress Test Med. Rx					
Class III or IV Max Rx	A	A	A	A	A	High Risk Max Rx	A	A	A	A	A
Class I or II Max Rx	U	A	A	A	A	High Risk No/min Rx	U	A	A	A	A
Asymptomatic Max Rx	U	U	U	U	A	Int. Risk Max Rx	U	A	A	A	A
Class III or IV No/min Rx	U	U	A	A	A	Int. Risk No/min Rx	U	U	U	A	A
Class I or II No/min Rx	U	U	U	A	A	Low Risk Max Rx	U	U	A	A	A
Asymptomatic No/min Rx			U	U	A	Low Risk No/min Rx			U	U	U
Coronary Anatomy	CTO of 1 vz.; no other disease	1-2 vz. disease; no Prox. LAD	1 vz. disease of Prox. LAD	2 vz. disease with Prox. LAD	3 vz. disease; no Left Main	Coronary Anatomy	CTO of 1 vz.; no other disease	1-2 vz. disease; no Prox. LAD	1 vz. disease of Prox. LAD	2 vz. disease with Prox. LAD	3 vz. disease; no Left Main

Figure 3. Appropriate Use Ratings by Intermediate-Risk Findings on Noninvasive Imaging Study and CCS Class I or II Angina (Patients Without Prior Bypass Surgery)

A = appropriate; CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; I = inappropriate; Int. = intermediate; Max = maximum; min = minimal; Med. = medical; prox. LAD = proximal left anterior descending artery; Rx = treatment; U = uncertain; vz. = vessel.

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High-Risk Findings on Noninvasive Study						CCS Class III or IV Angina					
Symptoms Med. Rx						Stress Test Med. Rx					
Class III or IV Max Rx	A	A	A	A	A	High Risk Max Rx	A	A	A	A	A
Class I or II Max Rx	A	A	A	A	A	High Risk Nolmin Rx	A	A	A	A	A
Asymptomatic Max Rx	U	A	A	A	A	Int. Risk Max Rx	A	A	A	A	A
Class III or IV Nolmin Rx	A	A	A	A	A	Int. Risk Nolmin Rx	U	U	A	A	A
Class I or II Nolmin Rx	U	A	A	A	A	Low Risk Max Rx	U	A	A	A	A
Asymptomatic Nolmin Rx	U	U	A	A	A	Low Risk Nolmin Rx		U	A	A	A
Coronary Anatomy	CTO of 1-vz.; no other disease	1-2-vz. disease; no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease; no left main	Coronary Anatomy	CTO of 1-vz.; no other disease	1-2-vz. disease; no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease; no left main

Figure 4. Appropriate Use Ratings by High-Risk Findings on Noninvasive Imaging Study and CCS Class III or IV Angina (Patients Without Prior Bypass Surgery)

A = appropriate; CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; I = inappropriate; Int. = intermediate; Max = maximum; min = minimal; Med. = medical; prox. LAD = proximal left anterior descending artery; Rx = treatment; U = uncertain; vz. = vessel.

	CABG	PCI
Two-vessel CAD with proximal LAD stenosis	A	A
Three-vessel CAD with low CAD burden (i.e., three focal stenosis, low SYNTAX score)	A	A
Three-vessel CAD with intermediate to high CAD burden (i.e., multiple diffuse lesions, presence of CTO, or high SYNTAX score)	A	U
Isolated left main stenosis	A	U
Left main stenosis and additional CAD with low CAD burden (i.e., one to two vessel additional involvement, low SYNTAX score)	A	U
Left main stenosis and additional CAD with intermediate to high CAD burden (i.e., three vessel involvement, presence of CTO, or high SYNTAX score)	A	

Figure 5. Method of Revascularization of Multivessel Coronary Artery Disease

A = appropriate; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CTO = chronic total occlusion; I = inappropriate; LAD = left anterior descending artery; PCI = percutaneous coronary intervention; SYNTAX = Synergy Between PCI With TAXUS and Cardiac Surgery; U = uncertain.

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Rating Revascularization Methods

Mode of Revascularization (Indications 62 to 69)

Recognizing that variability in revascularization methods is often based upon patient factors and local practice patterns, the majority of indications are not intended to distinguish between the specific modes of revascularization (i.e., PCI vs. CABG). However, the writing group recognized that among patients with extensive or complex atherosclerosis, the mode of revascularization is also of interest when revascularization is deemed appropriate. Therefore, Table 4 presents clinical scenarios where the technical panelists were asked to consider the appropriate use of PCI and CABG as the revascularization method independently of each other (such that each modality would receive separate scores based on each specific clinical indication). These ratings are not intended to be a competitive ranking of PCI versus CABG, or to prioritize a specific approach when both are rated to have the same level of appropriateness.

Many of the known clinical factors that increase the risk of revascularization are shared between CABG and percutaneous methods. In the original AUC for revascularization, clinical scenarios were developed that included diabetes and LV function to stratify patients, but when rated, these features did not result in different ratings and thus were not used in this focused update. However, in an attempt to further stratify patients, the SYNTAX score is used in some of the new clinical scenarios.

The clinical scenarios below specifically apply to patients with multivessel CAD. It is assumed for these clinical scenarios that all patients have unacceptable levels of symptoms despite appropriate medical therapy and evidence of intermediate- to high-risk findings on noninvasive testing. In other words, the technical panel assumed that revascularization is appropriate and focused on rating the merit of the different modes with the intent of complete coronary revascularization for each indication.

In addition, it is assumed that no unusual extenuating circumstances exist (inability to comply with antiplatelet agents, patient is do not resuscitate status, patient preference strongly favoring 1 therapy or comorbidities likely to markedly increase procedural risk substantially). As such, the technical panel rated the appropriateness of PCI and CABG based on the information in the indication alone, assuming other variables are not present that would impact the decision.

Discussion

The ultimate objective of AUC is to improve patient care and health outcomes. The ACCF and its collaborators believe that careful blending of a broad range of clinical experiences and available evidence-based information will help guide a more efficient and equitable allocation of healthcare resources in cardiovascular revascularization. This approach is not intended to diminish the acknowledged difficulty or uncertainty of clinical decision making. Appropriate use criteria are not substitutes for sound clinical judgment and practice experience. It is acknowledged that some patients seen in clinical practice may not be represented in the AUC or have extenuating features when compared with the clinical scenarios presented.

Since the publication of the original coronary revascularization AUC, there has been substantial national focus on the variability and appropriateness of coronary revascularization. The 2009 AUC specifically for coronary revascularization by PCI has been mapped to the National Cardiovascular Data, Registry (NCDR) CathPCI registry data, and each institution's benchmarked results are now provided to member facilities in quarterly reports as a test quality metric. This initial assessment of PCI appropriateness within the NCDR data was also published by Chan and colleagues (19). Hospitals and operators are encouraged to review their specific reports as part of a quality improvement program to ensure data accuracy and increase the use of appropriate revascularization. Additionally, the SYNTAX trial, which was not formally published until 2009, was anticipated to possibly have an impact on the AUC. Despite calls for earlier updates of specific clinical scenarios, such as the isolated left main coronary artery revascularization, the writing group awaited the peer-reviewed publication of both the original trial data and the intermediate-term follow-up.

This focused update highlights 2 specific areas that were felt to require reconsideration: 1) specific indications that represent gaps identified when mapping the 2009 AUC to the CathPCI registry; and 2) re-evaluation of the indications for the treatment of multivessel CAD with symptoms by method (PCI and CABG) of revascularization as a result of data from the SYNTAX trial.

New Clinical Scenarios to Address Gaps

The 2009 AUC document only had 1 clinical scenario for UA/NSTEMI and high-risk features, which was graded as appropriate. The ratings for these new clinical scenarios (Indications 9 and 10) focus on patients with UA/NSTEMI and low- or intermediate-risk features as determined by the TIMI score. Revascularization in such patients with a low-risk score was graded as uncertain, meaning that revascularization may be reasonable, with the caveat that there is limited data on clinical benefit. For patients with an intermediate-risk score, revascularization was rated appropriate as it was for patients at high risk (Fig. 1).

In the 2009 AUC document, the clinical scenario of an asymptomatic patient without prior bypass surgery and with 1- or 2-vessel disease not involving the proximal LAD in whom no noninvasive testing had been performed was not evaluated because this clinical scenario was felt to be uncommon. However, for future mapping of the AUC to the CathPCI registry, the appropriateness of this clinical scenario was graded

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in this focused update and determined to be inappropriate. This did not affect the appearance of Figures 2, 3, and 4 below because they include indications that were not updated.

PCI and CABG in Patients With Multivessel CAD

In this group of ratings, it is assumed that revascularization is appropriate, and the technical panel rated the appropriateness of the mode of revascularization independently for CABG and PCI (Fig. 5). The writing group and technical panel felt some quantification of CAD burden, either by description or SYNTAX score, could be helpful to clinicians. CABG was rated as appropriate in all of the new clinical scenarios developed, whereas PCI was rated as appropriate only in patients with 2-vessel CAD with involvement of the proximal LAD and in patients with 3-vessel disease with a low CAD burden. PCI for 3-vessel disease with a high CAD burden, however, was rated as uncertain. PCI for isolated left main stenosis is now graded as uncertain, as are scenarios with 3-vessel CAD with intermediate to high CAD burden and left main stenosis and additional CAD with low CAD burden. PCI is considered inappropriate for left main stenosis and additional CAD with intermediate to high CAD burden.

Clinical Judgment and Understanding the AUC Ratings

Although the appropriate use ratings reflect a general assessment of when revascularization may or may not be useful for specific patient populations, physicians and other stakeholders should continue to acknowledge the pivotal role of clinical judgment in determining whether revascularization is indicated for an individual patient. For example, the rating of a revascularization indication as inappropriate or uncertain should not preclude a provider from performing revascularization procedures when there are patient- and condition-specific data to support that decision. Indeed, this may reflect optimal clinical care, if supported by mitigating patient characteristics. Likewise, uncertain indications require individual physician judgment and understanding of the patient to better determine the usefulness of revascularization for a particular clinical scenario. The ranking of uncertain (4 to 6) **should not be viewed as excluding the use of revascularization for such patients.** Finally, there may be clinical scenarios in which the use of coronary revascularization for an indication considered to be appropriate does not always represent reasonable practice, such that the benefit of the procedure does not outweigh the risks. Accordingly, the AUC are intended to evaluate overall patterns of care regarding revascularization rather than adjudicating specific cases. In situations where there is substantial variation between the appropriate use rating and what the clinician believes is the best recommendation for the patient, further considerations or actions such as a second opinion may be appropriate. It is not anticipated that all physicians or facilities will have 100% of their revascularization procedures deemed appropriate. However, related to the overall patterns of care, if the national average of appropriate procedure ratings is 80%, e.g., and a physician or facility has only a 40% rate of appropriate procedures, further examination of the patterns of care may be warranted and helpful.

Stable Ischemic Heart Disease *With* Prior CABG

The writing group did not feel the focused update needed to address any clinical scenarios in patients with stable ischemic heart disease and prior CABG. These indications from the prior document show a pattern similar to that seen in patients without prior CABG; the presence of high-risk findings on noninvasive testing, higher severity of symptoms, or an increasing burden of disease in either the bypass grafts or native coronaries increased the likelihood of an appropriate rating. The only inappropriate ratings in patients with prior CABG were noted in patients receiving no or minimal anti-ischemic therapy or having low-risk findings on noninvasive testing. More uncertain ratings occurred in this group of patients, reflecting their higher complexity, higher risk, and the limited availability of published evidence regarding management outcome.

Application of Criteria

There are many potential applications for the AUC. Clinicians can use the ratings for decision support or as an educational tool when considering the need for revascularization. Moreover, these criteria can be used to facilitate discussion with patients and/or referring physicians about the need for revascularization. Facilities and payers may choose to use these criteria either prospectively in the design of protocols or pre-authorization procedures, or retrospectively for quality reports. It is hoped that payers would use these criteria to ensure that their members receive necessary, beneficial, and cost-effective cardiovascular care, rather than for other purposes.

It is expected that services performed for appropriate indications will receive reimbursement. In contrast, services performed for inappropriate indications may require additional documentation to justify payment because of the unique circumstances or the clinical profile that may exist in such a patient. This additional documentation should not be required for uncertain indications. It is critical to emphasize that the writing group, technical panel, AUC Task Force, and clinical community do not believe an uncertain rating justifies denial of reimbursement for revascularization. Rather, uncertain ratings are those in which the available data vary and many other factors exist that may affect the decision to perform or not perform revascularization. The opinions of the technical panel often varied for these indications, reflecting that additional research is needed. Indications with high clinical volume that are rated as uncertain identify important areas for further research. The AUC writing group and technical panel favor the collaborative interaction of cardiac surgeons and interventional cardiologists Heart Team approach regarding revascularization decisions in complex patients or coronary anatomy.

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When evaluating physician or facility performance, AUC should be used in conjunction with efforts that lead to quality improvement. Prospective pre-authorization procedures, if put in place, are most effective once a retrospective review has identified a pattern of potential inappropriate use. Because these criteria are based on current scientific evidence and the deliberations of the technical panel, they should be used prospectively to generate future discussions about reimbursement, but should not be applied retrospectively to cases completed before issuance of this report or documentation of centers/providers performing an unexpectedly high proportion of inappropriate cases as compared with their peers.

The writing group recognizes that these criteria will be evaluated during routine clinical care. To that end, specific data fields such as symptom status, presence or absence of acute coronary syndrome, history of bypass surgery, extent of ischemia on noninvasive imaging, CAD burden, and degree of antianginal therapy are anticipated to provide sufficient detail to determine individual appropriate use ratings. Because a reasonable and tolerated dose of antianginal therapy may vary significantly among different patients, the writing group continues to recommend the use of 2 classes of antianginal therapies as a minimum standard for medical therapy. The writing group also recognizes all data (e.g., visual assessment of stenosis severity, interpretation of noninvasive imaging, symptom severity) collected to assess appropriate use relies on its content accurately reflecting actual patient characteristics. Any current variability in these data points need to be addressed before accurate determination of appropriate use can be provided.

The primary objective of this report is to provide guidance regarding the suitability of coronary revascularization for diverse clinical scenarios. As with previous AUC documents, consensus among the technical panel members was desirable, but an attempt to achieve complete agreement within this diverse panel would have been artificial and was not the goal of the process. Two rounds of ratings with substantial discussion among the technical panel members between the ratings did lead to some consensus among panelists. However, further attempts to drive consensus would have diluted true differences in opinion among panelists and, therefore, was not undertaken. Moreover, remarkable concordance between the appropriateness ratings from the original criteria and 85 cardiologists not participating in the process, and blinded to the initial results, has been documented (20).

Future research analyzing patient outcomes for indications rated as appropriate will help ensure the equitable and efficient allocation of resources for coronary revascularization. Review of appropriateness patterns may also improve understanding of regional variations in the use of revascularization as highlighted in the Dartmouth Atlas Project (21). Further exploration of the indications rated as uncertain will help generate the information required to further define the appropriate use of coronary revascularization. Additionally, the criteria will need to be updated with the publication of ongoing trials in coronary revascularization and new clinical practice guidelines. For additional information and discussion of the literature, please see the ACCF/AHA PCI and CABG guidelines (12,13).

In conclusion, this document represents the current understanding of the clinical benefit of coronary revascularization with respect to health outcomes and survival. It is intended to provide a practical guide to clinicians and patients when considering revascularization. As with other AUC, the results of some of these ratings will require research and further evaluation to provide the greatest information and benefit to clinical decision making.

Appendix A: Additional Coronary Revascularization Definitions

Angina/Chest Pain Classification

Angina is a syndrome typically noted to include discomfort in the chest, jaw, shoulder, back, or arm that is aggravated by exertion or emotional stress and relieved by nitroglycerin. The quality of the discomfort, provoking factors, and relieving factors are used to define typical, atypical, and noncardiac chest pain. Atypical angina is generally defined by 2 of the above 3 characteristics, and noncardiac chest pain is generally defined as chest pain that meets 1 or none of the above criteria. These definitions are presented below.

Clinical Classification of Chest Pain (22):

- ***Typical* Angina (Definite):** Defined as 1) substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin.
- ***Atypical* Angina (Probable):** Chest pain or discomfort that **lacks 1** of the characteristics of definite or typical angina.
- ***Nonanginal* Chest Pain:** Chest pain or discomfort that **meets 1 or none** of the typical angina characteristics.

The writing group assumes that noninvasive assessments of coronary anatomy (i.e., cardiac computed tomography, cardiac magnetic resonance angiography) provide anatomic information that is potentially similar to x-ray angiography. However, these modalities do not currently provide information on ischemic burden and are not assumed to be present in the clinical scenarios.

Invasive Methods of Determining Hemodynamic Significance

The writing group recognizes that not all patients referred for revascularization will have previous noninvasive testing. In fact, there are several situations in which patients may be appropriately referred for coronary angiography based on symptom presentation and a high pretest probability of coronary artery disease. In these settings, there may be

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Table A2. Noninvasive Risk Stratification

High-risk (>3% annual mortality rate)
1. Severe resting left ventricular dysfunction (LVEF <35%)
2. High-risk treadmill score (score ≤−11)
3. Severe exercise left ventricular dysfunction (exercise LVEF <35%)
4. Stress-induced large perfusion defect (particularly if anterior)
5. Stress-induced multiple perfusion defects of moderate size
6. Large, fixed perfusion defect with LV dilation or increased lung uptake (thallium-201)
7. Stress-induced moderate perfusion defect with LV dilation or increased lung uptake (thallium-201)
8. Echocardiographic wall motion abnormality (involving >2 segments) developing at low dose of dobutamine (≤10 mg/kg/min) or at a low heart rate (<120 beats/min)
9. Stress echocardiographic evidence of extensive ischemia
Intermediate-risk (1% to 3% annual mortality rate)
1. Mild/moderate resting left ventricular dysfunction (LVEF 35% to 49%)
2. Intermediate-risk treadmill score (score between −11 and <5)
3. Stress-induced moderate perfusion defect without LV dilation or increased lung intake (thallium-201)
4. Limited stress echocardiographic ischemia with a wall motion abnormality only at higher doses of dobutamine involving less than or equal to 2 segments
Low-risk (<1% annual mortality rate)
1. Low-risk treadmill score (score ≥5)
2. Normal or small myocardial perfusion defect at rest or with stress*
3. Normal stress echocardiographic wall motion or no change of limited resting wall motion abnormalities during stress*

*Although the published data are limited, patients with these findings will probably not be at low risk in the presence of either a high-risk treadmill score or severe resting left ventricular dysfunction (LVEF <35%). Reprinted with permission from Patel et al. (1).
LV = left ventricular; LVEF = left ventricular ejection fraction.

situations where angiography shows a coronary narrowing of questionable hemodynamic importance in a patient with symptoms that can be related to myocardial ischemia. In such patients, the use of additional invasive measurements (such as fractional flow reserve or intravascular ultrasound) at the time of diagnostic angiography may be very helpful in further defining the need for revascularization and substituted for stress test findings (Table A2).

Appendix B: Additional Methods

See the earlier Methods section of the report for a description of technical panel selection, indication development, scope of indications, and rating process.

Relationships With Industry and Other Entities

The American College of Cardiology Foundation and its partnering organizations rigorously avoid any actual, perceived, or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the technical panel. Specifically, all panelists are asked to provide disclosure statements of all relationships that might be perceived as real or potential conflicts of interest. These statements were reviewed by the AUC Task Force, discussed with all members of the technical panel at the face-to-face meeting, and updated and reviewed as necessary. A table of disclosures by all participants, who are listed in Appendix C, in the Appropriate Use Criteria for Coronary Revascularization can be found in Appendix D. In addition, to ensure complete transparency, complete disclosure information—including relationships not pertinent to this document—is available online as a document supplement.

Literature Review

The technical panel members were asked to refer to the relevant guidelines for a summary of the relevant literature, guideline recommendation tables, and reference lists provided for each indication table when completing their ratings (Online Appendix).

Appendix C: ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update Participants

Coronary Revascularization Writing Group

Manesh R. Patel, MD, FACC—Chair, Appropriate Use Criteria for Coronary Revascularization Writing Group—Assistant Professor of Medicine, Division of Cardiology, Assistant Director, Cardiac Catheterization Lab, Duke University Medical Center, Durham, NC

Gregory J. Dehmer, MD, FACC, FACP, FSCAI, FAHA—Past President, Society for Cardiovascular Angiography and Interventions; Professor of Medicine, Texas A&M School of Medicine; and Director, Cardiology Division, Scott & White Clinic, Temple, TX

John W. Hirshfeld, MD, FACC—Professor of Medicine, Hospital of The University of Pennsylvania, Department of Medicine, Cardiovascular Medicine Division, Philadelphia, PA

Peter K. Smith, MD, FACC—Professor and Chief, Thoracic Surgery, Duke University, Durham, NC

John A. Spertus, MD, MPH, FACC—Professor, UMKC School of Medicine, Director of CV Education and Outcomes Research, MidAmerica Heart Institute of St. Luke's Hospital, Kansas City, MO

Coronary Revascularization Technical Panel

Frederick A. Masoudi, MD, MSPH, FACC, FAHA—Moderator for the Technical Panel—Associate Professor of Medicine (Cardiology), University of Colorado Denver, Aurora, CO

Ralph G. Brindis, MD, MPH, FACC, FSCAI*—Methodology Liaison for the Technical Panel—Regional Senior Advisor for Cardiovascular Disease, Northern California Kaiser Permanente; Clinical Professor of Medicine, University of California at San Francisco; Chief Medical Officer and Chairman, NCDR Management Board, American College of Cardiology Foundation, Washington, DC

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Gregory J. Dehmer, MD, FACC, FACP, FSCAI, FAHA—Writing Group Liaison for the Technical Panel—Past President, Society for Cardiovascular Angiography and Interventions, Professor of Medicine, Texas A&M School of Medicine; and Director, Cardiology Division, Scott & White Clinic, Temple, TX

Manesh R. Patel, MD, FACC—Writing Group Liaison for the Technical Panel—Assistant Professor of Medicine, Division of Cardiology, Duke University Medical Center, Durham, NC

Peter K. Smith, MD, FACC—Writing Group Liaison for the Technical Panel—Professor and Division Chief, Cardiothoracic Surgery, Duke University, Durham, NC

Karen J. Beckman, MD, FACC*—Professor of Medicine, University of Oklahoma Health Science Center, Cardiac Arrhythmia Research Institute, Oklahoma City, OK

Charles E. Chambers, MD, FACC, FSCAI—Professor of Medicine and Radiology, Penn State University, Hershey Medical Center, Hershey, PA

T. Bruce Ferguson Jr., MD, FACC, FAHA—Chairman, Department of Cardiovascular Sciences, East Carolina Heart Institute, Greenville, NC

Mario J. Garcia, MD, FACC—Professor of Medicine, Chief, Division of Cardiology Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, NY

Frederick L. Grover, MD, FACC—Professor and Chair, Department of Surgery, University of Colorado School of Medicine, Denver Veterans Affairs Medical Center, Denver, CO

David R. Holmes Jr., MD, FACC, FSCAI—Professor of Medicine, Mayo Clinic, Rochester, MN

Lloyd W. Klein, MD, FACC, FSCAI, FAHA—Advocate Illinois Masonic Medical Center, Chicago, IL

Marian C. Limacher, MD, FACC, FACP, FAHA—Senior Associate Dean for Faculty Affairs and Professional Development, AHA Endowed Professor of Cardiovascular Research, University of Florida College of Medicine, Gainesville, FL

Michael J. Mack, MD, FACC—Medical Director Cardiovascular Surgery, Baylor Healthcare System, Dallas, TX

David J. Malenka, MD, FACC, FAHA—Professor of Medicine, Dartmouth Hitchcock Medical Center, Lebanon, NH

Myung H. Park, MD, FACC—Associate Professor of Medicine and Director, Pulmonary Vascular Diseases Program, University of Maryland School of Medicine, Division of Cardiology, Baltimore, MD

Michael Ragosta III, MD, FACC, FSCAI—Director, Cardiac Catheterization Laboratory, Professor of Medicine, University of Virginia, Charlottesville, VA

James L. Ritchie, MD, FACC, FAHA—Consultant, Seattle Veterans Hospital, Bend, OR

Geoffrey A. Rose, MD, FACC, FASE—Director of Imaging, Sanger Heart & Vascular Institute, Clinical Professor of Medicine, University of North Carolina at Chapel Hill, Charlotte, NC

Alan B. Rosenberg, MD—Vice President, Clinical Pharmacy and Medical Policy, WellPoint, Inc., Chicago, IL

Andrea M. Russo, MD, FACC, FHRS†—Professor of Medicine, University of Medicine and Dentistry of New Jersey/Robert Wood Johnson Medical School, Director, Cardiac Electrophysiology and Arrhythmia Services, Cooper University Hospital, Camden, NJ

Richard J. Shemin, MD, FACC, FAHA—Professor of Surgery, UCLA David Geffen School of Medicine, Chief, Division of Cardiothoracic Surgery; Executive Vice Chair, Department of Surgery; and Co-Director, Cardiovascular Center, Ronald Reagan UCLA Medical Center, Los Angeles, CA

William S. Weintraub, MD, FACC, FAHA—Chief, Section of Cardiology, Director, Christiana Center for Outcomes Research, Christiana Care Health System, Newark, DE

*Participated in the 2009 Appropriate Use Criteria for Coronary Revascularization only
†Participated in the 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update only

External Reviewers of the Appropriate Use Criteria Indications*

Stephan Achenbach, MD, FACC, FESC—Professor of Medicine, Department of Cardiology, University of Giessen, Giessen, Germany

Joseph S. Alpert, MD, FACC, MACP, FAHA—Professor of Medicine and Director of Coronary Care, Cardiac Rehabilitation, and the Chest Pain Unit, University of Arizona Health Network, Tucson, AZ; Editor-in-Chief, *The American Journal of Medicine*

H. Vernon Anderson, MD, FACC, FAHA—Professor of Medicine, Cardiology Division, University of Texas Health Science Center, Houston, TX

Elliott M. Antman, MD, FACC, FAHA—Professor of Medicine, Cardiovascular Division, Brigham and Women's Hospital, Associate Dean for Clinical/Translational Research, Harvard Medical School, Boston, MA

Lee M. Arcement, MD, MPH, FACC, FCCP—Chief of Cardiology, Chabert Medical Center, Houma, LA; Division Director of Heart Failure Disease Management, Louisiana State University Health Care Services, Baton Rouge, LA

R. Morton Bolman III, MD, FACC—Professor of Surgery, Harvard Medical School, and Chief, Division of Cardiac Surgery, Brigham and Women's Hospital, Boston, MA

Javed Butler, MBBS, MPH, FACC, FAHA—Professor of Medicine and Director, Heart Failure Research, Emory University, Atlanta, GA

Jun R. Chiong, MD, MPH, FACC, FCCP—Associate Professor of Medicine Medical Director, Advanced Heart Failure Program Loma Linda University Medical Center, Loma Linda, CA

G. William Dec, MD, FACC, FAHA—Professor of Medicine, Harvard Medical School and Chief, Cardiology Division, Massachusetts General Hospital, Boston, MA

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David P. Faxon, MD, FACC—Vice Chair of Medicine for Strategic Planning, Department of Medicine, Brigham and Women's Hospital, Boston, MA

Raymond J. Gibbons, MD, FACC—Professor of Medicine, Mayo Clinic, Rochester, MN

Robert A. Guyton, MD, FACC—Professor of Surgery and Chief of Cardiothoracic Surgery, Emory University School of Medicine, Atlanta, GA

Alice K. Jacobs, MD, FACC—Professor of Medicine, Boston University School of Medicine; Director, Cardiac Catheterization Laboratories and Interventional Cardiology, Boston Medical Center, Boston, MA

John A. Kern, MD, FACS—Professor of Surgery, Co-Director Heart and Vascular Center, University of Virginia Health System, Charlottesville, VA

Lloyd W. Klein, MD, FACC, FSCAI, FAHA—Professor of Medicine, Rush University Medical Center, Chicago, IL

Michael J. Mack, MD, FACC—Director, Cardiopulmonary Research Science Technology Institute, Baylor Healthcare System, Dallas, TX

L. Brent Mitchell, MD, FACC, FRCPC—Professor and Head, Department of Cardiac Sciences, Calgary Health Region and University of Calgary; Director, Libin Cardiovascular Institute of Alberta, Calgary, AB, Canada

Marc R. Moon, MD, FACC—Joseph C. Bancroft Professor of Surgery, Barnes-Jewish Hospital/Washington University, St. Louis, MO

Douglass A. Morrison, MD, PhD, FACC, FSCAI—Professor of Medicine, Director, Cardiac Catheterization Lab, Yakima Heart Center, Yakima, WA

Reid T. Muller, MD, FACC, FACP—Albany Associates in Cardiology, St. Peter's Hospital, Albany, NY

Sherif F. Nagueh, MD, FACC—Professor of Medicine, Methodist DeBakey Heart and Vascular Center, Houston, TX

Navin C. Nanda, MD, FACC—Distinguished Professor of Medicine and Cardiovascular Disease and Director, Heart Station/Echocardiography Laboratories, University of Alabama at Birmingham, Birmingham, AL

William C. Nugent, MD—Professor and Chief, Cardiothoracic Surgery, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Myung H. Park, MD, FACC—Associate Professor of Medicine and Director, Pulmonary Vascular Diseases Program, University of Maryland School of Medicine, Division of Cardiology, Baltimore, MD

Michael Poon, MD, FACC—Associate Clinical Professor of Medicine, Cabrini Medical Center, New York, NY

John D. Puskas, MD, FACC—Professor of Surgery (Cardiothoracic) and Associate Chief of Cardiothoracic Surgery, Emory University; Chief of Cardiac Surgery, Emory Crawford Long Hospital, Atlanta, GA

J. Scott Rankin, MD—Associate Clinical Professor, Vanderbilt University, Nashville, TN

Rita F. Redberg, MD, MSc, FACC, FAHA—Professor of Medicine, University of California at San Francisco School of Medicine, Division of Cardiology, San Francisco, CA

Michael W. Rich, MD, FACC, FAHA—Professor of Medicine, Cardiovascular Division, Washington University School of Medicine, St. Louis, MO

Craig R. Smith, MD, FACC—Johnson & Johnson Distinguished Professor and Valentine Mott Professor of Surgery, Chairman, Department of Surgery, College of Physicians & Surgeons of Columbia University, Columbia University Medical Center, New York Presbyterian Hospital, New York, NY

Barry F. Uretsky, MD, FACC, FSCAI, FAHA—Clinical Professor of Medicine, University of Arkansas for Medical Sciences, Director, Interventional Cardiology, Central Arkansas Veterans Health System, Little Rock, AR

Edward D. Verrier, MD, FACC, FACS, FAHA—K. Alvin & Shirley Merendino Endowed Professor of Cardiovascular Surgery, Vice Chairman for Clinical Affairs, Department of Surgery, University of Washington, Surgical Director, Joint Council on Thoracic Surgery Education, Seattle, WA

Susan J. Zieman, MD, PhD, FACC—Medical Officer, Geriatrics Branch, Division of Geriatrics and Clinical Gerontology, National Institute on Aging/National Institutes of Health, Bethesda, MD

ACCF Appropriate Use Criteria Task Force

Michael J. Wolk, MD, MACC—Chair, Task Force, Past President, American College of Cardiology Foundation and Clinical Professor of Medicine, Weill-Cornell Medical School, New York, NY

Steven R. Bailey, MD, FACC, FSCAI, FAHA—Chair, Division of Cardiology, Professor of Medicine and Radiology, Janey Briscoe Distinguished Chair, University of Texas Health Sciences Center, San Antonio, TX

Pamela S. Douglas, MD, MACC, FAHA, FASE—Past President, American College of Cardiology Foundation; Past President American Society of Echocardiography; and Ursula Geller Professor of Research in Cardiovascular Diseases, Duke University Medical Center, Durham, NC

Robert C. Hendel, MD, FACC, FAHA, FASNC—Chair, Appropriate Use Criteria for Radionuclide Imaging Writing Group—Director of Cardiac Imaging and Outpatient Services, Division of Cardiology, Miami University School of Medicine, Miami, FL

Christopher M. Kramer, MD, FACC, FAHA—Professor of Medicine and Radiology and Director, Cardiovascular Imaging Center, University of Virginia Health System, Charlottesville, VA

James K. Min, MD, FACC—Director of Cardiac Imaging Research and Co-Director of Cardiac Imaging, Cedars-Sinai Heart Institute, Los Angeles, CA

Manesh R. Patel, MD, FACC—Assistant Professor of Medicine, Division of Cardiology, Duke University Medical Center, Durham, NC

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Leslee Shaw, PhD, FACC, FASNC—Professor of Medicine, Emory University School of Medicine, Atlanta, GA

Raymond F. Stainback, MD, FACC, FASE—Medical Director of Noninvasive Cardiac Imaging, Texas Heart Institute at St. Luke's Episcopal Hospital; Clinical Associate Professor of Medicine, Baylor College of Medicine, Houston, TX

Joseph M. Allen, MA—Director, TRIP (Translating Research Into Practice), American College of Cardiology Foundation, Washington, DC

Appendix D. ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 APPROPRIATE USE CRITERIA FOR CORONARY REVASCULARIZATION FOCUSED UPDATE WRITING GROUP, TECHNICAL PANEL, INDICATION REVIEWERS,* AND TASK FORCE—RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (IN ALPHABETICAL ORDER)

Participant	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Coronary Revascularization Appropriate Use Criteria Writing Group						
Manesh R. Patel	None	None	None	None	None	None
Gregory J. Dehmer	None	None	None	None	None	None
John W. Hirshfeld	• St. Jude Medical	None	None	None	None	None
Peter K. Smith	• Eli Lilly	None	None	None	None	None
John A. Spertus	• St. Jude Medical	None	None	• BMS/sanofi-aventis partnership† • Eli Lilly†	None	None
Coronary Revascularization Appropriate Use Criteria Technical Panel						
Frederick A. Masoudi	None	None	None	None	None	None
Ralph G. Brindis	None	None	None	None	None	None
Gregory J. Dehmer	None	None	None	None	None	None
Manesh R. Patel	None	None	None	None	None	None
Peter K. Smith	• Eli Lilly	None	None	None	None	None
Karen J. Beckman	None	None	None	None	None	None
Charles E. Chambers	None	None	None	None	None	None
T. Bruce Ferguson	None	None	None	None	None	None
Mario J. Garcia	None	None	None	None	None	None
Frederick L. Grover	None	None	None	None	None	None
David R. Holmes Jr.	None	None	None	None	None	None
Lloyd W. Klein	None	None	None	None	None	None
Marian C. Limacher	None	None	None	None	None	None
Michael J. Mack	None	None	None	None	None	None
David J. Malenka	None	None	None	• St. Jude Medical Foundation	None	None
Myung H. Park						
Michael Ragosta III	None	None	None	None	None	None
James L. Ritchie	None	None	None	None	None	None
Geoffrey A. Rose	None	None	None	None	None	None
Alan B. Rosenberg	None	None	• WellPoint, Inc.†	None	• WellPoint, Inc.†	None
Andrea M. Russo	• Medtronic • Sanofi-Aventis	• Boston Scientific • Medtronic • St. Jude Medical	None	• Medtronic	None	None
Richard J. Shemin	None	None	None	None	None	None
William S. Weintraub	None	None	None	None	None	None

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Participant	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Coronary Revascularization Appropriate Use Criteria Indication Reviewers*						
Stephan Achenbach	None	None	None	• Siemens Medical Solutions	None	None
Joseph S. Alpert	None	None	None	None	None	None
H. Vernon Anderson	None	• Bristol-Myers Squibb Pharmaceuticals • Sanofi-aventis Pharmaceuticals	None	None	None	None
Elliott M. Antman	• Eli Lilly • Sanofi-aventis	None	None	• Bristol-Myers Squibb Pharmaceutical Research Institute • Eli Lilly and Company • Sanofi-aventis	None	None
Lee M. Arcement	None	None	None	None	None	None
R. Morton Bolman	None	None	None	None	None	None
Javed Butler	None	None	None	None	None	None
Jun R. Chiong	None	None	None	None	None	None
G. William Dec	None	None	None	None	None	None
David P. Faxon	None	None	None	None	None	None
Raymond J. Gibbons	None	None	None	None	None	None
Robert A. Guyton	• Medtronic	None	None	None	None	None
Alice K. Jacobs	None	None	None	None	None	None
John A. Kern	None	None	None	None	None	None
Lloyd W. Klein	None	None	None	None	None	None
Michael J. Mack	None	None	None	None	None	None
L. Brent Mitchell	• Medtronic	• Medtronic Canada	None	• Medtronic Canada	None	None
Marc R. Moon	None	None	None	None	None	None
Douglass A. Morrison	None	None	None	None	None	None
Reid T. Muller	None	None	None	None	None	None
Sherif F. Nagueh	• GE Healthcare • St. Jude Medical	• Medtronic	None	None	None	None
Navin C. Nanda	Philips	None	None	None	None	None
William C. Nugent	None	None	None	None	None	None
Myung H. Park	None	None	None	None	None	None
Michael Poon	None	None	None	None	None	None
John D. Puskas	• Medtronic	None	None	• Medtronic (royalty income)	None	None
J. Scott Rankin	None	None	None	None	None	None
Rita F. Redberg	None	None	None	None	None	None
Michael W. Rich	None	None	None	None	None	None
Craig R. Smith	None	None	None	None	None	None
Barry F. Uretsky	None	None	None	None	None	None
Edward D. Verrier	None	None	None	None	None	None
Susan J. Zieman	None	None	None	None	None	None

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Participant	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Appropriate Use Criteria Task Force						
Michael J. Wolk	None	None	None	None	None	None
Steven R. Bailey	None	None	None	None	None	None
Pamela S. Douglas	None	None	None	None	None	None
Robert C. Hendel	None	None	None	None	None	None
Christopher M. Kramer	None	None	None	None	None	None
James K. Min	None	• GE Healthcare	None	None	None	None
Manesh R. Patel	None	None	None	None	None	None
Leslee Shaw	None	None	None	None	None	None
Raymond F. Stainback	None	None	None	None	None	None
Joseph M. Allen	None	None	None	None	None	None

This table represents the relevant relationships with industry and other entities that were disclosed by participants at the time of participation. It does not necessarily reflect relationships at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10,000 or more of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Participation does not imply endorsement of this document. *Relationships were recorded at the time of review for the 2009 publication. Because the reviewers did not review the focused update, their information was not updated for this document. †Significant relationship.

Staff

American College of Cardiology Foundation

John C. Lewin, MD, Chief Executive Officer
Joseph M. Allen, MA, Director, TRIP (Translating Research Into Practice)
Lea Binder, MA, Senior Research Specialist, Appropriate Use Criteria
Erin A. Barrett, MPS, Senior Specialist, Science and Clinical Policy

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Key Words: ACCF Appropriate Use Criteria ■ coronary artery bypass graft surgery ■ percutaneous coronary interventions ■ revascularization.

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EXHIBIT 13

CARDIAC SURGERY TRANSFER AGREEMENT BETWEEN

HARTFORD HOSPITAL
80 SEYMOUR STREET
HARTFORD, CT 06102
("Hospital")

AND

WILLIAM W. BACKUS HOSPITAL
326 WASHINGTON STREET
NORWICH, CT 06360
("Facility")

To facilitate continuity of care and the timely transfer of patients who require cardiac surgery and their records between the Hospital and the Facility, the parties named above agree as follows:

1. That the Hospital shall make its facilities available to receive and care for all patients who in the professional opinion of the patient's physician would receive more appropriate treatment or care in the Hospital; provided that at the time of the proposed transfer, the Hospital shall have the facilities available for the proper care for the transferring patient, in accordance with federal and state laws and regulations are met.

2. The Facility will send with each patient at the time of transfer and whenever possible with the driver of the vehicle which transports the patient, or in the case of emergency, as promptly as possible the completed transfer and referral forms mutually agreed upon to provide the medical and administrative information necessary to determine the appropriateness of the placement and to enable continuing care to the patient. The transfer and referral forms will include such information as current medical findings, diagnoses, a brief summary of the course of treatment followed in the Facility, nursing and dietary information, discharge medication list, ambulation status, and pertinent administrative and social information, as appropriate.

3. The Hospital shall make available its diagnostic and therapeutic services for the care and treatment of patients who require cardiac surgery as ordered or referred by the attending physician subject to federal and state laws and regulations and Hospital's policies and procedures.

4. The Facility will be responsible for the transfer or other appropriate disposition of personal effects, particularly money and valuables, and information related to these items.

5. The Facility will be responsible for affecting the transfer of the patient, including arranging for appropriate and safe transportation and care of the patient during the transfer in accordance with applicable federal and state laws and regulations.

6. The Hospital will have responsibility for the care of the patient upon acceptance of admission.

7. The Hospital agrees to provide cardiac surgical back up for urgent cases at all hours and for elective cases at mutually agreed hours for the Facility on an as needed basis.

8. Each institution shall be solely responsible for billing and collecting charges which result from services it rendered to the patient. Charges for services performed by either institution shall be collected by the institution rendering such services, directly from the patient, third-party payer, or other sources normally billed by the institution. Neither institution shall have any liability to the other for such charges. However, each institution will provide the other institution with appropriate information it possesses pertinent to the financial status of the patient, the responsible party for the patient and any applicable information on benefit or insurance coverage.

9. The governing body of each facility shall have exclusive control of policies, management, assets, and affairs of its respective institutions. Neither institution shall assume any liability by virtue of the agreement for any debts or other obligations of either a financial or legal nature incurred by the other party to this agreement.

10. Nothing in this agreement shall be construed as limiting the rights of either institution to contract with any other institution on a limited or general basis.

11. This agreement shall be in effect from the effective date identified below and shall remain in force unless terminated by (i) either institution providing thirty (30) days prior written notice; or (ii) immediately upon the revocation of either party's license to operate by the State of Connecticut or the failure of either party to be properly certified to participate in Medicare or Medicaid..

12. Any dispute arising under this agreement shall be discussed directly by the Administrator of the Facility and the director of Cardiology Services at Hartford Hospital. If no agreement is reached, the Director of Cardiology Services will bring the matter to the attention of the Hartford Hospital Administration.

13. This agreement may be modified or amended by mutual agreement of the parties in writing,

14. Nothing in this agreement shall be construed as allowing the use of the other party's name in any promotional or advertising material without the prior written approval of the institution whose name is to be used.

IN WITNESS THEREFORE, the parties hereto are duly authorized to execute this agreement to be effective on the __ day of _____, 2015.

HARTFORD HOSPITAL

By: _____
Stuart Markowitz, MD

Hartford Region President and
Senior Vice President, HHC

Date: _____

WILLIAM W. BACKUS HOSPITAL

By: _____
David Whitehead

East Region President and CEO, HHC
Senior Vice President

Date: _____

EXHIBIT 14

Angioplasty
Supply Cost

Supply Type	Par Level	# Needed Per Procedure
PTA Guiding Catheters	100	1
6 Fr	50	
8 Fr	50	
Steerable GuideWires	20	1.3
ATW	5	
SMW	5	
Stabilizer	5	
Hydrophil	5	
Dilatation Catheters	30	1.5
6 different sizes		
Stents	36	1.5
BMS	18	
DES	18	
Inflation Device	10	1
Angio Seal Closure device	20	1
GB II/III Agents (Integrilin)	8	1
75 mg infusion bottle		
bolus vial		
AngioJet Supplies		1
Spiroflex catheter & pump set	4	
Total		

Based on predicted 215 procedures over 1st year.
Supply replacement within 24 hours

EXHIBIT 15

Backus Hospital
A Hartford HealthCare Partner

Clinical Guideline

Title:	Transfer of Cath Lab Patients to an Acute Care Facility
Effective Date:	TBD
Approved By:	☐ Chief Medical Officer ☐ Regional Vice President, Patient Care Services ☐ Medical Executive Committee
Endorsed By: (when necessary)	☐

DRAFT

Purpose:	To ensure the safe and coordinated transfer of patients from the cardiac catheterization laboratory to another acute care facility, ensure that the appropriate level of care is provided during transfer and that the necessary pertinent patient information is provided to the receiving entity.
Criteria for Use:	
Procedure:	**I. GENERAL** 1) The interventional cardiologist or a designated physician will contact the receiving surgeon or interventionist to arrange for a bed at the accepting facility. 2) The Cath Lab staff will initiate a phone call to the appropriate ambulance service or Life Star. 3) Any patient with an IABP, temporary pacing wires, and/or receiving blood products must be transferred with an RN trained in those specific skills. 4) A Critical Care Unit (CCU) nurse will accompany CCU patients being transferred from the Cath Lab to another facility when nursing presence is required. 5) Report will be called by the Cath Lab nurse to receiving facility once a bed assignment has been determined. **II. TRANSFERRING A PATIENT THAT DOES NOT NEED TO BE ACCOMPANIED BY A NURSE** 1) Cath lab staff will call the appropriate transferring company and specify if it an urgent transfer. **Note: Specifying the need for a URGENT transfer will ensure dispatch of an ambulance within 5 minutes.** a. Cath lab staff will provide all necessary information to the transferring company including the need for a paramedic and whether or not a nurse will be accompanying the patient on transfer. b. Request an estimated time of arrival. If the estimated time of arrival is greater than 20 minutes, confirm bed assignment at receiving facility, and call next LIFE STAR for pick up. c. ground crew/air. **III. TRANSFER OF A PATIENT WHO MUST BE ACCOMPANIED BY A NURSE**

	Monday through Friday 7:30 am to 4:00 pm 1) All patients, excluding CCU patients, that need to be transferred with a nurse, will be accompanied by a Cath Lab RN (if not being transferred by Life Star) or a Life Star RN. 2) Follow Section I. Monday through Friday 4:00 pm to 7:30 am, weekends and holidays 1) The Cath Lab nurse will notify the nursing supervisor so that she/he can assess nurse staffing and determine the most appropriate resource to accompany the patient on transfer. Possible resources include: a. CCU/ICU nurse b. ED nurse for non IABP transfer (for example, patient getting blood products) c. Life Star 2) Follow Section I. **IV. DELAY IN TRANSPORT** 1) If a delay in transport greater than 30 minutes is expected, the patient will be transferred to CCU. 2) The Cath Lab staff must identify and notify the admitting physician responsible for writing ICU/CCU orders. 3) The nursing supervisor will be notified for the need of a critical care bed.
Special Considerations:	
Definitions	
Related Policies:	
Related Forms, Documents:	
References:	
Revised Dates:	
Reviewed Dates:	
Guideline Approval Form	

EXHIBIT 16

REGISTERED NURSE COMPETENCY FOR SEDATION

	DZ, RN	AT, RN	MP, RN	PA, RN	KR, RN	KL, RN	RO, RN	GK, RN	JP, RN	**, RN	**, CRT	**, CRT	LN, RT	LW, RT	LN, RT	TF, RT	J S, RT	BS, RT	MB, RN PD	DC, RT, PD	BA, RT PD	JC, CRT, PD
# years in Profession	23	8	20	25	25	37	10	41	25				30	23	24	21	16	11	7	11	4	20
# years in Cath Lab	3	#	13	9	#	2	1	#	#				13	13	13	13	10	7	2	5	2	19
# years in IR	1	2	1.5	1	1	22	5	10	<6mths				27	20	15	19	11	10	2	9	3	5
Hemodynamic Cath Training	N/A	N/A	10	N/A			N/A	N/A	N/A				#	5	11	N/A	N/A	N/A	4	N/A	N/A	19
Angiojet experience			x			x	x	x					x	x	x	x	x	x	x	x	x	N/A
IV Skills	x	x	x	x	x	x	x	x	x				x	x	x	x	x	x	X	x	x	x
ACLS	x	x	x	x	x	x	x	x	x				x	x	x	x	x	x	X	x	x	x
Moderate Sedation	x	x	x	x	x	x	x	x	x				N/A	N/A	N/A	N/A	N/A	N/A	X	N/A	N/A	N/A
IABP	x	x	x	x	x	x	x	x	x				x	x	x	x	x	x	X	x	x	x
iStat	x	x	x	x	x	x	x	x	x				x	x	x	x	x	x	x	x	x	x

#- in training

PD- Per Diem

**- will need to hire with CON approval

EXHIBIT 17

Exhibit 17

In addition to participating in the PCI registry, the following quality measurements will be monitored.

PCI Overall Outcome and Quality Measurements

- Appropriate indication for elective/emergent PCI
- Appropriate documentation of indication for elective /emergent PCI
- Assessment of Dual Antiplatelet therapy
- Documentation of estimated pre-procedure Glomerular Filtration Rate
- Documentation of contrast dose used during the procedure
- Radiation Dose Documentation
- Proportion of eligible patients administered guideline-based class I therapies
- Cardiac rehabilitation referral rate
- Procedural complication rate
- 30- day risk standardized readmission rate
- In-hospital risk adjusted mortality rate
- 30-day all case risk standardized mortality rate with STEMI and without STEMI
- Bleeding events within 72 hours post procedure
- On-call response times
- Annual provider volume
- Annual hospital volume, annual break out of STEMI vs. Elective volume
- Door-to first device time, non transfer patients
- From a referring hospital: ED door to balloon (first device used) time
- First medical contact to balloon inflation (first device used) time, non transfer patients
- First medical contact to balloon inflation time, transfer patients
- Proportion of eligible patients receiving reperfusion therapy
- Proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization Lab for intended primary PCI who
    - Do not undergo acute catheterization because of misdiagnosis
    - Undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 hours

Monthly quality review will take place to review the above quality indicators, PCI registry data along with group case review. Separate peer review will take place at least every quarter for discussion of complicated cases and in-depth medical review.

CathPCI Registry®

NCDR® CathPCI Registry® v4.4
Diagnostic Catheterization and Percutaneous Coronary Intervention Registry

A. Demographics

Last Name[2000]: | **First Name**[2010]: | **Middle Name**[2020]:

SSN[2030]: - - ☐ SSN N/A[2031] | **Patient ID**[2040]: (auto) | **Other ID**[2045]:

Birth Date[2050]: | **Sex**[2060]: O Male O Female

Race: (check all that apply)
☐ White[2070] ☐ Black/African American[2071] ☐ Asian[2072]
☐ American Indian/Alaskan Native[2073] ☐ Native Hawaiian/Pacific Islander[2074]

Hispanic or Latino Ethnicity[2076]: O No O Yes

B. Episode of Care

Arrival Date/Time[3000,3001]: | **Patient Zip Code**[3005]: | ☐ Zip Code N/A[3006]

Admit Source[3010]: O Emergency department O Transfer in from another acute care facility O Other

Insurance Payors: (check all that apply)
☐ Private Health Insurance[3020] ☐ Medicare[3021] ☐ Medicaid[3022] ☐ Military Health Care[3023]
☐ State-Specific Plan (non-Medicaid)[3024] ☐ Indian Health Service[3025] ☐ Non-US Insurance[3026] ☐ None[3027]

HIC #[3030]:

C. History and Risk Factors (On arrival to CathPCI facility)

Current/Recent Smoker (< 1 year)[4000]:	O No	O Yes	**Height**[4055]:	(cm)	
Hypertension[4005]:	O No	O Yes	**Weight**[4060]:	(kg)	
Dyslipidemia[4010]:	O No	O Yes	**Currently On Dialysis**[4065]:	O No	O Yes
Family History of Premature CAD[4015]:	O No	O Yes	**Cerebrovascular Disease**[4070]:	O No	O Yes
Prior MI[4020]:	O No	O Yes	**Peripheral Arterial Disease**[4075]:	O No	O Yes
Prior Heart Failure[4025]:	O No	O Yes	**Chronic Lung Disease**[4080]:	O No	O Yes
Prior Valve Surgery/Procedure[4030]:	O No	O Yes	**Diabetes Mellitus**[4085]:	O No	O Yes
Prior PCI[4035]:	O No	O Yes	→**If Yes, Diabetes Therapy**[4090]:	O None O Diet O Oral O Insulin O Other	
→**If Yes, Most Recent PCI Date**[4040]:					
Prior CABG[4045]:	O No	O Yes			
→**If Yes, Most Recent CABG Date**[4050]:					

903

D. Cath Lab Visit (Complete For Each Cath Lab Visit)

Clinical Evaluation Leading To The Procedure

CAD Presentation[5000]: O No Sxs, no angina *(14 days)* O Sx unlikely to be ischemic *(14 days)* O Stable angina *(42 days)*
O Unstable angina *(60 days)* O Non-STEMI *(7 days)* O STEMI *(7 days)*

→**If** STEMI or Non-STEMI, **Symptom Onset Date/Time**[5005,5006] *(7 days)*: _____ ☐ Time Estimated[5007] ☐ Time Not Available[5008]

→**If** STEMI, **Thrombolytics**[5010]: O No O Yes →**If Yes, Start Date/Time**[5015,5016]:

Anginal Classification w/in 2 Weeks[5020]: O No symptoms O CCS I O CCS II O CCS III O CCS IV

Anti-Anginal meds w/in 2 Weeks[5025]: O No O Yes → **If Yes, Type** (check all that apply):
☐ Beta Blockers[5026] ☐ Ca Channel Blockers[5027] ☐ Long Acting Nitrates[5028] ☐ Ranolazine[5029] ☐ Other[5030]

Heart Failure w/in 2 Weeks[5040]: O No O Yes
→**If Yes, NYHA Class w/in 2 Weeks**[5045]: O Class I O Class II O Class III O Class IV

Cardiomyopathy or LV Systolic Dysfunction[5050]:	O No	O Yes	**Cardiogenic Shock w/in 24 Hours**[5060]:	O No	O Yes
Pre-operative Evaluation Before Non-Cardiac Surgery[5055]:	O No	O Yes	**Cardiac Arrest w/in 24 Hours**[5065]:	O No	O Yes

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Stress or Imaging Studies Performed[5100]: O No O Yes →If Yes, **Specify Test Performed:**

Test Performed	No	Yes		Result			Risk/Extent Of Ischemia
Standard Exercise Stress Test[5200,5201,5202]: (w/o imaging)	O	O	→ If Yes,	O Negative O Positive O Indeterminant O Unavailable		→ If Positive,	O Low O Intermediate O High O Unavailable
Stress Echocardiogram[5210,5211,5212]:	O	O	→ If Yes,	O Negative O Positive O Indeterminant O Unavailable		→ If Positive,	O Low O Intermediate O High O Unavailable
Stress Testing w/SPECT MPI[5220,5221,5222]:	O	O	→ If Yes,	O Negative O Positive O Indeterminant O Unavailable		→ If Positive,	O Low O Intermediate O High O Unavailable
Stress Testing w/CMR[5230,5231,5232]:	O	O	→ If Yes,	O Negative O Positive O Indeterminant O Unavailable		→ If Positive,	O Low O Intermediate O High O Unavailable
Cardiac CTA[5240,5241]:	O	O	→ If Yes,	O No disease O 1VD O Indeterminant O Unavailable	O 2VD	O 3VD	
Coronary Calcium Score[5250]:	O	O	→ If Yes,	**Calcium Score:**[5251] _____			

PROCEDURE INFORMATION

Procedure Date/Time[5300/5301]: **Fluoro Time/Dose**[5320,5321]: minutes **OR** mGy

PCI[5305]: O No O Yes **Contrast Volume**[5325]:

Diagnostic Cath[5310]: O No O Yes

Other Procedure (in conj w/Dx Cath or PCI)[5315]: O No O Yes

MECHANICAL VENTRICULAR SUPPORT

IABP[5330]: O No O Yes

→ If Yes, **Timing**[5335]: O In place at start of procedure O Inserted during procedure and prior to PCI O Inserted after PCI has begun

Other Mechanical Ventricular Support[5340]: O No O Yes

→ If Yes, **Timing**[5345]: O In place at start of procedure O Inserted during procedure and prior to PCI O Inserted after PCI has begun

ARTERIAL ACCESS

Arterial Access Site[5350]: O Femoral O Brachial O Radial O Other

Closure Method(s)[5355]:

1
2
3
4

☐ Method Not Documented[5356]

E. DIAGNOSTIC CATHETERIZATION PROCEDURE (COMPLETE FOR EACH DIAGNOSTIC CATH)

Operator's Name[6000, 6005, 6010]: **Operator's NPI**[6015]:

Diagnostic Coronary Angiography[6020]: O No O Yes

Left Heart Cath[6025]: O No O Yes

Cardiac Transplant Evaluation[6030]: O No O Yes

→ If Yes, **Type**[6035]: O Donor for cardiac transplant O Candidate to receive a cardiac transplant O Post cardiac transplant follow up

Diag Cath Status[6040]: O Elective O Urgent O Emergency O Salvage

Rx Recommendation[6045]: (after diagnostic cath) O None O Medical therapy and/or counseling O PCI w/o planned CABG O CABG (including planned hybrid CABG/PCI procedures) O Other cardiac therapy without CABG or PCI

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F. Best Estimate of Coronary Anatomy (Complete for each Cath Lab visit)

Dominance[6100]: O Left O Right O Co-dominant

Coronary Territory	Native Artery Percent Stenosis in >=2mm vessels		Grafts Supplying Coronary Territory (Note 1) Percent Stenosis	
Left Main	_____%[6110]	☐ Not Available[6111]		
Prox LAD	_____%[6120]	☐ Not Available[6121]	_____%[6170]	☐ Not Available[6171]
Mid/Distal LAD, Diag Branches	_____%[6130]	☐ Not Available[6131]	_____%[6180]	☐ Not Available[6181]
Circ, OMs, LPDA, LPL Branches	_____%[6140]	☐ Not Available[6141]	_____%[6190]	☐ Not Available[6191]
RCA, RPDA, RPL, AM Branches	_____%[6150]	☐ Not Available[6151]	_____%[6200]	☐ Not Available[6201]
Ramus	_____%[6160]	☐ Not Available[6161]	_____%[6210]	☐ Not Available[6211]

G. PCI Procedure (Complete for each Cath Lab visit in which a PCI was attempted or performed)

Operator's Name[7000,7005,7010]: **Operator's NPI**[7015]:

PCI Status[7020]: O Elective O Urgent O Emergency O Salvage

Pre-PCI LVEF[7025]: % ☐ Pre-PCI LVEF Not Assessed[7026]

Cardiogenic Shock at Start of PCI[7030]: O No O Yes

PCI Indication[7035]:
O Immediate PCI for STEMI
O PCI for STEMI (Stable, >12 from hrs Sx onset)
O Rescue PCI for STEMI (after failed full-dose lytics)
O Staged PCI
O PCI for STEMI (Unstable, >12 hrs from Sx onset)
O PCI for STEMI (stable after successful full-dose Thrombolysis)
O PCI for high risk Non-STEMI or unstable angina
O Other

→ **If** Immediate PCI for STEMI, **STEMI or STEMI Equivalent First Noted**[7040]: O First ECG O Subsequent ECG

→ **If** Subsequent ECG, **Subsequent ECG with STEMI or STEMI Equivalent Date/Time**[7045, 7046]: _____

→ **If** Immediate PCI for STEMI, **First Device Activation Date/Time**[7050,7051]: _____

→ **If** Immediate PCI for STEMI, **Transferred In for Immediate PCI for STEMI**[7055]: O No O Yes

→ **If** Yes, **Date/Time ED Presentation at Referring Facility**[7060,7061]: _____ **905**

→ **If** Immediate PCI for STEMI, **Non-System Reason for Delay in PCI**[7065]:
O Difficult vascular access
O Patient delays in providing consent for the procedure
O Other
O Cardiac arrest and/or need for intubation before PCI
O Difficulty crossing the culprit lesion during the PCI procedure
O None

Procedure Medications (Administered within 24 hours prior to and during the PCI procedure)

Category	Medication[9500]	Administered[9510]			
Anticoagulants	Fondaparinux	O No	O Yes	O Contraindicated	O Blinded
	Low Molecular Weight Heparin (any)	O No	O Yes	O Contraindicated	O Blinded
	Unfractionated Heparin (any)	O No	O Yes	O Contraindicated	O Blinded
Aspirin	Aspirin (any)	O No	O Yes	O Contraindicated	O Blinded
Direct Thrombin Inhibitors	Bivalirudin	O No	O Yes	O Contraindicated	O Blinded
	Direct Thrombin Inhibitor (other)	O No	O Yes	O Contraindicated	O Blinded
Glycoprotein IIb/IIIa Inhibitors	GP IIb/IIIa (any)	O No	O Yes	O Contraindicated	O Blinded
Thienopyridines	Clopidogrel	O No	O Yes	O Contraindicated	O Blinded
	Ticlopidine	O No	O Yes	O Contraindicated	O Blinded
	Prasugrel	O No	O Yes	O Contraindicated	O Blinded
	Ticagrelor	O No	O Yes	O Contraindicated	O Blinded

Note 1: CABG Date[9020] must be less than Procedure Date/Time[5300/5301] or Prior CABG[4045] = "Yes" to complete these elements.

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H. Lesions and Devices (Complete for each PCI attempted or performed)

	1	2
Lesion Counter[7100]:		
Segment Number(s)[7105]:	_____, _____, _____, _____, _____	_____, _____, _____, _____, _____
If CAD Presentation[5000] is 'STEMI', 'Non-STEMI', or 'Unstable angina', **Culprit Lesion**[7110]:	O No O Yes O Unknown	O No O Yes O Unknown
Stenosis Immediately Prior to Rx[7115]:	_____%	_____%
→ **If** 100%, **Chronic Total Occlusion**[7120]:	O No O Yes	O No O Yes
→ **If** 40-70%, **IVUS**[7125]:	O No O Yes	O No O Yes
→ **If** 40-70%, **FFR**[7130]:	O No O Yes	O No O Yes
→ **If** Yes, **FFR Ratio**[7135]:	_____	_____
Pre-procedure TIMI Flow[7140]:	O 0 O 1 O 2 O 3	O 0 O 1 O 2 O 3
Prev Treated Lesion[7145]:	O No O Yes	O No O Yes
→ **If** Yes, **Timeframe**[7150]:	O < 1 month O 1-5 months O 6-12 months O 1-2 years O >2 years O Time unknown	O < 1 month O 1-5 months O 6-12 months O 1-2 years O >2 years O Time unknown
→ **If** Yes, **Treated with Stent**[7155]:	O No O Yes	O No O Yes
→ **If** Yes, **In-Stent Restenosis**[7160]:	O No O Yes	O No O Yes
In-Stent Thrombosis[7165]:	O No O Yes	O No O Yes
Stent Type[7170]:	O DES O Non-DES O Type unknown	O DES O Non-DES O Type unknown
Lesion in Graft[7175]:	O Not in Graft O Vein O LIMA O Other artery	O Not in Graft O Vein O LIMA O Other artery
→**If** Vein, LIMA, Other, **Location in Graft**[7180]:	O Aortic O Body O Distal	O Aortic O Body O Distal
Lesion Complexity[7185]:	O Non-High/Non-C O High/C	O Non-High/Non-C O High/C
Lesion Length (mm)[7190]:	_____mm	_____mm
Thrombus Present[7195]:	O No O Yes	O No O Yes
Bifurcation Lesion[7200]:	O No O Yes	O No O Yes
Guidewire Across Lesion[7205]:	O No O Yes	O No O Yes
→ **If** Yes, **Stenosis Post-Procedure**[7210]:	_____%	_____%
→ **If** Yes, **Post-Procedure TIMI Flow**[7215]:	O 0 O 1 O 2 O 3	O 0 O 1 O 2 O 3
→ **If** Yes, **Device(s) Deployed**[7220]:	O No O Yes	O No O Yes

	Intracoronary Device(s) Used[7225]	Associated Lesion(s)[7100]	Diameter[7235]	Length[7240]
1		_____, _____, _____		
2		_____, _____, _____		
3		_____, _____, _____		
4		_____, _____, _____		
5				

Intraprocedure Events — **Significant Dissection**[7245]: O No O Yes — **Perforation**[7250]: O No O Yes

I. Labs (Complete for each Cath Lab visit in which a PCI was attempted or performed)

Pre-Procedure (performed at your facility)			**Post-Procedure** (post-procedure only)			
CK-MB[7300]	_____ ng/mL	☐ CK Not Applicable[7301] ☐ CK Drawn and Normal[7302]	**CK-MB**[7325]	_____ ng/mL	☐ CK Not Applicable[7326] ☐ CK Drawn and Normal[7327]	(peak value 6-24 hrs)
Troponin I[7305]	_____ ng/mL	☐ Not Drawn[7306]	**Troponin I**[7330]	_____ ng/mL	☐ Not Drawn[7331]	(peak value 6-24 hrs)
Troponin T[7310]	_____ ng/mL	☐ Not Drawn[7311]	**Troponin T**[7335]	_____ ng/mL	☐ Not Drawn[7336]	(peak value 6-24 hrs)
Creatinine[7315]	_____ mg/dL	☐ Not Drawn[7316]	**Creatinine**[7340]	_____ mg/dL	☐ Not Drawn[7341]	(highest value)
Hemoglobin[7320]	_____ g/dL	☐ Not Drawn[7321]	**Hemoglobin**[7345]	_____ g/dL	☐ Not Drawn[7346]	(lowest w/in 72 hrs)

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J. Intra and Post-Procedure Events (Complete For Each Cath Lab Visit)

Myocardial Infarction[8000]: (Positive Biomarkers)	O No	O Yes	**Bleeding Event w/in 72 Hours**[8050]:	O No O Yes
Cardiogenic Shock[8005]:	O No	O Yes	→If Yes, **Bleeding at Access Site**[8055]:	O No O Yes
Heart Failure[8010]:	O No	O Yes	→If Yes, **Hematoma at Access Site**[8060]:	O No O Yes
CVA/Stroke[8015]:	O No	O Yes	→If Yes, **Size**[8061]:	O <3cm O 3-5cm O >5-10 O >10cm
→If Yes, **Hemorrhagic Stroke**[8021]:	O No	O Yes	→If Yes, **Retroperitoneal Bleeding**[8070]:	O No O Yes
Tamponade[8025]:	O No	O Yes	→If Yes, **GI Bleed**[8080]:	O No O Yes
New Requirement for Dialysis[8030]:	O No	O Yes	→If Yes, **GU Bleed**[8090]:	O No O Yes
Other Vascular Complications Req Rx[8035]:	O No	O Yes	→If Yes, **Other Bleed**[8100]:	O No O Yes
RBC/Whole Blood Transfusion[8040]:	O No	O Yes		
→If Yes, **Hgb Prior to Transfusion**[8041]:	_____ g/dL			

K. Discharge (Complete this section for each Episode of Care)

CABG[9000]: O No O Yes

→ If Yes, **CABG Status**[9005]: O Elective O Urgent O Emergency O Salvage

→ If Yes, **CABG Indication**[9010]: O PCI complication O PCI failure without clinical deterioration O Treatment of CAD without PCI immediately preceding CABG O PCI/CABG hybrid procedure

→If Yes, **Location**[9015]: O At your facility O Transferred to other facility

→If At your facility, **CABG Date/Time**[9020,9021]:

Other Major Surgery[9025]: O No O Yes

LVEF[9030]: % ☐ LVEF Not Assessed[9031]

Discharge Date[9035]:

Discharge Status[9040]: O Alive O Deceased

→If Alive, **Discharge Location**[9045]: O Home O Extended care/TCU/rehab O Other acute care hospital O Nursing home O Hospice O Other O Left against medical advice (AMA)

→If Alive, **Cardiac Rehabilitation Referral**[9050]: O No O Yes O Ineligible

→If Deceased, **Death in Lab**[9055]: O No O Yes

→If Deceased, **Primary Cause of Death**[9060]: O Cardiac O Neurologic O Renal O Vascular O Infection O Valvular O Pulmonary O Unknown O Other

Hospital Status[9065]: O Outpatient O Outpatient converted to inpatient O Inpatient

Discharge Medications (Prescribed at Discharge – Complete for each Episode of Care in which a PCI was attempted or performed)

Category	Medication[9505]	Administered[9510]
Discharge medications are not required for patients who expired or were discharged to 'Other acute care Hospital', 'Hospice', or 'AMA'.		
ACE Inhibitors	ACE Inhibitor (any)	O No O Yes O Contraindicated O Blinded
ARBs	ARB (any)	O No O Yes O Contraindicated O Blinded
Aspirin	Aspirin (any)	O No O Yes O Contraindicated O Blinded
Beta Blockers	Beta Blocker (any)	O No O Yes O Contraindicated O Blinded
Lipid Lowering Agents	Statin (any)	O No O Yes O Contraindicated O Blinded
	Non-Statin (any)	O No O Yes O Contraindicated O Blinded
Thienopyridines	Clopidogrel	O No O Yes O Contraindicated O Blinded
	Ticlopidine	O No O Yes O Contraindicated O Blinded
	Prasugrel	O No O Yes O Contraindicated O Blinded
	Ticagrelor	O No O Yes O Contraindicated O Blinded

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American College of Cardiology Foundation
American Heart Association
Society for Cardiovascular Angiography & Interventions
American Medical Association-convened Physician Consortium
for Performance Improvement® (PCPI®)
National Committee for Quality Assurance

Percutaneous Coronary Intervention
Performance Measurement Set

ACCF/AHA Approved January 2013
PCPI Approved February 2013

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Work Group Members
Percutaneous Coronary Intervention

Work Group Members

Brahmajee K. Nallamothu, MD, MPH, FACC, FAHA (Co-Chair) (interventional cardiology)
Carl Tommaso, MD, FACC, FSCAI (Co-Chair) (interventional cardiology)

H. Vernon Anderson, MD, FACC, FAHA, FSCAI, (interventional cardiology)
Jeffrey L. Anderson, MD, FACC, FAHA, MACP (cardiology)
R. Adams Dudley, MD, MBA (internal medicine/pulmonary/critical care)
Peter Louis Duffy, MD, MMM, FACC, FSCAI (interventional cardiology)
Joseph C. Cleveland, Jr., MD (cardiothoracic surgery)

David P. Faxon, MD, FACC, FAHA (cardiology)

Hitinder S. Gurm, MD, FACC (interventional cardiology)
Lawrence A. Hamilton (health plan representative)

Neil C. Jensen, MHA, MBA (health plan representative)

Richard A. Josephson MD, MS, FACC, FAHA (cardiac rehabilitation)

David J. Malenka, MD, FACC, FAHA(cardiology)

Calin V. Maniu, MD, FACC, FAHA, FSCAI (interventional cardiology)
Kevin W. McCabe, MD (consumer/purchaser representative)
James D. Mortimer (consumer/purchaser representative)
Manesh R. Patel, MD, FACC, FAHA (interventional cardiology)
Stephen D. Persell, MD, MPH (internal medicine; measure implementation)
John S. Rumsfeld, MD, PhD, FACC, FAHA (cardiology)

Kendrick A. Shunk, MD, PhD, FACC, FAHA, FSCAI(interventional cardiology)
Sidney C. Smith, Jr., MD, FACC, FAHA (cardiology; guideline development)
Stephen J. Stanko, MBA, BA, AA (patient representative)

Brook Watts, MD, MS (internal medicine; measure implementation)

Work Group Staff

American College of Cardiology Foundation
Susan Fitzgerald, RN, MS
Charlene L. May
Melanie Shahriary, RN, BSN

American Heart Association
Mark D. Stewart, MPH
Melanie B. Turner, MPH
Gayle Whitman, PhD, RN

American College of Cardiology Foundation/American Heart Association
Jensen S. Chiu, MHA

Society for Cardiovascular Angiography & Interventions
Joel Harder, MBA
Wayne Powell

American Medical Association (AMA) professional staff to the Physician Consortium for Performance Improvement® (PCPI®)
Sara Alafogianis, MPA
Mark Antman, DDS, MBA
Elvia Chavarria, MPH
Keri Christensen, MS
Kendra Hanley, MS
Diedra Joseph, MPH
Karen Kmetik, PhD
Samantha Tierney, MPH
Jennifer Trajkovski, MJ, RHIT
Greg Wozniak, PhD

National Committee for Quality Assurance
Manasi Tirodkar, PhD, MS

The Joint Commission
Millie J. Perich, MS, RN

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Executive Summary: Improving Outcomes for Patients undergoing PCI

Purpose of Measurement Set

The American College of Cardiology Foundation (ACCF), American Heart Association (AHA), the Society for Cardiovascular Angiography and Interventions (SCAI), the American Medical Association (AMA)-convened Physician Consortium for Performance Improvement® (PCPI®), and the National Committee for Quality Assurance (NCQA) formed a Percutaneous Coronary Intervention (PCI) Work Group to identify and define quality measures toward improving outcomes for patients undergoing PCI (see diagram at the end of this section).

Reasons for Prioritizing Improvement in PCI

High Impact Topic Area

PCI is the most commonly performed type of coronary revascularization in the United States, facilitating the relief of angina for patients with chronic stable coronary artery disease (CAD), and saving lives and preventing reinfarction for patients with acute coronary syndromes. Relevant facts regarding prioritizing improvement in PCI include the following:

- Approximately 600,000 PCIs are performed each year in the United States.[1]
- Of PCIs performed in the United States, approximately two-thirds are performed in men and 51% are performed in patients 65 years or older.[2]
- Unadjusted, in-hospital mortality rates for PCI range from 0.4-1.9%.[3]Mortality for PCI has remained stable during recent years despite an increase in the proportion of high-risk patients undergoing the procedure.[2]
- Estimates suggest each PCI costs over $12,000 but vary based on the patient and clinical context.[4] In the SYNTAX trial, follow-up costs over 1 year brought the total costs of PCI to $35,991 in patients with multivessel CAD, which remained favorable in comparison with coronary artery bypass grafting (CABG).[5]
- Drug-eluting coronary stents are increasingly being used during PCI. This technology is estimated to have added approximately $1.6 billion in annual Medicare expenditures from 2003 through 2006 among beneficiaries aged 66 to 85 years old.[6]

Demonstrated Opportunity for Improvement

Data suggest substantial variation in use and outcomes of PCI across the United States.

- Among hospital referral regions, PCI rates range nationally from 5 to 42 procedures per 1,000 Medicare beneficiaries.[7]
- An analysis of The National Cardiovascular Data Registry (NCDR©) CathPCI Registry© found that 98.6% of PCIs performed in acute settings were classified as appropriate according to appropriate use criteria for coronary revascularization. However, in non-acute settings, only 50% of PCIs were classified as appropriate, while 38% were uncertain and 12% were inappropriate. A rating of uncertain implies that more research, more patient information, or both would be needed to further classify the indication. Additionally, significant hospital-level variation in rates of inappropriate PCIs occurred in non-acute settings, ranging from 0% to 55%.[8]
- Although mortality rates after PCI in contemporary practice are low, approximately 1 in 7 fee for service Medicare patients who undergo PCI are readmitted within 30 days of hospital discharge. Median readmission rates vary significantly across hospitals with rates of 8.9% in the lowest decile to 22.0% in the highest decile. Readmissions were associated with additional coronary revascularization procedures in 27.5% of cases and also associated with an increased risk of mortality.[9]
- Optimal medical therapy (defined as use of aspirin or thienopyridine, beta-blocker, and statins) as reported in the CathPCI Registry remains concerning. Between 2005 and 2009, composite use of these evidence-based drugs (or reported contraindications to them) was 44% of patients before PCI and 65% patients following PCI.[10]

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- A minority of patients - approximately 40% - participate in cardiac rehabilitation after PCI despite evidence demonstrating an association between its use and improvements in outcomes.[11]

Disparities

An extensive body of research has demonstrated racial and gender differences in referral for diagnostic catheterization, use and patterns of coronary revascularization including PCI, and larger delays to treatment with PCI in the setting of ST-Elevation Myocardial Infarction (STEMI).[12]

Rigorous Clinical Evidence Base

The availability of a rigorous clinical evidence base for PCI based on randomized clinical trials, meta-analyses, and observational studies is unparalleled for a medical procedure. It forms an important foundation for understanding the appropriate application and management of PCI. This measurement set is based on guidelines from the ACCF/AHA/SCAI, published in 2011[13]. In addition, it borrows from Appropriate Use Criteria (AUC) for coronary revascularization developed by the ACCF in collaboration with other organizations in 2009[14] with a focused update in 2012.[15]

PCI Performance Measures and Other National Efforts

Outcome Measures

Ideally, a set of performance measures would include measures of outcomes, as well as key process and structural measures known to positively influence desirable outcomes and reduce undesirable outcomes.

Desirable outcomes for PCI include:

1. Reducing mortality (including short and long-term)
2. Improving angina or its equivalent ischemic symptoms
3. Achieving patient's goals and preferences for functional status, activity, and quality of life
4. Reducing procedural complications
5. Reducing "avoidable" readmissions related to the procedure

Several outcome measures for mortality in patients undergoing PCI have previously been developed. Many are already endorsed by the National Quality Forum (NQF), which is the national clearinghouse for vetting and approving measures. For example, there are 2 existing NQF-endorsed® risk-adjusted outcome measures for PCI that focus on 30-day mortality at the hospital level in (1) patients with STEMI or cardiogenic shock and (2) those without STEMI and cardiogenic shock. These measures incorporate complex risk-adjustment methodology to account for significant differences in patient populations across hospitals and have been implemented nationwide. In addition, the ACC also has developed standardized outcome measures for reporting quality of PCI among hospitals participating in the CathPCI Registry, including measures for mortality. Most recently, the NQF has endorsed a risk-adjusted outcome measure for readmission in patients undergoing PCI as well. We are unaware of existing outcome measures focused on specific procedural complications or improvement in angina, health status or quality of life.

Although we strongly endorse the use of mortality measures, we have avoided duplicating these earlier efforts by national organizations. These earlier efforts have been extensive and highly visible. We hope that this will minimize confusion by users of performance measures. The Work Group did consider other outcomes measures as well but felt that the availability of evidence as well as the feasibility of data collection prevented us from pursuing such options at this time. We believe this will be a key area of development for future Work Groups.

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Process and Structural Measures

A few key process measures already in place also exist for PCI in the setting of STEMI. For example, the measurement of time to reperfusion (ie, door-to-balloon time) is endorsed by the NQF. For the reasons noted above, we did not create a replicated measure and refer readers to these earlier efforts.

Following PCI, secondary prevention for CAD is essential as part of long-term therapy reducing future morbidity and mortality.[13]A number of performance measures addressing secondary prevention in the ambulatory setting for patients with CAD have been developed and are recommended to be incorporated as critical components of long-term patient management following PCI. In general, the PCI Work Group agrees with and supports the use of performance measures outlined in documents for STEMI and non-STEMI[16] and CAD/Hypertension (HTN).[17] In cases where the Work Group felt that the need was urgent or specific enough for PCI (eg, use of cardiac rehabilitation), we adapted an existing measure to focus on this specific patient population.

Distinction between Measures for Accountability and Quality Improvement or Measures for Quality Improvement Only

Measures that can be used for accountability provide information that can assist stakeholders in making choices about providers.[18]Accountability measures, such as those used in public reporting to facilitate comparisons across clinicians or facilities or possibly pay for performance programs, must meet certain attributes that would permit such a designation. In particular, these measures must be developed through a rigorous measure development process including a public comment and peer review period. These measures must also be based on guideline recommendations that were prioritized due to several important variables (ie, the clinical importance of the intervention and link to desired outcomes, the strength of evidence and strength of recommendation, gaps in care, validity, and feasibility). These criteria are consistent with those put forth by Chassin et al.[19] and the ACC/AHA Task Force On Performance Measures.[20] These measures are also intended to promote quality improvement. On the other hand, quality improvement *only* measures provide information that should be of value to stakeholders responsible for improving the quality of care[18] and cannot be used for accountability purposes. Quality improvement only measures fail to meet at least one of the aforementioned desired attributes and require further validation and testing.

PCI Work Group Recommendations

The PCI Work Group recommends the following new process and structural measures. We have organized them across the continuum of "preprocedural", "procedural" and "postprocedural" processes and structures that relate to providing optimal PCI care.

Process measures: Several key processes of care have been linked to desirable outcomes for patients undergoing PCI. Based on guidelines and AUC for coronary revascularization, we recommend:

Preprocedural measures that address potential overuse of procedure
Measure #1: Comprehensive Documentation of Indications for PCI
Measure #2: Appropriate Indication for Elective PCI *(QI only)*
Procedural measure that addresses underuse of effective services (evaluation and treatment strategies)
Measure #4: Use of Embolic Protection Devices in the Treatment of Saphenous Vein Bypass Graft Disease *(QI only)*
Postprocedural measures that address underuse of effective services (evaluation and treatment strategies)
Measure #7: Post-Procedural Optimal Medical Therapy Composite
Measure #8: Cardiac Rehabilitation Patient Referral
Preprocedural measure that addresses safety
Measure #3: Assessment of Candidacy for Dual Antiplatelet Therapy

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Postprocedural measures that address safety
Measure #5: Documentation of Pre-Procedural Glomerular Filtration Rate (GFR) and Contrast Dose Used During the Procedure *(QI only)*
Measure #6: Radiation Dose Documented *(QI only)*

Structural measures: The experience of the operator and hospital performing PCI has been associated with improved outcomes, and there continue to be standards established in the guidelines. Given evolving evidence in this area, however, we are hesitant to endorse a specific volume threshold within a performance measure. We therefore recommend:

Postprocedural measures that address structural aspects of care
Measure #9: Regional or National PCI Registry Participation
Measure #10: Annual Operator PCI Volume *(QI only)*
Measure #11: Annual Hospital PCI Volume

For the most part, these clinical performance measures are most suitable for practitioner and/or facility-level quality improvement to achieve better outcomes for patients undergoing PCI. Under certain conditions and unless otherwise indicated, the measures may also be appropriate for accountability if appropriate methodological, statistical, and implementation rules are achieved.[21]

Other Potential Measures: The PCI Work Group also considered several other measures, although we ultimately determined that they were unsuitable at this time for inclusion in the measurement set due to a lack of available evidence, challenges in risk-adjustment, and feasibility of collecting data. Future efforts should reconsider these potential measures as additional literature is generated. These included:

1) Procedural complications (eg, contrast-related nephropathy, bleeding)
2) Patient shared decision-making and knowledge regarding benefits and risks of PCI
3) Angina assessment and treatment
4) Rate of "false-positive" coronary angiograms

Measure Harmonization

As we have noted extensively above, when existing measures were available for the same measurement topics, the PCI Work Group attempted to avoid duplication and to harmonize overlapping measures to the extent feasible.

Technical Specifications Overview

There are several data sources available for collecting performance measures; generally different data sources require different sets of measure specifications, due to the structure of the systems storing the data. The PCPI™ plans to focus on the development of EHR specifications for current and future measure development projects, consistent with the information shared at the PCPI membership meeting held in October 2011. This new focus will align the PCPI with national initiatives that highlight the benefits and wealth of data that EHRs bring to healthcare. The PCPI™ intends to maintain prospective claims specifications for measures that are currently reportable in national reporting programs.

Additional detailed information regarding PCPI Specifications Methodology is included in the Technical Specifications section of this document.

Another venue for advancing this work in EHR data measurement is the AMA/NCQA/HIMSS Electronic Health Record Association (EHRA) Collaborative (see www.ama-assn.org/go/collaborative).

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Testing and Implementation of the Measurement Set

Performance measures in the set are being made available without any prior testing for reliability. The PCPI will welcome the opportunity to promote the initial testing of these measures and to ensure that any results available from testing are used to refine the measures before broader implementation. An initial analysis of the current feasibility of the measures within the framework of available data in the CathPCI Registry has been conducted and is provided.

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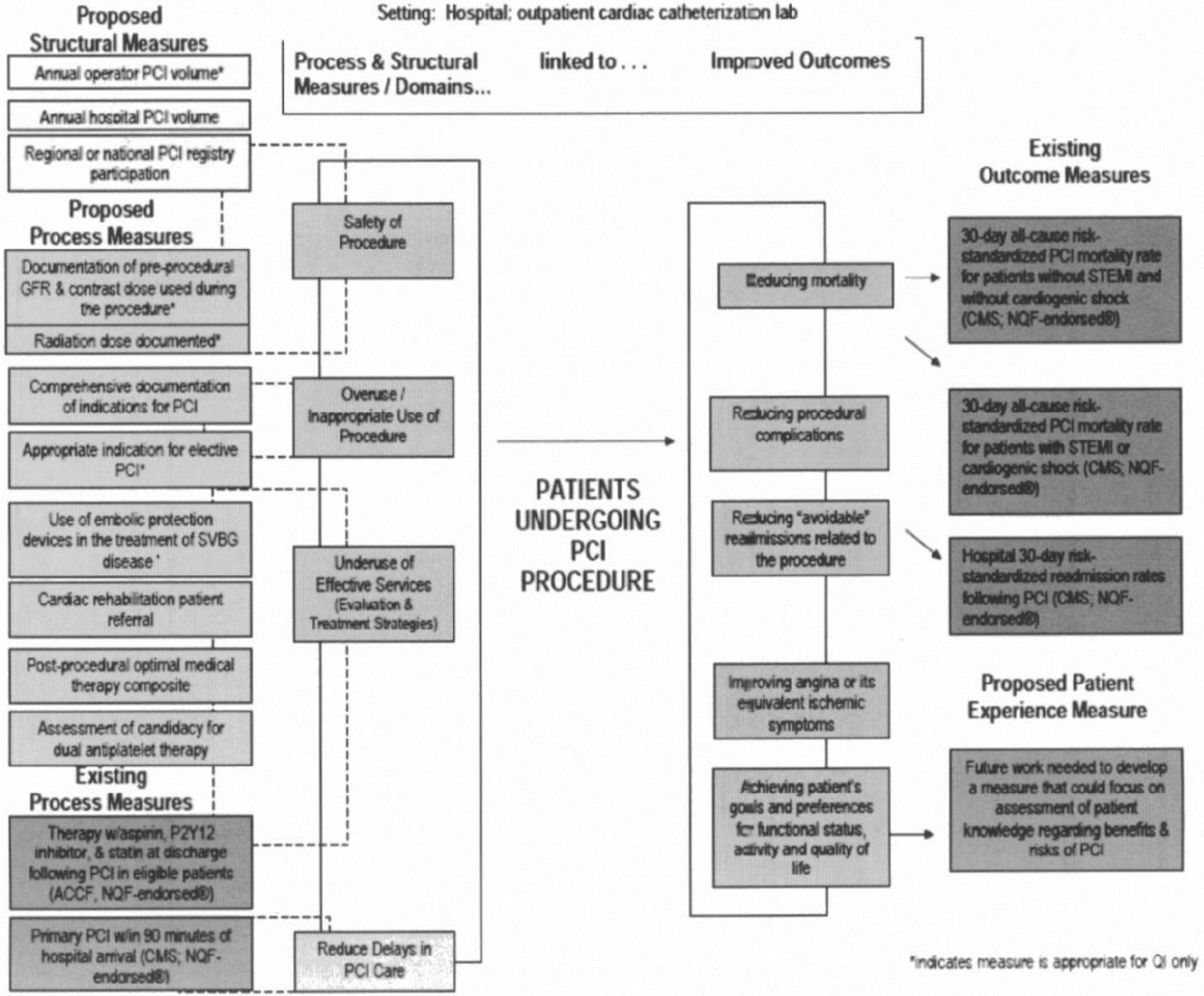
Link to Outcomes:

The proposed measurement set includes measures that focus on the appropriate application of PCI, effective therapeutic options following the procedure, enhancing patient safety and the avoidance of adverse events, and important structural aspects of care. The proposed measures are intended to be complementary to existing process measures for patients undergoing PCI and outcomes measures for mortality and readmission.



Purpose of Measurement Set

The American College of Cardiology Foundation (ACCF), American Heart Association (AHA), the Society for Cardiovascular Angiography and Interventions (SCAI), the American Medical Association (AMA)-convened Physician Consortium for Performance Improvement (PCPI), and the National Committee for Quality Assurance (NCQA) formed a Percutaneous Coronary Intervention (PCI) Work Group to identify and define quality measures toward improving outcomes for patients undergoing PCI. The Work Group aimed to develop a comprehensive set of measures that support the efficient delivery of high quality health care in each of the Institute of Medicine's (IOM) six domains for quality improvement (safe, effective, patient centered, timely, efficient, and equitable).[22]

In this document, PCI refers to a broad group of endovascular techniques for treating coronary atherosclerosis, including balloon angioplasty, implantation of intracoronary stents, and coronary atherectomy or thrombectomy.[23] For the specific purposes of the set of measures we propose, we have adopted the definition used by the CathPCI Registry which defines PCI "as the placement of an angioplasty guide wire, balloon, or other device (eg, stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization".[24] Future iterations of this work will consider expanding the definition of PCI, as newer technologies evolve, or including adjunctive diagnostic technologies (eg, intravascular ultrasound or fractional flow wire/coronary Doppler flow wire) where the measurement of performance may be relevant for PCI.

The Work Group was tasked with developing performance measures that reflect the most rigorous clinical evidence and address areas most in need of improvement. We discuss relevant outcome measures already available for PCI, but were hesitant to replicate earlier efforts that have provided sufficient measures in these instances. As a result, this measurement set includes process and structural measures that address areas most in need of improvement.

Importance of Topic

PCI is the most commonly performed type of coronary revascularization in the United States, facilitating the relief of angina for patients with chronic stable coronary artery disease and saving lives and preventing reinfarction for patients with acute coronary syndromes. In this document, we draw a clear distinction between the emergent use of PCI for patients with ST-segment elevation myocardial infarction (STEMI), termed 'primary PCI,' and all other procedures, which are included under the term 'non-emergent PCI.'"[23] A special term is utilized for 'elective PCI', which refers to PCI performed in the setting of chronic stable CAD in the outpatient setting and excludes all patients with acute coronary syndromes.

Prevalence and Incidence

- Approximately 600,000 PCI procedures are performed each year in the United States.[1]
- Of PCI procedures performed in the United States, approximately two thirds are performed in men and 51% are performed in patients 65 years or older.[1]
- Among cardiovascular services provided to Medicare beneficiaries from 1999 to 2004, PCI grew faster than other cardiovascular services with an average annual change in volume of+7.0% per Medicare beneficiary.[25]
- In more recent years, data from the Medicare Payment Advisory Commission indicate the rate of growth for PCI has slowed and even begun to decrease. From 2004 through 2008, there was an average annual change in volume of -2.5% per Medicare beneficiary. From 2008 to 2009, there was a decrease of -1.1% per Medicare beneficiary.[26] Despite this slight decrease, PCI remains one of the most commonly performed major procedures in the United States, affecting a large number of patients.

Mortality, Morbidity and Quality- of- Life

- Unadjusted, in-hospital mortality rates for PCI range from 0.4-1.9%.[3] Mortality for PCI has remained stable during recent years despite an increase in the proportion of high-risk patients undergoing the procedure.[1]

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- PCI has established benefits in decreasing fatal and nonfatal ischemic complications in acute myocardial infarction and other high-risk acute coronary syndromes.[12]
- The benefits of elective PCI for chronic stable coronary artery disease over medical therapy include the relief of angina and improved quality of life, although there is no reduction noted in mortality or subsequent risk of acute myocardial infarction.[27]

Cost

- Estimates suggest each PCI costs over $12,000, but vary based on the patient and clinical context.[4] Initial hospitalization costs, including index and repeat procedures for PCI were found to be $27,560 in the SYNTAX trial, a large randomized clinical trial comparing PCI with coronary artery bypass grafting (CABG). Follow-up costs over one year brought the total costs for PCI to $35,991 in patients with multivessel CAD.[5]
- Drug-eluting coronary stents are increasingly being used during PCI. This technology is estimated to have added approximately $1.6 billion in annual Medicare expenditures from 2003 through 2006 among beneficiaries aged 66 to 85 years old. The largest cost increase occurred among patients without acute coronary syndromes.[6] Notably, the release of drug-eluting coronary stents has also importantly been associated with lower rates of repeat revascularization and a decrease in cost of revascularization procedures.[28]
- While PCI rates have increased over time, rates of CABG have decreased. Medicare billing data from 2001-2008 indicate that the mean annual rate of CABG declined by 5%.[29] The SYNTAX trial reported that CABG costs at initial hospitalization and one year follow-up were higher than for PCI, although the differences between the 2 types of coronary revascularization decreased over time.[5]

Opportunity for Improvement

Outcomes

Unadjusted, in-hospital mortality rates for PCI range from 0.4-1.9%.3 A report from the state of New York reported the overall in-hospital/30-day observed mortality rate following PCI as 0.95% and noted substantial variation across hospitals with risk adjusted mortality rates ranging from 0.00 percent to 4.45 percent.[30]

Although mortality rates after PCI in contemporary practice are low, approximately 1 in 7 fee for service Medicare patients who undergo PCI are readmitted within 30 days of hospital discharge. Median readmission rates vary significantly across hospitals with rates of 8.9% in the lowest decile to 22.0% in the highest decile. Readmissions were associated with additional coronary revascularization procedures in 27.5% of cases and also associated with an increased risk of mortality.[9]

There is some evidence that variation in outcomes may be related to differences in processes of care which also vary across hospitals and lead to important gaps in care.

Appropriate use of PCI

Among hospital referral regions, PCI rates range nationally from 5 to 42 procedures per 1,000 Medicare beneficiaries.[7] The extent to which this variation may be due to underuse in some regions or overuse in others remains unknown. This makes standardization of approaches to PCI use an important opportunity.

Underuse

A 2001 study assessing the use of coronary revascularization procedures identified substantial underuse among patients for whom the procedure was rated as appropriate by an expert panel. In particular, 34% of patients classified as appropriate for PCI did not undergo the procedure. This underuse was associated with an increase in the risk of adverse clinical outcomes.[31]

Another study compared the use of revascularization within regions with high and low rates of PCI. The authors concluded that rates of PCI varied both because of overuse of the procedure in regions with high rates and underuse in regions with low rates.[32]

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Although these data raise concerns regarding underuse, they are outdated and do not consider changes in both PCI and medical therapy, as well as our overall understanding of revascularization, in the last decade.

Overuse
An analysis of the CathPCI Registry found that 98.6% of PCIs performed in acute settings were classified as appropriate according to appropriate use criteria for coronary revascularization. However, in non-acute settings, only 50% of PCIs were classified as appropriate, while 38% were uncertain, and 12% were inappropriate. A rating of uncertain implies that the procedure may be reasonable but more research, more patient specific information, or both would be needed to further classify the indication. Additionally, significant hospital-level variation in rates of inappropriate PCIs occurred in nonacute settings, ranging from 0% to 55%.8

Additional research also suggests opportunities for reducing the potential overuse by possibly increasing ischemia driven revascularization. A study indicated that the majority of Medicare patients with stable CAD do not have documentation of ischemia by noninvasive testing prior to elective PCI with regional variation in the proportion of patients with stress tests prior to PCI ranging from 22% to 71% among hospital referral regions.[33] The use of invasive FFR to direct ischemia driven revascularization has been shown to improve clinical outcomes and may be considered an invasive way to evaluate patients going directly to the catheterization laboratory due to increasing symptoms.[34,15]

In an effort to inform measure development, the PCPI sought to obtain and analyze data on the appropriate use of PCI in the non-elderly population in order to assess (1) variations in the use of PCI and (2) the extent to which the variations are associated with patient demographics, geographic location, and clinical conditions. Detailed findings are included in Appendix 1.

Processes of Care

Medical management and rehabilitation following the procedure
For PCI to be used in the most efficacious manner, it is important to consider its role in the context of optimal medical therapy. Borden and colleagues examined the use of optimal medical therapy both before and after PCI in the CathPCI Registry from 2005 to 2009. Optimal medical therapy was defined as patients being prescribed aspirin or thienopyridine, beta-blocker, and a statin, or having contraindications to these therapies. Among patients meeting study criteria, composite use of these evidence-based drugs (or reported contraindications to them) was 44% of patients before PCI and 65% patients following PCI.[10]

Long-term adherence with medical therapy also continues to be a challenge. One study found that approximately 14% of patients inappropriately discontinued thienopyridines after placement of a drug-eluting stent, which significantly increased their risk of stent thrombosis.[35] A second study found that despite strong recommendations to take thienopyridines in an uninterrupted fashion for 12 months, 6.9% of patients never filled a single prescription after hospital discharge, 1 in 5 patients had suboptimal adherence, and more than 1 in 4 patients discontinued thienopyridines within 6 months after drug-eluting stent placement.[36]

Finally, despite evidence demonstrating an association between use of cardiac rehabilitation after PCI and improvements in outcomes, a minority of patients - approximately 40% - participated in these programs.[11]

Disparities
2009 data indicated that PCIs were performed twice as often for males than females.[37] Research has found that women are referred for diagnostic catheterization less frequently than men, are less likely to receive PCI, and experience longer delays to treatment in the setting of STEMI.[12]

Furthermore, several studies have examined the use of coronary revascularization, including time to treatment during STEMI, by race and ethnicity.

- Data from the National Registry of Myocardial Infarction (NRMI) were analyzed from 1999 to 2002 for patients hospitalized with STEMI. Door-to-balloon times for black or Hispanic patients were found to be significantly longer than for white patients. Although these

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racial/ethnic differences were reduced after accounting for differences in hospital mean times to treatment, they remained significant and persisted after multivariable adjustment.[38]

- NRMI data were analyzed more recently and identified significant sex and racial differences in rates of coronary angiography. More specifically, for white men, white women, black men, and black women rates were as follows: 69.1, 55.9, 64.0, and 55.0 percent, respectively.[39]

- An analysis of Medicare claims data of patients admitted for ischemic heart disease also identified racial and ethnic disparities. While Black and American Indian patients undergo invasive diagnostic and surgical revascularization far less often than Whites, the authors found that Asians and Hispanics were slightly more likely than whites to undergo revascularization.[40]

- A study by Hravnak et al. found that symptoms expressed by patients with coronary heart disease may vary by race, with Black patients expressing more dyspnea. The findings also indicate that shortness of breath is associated with a lower likelihood that physicians will recommend coronary revascularization, even with documented significant stenosis on catheterization, regardless of race. There was no significant difference in the recommendations for coronary revascularization by race.[41]

The PCPI believes that, when feasible, performance measure data should be stratified by race, ethnicity, and primary written and spoken language to assess disparities and initiate subsequent quality improvement activities addressing identified disparities. These categories are consistent with national efforts to standardize the collection of race and ethnicity data. A 2008 NQF report endorsed 45 practices including stratification by the aforementioned variables.[42] A 2009 IOM report "recommends collection of the existing Office of Management and Budget (OMB) race and Hispanic ethnicity categories as well as more fine-grained categories of ethnicity (referred to as granular ethnicity and based on one's ancestry) and language need (a rating of spoken English language proficiency of less than very well and one's preferred language for health-related encounters)."[43]

Clinical Evidence Base

Clinical practice guidelines serve as the foundation for the development of performance measures. Relevant guidelines from ACCF/AHA/SCAI for the appropriate application and management of PCI, published in 2011[13], were reviewed during the development process. Additional guidelines from the AHA/ACCF and other groups that focused on specific dimensions in the care of patients undergoing PCI were also considered.

Relevant guidelines met all of the required elements and many, if not all, of the preferred elements outlined in a PCPI position statement establishing a framework for consistent and objective selection of clinical practice guidelines from which PCPI Work Groups may derive clinical performance measures.[44]

Appropriate use criteria developed by ACCF in collaboration with other organizations were also reviewed during the development process.[15] These criteria "reflect an ongoing effort to critically and systematically create, review, and categorize the appropriate use of cardiovascular procedures and diagnostic tests"[45] and are developed by a "process that combines evidence-based medicine and practice experience by engaging a technical panel in a modified Delphi exercise."[45] We supplemented guidelines by also considering appropriate use criteria for indications where significant consensus had been reached about the need for coronary revascularization.

Performance measures, however, are not clinical practice guidelines or appropriate use criteria. They cannot capture the full spectrum of care for all patients undergoing PCI, nor are they meant to do so. Instead, performance measures are meant to emphasize the strongest recommendations within these documents that represent the highest level of evidence and the greatest opportunity to improve PCI care.

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Outcome Measures

Ideally, a set of performance measures would include measures of outcomes as well as key process and structural measures known to positively influence desirable outcomes. Desired outcomes for PCI include:

1. Reducing mortality (including short and long-term)
2. Improving angina or its equivalent ischemic symptoms
3. Achieving patient's goals and preferences for functional status, level of activity, quality of life
4. Reducing procedural complications
5. Reducing "avoidable" readmissions related to the procedure

Several outcome measures for mortality in patients undergoing PCI have previously been developed and many are endorsed by the NQF, including

Measure	Developer
30-day all-cause risk-standardized mortality rate following percutaneous coronary intervention (PCI) for patients without ST segment elevation myocardial infarction (STEMI) and without cardiogenic shock *(NQF- endorsed®)*	Centers for Medicare and Medicaid Services (CMS)
30-day all-cause risk-standardized mortality rate following Percutaneous coronary intervention (PCI) for patients with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock *(NQF- endorsed®)*	CMS
In-hospital risk adjusted mortality for percutaneous coronary intervention (PCI) *(NQF- endorsed®)*	ACC
Hospital 30-day risk-standardized readmission rates following percutaneous coronary intervention (PCI) *(NQF- endorsed®)*	CMS

The existing NQF-endorsed® outcome measures, developed by CMS, addressing mortality rate at the institutional or system level were well-developed and incorporate risk-adjustment methodology to account for significant differences in patient populations across hospitals. These measures are currently implemented nationwide and should continue to be collected and assessed. In addition, the ACC also has developed standardized outcome measures for reporting quality of PCI among hospitals participating in the CathPCI registry, including measures for mortality. Most recently, the NQF has endorsed a risk-adjusted outcome measure for readmission in patients undergoing PCI as well. For additional details about these outcomes measures, please visit the NQF web site at www.qualityforum.org. We are unaware of existing outcome measures focused on specific procedural complications or improvement in angina, health status or quality of life.

Although we strongly endorse the use of mortality measures, we have avoided duplicating these earlier efforts by national organizations. These earlier efforts have been extensive and highly visible. We hope that this will minimize confusion by users of performance measures. The Work Group did consider other outcomes measures as well but felt that the availability of evidence as well as the feasibility of data collection prevented us from pursuing such options at this time. We believe this will be a key area of development for future Work Groups.

Process and Structural Measures

A few key process measures already in place also exist for PCI in the setting of STEMI. For example, the measurement of time to reperfusion (ie, door-to-balloon time) is endorsed by the NQF. For the reasons noted above, we did not create a replicated measure and refer readers to these earlier efforts.

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Following PCI, secondary prevention for CAD is essential as part of long-term therapy reducing future morbidity and mortality.[13] A number of performance measures addressing secondary prevention in the ambulatory setting for patients with CAD have been developed and are recommended to be incorporated as critical components of long-term patient management following PCI. In general, the PCI Work Group agrees with and supports the use of performance measures outlined in documents for STEMI and non-STEMI[16] and CAD/HTN.[17] Additional measures included in the CAD set focus on assessing patient's symptoms and subsequent management and are of particular importance both before and after PCI, given that the control of symptoms is one of the primary goals of treatment. In cases where the Work Group felt that the need was urgent or specific enough for PCI (eg, use of cardiac rehabilitation), we developed a new measure to focus on this specific patient population.

Together with the proposed measures from the PCI Work Group, we believe these measures can provide a view of care quality and hospital or physician performance, as appropriate.

Intended Audience, Care Setting, and Patient Population

The PCPI encourages use of these measures by physicians and other health care professionals, where appropriate, to manage the care for all patients aged 18 years and older for whom PCI is performed.

PCI Work Group Recommendations

The PCI Work Group has recommended several new process and structural measures across the continuum of "preprocedural," "procedural" and "postprocedural" PCI processes and structures that relate to providing optimal PCI care. The proposed measurement set includes measures that focus on the appropriate application of PCI, effective therapeutic options following the procedure, enhancing patient safety and the avoidance of adverse events, and important structural aspects of care. The proposed measures are intended to be complementary to existing process measures for patients undergoing PCI and outcomes measures for mortality and readmission.

The PCI Work Group identified several other desired outcomes for patients who undergo PCI (see "PCI Outcomes and Other National Efforts" section above). Current quality gaps in the care of patients undergoing PCI emphasize the need to also improve specific processes that have been demonstrated to improve PCI outcomes (eg, the assessment of candidacy for dual-antiplatelet therapy, prescription of optimal medical therapy at discharge, appropriate identification of patients for the procedure). As a result, several measures in the measurement set focus on the provision of effective patient care.

For the most part, these clinical performance measures are most suitable for practitioner and/or facility-level quality improvement to achieve better outcomes for patients undergoing PCI. Under certain conditions and unless otherwise indicated, the measures may also be appropriate for accountability if appropriate methodological, statistical, and implementation rules are achieved.[21]

Distinction between Measures for Accountability and Quality Improvement or Measures for Quality Improvement Only

Measures that can be used for accountability provide information that can assist stakeholders in making choices about providers.[18] Accountability measures, such as those used in public reporting to facilitate comparisons across clinicians or facilities or possibly pay for performance programs, must meet certain attributes that would permit such a designation. In particular, these measures must be developed through a rigorous measure development process including a public comment and peer review period. These measures must also be based on guideline recommendations that were prioritized due to several important variables (ie, the clinical importance of the intervention and link to desired outcomes, the strength of evidence and strength of recommendation, gaps in care, validity, and feasibility). These criteria are consistent with those put forth by Chassin et al.[19] and the ACC/AHA Task Force On Performance Measures.[20] These measures are also intended to promote quality improvement. On the other hand, quality improvement *only* measures provide information that should be of value to stakeholders responsible for improving the quality of care[18] and cannot be used for accountability purposes.

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Quality improvement only measures fail to meet at least one of the aforementioned desired attributes and require further validation and testing.

Process measures: Several key processes of care have been linked to desirable outcomes for patients undergoing PCI. Based on guidelines and AUC for coronary revascularization, we recommend:

Preprocedural measures that address potential overuse of procedure
Measure #1: Comprehensive Documentation of Indications for PCI
Measure #2: Appropriate Indication for Elective PCI *(QI only)*
Procedural measure that addresses underuse of effective services (evaluation and treatment strategies)
Measure #4: Use of Embolic Protection Devices in the Treatment of Saphenous Vein Bypass Graft Disease *(QI only)*
Postprocedural measures that address underuse of effective services (evaluation and treatment strategies)
Measure #7: Post-Procedural Optimal Medical Therapy Composite
Measure #8: Cardiac Rehabilitation Patient Referral
Preprocedural measure that addresses safety
Measure #3: Assessment of Candidacy for Dual Antiplatelet Therapy
Postprocedural measures that address safety
Measure #5: Documentation of Pre-Procedural Glomerular Filtration Rate (GFR)and Contrast Dose Used During the Procedure *(QI only)*
Measure #6: Radiation Dose Documented *(QI only)*

Structural measures: The experience of the operator and hospital performing PCI has been associated with improved outcomes, and there continue to be standards established in the guidelines. Given evolving evidence in this area, however, we are hesitant to endorse a specific volume threshold within a performance measure. We therefore recommend:

Postprocedural measures that address structural aspects of care
Measure #9: Regional or National PCI Registry Participation
Measure #10: Annual Operator PCI Volume *(QI only)*
Measure #11: Annual Hospital PCI Volume

These measures support the efficient delivery of high quality health care in many of the Institute of Medicine's (IOM) six aims for quality improvement[22] as described in the following table:

IOM Domains of Health Care Quality		Safe	Effective		Patient-centered	Timely	Efficient	Equitable
			Underuse	Overuse				
Measures								
1	Comprehensive Documentation of Indications for PCI		√	√			√	√
2	Appropriate Indication for Elective PCI *(QI only)*			√	√		√	√
3	Assessment of Candidacy for Dual Antiplatelet Therapy	√			√			√
4	Use of Embolic Protection Devices in the Treatment of Saphenous Vein Bypass Graft Disease *(QI only)*		√					√
5	Documentation of Pre-Procedural Glomerular Filtration Rate (GFR) and Contrast Dose Used During the Procedure *(QI only)*	√						√
6	Radiation Dose Documented*(QI only)*	√						√

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7	Post-Procedural Optimal Medical Therapy Composite		√					√
8	Cardiac Rehabilitation Patient Referral		√					√
9	Regional or National PCI Registry Participation		√					√
10	Annual Operator PCI Volume *(QI only)*	√						√
11	Annual Hospital PCI Volume	√						√

Other Potential Measures

The PCI Work Group also considered several other measures, although we ultimately determined that they were unsuitable at this time for inclusion in the measurement set.

For example, the Work Group examined the possibility of including additional outcome measures in the resulting measurement set. In particular, the Work Group discussed including measures that evaluated specific post-procedure complications (eg, contrast related nephropathy, blood transfusion post-procedure). The difficulty in constructing risk-adjusted measures around these complications was too challenging to justify their inclusion as performance measures at this time. CathPCI Registry now has risk-adjusted models for acute kidney injury and for bleeding that are being reported and tested and will help inform future measure development efforts.

In addition, the Work Group considered 3 areas where innovative performance measures might be worthwhile. First, we considered a measure to assess patient knowledge of the procedure prior to PCI. Various studies have demonstrated that a large majority of patients with chronic stable angina believe incorrectly that elective PCI provides a mortality benefit and reduces their risk of myocardial infarction.[27,46,47] Although the Work Group explored creating a measure that would assess adequate knowledge about the benefits and harms of PCI, without a validated tool the concept was felt to be premature to serve as the basis for a performance measure at this time. Constructing measures that assess patient knowledge is a critical next step for the field of performance measurement, in general, and for PCI, in particular. Second, we explored the possibility of a measure to assess underuse. Yet, because of a lack of existing data on the prevalence of this concern as well as its more relevant role in 'upstream' decision-making about cardiac catheterization, the Work Group was less enthusiastic about a performance measure at this time. Finally, we considered the potential for generating several performance measures around 'scenarios' for identifying inappropriate indications for PCI. However due to the complexity of decision-making regarding the appropriate use of elective PCI, we felt that the best approach would be to initially generate a 'combined' measure for quality improvement only (see Measure 2 above) with the hope of refining this measure in the future as additional data become available.

Measure Harmonization

As we have noted extensively throughout earlier sections of the document, when existing hospital-level or plan-level measures are available for the same measurement topics, the PCI Work Group attempted to avoid duplication and to harmonize overlapping measures to the extent feasible. Special attention was paid to the measures that are included in the CathPCI Registry, as well as measures developed by CMS.

Please see individual measure documentation for additional information regarding measure harmonization.

Technical Specifications: Overview

There are several data sources available for collecting performance measures; generally different data sources require different sets of measure specifications, due to the structure of the systems storing the data. The PCPI recognizes that Electronic Health Records (EHRs) are the state of the art for clinical encounters and is focusing significant resources and expertise toward specifying

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and testing measures within EHRs, as they hold the promise of providing the relevant clinical data for measures and for providing feedback to physicians and other health care providers that is timely and actionable.

While the PCPI values prospective claims reporting programs and the data these programs can provide, the PCPI is looking to leverage the data in EHRs. This new focus will align the PCPI with national initiatives that highlight the benefits and wealth of data that EHRs bring to healthcare. The PCPI intends to maintain prospective claims specifications for measures that are currently reportable in national reporting programs.

PCPI Specifications Staff have identified the data elements required to collect and calculate the PCI measures in an electronic health record. The identification of data elements is the first step in developing specifications for implementation in an EHR. The data elements are classified according to the National Quality Forum's Quality Model, Version 2.1 (QDM). The QDM is a framework that can be used to clearly define concepts used in quality measures and clinical care. It provides a standardized method to describe data elements for electronic health record capture. Additional background information on the Quality Data Set can be found on the NQF Website at:
http://www.qualityforum.org/Projects/h/QDS_Model/Quality_Data_Model.aspx

Another venue for advancing this work in EHR data measurement is the AMA/NCQA/HIMSS Electronic Health Record Association (EHRA) Collaborative (see www.ama-assn.org/go/collaborative).

To inquire about future development of eSpecifications (referenced above) for PCI measures, contact the AMA-PCPI at pcpiconsulting@ama-assn.org.

Measure Exclusions and Exceptions

Measure Exclusions
In the context of physician performance measurement, exclusions arise when the intervention required by the numerator is not appropriate for a group of patients who are otherwise included in the initial patient or eligible population of a measure (ie, the denominator). Exclusions are absolute and are to be removed from the denominator of a measure and therefore clinical judgment does not enter the decision.

Measure Exceptions
Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. Otherwise, the patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences.

For ***process measures***, the PCPI provides three categories of reasons for which a patient may be excluded from the denominator of an individual measure:

- **Medical reasons**
  Includes:
  - not indicated (absence of organ/limb, already received/performed, other)
  - contraindicated (patient allergic history, potential adverse drug interaction, other)

- **Patient reasons**
  Includes:
  - patient declined
  - social or religious reasons
  - other patient reasons

- **System reasons**
  Includes:
  - resources to perform the services not available
  - insurance coverage/payor-related limitations
  - other reasons attributable to health care delivery system

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These measure exception categories are not available uniformly across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. For some measures, examples have been provided in the measure exception language of instances that would constitute an exception. Examples are intended to guide clinicians and are not all-inclusive lists of all possible reasons why a patient could be excluded from a measure. The exception of a patient may be reported by appending the appropriate modifier to the CPT Category II code designated for the measure:

- **Medical reasons**: modifier 1P
- **Patient reasons**: modifier 2P
- **System reasons**: modifier 3P

Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the *specific* reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception.

Please refer to documentation for each individual measure for information on the acceptable exception categories and the codes and modifiers to be used for reporting. The full position statement[18] that discusses exclusions/exceptions and their use may be accessed through the PCPI website (www.physicianconsortium.org).

Testing and Implementation of the Measurement Set

The measures in the set are being made available without any prior testing for reliability. The PCPI recognizes the importance of testing all of its measures and encourages testing of the PCI measurement set by organizations or individuals positioned to do so. The Measure Testing Protocol for PCPI Measures was approved by the PCPI in 2007 and is available on the PCPI web site (see Position Papers at www.physicianconsortium.org); interested parties are encouraged to review this document and to contact AMA professional staff to the PCPI. The PCPI will welcome the opportunity to promote the initial testing of these measures and to ensure that any results available from testing are used to refine the measures before broader implementation.

Feasibility Testing

An initial analysis of the current feasibility of many of the measures within the CathPCI registry has been conducted.

The five process measures analyzed have varying degrees of feasibility. Of these measures, three require data not currently available through the registry. For the proposed appropriate indication for elective PCI measure, the registry collects data elements that correspond to many of the indications included within the measure, however, the data for sudden cardiac death or life-threatening VT is only captured within 24 hours of cardiac arrest. The measures for assessment of candidacy for dual anti-platelet therapy and optimal medical therapy will also require data that is not currently available through the registry. These data may be able to be obtained through other data sources specified in the measures, including electronic health record systems. These additional sources of data may enable measure testing and feasibility for measures where current registry data are unavailable.

Two of the structural measures in the PCI measurement set are based on evidence linking patient outcome to PCI operator volume and hospital procedure volume. For operators and hospitals with CathPCI Registry procedures, the data regarding the mean annual volume of PCIs performed over 3 years should be available. As long as facilities are submitting current data, the implementation of these measures should be feasible. Since these measures do not provide for exceptions in the denominator, excluding facilities that do not meet data quality inclusion criteria does not present any significant challenges to implementation.

Please refer to appendix 2 for a detailed analysis of the feasibility testing results.

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Measure #1: Comprehensive Documentation of Indications for PCI

Percutaneous Coronary Intervention

Measure Description

Percentage of patients aged 18 years and older for whom PCI is performed with comprehensive documentation for the procedure that includes, at a minimum, the following elements: priority (acute coronary syndrome, urgent, elective, emergency/salvage); presence and severity of angina symptoms; use of antianginal medical therapies within two weeks prior to the procedure, if any; presence, results, and timing of non-invasive stress test, fractional flow reserve (FFR), or intravascular ultrasound (IVUS), if performed; and significance of angiographic stenosis (may be quantitative or qualitative) on coronary angiography for treated lesion

Measure Components

Numerator Statement	Patients with comprehensive documentation for the procedure that includes, at a minimum, the following elements: • Priority: acute coronary syndrome, urgent, elective, emergency/salvage • Presence and severity of angina symptoms [eg, Canadian Cardiovascular Society Classification (CCS) system] • Use of antianginal medical therapies within two weeks prior to the procedure, if any • Presence, results, and timing of non-invasive stress test, fractional flow reserve (FFR) or intravascular ultrasound (IVUS), if performed • Significance of angiographic stenosis (may be quantitative or qualitative) on coronary angiography for treated lesion
Denominator Statement	All patients aged 18 years and older for whom PCI is performed
Denominator Exclusions	None
Denominator Exceptions	None
Supporting Guideline and Other References	Clinical practice guidelines from ACCF/AHA/SCAI for the appropriate application and management of PCI, published in 2011, include a number of Class I and III revascularization recommendations to improve survival and/or symptoms. Each recommendation is based on the extent and complexity of CAD and includes a variety of patient characteristics identified as key documentation elements within this measure. For these specific guideline recommendation statements, please refer to section 2 of the guidelines as well as the supporting guideline section for measure #2, which are specific to the appropriate use and application of elective PCI.[13] The following statement is quoted **verbatim** from the referenced AUC: Each clinical scenario [in the appropriate use criteria] includes the patient's clinical status/symptom complex, ischemic burden by noninvasive functional testing when presented, burden of coronary atherosclerosis as determined by angiography, and intensity of medical therapy in the determination of the appropriate use of coronary revascularization. (ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT, 2012)[15]

Measure Importance

Relationship to A number of indications for PCI have been identified and enumerated in clinical practice

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desired outcome	guidelines and AUC, including evidence of symptoms and ischemia. Anderson et al. demonstrated a significant relationship between evidence-based indications recommended for PCI and in-hospital outcomes of post-procedure MI, same-admission CABG, and death.[49] In particular, cardiac stress testing to document the presence of ischemia prior to cardiac catheterization and angioplasty has also been associated with lower overall diagnostic costs, shorter hospital stays, and lower rates of revascularization, without adverse effects on cardiac death or myocardial infarction.[33] The characteristics of a patient included as key documentation elements within the measure are important in determining the need and appropriateness of PCI.
Opportunity for Improvement	Data from patients who underwent CABG surgery and PCI without ACS or previous CABG surgery in New York in 2009 and 2010 were analyzed to assess appropriateness and examine variation across hospitals. Of the 33,970 PCI patients eligible for rating, 28% lacked sufficient information to be rated.[50] A recent analysis of the CathPCI Registry to assess the appropriateness of PCI in the U.S. found that many of the PCIs performed during the study period were lacking essential data required to determine the appropriateness of the procedure.[8] Although hospitals participating in the registry collect detailed information on patient characteristics using standardized data elements, the study authors needed to exclude 17% of the PCIs from their appropriateness analysis. The primary reason for exclusion included the absence of documentation on the use of noninvasive stress tests for nonacute procedures. Additional nonacute procedures were excluded as a result of: missing data on extent of ischemia risk in patients with a prior stress test; missing data on symptoms, coronary angiography, or the availability of additional testing (eg, CT angiography or coronary calcium testing). Additionally, a relatively smaller number of acute procedures were excluded due to missing data on symptoms after thrombolysis for STEMI. Finally, another study indicated that the majority of Medicare patients with stable CAD do not have documentation of ischemia by noninvasive testing prior to elective PCI with regional variation in the proportion of patients with stress tests prior to PCI ranging from 22% to 71% among hospital referral regions.[33]
Exception Justification	This measure has no exceptions.
Harmonization with Existing Measures	There are no known similar existing measures therefore harmonization was not applicable to this measure.

Measure Designation

Measure purpose	•	Quality Improvement
	•	Accountability
Type of measure	•	Process
Level of Measurement	•	Facility
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #2: Appropriate Indication for Elective PCI *(QI only)*

Percutaneous Coronary Intervention

Measure Description

Percentage of patients aged 18 years and older for whom elective PCI is performed in a native coronary artery who have an appropriate indication for the procedure that suggests its overall benefits outweigh its risks

Measure Components

Numerator Statement	Patients with at least one of the following indications documented: 1) significant angiographic stenosis (>50%) in the left main coronary artery in a patient at an increased risk for adverse outcomes with coronary artery bypass grafting surgery (eg, Society of Thoracic Surgeons-predicted risk of operative mortality >5% or documentation of consultation with a cardiac surgeon) 2) significant angiographic stenosis (>70%) in the proximal left anterior descending coronary artery in the presence of either: • abnormal non-invasive testing for myocardial ischemia or • CCS class angina ≥1 on guidelines-directed medical therapy that includes at least 2 anti-anginal drugs 3) significant angiographic stenosis (>70%) in a major epicardial artery (excluding the proximal left anterior descending coronary artery) in the presence of either: • an high-risk noninvasive test for myocardial ischemia or • CCS class angina ≥1 on guidelines-directed medical therapy that includes at least 2 anti-anginal drugs 4) borderline angiographic stenosis (eg, 40 to 70%) in a major epicardial artery where an FFR is less than or equal to 0.80 and/or IVUS shows significant reduction in cross-sectional area in the presence of CCS class angina ≥1 on guidelines-directed medical therapy that includes at least 2 anti-anginal drugs 5) demonstration of left ventricular systolic dysfunction (ie, ejection fraction <50%) on most recent non-invasive testing for myocardial ischemia felt to be attributable to a significant angiographic stenosis (>70%) in a major epicardial artery 6) history of sudden cardiac arrest or life-threatening ventricular tachyarrhythmia (eg, ventricular fibrillation or sustained ventricular tachycardia) felt to be attributable to a significant angiographic stenosis (>70%) in a major epicardial artery
Denominator Statement	All patients aged 18 years and older for whom elective PCI is performed in a native coronary artery
Denominator Exclusions	All patients with recent acute coronary syndromes (including unstable angina) within the prior 4 weeks or prior coronary artery bypass grafts
Denominator Exceptions	Documentation of medical reason(s) for performing PCI in patients without the stated indications (eg, significant valvular or structural heart disease, upcoming solid organ transplantation, other medical reasons [inability to tolerate anti-anginal therapy])
Supporting Guideline	The following evidence statements are quoted **verbatim** from the referenced clinical guidelines (emphasis added). PCI ***to improve survival*** is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left

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	main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%). (Class IIa, Level of Evidence: B) (ACCF/AHA/SCAI, 2011)[13] PCI ***to improve survival*** may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality >2%). (Class IIb, Level of Evidence: B) (ACCF/AHA/SCAI, 2011)[13] PCI ***to improve survival*** should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG. (Class III, Level of Evidence: B)(ACCF/AHA/SCAI, 2011)[13] CABG or PCI ***to improve survival*** is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by significant (≥70% diameter) stenosis in a major coronary artery. (Class I, Level of Evidence: C)(ACCF/AHA/SCAI, 2011)[13] The usefulness of PCI ***to improve survival*** is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease. (Class IIb, Level of Evidence: B)(ACCF/AHA/SCAI, 2011)[13] CABG or PCI should not be performed with the primary or sole intent ***to improve survival*** in patients with SIHD with 1 or more coronary stenoses that are not anatomically or functionally significant (e.g., <70% diameter non-left main coronary artery stenosis, FFR>0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium. (Class III, Level of Evidence: B) (ACCF/AHA/SCAI, 2011)[13] CABG or PCI ***to improve symptoms*** is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite [guideline-directed medical therapy (GDMT)]. (Class I, Level of Evidence: A) (ACCF/AHA/SCAI, 2011)[13] CABG or PCI ***to improve symptoms*** is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences. (Class IIa, Level of Evidence: C) (ACCF/AHA/SCAI, 2011)[13] CABG or PCI ***to improve symptoms*** should not be performed in patients who do not meet anatomic (≥50% diameter left main or ≥70% non-left main stenosis diameter) or physiological (e.g., abnormal FFR) criteria for revascularization. (Class III, Level of Evidence: C) (ACCF/AHA/SCAI, 2011)[13] Readers should also refer to the most current ACCF/SCAI/STS/AATS/AHA/ASNC AUC for Coronary Revascularization which are updated regularly according to changes in the guidelines and corresponding evidence.[15]

Measure Importance

Relationship to desired Elective PCI should be performed in patients for whom there is a reasonable expectation of benefit. A number of indications for elective PCI have been identified and enumerated in clinical practice guidelines and AUC, including evidence of symptoms and ischemia.

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outcome	Anderson et al. demonstrated a significant relationship between evidence-based indications recommended for PCI and in-hospital outcomes of post-procedure MI, same-admission CABG, and death.[49] In particular, cardiac stress testing to document the presence of ischemia prior to cardiac catheterization and angioplasty has also been associated with lower overall diagnostic costs, shorter hospital stays, and lower rates of revascularization, without adverse effects on cardiac death or myocardial infarction.[33]
Opportunity for Improvement	Data from patients who underwent CABG surgery and PCI without ACS or previous CABG surgery in New York in 2009 and 2010 were analyzed to assess appropriateness and examine variation across hospitals. Of the patients undergoing PCI who could be rated, 36.1% of the procedures were classified as appropriate, 14.3% were classified as inappropriate, and 49.6% were classified as uncertain. A total of 91% of the PCI patient undergoing inappropriate procedures had 1- or 2-vessel disease without proximal left anterior descending artery disease and had no or minimal anti-ischemic medical therapy. The authors also found significant variability among hospitals with ranges from 1-40% of PCI patients who were inappropriate for revascularization, among hospitals with PCI volumes > 400.[50]An analysis of the large CathPCI Registry found that 98.6% of PCIs performed in acute settings were classified as appropriate according to appropriate use criteria for coronary revascularization. However, in nonacute settings, only 50% of PCIs were classified as appropriate, 38% as uncertain, and 12% as inappropriate. A rating of uncertain implies that more research, more patient information, or both would be needed to further classify the indication. Additionally, there was significant hospital variation in rates of inappropriate PCIs in nonacute settings, ranging from 0% to 55% of the proportion of patients undergoing PCI.8 Additional research also suggests opportunities for improving overuse. A study indicated that the majority of Medicare patients with stable coronary artery disease do not have documentation of ischemia by noninvasive testing prior to elective PCI with regional variation in the proportion of patients with stress tests prior to PCI ranging from 22% to 71% among hospital referral regions. Women and patients treated by physicians performing150 or more PCIs per year were less likely to have stress testing before a PCI.[33]
Exception Justification	The PCI Work Group agreed to include appropriate medical reasons as an exception so that clinicians can exclude patients for whom PCI may be justified even if other criteria are not met (eg, significant valvular or structural heart disease, upcoming solid organ transplantation, other medical reasons [inability to tolerate anti-anginal therapy]).
Harmonization with Existing Measures	There are no known similar existing measures therefore harmonization was not applicable.

Measure Designation

Measure purpose	•	Quality Improvement
Type of measure	•	Process
Level of Measurement	•	Facility
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #3: Assessment of Candidacy for Dual Antiplatelet Therapy

Percutaneous Coronary Intervention

Measure Description

Percentage of patients aged 18 years and older for whom PCI is performed who have documentation in the medical record that an assessment of candidacy for initiation and duration of dual antiplatelet therapy was performed prior to the procedure

Measure Components

Numerator Statement	Patients who have documentation in the medical record that an assessment of candidacy* for initiation and duration of dual antiplatelet therapy (DAPT) was performed prior to the procedure *Examples of assessment may include (but are not limited to) consideration of the following medical and personal issues, such as: • High risk of bleeding • Anticipated invasive or surgical procedures requiring early discontinuation of therapy • Accessibility of medications (eg, cost considerations) • Adherence with medications
Denominator Statement	All patients aged 18 years and older for whom PCI is performed
Denominator Exclusions	None
Denominator Exceptions	Documentation of medical reason(s) for not performing an assessment of candidacy for long-term dual antiplatelet therapy (eg, patient unresponsive, emergency PCI with insufficient time prior to the procedure, other medical reasons)
Supporting Guideline	The following evidence statements are quoted **verbatim** from the referenced clinical guidelines. Before implantation of DES, the interventional cardiologist should discuss with the patient the need for and duration of DAPT and the ability of the patient to comply with and tolerate DAPT. (Class I, Level of Evidence: C) (ACCF/AHA/SCAI, 2011)[13] Patients should be counseled on the need for and risks of DAPT before placement of intracoronary stents, especially DES, and alternative therapies should be pursued if patients are unwilling or unable to comply with the recommended duration of DAPT. (Class I, Level of Evidence: C) (ACCF/AHA/SCAI, 2011)[13] PCI with coronary stenting should not be performed if the patient is not likely to be able to tolerate and comply with DAPT.(Class III, Level of Evidence: B) (ACCF/AHA/SCAI, 2011)[13] DES should not be implanted if the patient is not likely to be able to tolerate and comply with prolonged DAPT or this cannot be determined before stent implantation. (Class III, Level of Evidence: B) (ACCF/AHA/SCAI, 2011)[13]

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Measure Importance

Relationship to desired outcome	Dual antiplatelet therapy after PCI provides protection from thrombotic and cardiovascular ischemic events. The leading adverse event associated with early antiplatelet discontinuation is stent thrombosis, and the majority of these events lead to acute myocardial infarction (MI) or death.[51,52] Evaluating a patient's tolerability of dual antiplatelet therapy may help ensure long-term adherence to minimize risks. Evaluation may also indicate the need for a lower dose of dual antiplatelet therapy to reduce the incidence of bleeding complications.[53]
Opportunity for Improvement	Despite its benefits, antiplatelet therapy is often discontinued within the first year after stent implantation with severe adverse consequences. One study revealed that 14% of patients had discontinued dual antiplatelet therapy 30 days after discharge for stent implantation. Patients who were not taking a thienopyridine at 30 days were less likely to have been given discharge instructions about their medications.[54]A second study found that despite strong recommendations from practice guidelines to take thienopyridine therapy in an uninterrupted fashion for 12 months, 6.9% of patients never filled a single prescription after hospital discharge, 1 in 5 patients had suboptimal adherence, and >1 in 4 patients discontinued thienopyridine within 6 months after drug-eluting stent placement.[36]
Exception Justification	The PCI Work Group agreed to include a medical reason exception so that clinicians can exclude patients for whom the assessment cannot be performed (eg, patient unresponsive, emergency procedure with insufficient time prior to the procedure, other medical reason).
Harmonization with Existing Measures	There are no known similar existing measures therefore harmonization was not applicable to this measure.

Measure Designation

Measure purpose	•	Quality Improvement
	•	Accountability
Type of measure	•	Process
Level of Measurement	•	Individual practitioner
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #4: Use of Embolic Protection Devices in the Treatment of Saphenous Vein Bypass Graft Disease *(QI only)*

Percutaneous Coronary Intervention

Measure Description

Percentage of patients aged 18 years and older for whom saphenous vein graft PCI is performed who received an embolic protection device during the procedure

Measure Components

Numerator Statement	Patients who received an embolic protection device during the procedure
Denominator Statement	All patients aged 18 years and older for whom saphenous vein graft PCI is performed
Denominator Exclusions	None
Denominator Exceptions	Documentation of medical reason(s) for not receiving an embolic protection device during the procedure (eg, anatomic considerations, other medical reasons)
Supporting Guideline	The following evidence statements are quoted verbatim from the referenced clinical guidelines. Embolic protection devices (EPDs) should be used during saphenous vein graft (SVG) PCI when technically feasible. (Class I, Level of Evidence: B) (ACCF/AHA/SCAI, 2011)[13]

Measure Importance

Relationship to desired outcome	Treatment of saphenous vein graft stenosis with PCI is associated with a high incidence of major adverse cardiac events within 30 days following the procedure, particularly in comparison to native-artery PCI.[13,55] The use of an embolic protection device during saphenous vein graft PCIs has been shown to decrease the incidence of these major cardiac events with one trial demonstrating a decreased 30-day composite outcome of death, MI, emergency CABG, or target-lesion revascularization.[56]
Opportunity for Improvement	An analysis from the CathPCI Registry of approximately 91,000 patients who underwent PCI of a saphenous vein graft lesion found that an embolic protection device was used in 23% of patients.[57] Another study focusing more narrowly on saphenous vein graft PCIs *eligible* for an embolic protection device found a use rate of 53%.[58]
Exception Justification	The PCI Work Group agreed to include a medical reason exception so that clinicians can exclude patients with unsuitable anatomy for deployment of an embolic protection device during a saphenous vein graft PCI which research estimates accounts for about half of saphenous vein graft stenoses.[59]
Harmonization with Existing Measures	There are no known similar existing measures therefore harmonization was not applicable to this measure.

Measure Designation

Measure purpose	•	Quality Improvement
Type of measure	•	Process

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Level of Measurement	•	Individual practitioner
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #5: Documentation of Pre- Procedural Glomerular Filtration Rate (GFR) and Contrast Dose Used During the Procedure *(QI only)*

Percutaneous Coronary Intervention

Measure Description

Percentage of patients aged 18 years and older for whom PCI is performed who have both pre-procedural estimated glomerular filtration rate (GFR) or an indication that the patient is on dialysis AND contrast dose administered documented in the catheterization report or procedure notes

Measure Components

Numerator Statement	Patients who have both pre-procedural estimated glomerular filtration rate (GFR) or an indication that the patient is on dialysis AND contrast dose administered* documented in the catheterization report or procedure notes *Contrast dose administered should include the total dose used during both diagnostic and interventional procedures that occur during the same catheterization laboratory session.
Denominator Statement	All patients aged 18 years and older for whom PCI is performed
Denominator Exclusions	None
Denominator Exceptions	None
Supporting Guideline	The following evidence statements are quoted **verbatim** from the referenced clinical guidelines (emphasis added). In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted. (Class I, Level of Evidence: B) (ACCF/AHA/SCAI, 2011)[13] Calculation of the contrast volume to [creatinine clearance (CrCl)] ratio is useful to predict the maximum volume of contrast media that can be given without significantly increasing the risk of contrast-associated nephropathy. (Class I, Level of Evidence: B) (ACCF/AHA, 2011)[60]

Measure Importance

Relationship to desired outcome	Increased use of contrast media during radiological procedures is associated with an increased incidence of contrast-induced nephropathy (CIN). CIN is one of the most common sources of acute renal failure among hospitalized patients and is associated with prolonged in-hospital stay and increased morbidity, mortality, and costs.[61]
Opportunity for Improvement	In patients undergoing coronary angiography, the reported incidence of contrast induced nephropathy (defined as an increase in serum creatinine [Cr] > 0.5 mg/dL from baseline) is 3.3% with approximately 0.26% experiencing acute renal failure requiring hemodialysis.[62] Female patients were found to have a higher incidence of CIN than male patients. Patients with pre-PCI co-morbidities including chronic renal failure, diabetes and hypertension are at higher risk of CIN.[62]
Exception	This measure has no exceptions.

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Justification

Harmonization with Existing Measures	There are no known measures that evaluate the documentation of contrast dose that a patient received during PCI. It is included as a data element for collection in the CathPCI Registry.

Measure Designation

Measure purpose	•	Quality Improvement
Type of measure	•	Process
Level of Measurement	•	Facility
	•	Individual practitioner
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #6: Radiation Dose Documented *(QI only)*

Percutaneous Coronary Intervention

Measure Description

Percentage of patients aged 18 years and older for whom PCI is performed who have radiation dose administered documented in the catheterization report or procedure notes

Measure Components

Numerator Statement	Patients who have radiation dose administered* documented in the catheterization report or procedure notes *Radiation dose administered should include the total dose used during both diagnostic and interventional procedures that occur during the same catheterization laboratory session. Radiation dose administered should include fluoroscopy time, at a minimum, and if possible, total air kerma at the international reference point [$K_{a,r}$] and air kerma-area product [P_{KA}].
Denominator Statement	All patients aged 18 years and older for whom PCI is performed
Denominator Exclusions	None
Denominator Exceptions	None
Supporting Guideline	The following evidence statements are quoted **verbatim** from the referenced clinical guidelines (emphasis added). Cardiac catheterization laboratories should routinely record relevant available patient procedural radiation dose data (e.g., total air kerma at the international reference point [$K_{a,r}$], air kerma [area] product [P_{KA}], fluoroscopy time, number of cine images), and should define thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose. (Class I, Level of Evidence: C). (ACCF/AHA/SCAI, 2011)[13]

Measure Importance

Relationship to desired outcome	Radiation is used extensively in PCI procedures. Exposure to radiation poses risks to patients including deterministic risk of various types of skin injury and stochastic risk of malignant disease.[63] The risk of radiation-related complications in any individual patient cannot be predicted unless that patient's radiation dose is known.[64]
Opportunity for Improvement	Radiation exposure in patients who undergo medical imaging procedures including PCI is not typically monitored. One study found variation in the rates of exposure to radiation from medical imaging procedures. Moderate doses (>3-20 mSv/yr) were incurred at an annual rate of 193.8 per 1000 enrollees, whereas high (>20-50 mSv/yr) and very high doses (>50 mSv/yr) were incurred at an annual rate of 18.6 and 1.9 per 1000 enrollees, respectively.[65]
Exception Justification	This measure has no exceptions.
Harmonization with Existing Measures	There are no known measures that evaluate the documentation of radiation dose that a patient received during PCI. It is included as a data element for collection in the CathPCI Registry.

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Measure Designation

Measure purpose	•	Quality Improvement
Type of measure	•	Process
Level of Measurement	•	Facility
	•	Individual practitioner
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #7: Post- Procedural Optimal Medical Therapy Composite

Percutaneous Coronary Intervention

Measure Description

Percentage of patients aged 18 years and older for whom PCI is performed who are prescribed optimal medical therapy at discharge

Measure Components

Numerator Statement	Patients who are prescribed* all of the medications, for which they are eligible, at discharge *Prescribed may include prescription given to the patient for medications at discharge OR patient already taking medications as documented in current medication list
Denominator Statement	All patients aged 18 years and older for whom PCI is performed who are eligible for any of the following medications (ie, patient has no contraindication, allergy, intolerance): • Aspirin • P2Y12 inhibitor (only for PCIs with stenting) • Statin
Denominator Exclusions	Patients who expired Patients who left against medical advice Patient discharged to hospice or for whom comfort care measures only is documented Patient discharged to other acute care hospital
Supporting Guideline	The following evidence statements are quoted **verbatim** from the referenced clinical guidelines. After PCI, use of aspirin should be continued indefinitely. (Class I, Level of Evidence: A)(ACCF/AHA/SCAI, 2011) The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows: a. In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily, prasugrel 10 mg daily, and ticagrelor 90 mg twice daily. (Class I, Level of Evidence: B) b. In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if the patient is not at high risk of bleeding. (Class I, Level of Evidence: B) c. In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks). (Class I, Level of Evidence: B) (ACCF/AHA/SCAI, 2011) A lipid profile in all patients [with coronary and other atherosclerotic vascular disease] should be established, and for hospitalized patients, lipid lowering therapy as recommended below should be initiated before discharge. (Class I, Level of Evidence: B) (AHA/ACCF, 2011)[66] In addition to therapeutic lifestyle changes, statin therapy should be prescribed in the absence of contraindications or documented adverse effects. (Class I, Level of Evidence: A)

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	(AHA/ACCF, 2011)[66]

Measure Importance

Relationship to desired outcome	After PCI, continued treatment with the combination of aspirin and $P2Y_{12}$ inhibitor therapy appears to reduce major adverse cardiovascular events.[13]The use of statin therapy lowers lipids and also has a favorable effect on platelet adhesion, thrombosis, endothelial function, inflammation, and plaque stability, which may potentially improve outcomes after PCI and reduce the risk of major adverse cardiac events. Statin therapy within the first year after PCI is associated with reduced mortality and morbidity including myocardial infarction.[67,68]
Opportunity for Improvement	The rate of prescribed optimal medical therapy after PCI is suboptimal.[10] CathPCI Registry data from January 2010 through June 2011 were analyzed to provide a contemporary snapshot of PCI as performed in the United States. While many patients without contraindications were receiving aspirin, P2Y12 inhibitor, and statin therapy, there remains an opportunity for improvement. Among the nearly 1500 facilities voluntarily participating in the CathPCI Registry, the 50th percentile of aspirin, $P2Y_{12}$ inhibitor, and statin therapy use at discharge was 97.9%, 98.9% and 90.5% respectively. [69]
Exception Justification	The PCI Work Group agreed to include a medical reason exception so that clinicians can exclude patients for whom the prescription of aspirin, $P2Y_{12}$ inhibitor, or statin therapy may not be appropriate (eg, allergy, intolerance, other medical reasons for not prescribing the therapy at discharge). A patient reason exception has been included for patients who might decline any of these particular pharmacologic agents.
Harmonization with Existing Measures	This measure was harmonized to the extent feasible with the facility-level ACCF measure for therapy with aspirin, $P2Y_{12}$ inhibitor and statin at discharge for patients undergoing PCI.

Measure Designation

Measure purpose	•	Quality Improvement
	•	Accountability
Type of measure	•	Process
Level of Measurement	•	Individual practitioner
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #8: Cardiac Rehabilitation Patient Referral

Percutaneous Coronary Intervention

Measure Description

Percentage of patients aged 18 years and older for whom PCI is performed who have been referred to an outpatient cardiac rehabilitation/secondary prevention (CR) program.

Measure Components

Numerator Statement	Patients who have been referred* to an outpatient CR program** prior to hospital discharge *A referral is defined as an official communication between the healthcare provider and the patient to recommend and carry out a referral order to an early outpatient CR program. This includes the provision of all necessary information to the patient that will allow the patient to enroll in an early outpatient CR program. This also includes a written or electronic communication between the healthcare provider or healthcare system and the CR program that includes the patient's enrollment information for the program. A hospital discharge summary or office note may potentially be formatted to include the necessary patient information to communicate to the CR program (eg, the patient's cardiovascular history, testing, and treatments). All communications must maintain appropriate confidentiality as outlined by the 1996 Health Insurance Portability and Accountability Act [HIPAA].) **The program may include a traditional CR program based on face-to-face interactions and training sessions or may include other options such as home-based approaches. If alternative CR approaches are used, they should be designed to meet appropriate safety standards.
Denominator Statement	All patients aged 18 years and older for whom PCI is performed (Note: Patients for whom PCI is performed who are to be discharged for a short-term stay in an inpatient medical rehabilitation facility are still expected to be referred to an outpatient cardiac rehabilitation program by the in-patient team during the index hospitalization. This referral should be reinforced by the care team at the medical rehabilitation facility.)
Denominator Exclusions	None
Denominator Exceptions	Documentation of medical reason(s) for not referring a patient to an outpatient CR program (eg, patient deemed by provider to have a medically unstable, life-threatening condition) Documentation of patient reason(s) for not referring a patient to an outpatient CR program (eg, patient to be discharged to a nursing care facility for long-term care) Documentation of system reason(s) for not referring a patient to an outpatient CR program (eg, no cardiac rehabilitation program available within 60 minutes of travel time from the patient's home)
Supporting Guideline	The following evidence statements are quoted verbatim from the referenced clinical guidelines. Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted. (Class I, Level of Evidence: A) (ACCF/AHA/SCAI, 2011)[13]

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Measure Importance

Relationship to desired outcome	Evidence clearly shows that patients who participate in cardiac rehabilitation receive a number of health benefits, including the following: • Coordination of post-hospital care through the provision of a medically supervised, comprehensive treatment plan with frequent follow-up and reinforcement during the recuperation phase following a cardiac event.[70] • Improved control of cardiovascular disease risk factors, through aggressive lifestyle changes and the use of appropriate and life-saving preventive medications.[71,72,73] • Cardiac rehabilitation improves psychological health by reducing depression and anxiety among participants. This is important because depression and anxiety are common among cardiac patients, and limit both long-term adherence to therapy and follow-up of care.[74,75,76] • Significant reduction in rehospitalization rates and unnecessary emergency room visits.[77] • Reduction in all-cause mortality rates by approximately 25%.[78,79,80,81,82]
Opportunity for Improvement	Approximately 40% of patients participate in cardiac rehabilitation after PCI despite evidence demonstrating an association between its use and improvements in outcomes.[11] There is significant geographical variation in cardiac rehabilitation participation in the United States. One study of Medicare beneficiaries found that cardiac rehabilitation participation by eligible patients ranged from a low of 7% in Idaho to a high of 56% in Nebraska[83]. Reasons for the under-utilization of cardiac rehabilitation services have been identified, and include patient-related barriers (patient refusal, lack of healthcare insurance, home located far from a cardiac rehabilitation center, etc.), provider-related barriers (provider erroneously omits cardiac rehabilitation referral for patient, provider omits referral due to a medical contraindication, etc.), and healthcare system-related barriers (language/cultural barriers, lack of functioning cardiac rehabilitation services, limited capacity or hours of operation for the cardiac rehabilitation program, etc.)[84,85]. Systematic approaches to improve referral rates appear to improve patient participation in cardiac rehabilitation programs and the anticipated health outcomes. The CHAMP and Get With The Guidelines projects have demonstrated significant improvements in the number of patients referred to outpatient cardiac rehabilitation programs using a systematic referral process. Other studies, using such processes as standing orders for referral, have also been shown to increase referral rates[86,87,88,89].
Exception Justification	Patients who are potentially eligible for cardiac rehabilitation may have barriers that limit their participation. A medical reason exception has been included so that clinicians can exclude patients who have a high-risk condition or a contraindication to exercise that prevent their participation in cardiac rehabilitation. A patient reason exception has been included so that patients discharged to a nursing care facility for long-term care can be excluded. Additionally, a system reason exception has been included to account for the potential unavailability of a cardiac rehabilitation/secondary prevention program in the patient's community.
Harmonization with Existing Measures	This measure has been adapted from the AACVPR/ACCF/AHA 2010Update: Performance Measures on Cardiac Rehabilitation for Referral to and Delivery of Cardiac Rehabilitation/Secondary Prevention Services.[90]

Measure Designation

Measure purpose	•	Quality Improvement
	•	Accountability
Type of measure	•	Process
Level of Measurement	•	Facility
Care setting	•	Hospital OR

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	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #9: Regional or National PCI Registry Participation

Percutaneous Coronary Intervention

Measure Description

Participation in a national or multi-system geographic regional PCI registry that provides regular performance reports based on benchmarked data

Measure Components

Numerator Statement	Does the facility participate in a national or multi-system geographic regional PCI registry that provides regular performance reports based on benchmarked data? (y/n)
Denominator Statement	Not applicable
Denominator Exclusions	None
Denominator Exceptions	None
Supporting Guideline	The following evidence statements are quoted verbatim from the referenced clinical guidelines. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms. (Class I, Level of Evidence: C) (ACCF/AHA/SCAI, 2011)[13]

Measure Importance

Relationship to desired outcome	Clinical registries are an important tool for measuring the delivery of care and supporting quality improvement.[91] An international study analyzing the impact of 13 disease registries in 5 countries identified several instances where major improvements in health outcomes were associated with the existence of registries.[92] Although the authors could not determine causality from such associations, they found many indications that the registries played a significant role in encouraging changes in clinical practice that impacted health outcomes.
Opportunity for Improvement	Quality monitoring among PCI programs varies with individual state regulatory practices, with national or regional registry participation mandated in certain states.[93] Nevertheless, there remains an opportunity for improvement with approximately 60% of the nation's cardiac catheterization laboratories participating in the CathPCI Registry.[94]
Exception Justification	This measure has no exceptions.
Harmonization with Existing Measures	This measure has been harmonized to the extent feasible with the "Participation in a Systematic Database for Cardiac Surgery" measure from the Society of Thoracic Surgeons.

Measure Designation

Measure purpose	•	Quality Improvement
	•	Accountability
Type of measure	•	Structural

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Level of Measurement	•	Facility
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #10: Annual Operator PCI Volume
(QI only)
Percutaneous Coronary Intervention

Measure Description

Average annual volume of PCIs performed by an operator over the last 2 calendar years

Measure Components

Numerator Statement	Average annual volume of PCIs performed by an operator over the last 2 calendar years PCI is defined as the placement of an angioplasty guide wire, balloon, or other device (eg, stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization.[24] An operator is defined as any physician performing at least 1 or more PCIs within each year over the last 2 calendar years.
Denominator Statement	Not applicable
Denominator Exclusions	None
Denominator Exceptions	None
Supporting Guideline and Other References	The following evidence statements are quoted verbatim from the referenced clinical guidelines. There is less evidence [than for institutional volume] to support a threshold for individual operator volume for both elective and primary PCI. It is the writing committee's recommendation that interventional cardiologists perform a minimum of 50 PCI procedures per year (averaged over a 2-year period) to maintain competency. The writing committee cautions against focusing on specific volume recommendations, and emphasizes that procedural volume is 1 of several variables to consider when determining operator competency. Volume is not a surrogate for quality and should not be substituted for risk-adjusted outcomes and other measures of quality. (ACCF/AHA/SCAI 2013)[95]

Measure Importance

Relationship to desired outcome	Operator volume has been correlated with better outcomes after PCI and fewer complications in earlier studies.[96,97] However, operator volume in PCI is just one of a number of factors that should be considered in assessing operator competence including lifetime experience, institutional volume, volume with other cardiovascular interventions, along with direct quality assessment of the operator's ongoing performance. Therefore it would be premature and simplistic to endorse a specific volume threshold within this performance measure.
Opportunity for Improvement	Volume across individual operators has been shown to vary significantly. In one study, 7% of patients underwent a PCI by a low-volume operator (less than 75 procedures per year).[96] Patients undergoing PCI with low-volume operators had a 65% increased odds of undergoing same-day CABG and a 55% increased odds of undergoing "same-stay" CABG.
Exception Justification	This measure has no exceptions.

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Harmonization with Existing Measures There are no known similar existing measures therefore harmonization was not applicable.

Measure Designation		
Measure purpose	•	Quality Improvement
Type of measure	•	Structural
Level of Measurement	•	Individual practitioner
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Measure #11: Annual Hospital PCI Volume

Percutaneous Coronary Intervention

Measure Description

Annual volume of PCIs performed by a hospital over the last calendar year

Measure Components

Numerator Statement	Annual volume of PCIs performed by a hospital over the last calendar year PCI is defined as the placement of an angioplasty guide wire, balloon, or other device (eg, stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization.[24] Only hospitals with an established PCI program for 3 full calendar years prior to the measurement period should report this measure.
Denominator Statement	Not Applicable
Denominator Exclusions	None
Denominator Exceptions	None
Supporting Guideline and Other References	The following evidence statements are quoted **verbatim** from the referenced clinical guidelines. The writing committee recognizes the wide variability of institutional volume thresholds used in the different studies and the complexity and multitude of factors influencing PCI outcomes. However, it is important to note that a signal exists suggesting that an institutional volume threshold <200 PCIs/year appears to be consistently associated with worse outcomes across the various studies...Accordingly, the writing committee recommends a minimum institutional volume threshold of 200 PCIs per year. (ACCF/AHA/SCAI 2013) [95]

Measure Importance

Relationship to desired outcome	Hospital volume has been correlated with better outcomes after PCI and fewer complications in earlier studies.[96,97] However, hospital volume in PCI is just one of a number of factors that should be considered in assessing institutional competence. Therefore it would be premature and simplistic to endorse a specific volume threshold within this performance measure.
Opportunity for Improvement	An analysis of CathPCI Registry found that 49% of participating facilities performed 400 or fewer PCI procedures annually and 13% performed more than 1,000 PCI procedures annually. 26% of facilities performed 200 or fewer PCI procedures annually, accounting for approximately 4% of the total PCI procedures.[98]
Exception Justification	This measure has no exceptions.
Harmonization with Existing Measures	There are no known similar existing measures therefore harmonization was not applicable.

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Measure Designation

Measure purpose	•	Quality Improvement
	•	Accountability
Type of measure	•	Structural
Level of Measurement	•	Facility
Care setting	•	Hospital OR
	•	Outpatient cardiac catheterization laboratory
Data source	•	Electronic health record system
	•	Registry
	•	Prospective data collection flowsheet

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Guideline Evidence Classification and Rating Schemes
Percutaneous Coronary Intervention

ACCF/AHA/SCAI guideline for percutaneous coronary intervention
Classification of Recommendations
Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.
Level of Evidence
Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.
Level of Evidence B: Data derived from a single randomized trial, or nonrandomized studies.
Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

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Summary of Non- Material Interest Disclosures

Percutaneous Coronary Intervention

None of the members of the PCI Work Group had any disqualifying material interests under the PCPI Conflict of Interest Policy. The following is a summary of non-disqualifying interests disclosed on Work Group members' Material Interest Disclosure Statements. Completed Material Interest Disclosure Statements are available upon request.

Work Group Member	Disclosures
Brahmajee K. Nallamothu (Co-Chair)	None
Carl Tommaso (Co-Chair)	None
H. Vernon Anderson	Payment for consulting services: Premier, Inc. Speaking honoraria: Bristol-Myers Squibb, Sanofi Aventis
Jeffrey L. Anderson	Payment for consulting services: Astra Zeneca
R. Adams Dudley	None
Peter Louis Duffy	None
Joseph C. Cleveland, Jr.	None
David P. Faxon	Payment for consulting services: Johnson and Johnson Salary support: AHA Stock ownership: RIVA Medical
Hitinder S. Gurm	None
Lawrence A. Hamilton	None
Neil C. Jensen	None
Richard A. Josephson	Payment for consulting services: Eli Lilly
David J. Malenka	Grant support: St. Jude Medical Foundation
Calin V. Maniu	None
Kevin W. McCabe	None
James D. Mortimer	None
Manesh R. Patel	None
Stephen D. Persell	Grant support: Agency for Healthcare Research and Quality
John S. Rumsfeld	Salary support: ACC NCDR
Kendrick A. Shunk	Payment for consulting services: GE Health Care Research support: Abbott Vascular, Siemens Medical Systems
Sidney C. Smith, Jr.,	None
Stephen J. Stanko	None
Brook Watts	None

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report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines: (2007 Writing Group to Review New Evidence and Update the 2005 ACC/AHA/SCAI Guideline Update for Percutaneous Coronary Intervention). *J Am Coll Cardiol.* 2008;51:172-209
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Appendix 1: Summary - Utilization of PCI in a Non-Elderly Population

The Physician Consortium for Performance Improvement® (PCPI®) seeks to obtain and analyze data regarding gaps in care, variations in care, and appropriateness of care to inform its measure development activities. This report provides a summary of an analysis of data on the appropriate use of percutaneous coronary interventions (PCI) in the non-elderly population in order to assess (1) variations in the use of PCI and (2) the extent to which the variations are associated with patient demographics, geographic location, and clinical conditions.

Background

With funding from the United Health Foundation, in a grant to the American Medical Association (AMA) Foundation, the PCPI was able to gather and analyze recent claims data from three national health plans, representing approximately 18 million members, on utilization PCI and non-invasive stress tests, and regarding patient comorbidities and demographics. Mathematica Policy Research was contracted to aggregate the data from the three plans, conduct data analyses, and prepare the project report (Mathematica Policy Research, *Utilization of Percutaneous Coronary Interventions in a Non- Elderly Population*, Final Report, March 1, 2010.)

Though many of the PCI procedures are performed on an emergency basis, when patient presents with acute myocardial infarction or unstable angina (ie, primary PCI), they may also be performed on an elective basis when patients experience continued anginal symptoms. The American College of Cardiology (ACC) has developed criteria related to appropriate use of PCI. Much of the data required to make such determinations are only available in medical records and not easily accessible in insurance claims (eg, grading of angina based on the Canadian Cardiovascular Society classification system). Risk findings based on non-invasive stress testing, however, is one factor included in the ACC appropriateness criteria when assessing a patient for PCI, and the use of these tests is available in the data for this analysis.

A primary purpose of the project is to help quantify the frequency of primary versus elective PCIs, and the number of patients undergoing elective PCIs who fail to undergo pre-PCI stress testing. Patients with primary PCIs were defined as those with a diagnosis code of acute coronary syndrome (which includes unstable angina) or myocardial infarction, with all other PCI patients being classified as elective.

Summary of Findings

Over 24,000 members, between 18 and 64 years of age, were found to have received a PCI between December 1, 2007, and November 30, 2008. The major findings from the analysis are as follows:

- About 54 percent of PCIs are elective, rather than primary PCI
- The majority of PCIs are performed in inpatient settings
- The 30-day outcomes are somewhat worse for primary versus elective PCIs - a higher proportion of patients receiving primary PCIs are readmitted to the hospital for any cause and for a cause related to the circulatory system; and are more likely to have another revascularization within 30 days
- Patients less than 50 years of age are more likely to undergo a primary versus elective PCI
- Men are more likely than women to undergo a primary rather than elective PCI
- The proportion of elective PCIs ranged from 51 percent in the Midwest to 56 percent in the South
- Approximately 45 percent of all members resided in the South, yet over half of all patients undergoing primary or elective PCIs lived in the South

Among patients opting for elective PCIs, about 56 percent underwent a stress test within 12 months of PCI. Several demographic and clinical factors were found to be associated with whether a patient had pre-PCI stress test:

- Compared to PCIs preceded by a stress test, a greater proportion of PCIs without pre-PCI stress testing were performed in inpatient rather than in an outpatient setting
- Age was found to be associated with pre-PCI stress testing for elective PCIs

- Similar to primary versus elective PCIs, a stress test before an elective PCI does not vary across Census regions
- Primary diagnosis appears to have some influence on whether stress tests take place before elective PCIs - patients with stable angina are more likely to undergo a stress test while those with congestive heart failure or cardiac dysrhythmia are less likely to do so

Finally, using Medicare reimbursement rates, the economic cost of PCIs without pre-PCI stress tests were estimated to be nearly $68 million ($63 million of inpatient and outpatient facility costs, and $5 million in physician costs) in the population of 18 million privately insured individuals between age 18 and 64 years. Average cost per patient, among those opting for elective PCIs and not undergoing pre-PCI stress testing was found to be $11,591, ranging from $9,206 for angioplasty to $11,729 for stents. On a per patient basis, average inpatient procedure cost is between one-third and two-thirds greater than that of outpatient procedures. By type of procedure, the average costs are:

- Angioplasty - inpatient $10,883 versus outpatient $3,585
- Stent - inpatient $12,853 versus outpatient $8,108

These estimates capture only a portion of total costs in that they exclude other payments (such as fees from other physicians, eg, anesthesiologists), and the costs of any potential complications (including readmissions or repeat revascularizations within 30 days).

Appendix 2: Feasibility Analysis for Several Draft PCI Measures*

Measure	Feasibility		
	Yes	No	Partial/Uncertain
Measure #2: Appropriate Indication for Elective PCI Data Required **Numerator**: Patients with at least one of the following indications documented: 1. significant angiographic stenosis (>50%) in the left main coronary artery in a patient at an increased risk for adverse outcomes with coronary artery bypass grafting surgery 2. significant angiographic stenosis (>70%) in the proximal left anterior descending coronary artery in the presence of low, intermediate, or high-risk non-invasive testing or CCS class angina ≥2 on guidelines-directed medical therapy that includes at least 2 anti-anginal drugs 3. significant angiographic stenosis (>70%) in a major epicardial artery (excluding the proximal left anterior descending coronary artery) in the presence of an intermediate/high-risk noninvasive test or CCS class angina ≥2 on guidelines-directed medical therapy that includes at least 2 anti-anginal drugs 4. borderline angiographic stenosis (eg, 40 to 70%) in a major epicardial artery where an FFR is less than or equal to 0.80 and/or IVUS shows significant reduction in	Data Availability **Numerator**: Pre-PCI stenosis and one of the following: 1. Positive stress/imaging study within the past 6 months 2. Presence of ischemia on FFR 3. CCS with one or two antianginal medications **Denominator**: All data available through NCDR	Data Availability **Numerator**: Presence of ischemia on FFR or significant angiographic disease on IVUS	Additional Data Elements Required **Numerator**: Data capture of sudden cardiac death or life threatening VT needs to be expanded beyond current parameters of the data elements (registry data limited to cardiac arrest within 24 hours) **Denominator Exclusions**: Previous CABG, previous PCI

* Note: This analysis was performed on previous iterations of the measure and in some cases does not represent the final measure.

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cross-sectional area in the presence of CCS class angina ≥2 on guidelines-directed medical therapy that includes at least 2 anti-anginal drugs 5. demonstration of left ventricular systolic dysfunction (ie, ejection fraction <50%) on most recent non-invasive testing felt to be attributable to a significant angiographic stenosis (>70%) in a major epicardial artery 6. history of sudden cardiac death or life-threatening ventricular tachyarrhythmia (eg, ventricular fibrillation or sustained ventricular tachycardia) felt to be attributable to a significant angiographic stenosis (>70%) in a major epicardial artery **Denominator**: All patients aged 18 years and older for whom elective PCI is performed in a native coronary artery **Denominator Exclusions:** All patients with recent acute coronary syndromes (including unstable angina) within the prior 4 weeks or prior coronary artery bypass grafts are excluded **Denominator Exceptions**: Documentation of medical reason(s) for performing PCI in patients without the stated indications (eg, significant valvular or structural heart disease, upcoming solid organ transplantation, other medical reasons [inability to tolerate anti-anginal therapy])			

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Measure #3: Assessment of Candidacy for Dual Antiplatelet Therapy Data Required **Numerator**: Patients who have documentation in the medical record that an assessment of candidacy and initiation and duration of dual antiplatelet therapy (DAPT) was performed prior to the procedure **Denominator**: All patients aged 18 years and older in whom PCI is performed **Denominator Exceptions**: Documentation of medical reason(s) for not performing an assessment for candidacy for long-term dual antiplatelet therapy		Unable to measure	

Measure #5: Contrast Dose Documented Data Required **Numerator**: Patients who have contrast dose administered documented in the cath report or procedure notes **Denominator**: All patients aged 18 years and older for who PCI is performed **Denominator Exceptions**: None	Data Availability **Numerator**: PCI procedures with contrast volume not null **Denominator**: All data available through NCDR		

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Measure #6: Radiation Dose Documented Data Required **Numerator**: Patients who have radiation dose administered documented in the cath report or procedure notes **Denominator**: All patients aged 18 years and older for who PCI is performed **Denominator Exceptions**: None	Data Availability **Numerator**: PCI procedures with fluoro time and/or dose not null **Denominator**: All data available through NCDR		
Measure #7: Statin Therapy at Discharge Data Required **Numerator**: Patients who are prescribed a statin medication at discharge **Denominator**: All patients aged 18 years and older for whom PCI is performed **Denominator Exclusions**: Patient who expired; Patient who left against medical advice; Patients discharged to hospice or for whom comfort care measures only is documented **Denominator Exceptions**: Documentation of medical, patient or system reasons for not prescribing a statin	Data Availability **Numerator**: All data available through NCDR **Denominator**: All data available through NCDR		Additional Data Elements Required **Denominator Exceptions**: Data capture needs to be expanded to include exceptions for specific medical, patient, or system reasons (registry data is limited to contraindicated or blinded)
Measure #10: Annual Operator PCI Volume Data Required **Numerator**: Mean annual volume of PCIs performed by an operator over the last 3 years **Denominator**: Any physician performing at	**Data Availability**: All data available through NCDR		

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least one or more PCIs within each year over the last 3 years **Denominator Exceptions**: None			

Measure #11: Annual Hospital PCI Volume Data Required **Numerator**: Mean annual volume of PCIs performed by a hospital over the last 3 years **Denominator**: Any hospital with an established PCI program for 3 years prior to the reporting period **Denominator Exceptions**: None	**Data Availability**: Annual volume of PCIs performed over 3 years; Each facility with PCI procedures and quarterly reporting		

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EXHIBIT 18

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel Malloy
Governor

Date: January 23, 2012

To: EMS Chiefs of Service
EMS Medical Directors
EMS Pre-hospital Care Coordinators
CMED/Regional Communication Centers

From: Jewel Mullen, MD, MPH, MPA, and Commissioner

Re: DPH Policy Guidance for STEMI patients

The Department of Public Health approved the attached ST Elevation Myocardial Infarction (STEMI) guidelines to close gaps that may delay appropriate treatment for STEMI patients. Connecticut's Emergency Medical Services (EMS) Advisory Board and Medical Advisory Committee collaborated to develop this guidance.

The goals of the guidance are to ensure that authorized EMS personnel obtain a 12-lead electrocardiogram in the field on all patients with suspected MI, thereby increasing the likelihood they will be transported for treatment with percutaneous coronary intervention within 90 minutes of first medical contact.

PHONE: (860) 509-7101 FAX: (860) 509-7111
410 CAPITOL AVENUE - MS#13COM, P.O. BOX 340308, HARTFORD, CONNECTICUT 06134-0308
Affirmative Action / Equal Employment Opportunity Employer

Connecticut EMS STEMI Guideline

CEMSMAC 2011

Goals:

Authorized transporting EMS personnel obtain a 12-lead ECG in the field on all patients with suspected Acute Coronary Syndrome.

ECG findings are obtained by properly trained, equipped and authorized EMS personnel and communicated to direct medical oversight via paramedic interpretation, automated computer algorithm interpretation, wireless transmission with subsequent physician interpretation or any combination of these three strategies to the receiving hospital.

Goal – to receive primary PCI within 90 minutes from first medical contact.

Definitions: patient with STEMI

1. Active chest pain or equivalent symptoms (nausea, SOB)
2. 12-lead ECG of good quality showing STEMI:
    a. ST-elevation
        i. ≥2 mm in 2 contiguous leads (V1-V4) and/or
        ii. ≥1 mm in 2 contiguous leads (limb, lateral)
    b. QRS duration ≤0.12 seconds
    c. ***Acute MI*** or equivalent prints on 12-lead ECG; paramedic agrees
3. No major bleeding (e.g., vomiting frank blood)
4. No significant trauma

Guidelines:

1. Transport patients with prehospital-diagnosed STEMI (as defined above) according to the following protocol:
    a. <30 min transport time interval
        i. Directly to a primary PCI hospital under direct or indirect medical oversight
    b. ≥30 min transport time
        ii. Decision regarding appropriate destination hospital should be made in conjunction with indirect and/or direct medical oversight

2. Interfacility transfer
   a. Non-PCI hospitals should have an established process developed to ensure timely transfer of STEMI patients to a PCI center. Interfacility transfer care should be in conjunction with direct and/or indirect medical oversight, consistent with local EMS policies and protocols.

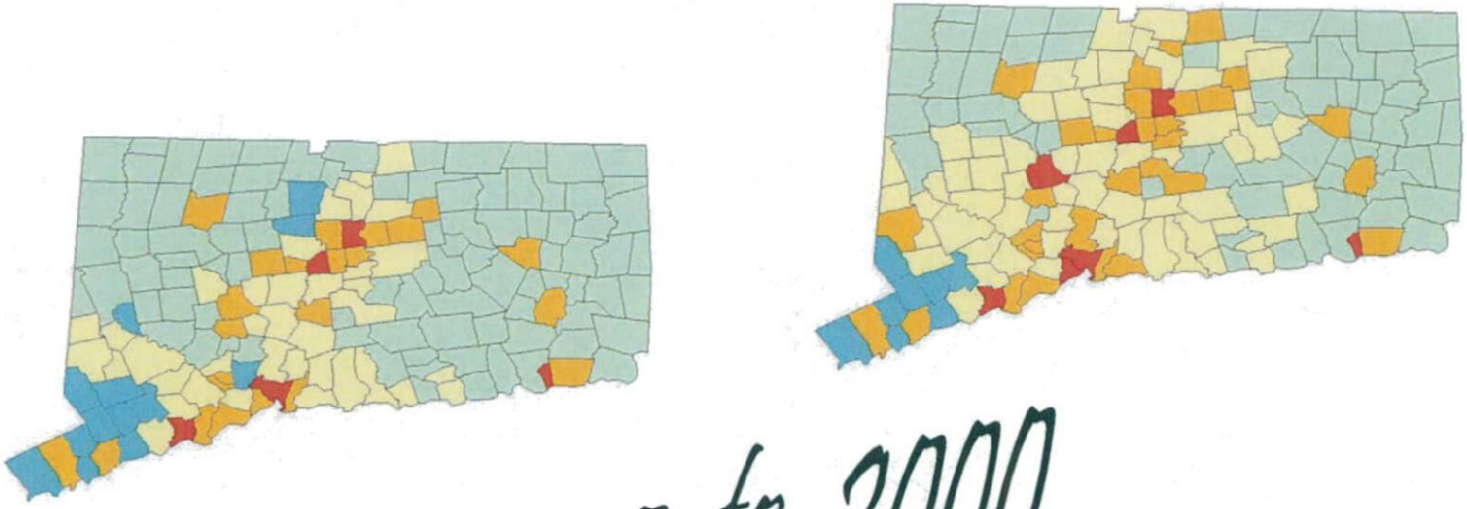
3. If anticipated time to primary PCI > 90 minutes, administration of fibrinolytic therapy at a non-PCI capable hospital, for fibrinolytic-eligible patients

Approved by CEMSMAC 3/11
Approved by CT EMS Advisory Board and referred back to CEMSMAC for reconciliation. 5/11.
Board position accepted by CEMSMAC. 9/11

EXHIBIT 19

The Changing Demographics of Connecticut - 1990 to 2000

Part 2: The Five Connecticuts



1990 to 2000

Occasional Paper Number: OP 2004-01
May 2004

UCONN CtSDC
Connecticut State Data Center

Connecticut State Data Center
University of Connecticut
341 Mansfield Road, Room 401
Unit 1221
Storrs, CT 06269-1221
(860) 486-9269, (860) 486-9270 fax

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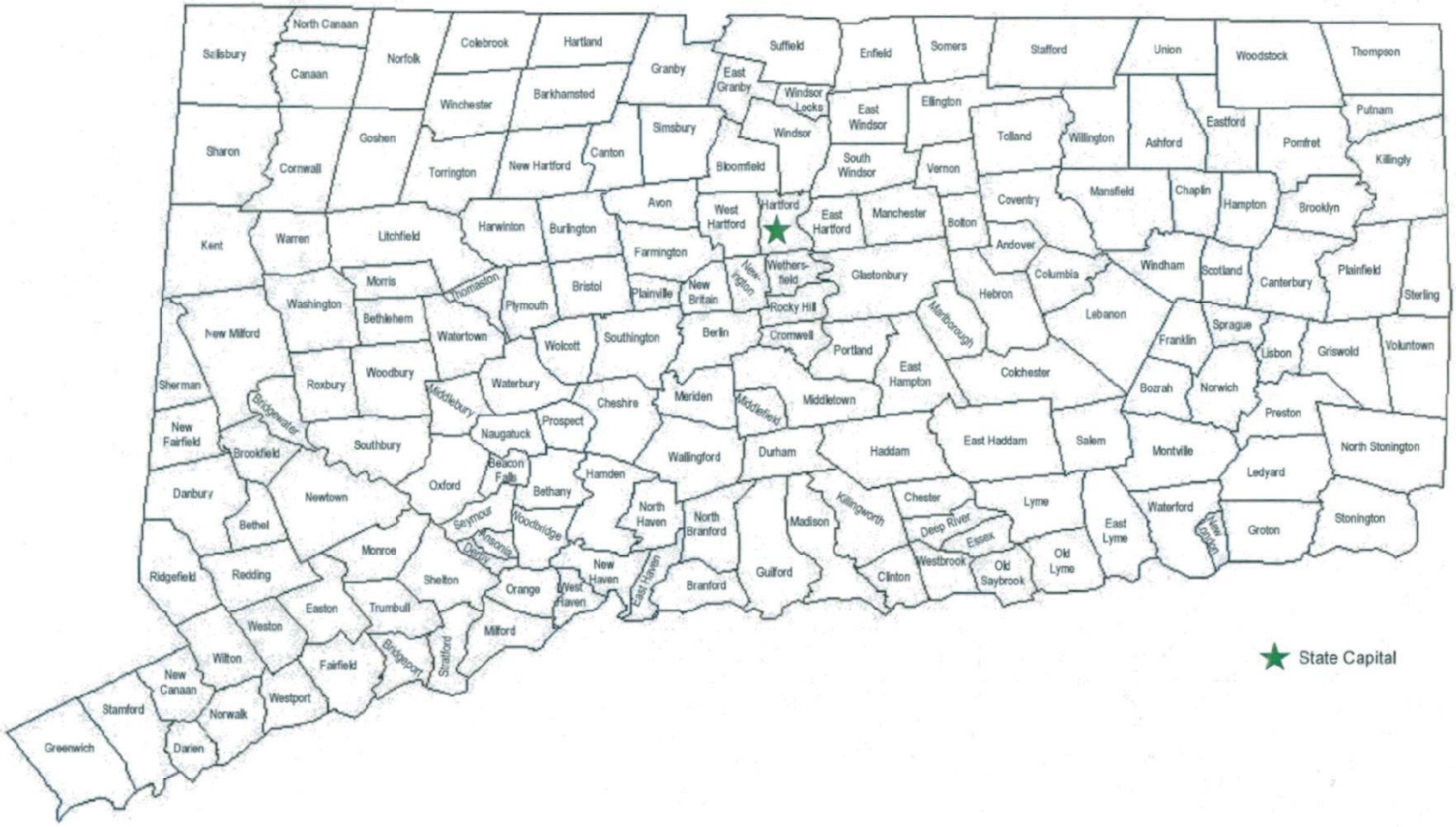
Figure 1: Map of Connecticut Towns



Introduction

This report is the second in the series titled *The Changing Demographics of Connecticut - 1990 to 2000*. In the preceding report, *Part 1: Comparing Connecticut to National Averages*, it was shown that Connecticut's statewide averages, whether in terms of income, poverty, or racial composition, provided a misleading description of the state's socioeconomics.

In this report a more representative description of town demographics is provided. Each town has been assigned to one of five town groups. These five town groups reflect separate and distinct Connecticuts and allow the reader to more easily see the separate socioeconomic trends within the state. Specifics on the methods used to make town group assignments are detailed in the *Methodology* section at the end of this the report.

This report is based predominately on data gathered by the U.S. Census Bureau in the 1990 and 2000 Decennial Census. More recent data from estimates or projections are not used as they have an unacceptable level of error or uncertainty and may not cover all towns.

Some paragraphs are preceded with reference numbers such as 33-34. These numbers refer to the figure/s that coincide with the discussion in the corresponding paragraph/s.

The Top 10 Socioeconomic Issues

Contrary to popular perceptions, Connecticut is not balanced in terms of socioeconomics. In particular, individual towns can be categorized into one of five distinct, enduring, and separate groups. The groups are:

- ***Wealthy*** Connecticut has exceptionally high income, low poverty, and moderate population density.
- ***Suburban*** Connecticut has above average income, low poverty, and moderate population density.
- ***Rural*** Connecticut has average income, below average poverty, and the lowest population density.
- The ***Urban Periphery*** of Connecticut has below average income, average poverty, and high population density.
- The ***Urban Core*** of Connecticut has the lowest income, highest poverty, and the highest population density.

The Top Ten Socioeconomic Issues

1. ***Gains in income*** were becoming increasingly ***concentrated*** in Wealthy Connecticut. Between 1990 and 2000, the population of Wealthy Connecticut decreased from 6.8% to 5.4% of the state's total population partially due to the reclassification of five towns from Wealthy to Suburban. Per capita income in Wealthy Connecticut went from 2.1 times the state average in 1989 to 2.5 times the state average in 1999. *Furthermore, true income levels for Wealthy Connecticut are higher than what is reported here as the Census does not report capital gains.* Consequently, income growth is even more concentrated in Wealthy Connecticut than what is reported here.
2. Connecticut's ***racial minorities are concentrated in Urban Core*** towns. In 2000, the Urban Core accounted for 19% of the state's population. However, 54% of all Hispanics and 55% of all Blacks lived in the Urban Core. Also in 2000, 55% of all Whites lived in towns that were at least 90% white. Furthermore, 78% (132 of 169) of towns were at least 90% White.
3. Rural Connecticut is transforming into Suburban Connecticut. Between 1990 and 2000, 824 sq. miles of Rural Connecticut became Suburban. This was a ***loss of 28% of Rural Connecticut***. Please note that this report does not define rural areas by land use. Rural areas are a socioeconomic classification that includes the area of entire towns.
4. Between 1990 and 2000, Suburban Connecticut ***became less racially diverse*** due to a decrease in the percentage of minority residents.
5. Rural Connecticut experienced ***increasing poverty, low income growth, and lagging educational attainment***.
6. The Urban Periphery had the largest growth in population between 1990 and 2000. The Urban Periphery experienced ***increasing poverty and mixed income growth*** trends.
7. The socioeconomic conditions in the ***Urban Core*** were ***extremely stressed*** during the 1990's. Between 1990 and 2000, the population of the Urban Core grew by 125,643 or 24%. In 2000, the poverty rate was 19.4% as compared with the statewide average of 7.6% and the national average of 12.1%. Also in 2000, 29% of all children in the Urban Core lived in poverty. Educational attainment in the Urban Core was below the national average.
8. The percentage of state's population living in ***extreme poverty*** grew from 2.8% to 3.7% during the 1990's. The largest increase was in the Urban Core where extreme poverty increased from 8.5% to 9.8%.
9. Between 1990 and 2000, statewide ***public school enrollment*** in grades 1-12 increased by 95,320 students or ***21.9%***. The largest increases in public school enrollment were 45,837 students, or 36.3%, in the Urban Periphery and 33,337 students, or 45%, in the Urban Core.
10. The Urban Periphery most closely reflected the typical Connecticut in both 1990 and 2000. ***Mixed socioeconomic*** trends in the Urban Periphery could foretell the ***future*** of Connecticut.

The State of Connecticut does not currently make public town level income statistics.

A forthcoming report by the Connecticut State Data Center estimates that the Decennial Census does not report a significant portion of the state's income. This report uses 1999 Connecticut State personal income tax revenues to estimate town level Adjusted Gross Income (AGI).

Data for all 169 towns can be found at our website http://ctsdc.uconn.edu

Extreme poverty is defined as having income that is below 50% of the poverty threshold.

Poverty may be understated in Connecticut as Census poverty thresholds do not take regional cost-of-living into account.

The Equal Share Percentage (ESP)

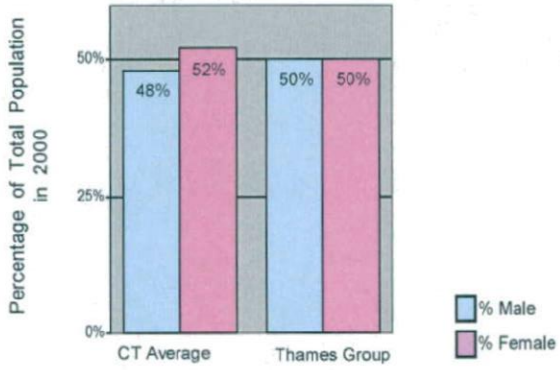
This report relies heavily on the use of the ***Equal Share Percentage*** (ESP) for making comparisons between town groups. The ESP provides an apples-to-apples comparison of socioeconomic variables, such as income, between groups having different population sizes.

Assume that you want to compare the size of the male versus female population of towns on the Thames river - the Thames Group. The towns in the Thames Group include New London, Groton, Waterford, Ledyard, and Montville.

There has been anecdotal evidence that the population of the Thames Group had disproportionately more men than the statewide average. However, the total population of the Thames Group was significantly less than the statewide population, which made it difficult to make a comparison. Also, a common reference point is needed that will account for the average male and female percentages statewide.

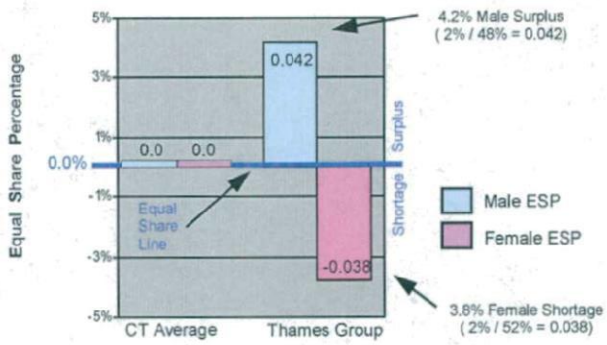
2. The 2000 Census reported a statewide percentage of 48% male and 52% female for Connecticut. By contrast, Census 2000 reported the Thames Group to be 50% male and 50% female. In 2000, the total population of the Thames Group was only 117,963 as compared to a statewide total population of 3,405,565. By how much did the male-female population in Thames Group differ from the statewide average?

Figure 2: Thames Group Gender



3. In this example, the ESP is calculated by dividing the group's percentage male or female by the corresponding statewide percentage male or female and then determining the difference from the statewide total percentage (100% or 1.0). The ESP for the male population in the Thames Group is calculated at 4.2% ((0.50/0.48)-1.0). The ESP for the female population in the Thames Group is calculated at –3.8% ((0.50/0.52)-1).

Figure 3: Thames Group ESP



These ESP's indicate that there is a 4.2% ***surplus*** of males in the Thames Group - relative to the group's share of the statewide population. Whenever the ESP is above 0% it is referred to as a surplus - the group has more than its equal share.

Also, there is a 3.8% ***shortage*** of females in the Thames Group - relative to the group's share of the statewide population. Whenever the ESP value is below 0% it is referred to as a shortage - the group has less than its equal share.

Apparently, the anecdotal evidence was correct and the Thames Group did have disproportionately more men (4.2%) than women (-3.8%) than was normal for Connecticut.

The ESP is used throughout this report. It is a very important measure. It can reveal small populations with a surplus (disproportionate high share) relative to their population size. It can also reveal large populations with a shortage (disproportionate low share) relative to their population size.

The underlying assumption of the ESP is that socioeconomic variables (gender, race, wealth, poverty, etc…) are shared, or distributed, equally throughout the state with no deviation (ESP = 0%). The resulting implication is that the statewide average would be an accurate measure of any socioeconomic variable at any location in the state. For example, the statewide average percentage of males, at 48%, and females, at 52%, would be the same in every town in the state. Obviously, this is not reality. However, using this assumption creates a common reference point, a ruler, from which to measure true variations among groups by using the ESP.

The Equal Share Line (where ESP = 0%) marks where the share of a variable does not differ from the statewide average.

Surplus or high share: The group has more than its equal share when the ESP value is greater than 0%

Shortage or low share: The group has less than its equal share when the ESP value is below 0%

Assembling the Five Groups

The process of determining group membership for each town was both data-driven and exploratory. Group membership was determined by combining towns with similar population density, income, and poverty. This was determined by using statistical analysis and familiarity with Connecticut towns. Specifics on the methods used to make group assignments are detailed in the *Methodology* section later in the report.

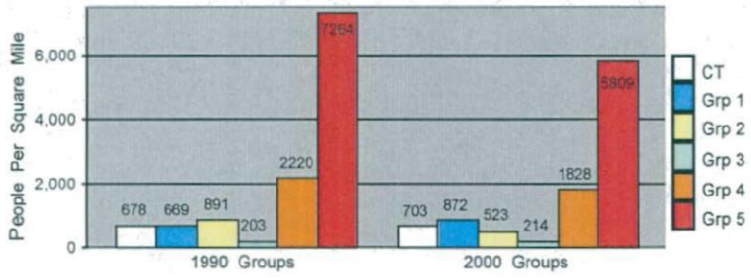
It is important to note that ***race*** was ***not*** used to determine group membership. Any trends in group membership that appear to be racially linked are, in fact, associated with either population density, income, poverty, or some combination of these variables.

The process began with nine socioeconomic input variables and seven town groups. Through numerous iterations it was determined that having five separate town groups would most clearly and accurately describe population distributions in Connecticut.

Ultimately, group assignment for each town was culled from nine to three socioeconomic variables - ***population density***, ***median family income***, and ***poverty***. For the purposes of this report, the distinctness of each of Connecticut's 169 towns could be explained by using these three variables.

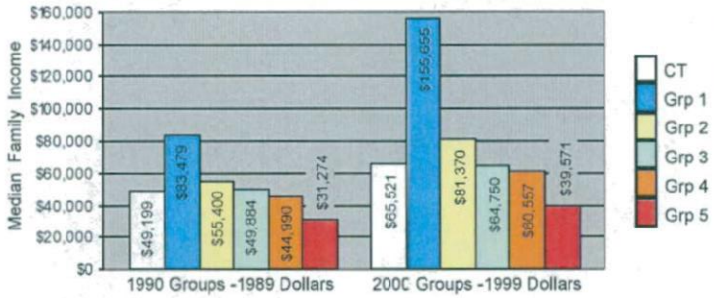
4. **Population Density**. No matter whether we use terms like city, town, urban center, or rural area, the character of Connecticut's towns is affected by population density. In 2000, town population ranged from a low of 693 in Union to a high of 139,529 in Bridgeport. The land area of towns ranges from a low of 5 square miles in Derby to a high of 62 square miles in New Milford. The result was a population density that ranged from a low of 24 people-per-sq.-mile (psm) in Union to a high of 8,721psm in Bridgeport.

Figure 4: Population Density by Town Group



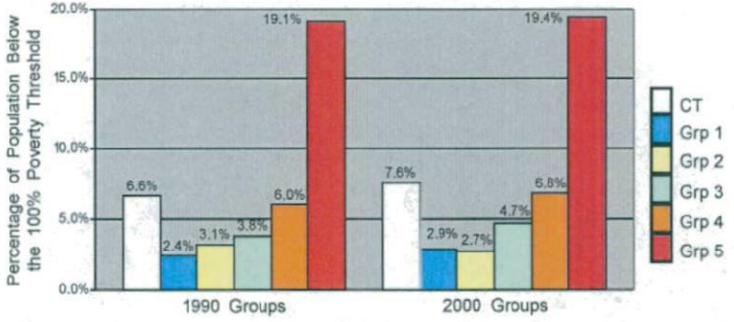
5. **Median Family Income**. Initially, per capita income, median family income, and median household income were all used for grouping. Ultimately, it was determined that median family income was the best single measure. Per capita income and median household income tended to produce misleading results in areas dominated by colleges or universities.

Figure 5: Median Family Income by Town Group



6. **Poverty**. There are numerous socioeconomic variables that can be used to measure poverty. However, it was determined that ***"the population below the 100% poverty threshold"*** was sufficient to measure poverty at the town level.

Figure 6: Percentage of Population Living in Poverty by Town Group



Poverty status is determined by the U.S. Census using income thresholds that are "... the same for all parts of the country - they are not adjusted for regional, state or local variations in the cost of living."

The U.S. Census Bureau may undercount poverty in Connecticut because of the higher cost-of-living in this state.

Some towns in Group 1 have significant income from capital gains that is not included in the Decennial Census income statistics.

True income levels for Group 1 are higher than what is reported by the 1990 and 2000 Decennial Census.

psm: people-per-sq.-mile

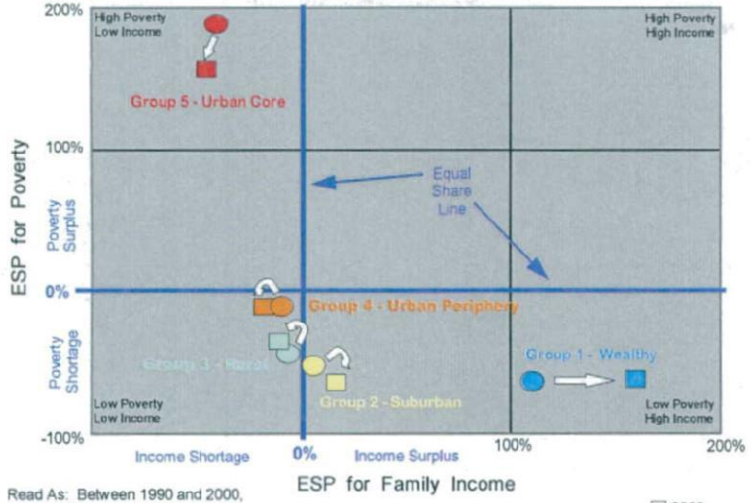
Group Characteristics

7. In 2000, 44 towns were reclassified from their 1990 groups into different groups. Nonetheless, the five groups still remained clearly distinguishable in both 1990 and 2000. Note in the graph below that the relative positions of the five groups remained similar even though some individual towns changed groups in 2000.

7. Figure 7 below shows groups in 1990 and 2000 plotted by their ESP's for poverty versus their ESP's for family income. The changes between 1990 and 2000 were as follows:

- In ***Group 1*** the share of poverty remained virtually unchanged but the share of family income grew significantly.
- ***Group 2*** experienced a drop in its share of poverty and had an increase in its share of family income.
- ***Group 3*** had a slight increase in its share of poverty and a decrease in its share of family income.
- In ***Group 4*** the share of poverty remained virtually unchanged and there was a slight decrease in the share of family income.
- ***Group 5*** experienced a decrease in its share of poverty and a slight decrease in its share of family income. This does not mean that the rate of poverty decreased in group 5. It does mean that the rate of poverty increased in other groups.

Figure 7: 1990 to 2000 Group Changes in Poverty and Income



Read As: Between 1990 and 2000, Group 2 (Suburban) experienced a decrease in its share of poverty and an increase in its share of income.

7. Between 1990 and 2000, the most striking issue among the five Connecticuts was the ***unmatched increase*** in the share of family income for Wealthy Connecticut. Also, note the increasing separation in poverty and income between Groups 3-4 and Group 2. This suggests a trend of increasing disparity between towns in Groups 3-4 and Group 2.

4-8,11. Group 1 had the lowest share of poverty in 1990 and the highest share of family income in both 1990 and 2000. Group 1 towns can be characterized as having ***exceptionally high income, low poverty***, and ***moderate population density.*** The single variable that best distinguishes this group is its high income or wealth. This is ***Wealthy*** Connecticut.

4-8,11. Group 2 had a low share of poverty in both 1990 and 2000. Its share of family income was the second highest in both 1990 and 2000. Group 2 towns can be characterized as having ***above average income, low poverty***, and ***moderate population density.*** Towns in this group are best distinguished as suburbs of more densely populated urban areas. This is ***Suburban*** Connecticut.

4-8,11. Group 3 had a low share of poverty in both 1990 and 2000. It had a near to equal share of family income in 1990 and 2000. Group 3 towns can be characterized as having ***average income, below average poverty***, and the ***lowest population density***. Rural towns with low population density distinguish this group. This is ***Rural*** Connecticut.

4-8,11. Group 4 had a near to equal share of poverty in both 1990 and 2000. Its share of family income was slightly low in both 1990 and 2000. Group 4 towns can be characterized as having ***below average income, average poverty***, and ***high population density***. This group had the largest population of the five groups. In 2000, 36% of the state's population lived in this group. These towns are best described as transitional towns between the urban cores and the suburbs. Group 4 towns are peripheral to the urban cores. This is the ***Urban Periphery*** of Connecticut.

4-8,11. Group 5 had the highest share of poverty in both 1990 and 2000. It also had the lowest share of family income in both 1990 and 2000. Group 5 can be characterized as having the ***lowest income, highest poverty***, and ***highest population density.*** The single most distinguishing characteristic is the extremely high population densities of towns in this group. These towns are the densely populated ***Urban Core*** of Connecticut.

Between 1990 and 2000, Group 1 (Wealthy) increased its share of family income from an 111% surplus to a 160% surplus.

Between 1990 and 2000, Group 2 (Suburban) increased its share of family income from a 7% surplus to a 17% surplus.

Between 1990 and 2000, Group 3 (Rural) had a decrease in its share of family income from a 5% shortage to a 12% shortage.

Between 1990 and 2000, Group 4 (Urban Periphery) had a decrease in its share of family income from an 11% shortage to a 14% shortage.

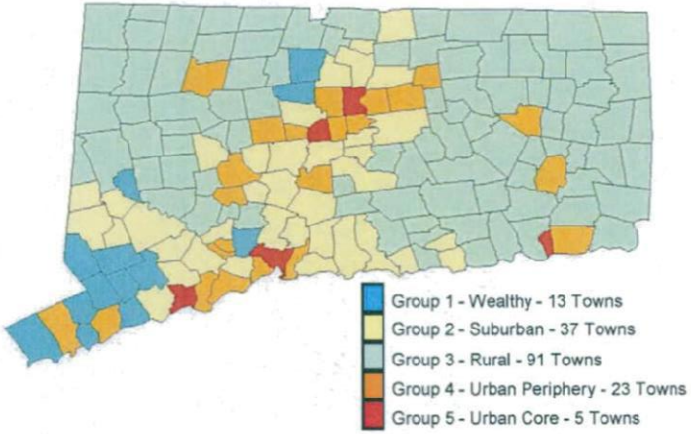
Between 1990 and 2000, Group 5 (Urban Core) had a decrease in its share of family income from a 40% shortage to a 45% shortage.

Mapping the Five Groups

The location of towns was not taken into account when assembling the Five Connecticuts. Resulting geographic patterns are a consequence of population density, income, and poverty as previously discussed.

8. In 1990, the majority of Connecticut towns were classified as Rural with 91 towns. The Suburban group had the second highest number of towns at 37. The Urban Periphery was third with 23 towns and Wealthy Connecticut was fourth with 13 towns. The Urban Core had the smallest number of towns with 5.

Figure 8: Map of 1990 Town Groups



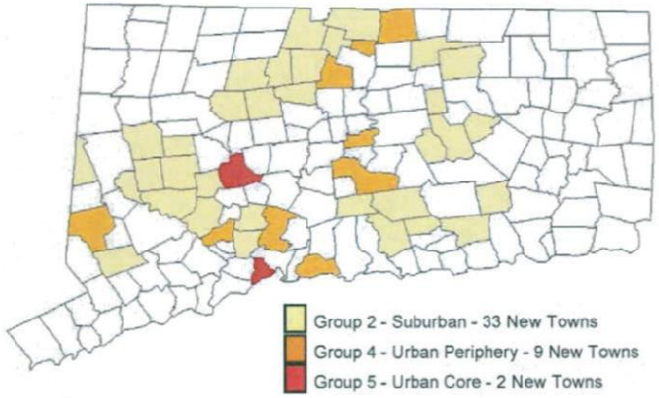
9-10. In 2000, a total of 44 towns were reclassified as shown in the table below. Wealthy Connecticut lost 5 towns to Suburban Connecticut. Suburban Connecticut lost 9 towns to the Urban Periphery. Rural Connecticut had the largest reclassification with 28 towns becoming Suburban. The Urban Periphery lost 2 towns to the Urban Core.

Figure 9:
1990 to 2000 Town Reclassification Table

Read Chart As: In 2000, five towns were reclassified from Wealthy to Suburban.

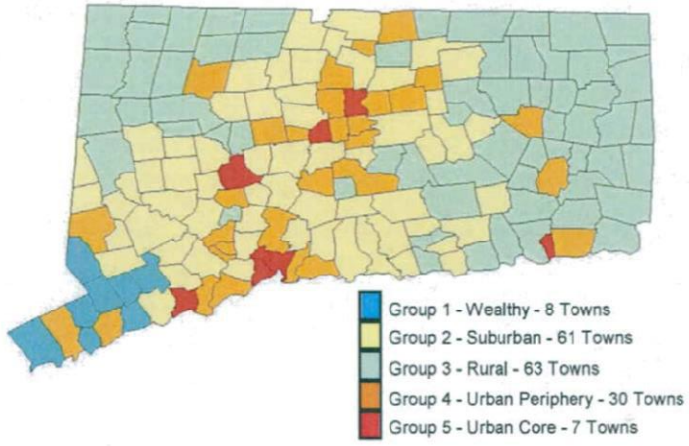
From 1990 Groups	To 2000 Groups: Subu	Urban Periphery	Urban Core	
Wealthy	5			
Suburban		9		
Rural	28			
Urban			2	
Total:	33	9	2	= 44

Figure 10: Map of Towns Reclassified in 2000



10-11. In 2000, the number of towns in Wealthy Connecticut narrowed by 5 towns going from 13 to 8. All 5 towns went to Suburban Connecticut. Suburban Connecticut lost 9 towns but gained 33 towns with a net expansion of 24 from 37 to 61 towns. Rural Connecticut shrank losing 28 towns, from 91 to 63, to Suburban Connecticut. The Urban Periphery lost 2 towns to the Urban Core but also gained 9 towns from Suburban Connecticut for a net expansion of 7 towns. The Urban Core gained 2 towns from the Urban Periphery.

Figure 11: Map of 2000 Town Groups



In 2000, 5 towns were reclassified from Wealthy to Suburban.

In 2000, 9 towns were reclassified from Suburban to Urban Periphery.

In 2000, 28 towns were reclassified from Rural to Suburban.

In 2000, 2 towns were reclassified from Urban Periphery to Urban Core.

The land area of Suburban Connecticut expanded by 714 sq. miles between 1990 and 2000.

The land area of Rural Connecticut shrank by 824 sq. miles between 1990 and 2000.

The land area of the Urban Periphery expanded by 195 sq. miles between 1990 and 2000.

The land area of the Urban Core expanded by 39 sq. miles between 1990 and 2000.

Wealthy - Westport Type Towns

This group of towns can be characterized as having ***exceptionally high income***, ***low poverty***, and ***moderate population density***. The single variable that best distinguishes this group is its high income or ***wealth***. Located in southwestern Connecticut, the coastal town of *Westport* was the most representative of this group.

12-14. In 1990, Wealthy Connecticut had 13 towns and a population of 224,235 resulting in the 2nd lowest population density of 669psm. In 2000, 5 towns were reclassified as Suburban because their income did not increase at the same rate as in the remaining 8 towns. By 2000, the remaining 8 towns had a population of 184,437 and population density had increased to 3rd highest at 872psm.

14. In 1989, median family income was ***$107,073*** (in 1999 dollars), as compared to the statewide median of $63,104 (in 1999 dollars). By 1999, the median family income had grown by $48,582, or ***45.4%***, to ***$155,655***, as compared with the statewide median family income of $65,521. The ESP's indicate that this group's share of family income grew substantially from an ***111% surplus*** in 1989 to a ***160% surplus*** in 1999.

14. In 1990, 2.4% of the population lived in poverty, which was well below the state average of 6.6%. By 2000, poverty had increased slightly to 2.9% of the population, but this still remained well below the state average of 7.6%. The ESP's indicate that this group's share of poverty increased only fractionally from a ***63% shortage*** in 1990 to a ***62% shortage*** in 2000.

Between 1990 and 2000, Wealthy Connecticut made significant gains in income. Poverty increased slightly but still remained low. Population density also increased but remained moderate.

Statistically, Westport best represented this group in both 1990 and 2000. Westport had 25,749 residents and a population density of 1,287psm in 2000. The population density was higher than the group average. In 1999, the median family income was $152,894, which was slightly below the group median of $155,655. Westport had a poverty rate of 2.6%, which was below the group average of 2.9% in 2000.

Figure 12: 1990 Map of Wealthy Connecticut

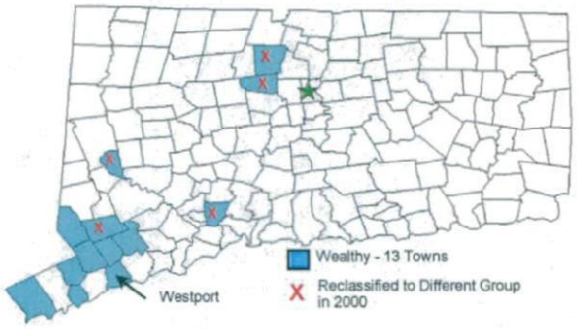


Figure 13: 2000 Map of Wealthy Connecticut

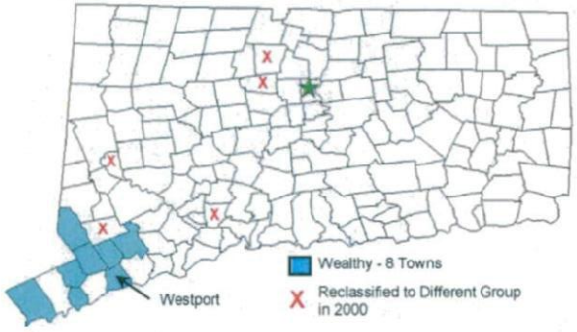
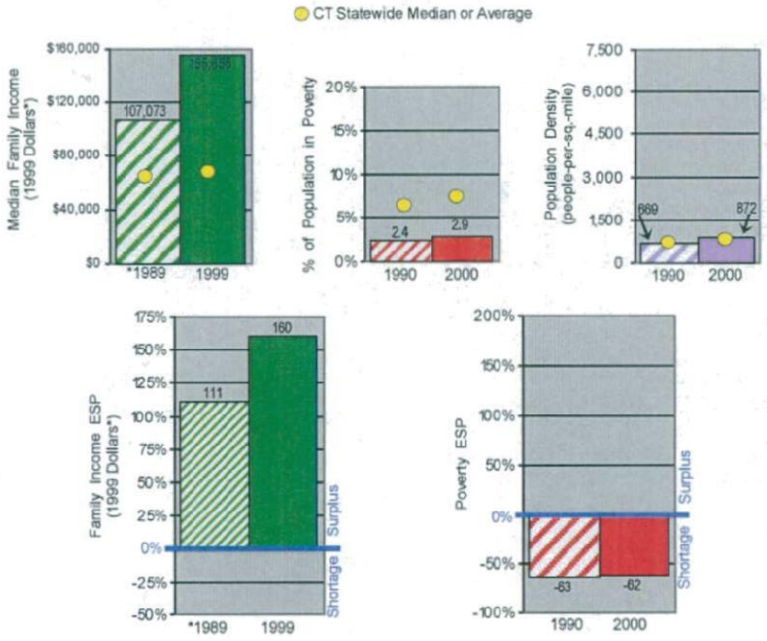


Figure 14: 1990 and 2000 Statistics for Wealthy Connecticut



Some towns in this group have significant income from capital gains that is not reported by the Decennial Census.

True income levels for this group were higher than what was reported by the 1990 and 2000 Census.

Between 1989 and 1999, median family income in Wealthy Connecticut increased by 45.4% while the statewide median increase was 3.8%.

The median family income in Wealthy Connecticut was $155,655 in 1999. This was 2.4 times the statewide median income of $65,521.

In both 1990 and 2000, Wealthy Connecticut had the lowest rate for families living in poverty.

psm: people-per-sq.-mile

Suburban - Cheshire Type Towns

This group of towns can be characterized as having ***above average income***, ***low poverty***, and ***moderate population density***. Towns in this group are best distinguished as ***suburbs*** of more densely populated urban areas. Located in the midsection of Connecticut, the town of *Cheshire* was the most representative of this group. Cheshire is a suburb of both Waterbury and New Haven.

15-17. In 1990, Suburban Connecticut had 37 towns and a population of 885,764 resulting in a population density of 891psm. In 2000, there was a net gain of 24 towns for a total group population of 894,213. The resulting population density decreased to 523psm in 2000.

In 2000, 28 Rural towns were reclassified as Suburban due to increasing population density and increasing income associated with residential development. Also in 2000, 9 Suburban towns were reclassified as Urban Periphery due to increased population density and lagging increases in income. Another 5 towns were reclassified from Wealthy to Suburban in 2000. These former Wealthy towns had lower increases in income compared to the remaining 8 Wealthy towns.

Figure 15: 1990 Map of Suburban Connecticut

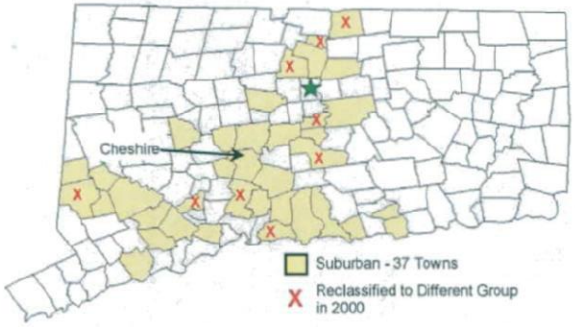
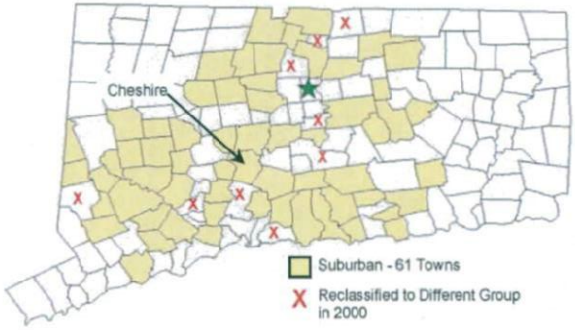


Figure 16: 2000 Map of Suburban Connecticut



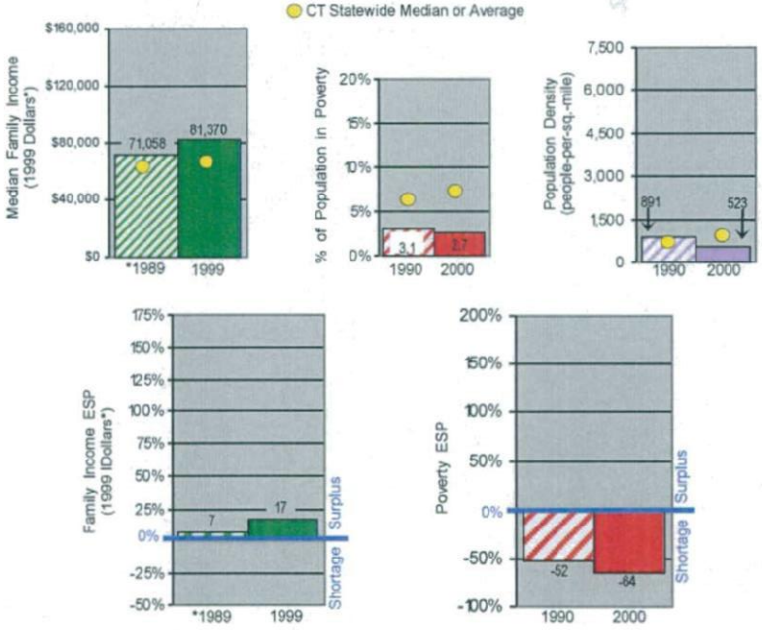
17. In 1989, median family income was ***$71,058*** (in 1999 dollars), as compared to the statewide median of $63,104 (in 1999 dollars). By 1999, the median family income had grown by $10,312, or ***14.5%***, to ***$81,370***, as compared with the statewide median family income of $65,521. The ESP's indicate that this group's statewide share of family income grew from a ***7% surplus*** in 1989 to a ***17% surplus*** in 1999.

17. In 1990, 3.1% of the population lived in poverty, which was well below the state average of 6.6%. By 2000, poverty had decreased slightly to 2.7% of the population, which was well below the state average of 7.6%. The ESP's indicate that this group's share of poverty decreased from a ***52% shortage*** in 1990 to a ***64% shortage*** in 2000.

Between 1990 and 2000, Suburban Connecticut had gains in family income that exceeded the statewide average growth rate. Poverty ***decreased*** which was opposite to the statewide trend.

Statistically, Cheshire best represented this group in both 1990 and 2000. In 2000, Cheshire had a population of 28,543 and a population density of 867psm, which was higher than the group average. In 1999, the median family income in Cheshire was $90,774, which was above the group median of $81,370. Cheshire had a poverty rate of 2.6%, which nearly matched the group average of 2.7% in 2000.

Figure 17: 1990 and 2000 Statistics for Suburban Connecticut



Between 1989 and 1999, median family income in Suburban Connecticut increased by 14.5%, while the statewide median increase was 3.8%.

In 2000, Suburban Connecticut had the lowest rate, at 2.58%, for children living in poverty.

Between 1990 and 2000, the land area of Suburban Connecticut expanded by 714 sq. miles but the population grew by only 8,449.

The population density of Suburban Connecticut dropped from 891psm in 1990 to 523psm in 2000.

In 2000, Suburban Connecticut gained 33 towns and lost 9 towns for a net gain of 24 towns.

psm: people-per-sq.-mile

Rural - North Stonington Type Towns

This group of towns can be characterized as having ***average income***, ***below average poverty***, and the ***lowest population density***. Rural towns with the lowest population densities distinguish this group. Located in the southeast corner of Connecticut, the town of *North Stonington* was the most representative of this group.

18-20. In 1990, Rural Connecticut had 91 towns and a population of 602,468 resulting in the lowest population density of 203psm. In 2000, 28 towns were reclassified as Suburban due to increasing income and population density associated with residential development. Town membership dropped to 63 towns and a population of 457,770. The resulting population density was still the lowest at 214psm.

Figure 18: 1990 Map of Rural Connecticut

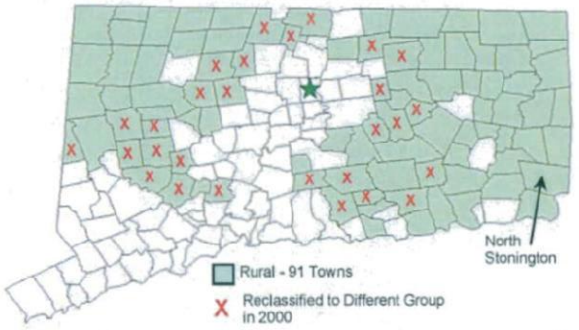
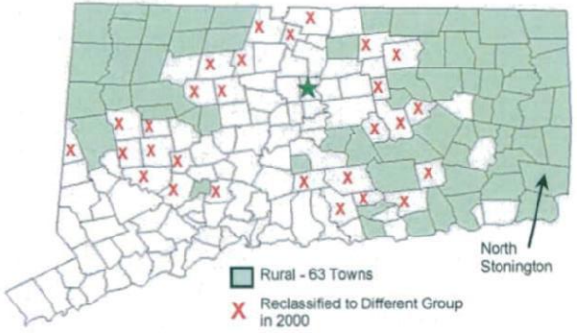


Figure 19: 2000 Map of Rural Connecticut



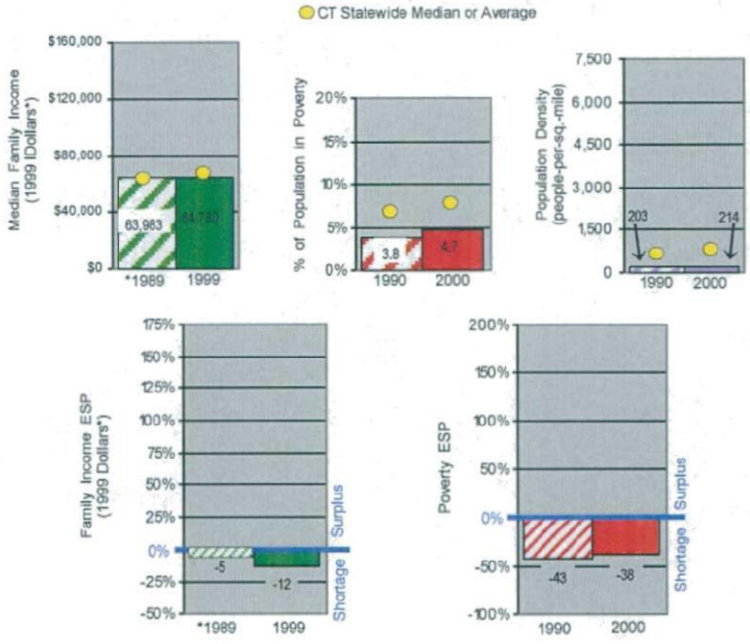
20. In 1989, median family income was ***$63,983*** (in 1999 dollars), as compared to the statewide median of $63,104. By 1999, the median family income had grown by $767, or ***1.2%***, to ***$64,750***, as compared with the statewide median family income of $65,521. The ESP's indicate that this group's share of family income dropped from a ***5% shortage*** in 1989 to a ***12% shortage*** in 1999.

20. In 1990, 3.8% of the population lived in poverty, which was below the state average of 6.6%. By 2000, poverty had increased to 4.7% of the population, but this still remained below the state average of 7.6%. The ESP's indicate that this group's share of poverty increased from a ***43% shortage*** in 1990 to a ***38% shortage*** in 2000.

Between 1990 and 2000, family income growth in Rural Connecticut lagged behind the statewide growth rate. Poverty increased but still remained below the statewide average.

Statistically, North Stonington best represented this group in both 1990 and 2000. North Stonington had 4,991 residents and a population density of 92psm in 2000. The population density was lower than the group average. In 1999, the median family income was $61,733, which was below the group median of 64,750. North Stonington had a poverty rate of 4.7%, which matched the group average in 2000.

Figure 20: 1990 and 2000 Statistics for Rural Connecticut



Between 1989 and 1999, median family income in Rural Connecticut increased by only 1.2%, while the statewide median increase was 3.8%.

In 2000, 824 sq. miles of Rural Connecticut were reclassified as Suburban Connecticut.

psm: people-per-sq.-mile

The population density of Rural Connecticut increased only slightly from 203psm in 1990 to 214psm in 2000.

The poverty rate increased in Rural Connecticut between 1990 and 2000.

Urban Periphery - Manchester Type Towns

This group of towns can be characterized as having ***below average income***, ***average poverty***, and ***high population density***. In 2000, 36% of the state's population lived in the Urban Periphery making this the group with the highest population. These towns are best described as transitional towns between the urban cores and the suburbs. Located in central Connecticut, the town of *Manchester* was most representative of this group.

21-23. In 1990, the Urban Periphery had 23 towns and a population of 1,058,719 resulting in the 2nd highest population density of 2,220psm. In 2000, there was a net gain of 7 towns for a total population of 1,227,572. By 2000, population density had decreased but it was still the 2nd highest at 1,828psm.

In 2000, 9 Suburban towns were reclassified as Urban Periphery due to increases in population density and lagging increases in income. The Urban Periphery also lost 2 towns to the Urban Core due to income, poverty, and population density measures that had become more similar to the Urban Core.

23. In 1989, median family income was ***$57,706*** (in 1999 dollars), as compared to the statewide median of $63,104. By 1999, median family income had grown by $2,851, or ***4.9%***, to ***$60,557***, as compared with the statewide median family income of $65,521. The ESP's indicate that this group's share of family income dropped from an ***11% shortage*** in 1989 to a ***14% shortage*** in 1999.

23. In 1990, 6.0% of the population lived in poverty, which was below the state average of 6.6%. By 2000, poverty had increased to 6.8% of the population, but this still remained below the state average of 7.6%. The ESP's indicate that this group's share of poverty decreased slightly from a ***10% shortage*** in 1990 to an ***11% shortage*** in 2000. This does not mean that poverty decreased in the Urban Periphery. These seemingly contradictory figures indicate that other groups had increases for the population living in poverty.

Between 1990 and 2000, family income growth in the Urban Periphery was above the statewide growth rate. However, median family income for this group was still below the state median. The rate of poverty increased but remained below the statewide average.

Statistically, Manchester best represented this group in both 1990 and 2000. Manchester had 54,740 residents and a population density of 2,008psm in 2000. The population density was higher than the group average. In 1999, the median family income was $58,769, which was lower than the group median of $60,557. In 2000, Manchester had a poverty rate of 7.8%, which was higher than both the group average of 6.8% and the statewide average of 7.6%.

Figure 21: 1990 Map of the Urban Periphery

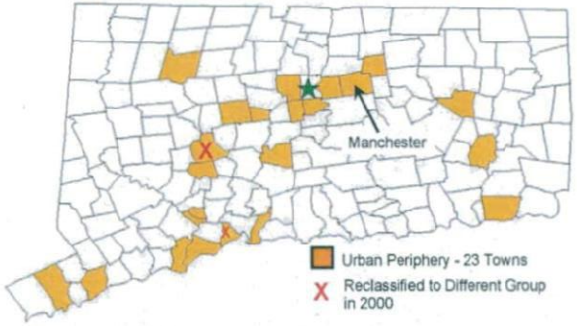


Figure 22: 2000 Map of the Urban Periphery

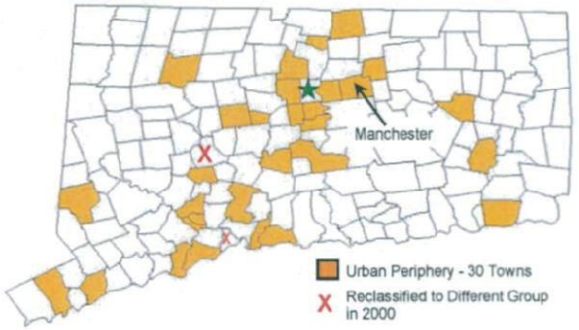
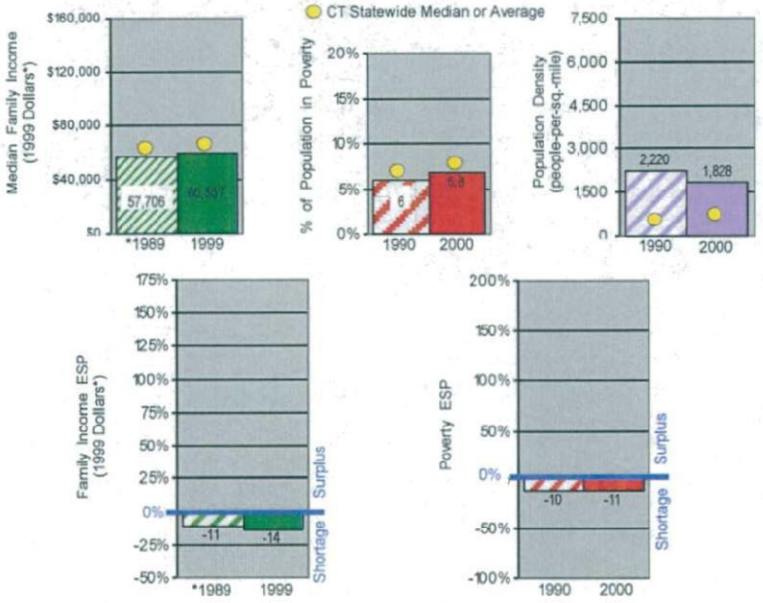


Figure 23: 1990 and 2000 Statistics for the Urban Periphery



Between 1989 and 1999, median family income in the Urban Periphery increased by 4.9%, which was slightly above the statewide median increase of 3.8%. However, in both 1989 and 1999, median family income in the Urban Periphery still remained below the statewide median.

Over 30% of the state's population lived in the Urban Periphery in both 1990 and 2000.

psm: people-per-sq.-mile

The population density of the Urban Periphery decreased from 2220psm in 1990 to 1828psm in 2000.

The poverty rate in the Urban Periphery was the closest to the statewide average in both 1990 and 2000.

The population of the Urban Periphery increased by 168,853 from 1990 to 2000. This was the largest increase of the five groups.

Urban Core - Bridgeport Type Towns

This group of towns can be characterized as having the ***lowest income***, ***highest poverty***, and ***the highest population density***. This group is very different from all other groups in income, poverty, and population density. The single most distinguishing characteristic is the extremely high population density. These towns are the densely populated urban core. Located in southwestern Connecticut, the coastal town of *Bridgeport* was the most representative of this group.

24-26. In 1990, the Urban Core had 5 towns and a population of 515,930 resulting in the highest population density of 7,264psm. In 2000, 2 towns were reclassified as Urban Core and the population totaled 641,573 for the group. By 2000, the population density had decreased but it was still the highest at 5,809psm.

The two towns reclassified as Urban Core in 2000 had previously been in the Urban Periphery. These towns were reclassified as Urban Core because their income, poverty, and population density measures had become more similar to those of Urban Core.

26. In 1989, median family income was ***$40,113*** (in 1999 dollars), as compared to the statewide median of $63,104. By 1999, the median family income had dropped by $542, or ***-1.4%***, to ***$39,571***, as compared with the statewide median family income of $65,521. The ESP's indicate that this group's share of family income dropped from a ***40% shortage*** in 1989 to a ***45% shortage*** in 1999.

26. In 1990, 19.1% of the population lived in poverty, which was above the state average of 6.6%. By 2000, poverty had increased to 19.4% of the population and remained above both the state average of 7.6% and the national average of 12.1%. The ESP's indicate that this group's share of poverty decreased from a ***188% surplus*** in 1990 to a ***155% surplus*** in 2000. This does not mean that poverty decreased in the Urban Core. These seemingly contradictory figures indicate that other groups had increases for the population living in poverty.

Between 1990 and 2000, family income growth in the Urban Core was negative. That is, after adjusting for inflation, family income was higher in 1990 than in 2000. The poverty rate increased between 1990 and 2000.

Statistically, Bridgeport best represented this group in both 1990 and 2000. Bridgeport had the highest population density of any town in both 1990 and 2000. In 1999, the median family income was $39,571, which was also the group median. Bridgeport had a poverty rate of 17.9%, which was below the group average of 19.4% in 2000.

Figure 24: 1990 Map of the Urban Core

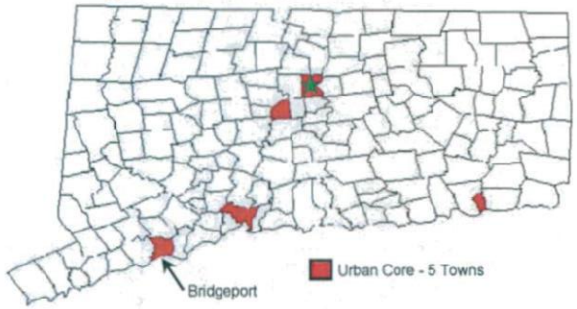


Figure 25: 2000 Map of the Urban Core

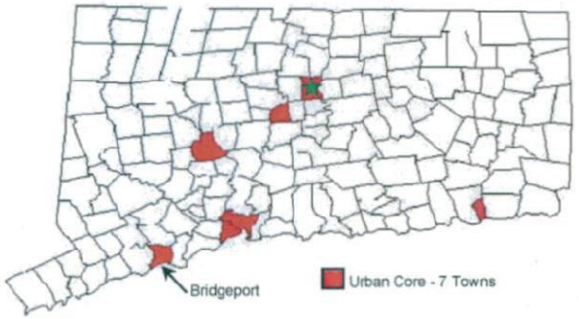
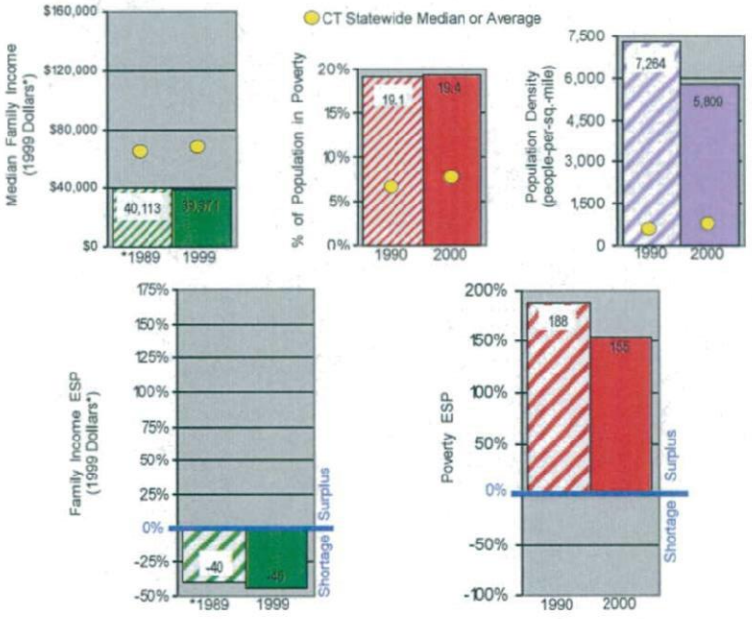


Figure 26: 1990 and 2000 Statistics for the Urban Core



Between 1989 and 1999, median family income decreased in Urban Core - after adjusting for inflation.

The poverty rate in the Urban Core was higher than the national average in both 1990 and 2000.

The population of the Urban Core increased by 125,643 from 1990 to 2000. This was the 2nd largest increase of the five groups.

In 2000, 10% of the population in the Urban Core lived in extreme poverty.

In 2000, 29% of children in the Urban Core lived in poverty.

psm: people-per-sq.-mile

The population density of the Urban Core dropped from 7,264psm in 1990 to 5,809psm in 2000.

Figure 27: 1990 to 2000 Town-Group Cross Reference

Town	1990 Group	New 2000 Group
Andover	Rural	
Ansonia	Urban Periphery	
Ashford	Rural	
Avon	Wealthy	Suburban
Barkhamsted	Rural	
Beacon Falls	Rural	
Berlin	Suburban	
Bethany	Rural	Suburban
Bethel	Suburban	
Bethlehem	Rural	Suburban
Bloomfield	Suburban	Urban Periphery
Bolton	Rural	Suburban
Bozrah	Rural	
Branford	Suburban	Urban Periphery
Bridgeport	Urban Core	
Bridgewater	Wealthy	Suburban
Bristol	Urban Periphery	
Brookfield	Suburban	
Brooklyn	Rural	
Burlington	Rural	Suburban
Canaan	Rural	
Canterbury	Rural	
Canton	Rural	Suburban
Chaplin	Rural	
Cheshire	Suburban	
Chester	Rural	Suburban
Clinton	Suburban	
Colchester	Rural	
Colebrook	Rural	
Columbia	Rural	Suburban
Cornwall	Rural	
Coventry	Rural	
Cromwell	Suburban	
Danbury	Suburban	Urban Periphery
Darien	Wealthy	
Deep River	Rural	
Derby	Urban Periphery	
Durham	Rural	Suburban
East Granby	Rural	Suburban
East Haddam	Rural	
East Hampton	Rural	
East Hartford	Urban Periphery	
East Haven	Urban Periphery	
East Lyme	Rural	
East Windsor	Rural	
Eastford	Rural	
Easton	Wealthy	
Ellington	Rural	Suburban
Enfield	Suburban	Urban Periphery
Essex	Suburban	

Town	1990 Group	New 2000 Group
Fairfield	Suburban	
Farmington	Suburban	
Franklin	Rural	
Glastonbury	Suburban	
Goshen	Rural	
Granby	Rural	Suburban
Greenwich	Wealthy	
Griswold	Rural	
Groton	Urban Periphery	
Guilford	Suburban	
Haddam	Rural	Suburban
Hamden	Suburban	Urban Periphery
Hampton	Rural	
Hartford	Urban Core	
Hartland	Rural	
Harwinton	Rural	Suburban
Hebron	Rural	Suburban
Kent	Rural	
Killingly	Rural	
Killingworth	Rural	Suburban
Lebanon	Rural	
Ledyard	Rural	
Lisbon	Rural	
Litchfield	Rural	
Lyme	Rural	Suburban
Madison	Suburban	
Manchester	Urban Periphery	
Mansfield	Rural	
Marlborough	Rural	Suburban
Meriden	Urban Periphery	
Middlebury	Rural	Suburban
Middlefield	Rural	
Middletown	Suburban	Urban Periphery
Milford	Urban Periphery	
Monroe	Suburban	
Montville	Rural	
Morris	Rural	
Naugatuck	Urban Periphery	
New Britain	Urban Core	
New Canaan	Wealthy	
New Fairfield	Suburban	
New Hartford	Rural	Suburban
New Haven	Urban Core	
New London	Urban Core	
New Milford	Rural	
Newington	Urban Periphery	
Newtown	Suburban	
Norfolk	Rural	
North Branford	Suburban	
North Canaan	Rural	

Town	1990 Group	New 2000 Group
North Haven	Suburban	
North Stonington	Rural	
Norwalk	Urban Periphery	
Norwich	Urban Periphery	
Old Lyme	Rural	
Old Saybrook	Suburban	
Orange	Suburban	
Oxford	Rural	Suburban
Plainfield	Rural	
Plainville	Urban Periphery	
Plymouth	Rural	
Pomfret	Rural	
Portland	Rural	
Preston	Rural	
Prospect	Suburban	
Putnam	Rural	
Redding	Wealthy	Suburban
Ridgefield	Wealthy	
Rocky Hill	Suburban	Urban Periphery
Roxbury	Rural	Suburban
Salem	Rural	Suburban
Salisbury	Rural	
Scotland	Rural	
Seymour	Suburban	Urban Periphery
Sharon	Rural	
Shelton	Suburban	
Sherman	Rural	Suburban
Simsbury	Wealthy	Suburban
Somers	Rural	
South Windsor	Suburban	
Southbury	Rural	Suburban
Southington	Suburban	
Sprague	Rural	
Stafford	Rural	
Stamford	Urban Periphery	
Sterling	Rural	
Stonington	Rural	
Stratford	Urban Periphery	
Suffield	Rural	Suburban
Thomaston	Rural	
Thompson	Rural	
Tolland	Rural	Suburban
Torrington	Urban Periphery	
Trumbull	Suburban	
Union	Rural	
Vernon	Urban Periphery	
Voluntown	Rural	
Wallingford	Suburban	
Warren	Rural	
Washington	Rural	Suburban

Town	1990 Group	New 2000 Group
Waterbury	Urban Periphery	Urban Core
Waterford	Rural	
Watertown	Suburban	
West Hartford	Urban Periphery	
West Haven	Urban Periphery	Urban Core
Westbrook	Rural	
Weston	Wealthy	
Westport	Wealthy	
Wethersfield	Urban Periphery	
Willington	Rural	
Wilton	Wealthy	
Winchester	Rural	
Windham	Urban Periphery	
Windsor	Suburban	
Windsor Locks	Suburban	Urban Periphery
Wolcott	Suburban	
Woodbridge	Wealthy	Suburban
Woodbury	Rural	Suburban
Woodstock	Rural	

Race

Race was ***not*** used to determine group membership. Any trends in group membership that appear to be racially linked may, in fact, be related to some other variable/s. Consult the preceding report in this series, *Part 1: Comparing Connecticut to National Averages,* for information on bridging 1990 and 2000 race categories. Multiracial respondents in 2000 were bridged to either Hispanic, White, Black, or Other depending upon the combination of ethnicity and races selected.

In this report Hispanics are treated as a separate race. Whites, Blacks, and Other race categories do not include Hispanics.

In 1990, the racial composition of Connecticut was 83.8% White, 6.5% Hispanic, 7.9% Black, and 1.8% Other. By 2000, the percentages had changed to 78.3% White, 9.4% Hispanic, 9.4% Black, and 3% Other.

From 1990 to 2000, Connecticut's population increased by 118,449 from 3,287,116, in 1990, to 3,405,565 in 2000. The White population decreased in absolute numbers by 88,747; Hispanics increased by 107,207; Blacks increased by 57,779; and Other increased by 42,210.

Race ESP's are relative to the group's population size. The "Other" racial group was composed predominately of Asians.

Wealthy - Westport Type Towns

28a-b. In 1990, the racial composition of this group was 94.4% White, 2.2% Hispanic, 1.1% Black, and 2.3% Other. By 2000, the racial composition was 91.9% White, 3.4% Hispanic, 1.2% Black, and 3.5% Other.

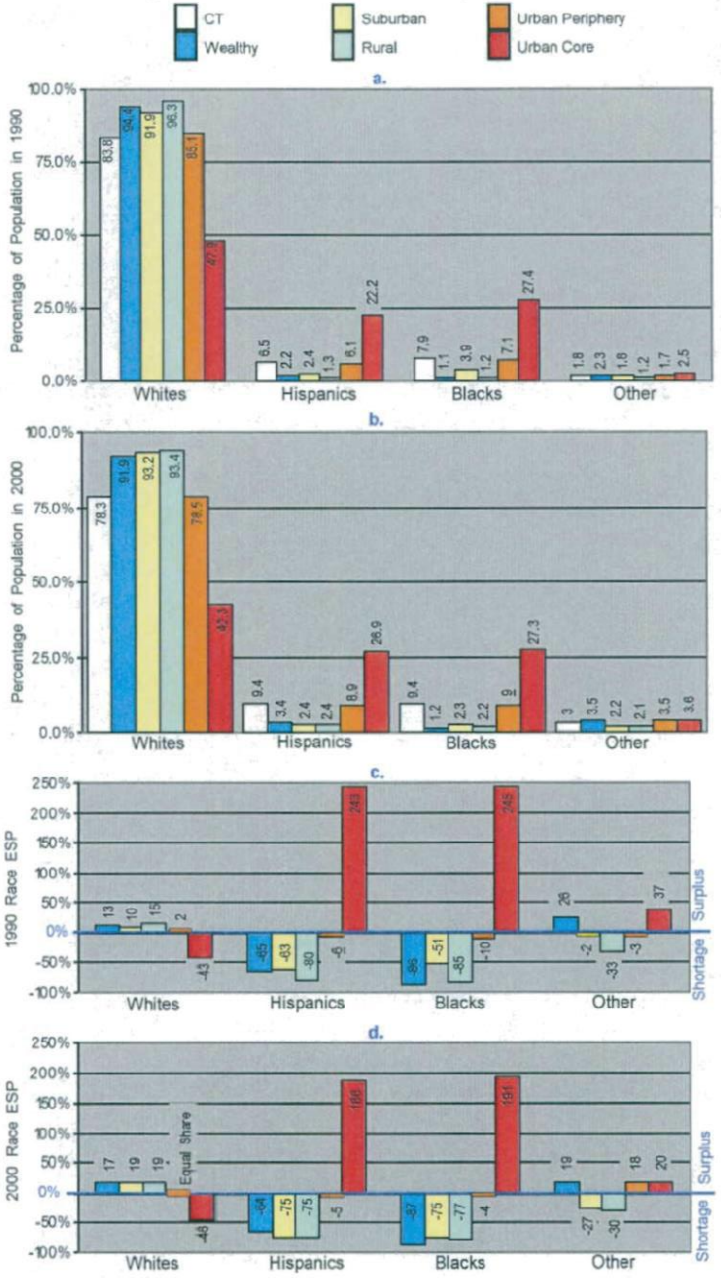
28c-d. The 1990 to 2000 ESP's indicate that the share of Whites increased from a 13% surplus to a 17% surplus; Hispanics increased slightly from a 65% shortage to a 64% shortage; Blacks decreased slightly from an 86% shortage to an 87% shortage; and Other decreased from a 26% surplus to a 19% surplus.

Between 1990 and 2000, Wealthy Connecticut ***changed little*** in its racial composition. The percentage of White residents decreased slightly from 94.4% in 1990 to 91.9% in 2000, however, this was still a much higher percentage than the statewide average of 78.3% in 2000. There was an increase in the share of Whites from a 13% surplus in 1990 to a 17% surplus in 2000. This increase in share occurred because other groups lost Whites at a higher rate than Wealthy Connecticut.

Suburban - Cheshire Type Towns

28a-b. In 1990, the racial composition of this group was 91.9% White, 2.4% Hispanic, 3.9% Black, and 1.8% Other. By 2000, the racial composition was 93.2% White, 2.4% Hispanic, 2.3% Black, and 2.2% Other.

Figure 28: 1990 and 2000 Race by Town Group



The U.S Census defines racial categories as "socio-political constructs and should not be interpreted as being scientific or anthropological in nature."

In Connecticut, between 1990 and 2000, the White population decreased in absolute numbers by 88,747; Hispanics increased by 107,207; Blacks increased by 57,779; and those classified as Other increased by 42,210.

In both 1990 and 2000, Wealthy Connecticut had the lowest percentage of Blacks.

Between 1990 and 2000, Suburban Connecticut was the only group to have an increase in the percentage of Whites.

28c-d. The 1990 to 2000 ESP's indicate that the share of Whites increased from a 10% surplus to a 19% surplus; Hispanics decreased from a 63% shortage to a 75% shortage; Blacks decreased from a 51% shortage to a 75% shortage; and Other decreased from a 2% shortage to a 27% shortage.

Between 1990 and 2000, Suburban Connecticut became ***more White***. The percentage of White residents increased from 91.9% in 1990 to 93.2% in 2000. This was the only group to experience a decrease in the percentage of nonwhites. Racial transition in Suburban Connecticut was also opposite the statewide trend which saw a decrease in the percentage of the White population.

Rural - North Stonington Type Towns

28a-b. In 1990, the racial composition of this group was 96.3% White, 1.3% Hispanic, 1.2% Black, and 1.2% Other. By 2000, the racial composition was 93.4% White, 2.4% Hispanic, 2.2% Black, and 2.1% Other.

28c-d. The 1990 to 2000 ESP's indicate that the share of Whites increased from a 15% surplus to a 19% surplus; Hispanics increased from a 80% shortage to a 75% shortage; Blacks increased from an 85% shortage to a 77% shortage; and Other increased from a 33% shortage to a 30% shortage.

Rural Connecticut had the highest percentage of Whites in both 1990 and 2000. However, between 1990 and 2000, Rural Connecticut became ***slightly less White***. The percentage of White residents decreased from 96.3% in 1990 to 93.4% in 2000, however, this was still a much higher percentage than the statewide average of 78.3% in 2000. There was an increase in the share of Whites from a 15% surplus in 1990 to a 19% surplus in 2000. This increase in share occurred because other groups lost Whites at a higher rate than Rural Connecticut.

Urban Periphery - Manchester Type Towns

28a-b. In 1990, the racial composition of this group was 85.1% White, 6.1% Hispanic, 7.1% Black, and 1.7% Other. By 2000, the racial composition was 78.5% White, 8.9% Hispanic, 9.0% Black, and 3.5% Other.

28c-d. The 1990 to 2000 ESP's indicate that the share of Whites decreased slightly from a 2% surplus to an equal share; Hispanics increased slightly from a 6% shortage to a 5% shortage; Blacks increased from a 10% shortage to a 4% shortage; and Other increased from a 3% shortage to an 18% surplus.

The Urban Periphery was home to over 30% of state residents in both 1990 and 2000. The racial transition, between 1990 and 2000, in this group paralleled statewide trends. The racial composition of the Urban Periphery, in both 1990 and 2000, was the ***most similar*** to the ***statewide averages*** of any of the five groups.

Urban Core - Bridgeport Type Towns

28a-b. In 1990, the racial composition of this group was 47.9% White, 22.2% Hispanic, 27.4% Black, and 2.5% Other. By 2000, the racial composition was 42.3% White, 26.9% Hispanic, 27.3% Black, and 3.6% Other.

28c-d. The 1990 to 2000 ESP's indicate that the share of Whites decreased from a 43% shortage to a 46% shortage; Hispanics decreased from a 243% surplus to a 186% surplus; Blacks decreased from a 245% surplus to a 191% surplus; and Other decreased from a 37% surplus to a 20% surplus.

The racial composition of the Urban Core was very different from all other groups. It had the ***most minorities*** of any group in both 1990 and 2000, and became even less white in 2000. Connecticut's minority population is concentrated in the Urban Core, which was home to over half of all Hispanics and Blacks in Connecticut. In 2000, only 18.8% of the state's population lived in the Urban Core. However, ***54%*** of all Hispanics statewide and ***55%*** of all Blacks statewide lived in the Urban Core.

Summary

There was a surplus of Whites in Wealthy, Suburban, and Rural Connecticut. Whites had a balanced incidence only in the Urban Periphery. In the Urban Core there was a large shortage of Whites.

There was a shortage of Hispanics and Blacks in Wealthy, Suburban, and Rural Connecticut. Hispanics and Blacks had the most balanced incidence in the Urban Periphery. There was a surplus of Hispanics and Blacks in the Urban Core.

The Other racial category, which is mostly Asian, had a surplus in Wealthy, the Urban Core, and in the Urban Periphery in 2000. However, there was a shortage of Others in Suburban and Rural Connecticut.

Connecticut's white and nonwhite populations were not uniformly spread across the state. In 2000, over half, ***55%***, of ***Whites*** in Connecticut lived in towns that were at least ***90%*** White. This corresponded with ***78%***, 132 of 169, of Connecticut towns being at least 90% White.

In 2000, the 10 towns with the highest population of Hispanics accounted for ***71%*** of all ***Hispanics*** in Connecticut.

In 2000, the 10 towns with the highest population of Blacks accounted for ***70%*** of all ***Blacks*** in Connecticut.

Also in 2000, the 10 towns with the highest population of Other, who are predominately Asian, accounted for ***42%*** of all ***Others*** in Connecticut. The Other racial group was not as geographically

Rural Connecticut had the highest percentage of Whites in both 1990 and 2000.

The racial composition of the Urban Periphery, in both 1990 and 2000, was the most similar to the statewide averages of any of the five groups.

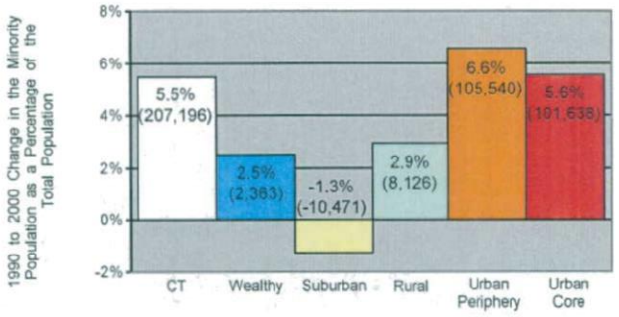
In 2000, 54% of all Hispanics statewide and 55% of all Blacks statewide lived in the Urban Core.

In 2000, over half, 55%, of Whites in Connecticut lived in towns that were at least 90% white.

In 2000, the 10 towns with the highest population of Hispanics accounted for 71% of all Hispanics in Connecticut.

In 2000, the 10 towns with the highest population of Blacks accounted for 70% of all Blacks in Connecticut.

Figure 29: 1990 to 2000 Percentage Change in Minorities by Town Group



concentrated as Hispanics and Blacks.

29. Between 1990 and 2000, the growth in the minority (nonwhite) population was also different among the groups. The minority population in Wealthy Connecticut grew by 2.5%, while the minority population in Suburban Connecticut ***decreased*** by 1.3%. Rural Connecticut had an increase of 2.9%. The Urban Periphery, with a 6.6% increase, and the Urban Core, with a 5.6% increase, had increases that were closest to the statewide increase of 5.5%.

Age

In 1990, age distribution in Connecticut was 22.8% children (17 and under), 10.5% young adults (18 to 24), and 66.7% adults (25 and over). By 2000, the statewide percentages were 24.7% children, 8% young adults, and 67.3% adults. Statewide, the percentage of children and adults increased while the percentage of young adults decreased.

Age ESP's are relative to the group's population size.

Wealthy - Westport Type Towns

30a-b. In 1990, Wealthy Connecticut was composed of 22.8% children, 7.4% young adults, and 69.8% adults. By 2000, the age distribution was 28.9% children, 3.4% young adults, and 67.7% adults.

30c-d. The 1990 to 2000 ESP's indicate that the share of children increased from an equal share to a 17% surplus; young adults decreased from a 30% shortage to a 58% shortage; and adults decreased from a 5% surplus to a 1% surplus.

Wealthy Connecticut had the smallest percentage of young adults in both 1990 and 2000. Furthermore, the percentage of young adults dropped from 7.4% to 3.4% during this same period. In contrast, by 2000, Wealthy Connecticut had the highest percentage, 28.9%, of children in the state.

Suburban - Cheshire Type Towns

30a-b. In 1990, Suburban Connecticut was composed of 22.3% children, 9.6% young adults, and 68.1% adults. By 2000, the age distribution was 25.6% children, 5.4% young adults, and 69% adults.

30c-d. The 1990 to 2000 ESP's indicate that the share of children increased from a 2% shortage to a 3% surplus; young adults decreased from a 9% shortage to a 32% shortage; and adults increased from a 2% surplus to a 3% surplus.

Between 1990 and 2000, Suburban Connecticut experienced a drop in young adults from 9.6% in 1990 to 5.4% in 2000. In contrast, Suburban Connecticut had an increase in children from 22.3% in 1990 to 25.6% in 2000. These trends paralleled what was happening in Wealthy Connecticut.

Rural - North Stonington Type Towns

30a-b. In 1990, Rural Connecticut was composed of 24% children, 9.9% young adults, and 66.1% adults. By 2000, the age distribution was 24.2% children, 8.7% young adults, and 67.1% adults.

30c-d. The 1990 to 2000 ESP's indicate that the share of children decreased from a 5% surplus to a 2% shortage; young adults increased from a 6% shortage to an 8% surplus; and adults increased from a 1% shortage to an equal share.

Between 1990 and 2000, Rural Connecticut's share of children decreased and its share of young adults increased. This was opposite to the trends in Wealthy and Suburban Connecticut.

Urban Periphery - Manchester Type Towns

30a-b. In 1990, the Urban Periphery of Connecticut was composed of 21.6% children, 10.2% young adults, and 68.3% adults. By 2000, the age distribution was 22.6% children, 8% young adults, and 69.4% adults.

30c-d. The 1990 to 2000 ESP's indicate that the share of children decreased from a 5% shortage to a 9% shortage; young adults increased from a 3% shortage to an equal share; and adults increased from a 2% surplus to a 3% surplus.

Trends in the Urban Periphery were similar to what happened in Rural Connecticut. The share of children was down and the share of young adults was up. In 2000, the Urban Periphery had the highest percentage of adults at 69.4%.

Urban Core - Bridgeport Type Towns

30a-b. In 1990, the Urban Periphery of Connecticut was composed of 24.8% children, 14.9% young adults, and 60.3% adults. By 2000, the age distribution was 26.7% children, 12.3% young adults, and 60.9% adults.

30c-d. The 1990 to 2000 ESP's indicate that the share of children

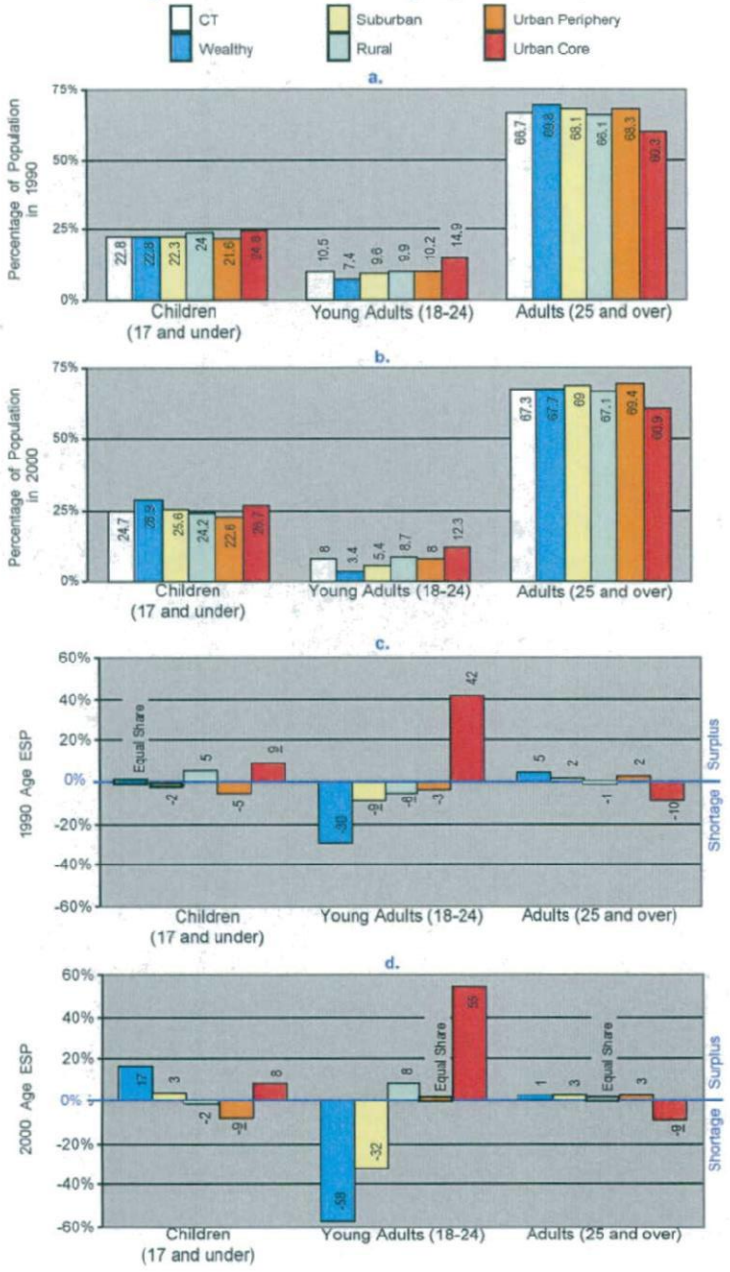
In 2000, the Wealthy group had a 58% shortage in young adults.

In 2000, the Urban Core had a 55% surplus of young adults.

In 2000, 29% of all young adults in Connecticut lived in the Urban Core, while only 18.8% of the state's total population lived in the Urban Core.

Between 1990 and 2000, the share of children decreased and the share of young adults increased in both Rural Connecticut and the Urban Periphery.

Figure 30: 1990 and 2000 Age by Town Group



decreased slightly from a 9% surplus to an 8% surplus; young adults increased from a 42% surplus to 55% surplus; and adults increased slightly from a 10% shortage to a 9% shortage.

The most striking age related trend in the Urban Core was the group's increase in its share of young adults. Statewide, there was a net loss in young adults. However, the Urban Core retained a disproportionate share of young adults compared to other groups. In 2000, only 18.8% of the state's total population lived in the Urban Core, however, 29% of all young adults in Connecticut lived in the Urban Core.

Summary

Between 1990 and 2000 there were both similarities and differences in age distribution among the five town groups.

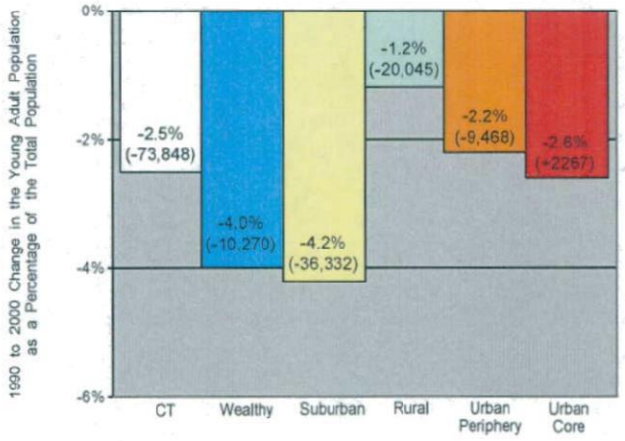
The percentage of children increased in all groups. This was most evident in the Wealthy and Suburban groups.

The percentage of adults increased in all groups except Wealthy Connecticut.

31. There was a drop in the percentage of young adults in all groups. The Wealthy group, at –4%, and the Suburban group, at –4.2, had the largest percentage losses in young adults. The Rural group had the smallest loss at 1.2%. The Urban Periphery, at –2.2%, and the Urban Core, at –2.6%, approximated the statewide loss of –2.5%.

The result was an increase in the share of young adults in Rural Connecticut, the Urban Periphery, and the Urban Core.

Figure 31: 1990 to 2000 Percentage Change in Young Adults by Town Group



Between 1990 and 2000, the percentage of young adults dropped in all five groups.

The Wealthy and Suburban groups had the largest percentage drop in young adults.

The lowest percentage drop in young adults was in the Rural group.

Household Types

In 1990, the statewide division of households was 29.1% nonfamily, 56.8% married couples, 11.1% female-headed, and 3% male-headed. By 2000, the percentages had changed to 32% nonfamily, 52.7% married couples, 11.7% female-headed, and 3.6% male-headed.

Between 1990 and 2000, statewide averages indicated that the percentage of nonfamily households increased with a corresponding decrease in the percentage of married couple households.

Households ESP's are based on the number of households in the group.

Wealthy - Westport Type Towns

32a-b. In 1990, Wealthy Connecticut households were divided into 22.7% nonfamily, 68.1% married couples, 7.1% female-headed, and 2.2% male-headed households. By 2000, Wealthy Connecticut households were divided into 23.9% nonfamilies, 68.3% married couples, 6.1% female-headed, and 1.6% male-headed.

32c-d. The 1990 to 2000 ESP's indicate that the share of nonfamilies decreased from a 22% shortage to a 25% shortage; married couples increased from a 20% surplus to a 30% surplus; female-headed households decreased from a 36% shortage to a 48% shortage; and male -headed households decreased from a 28% shortage to a 54% shortage.

In both 1990 and 2000, Wealthy Connecticut had the largest percentage of married couple households of any group. It also had the lowest percentage of nonfamilies, female-headed, and male-headed households of any group. Between 1990 and 2000, this group increased its share of married couple households while decreasing its share of all other household types.

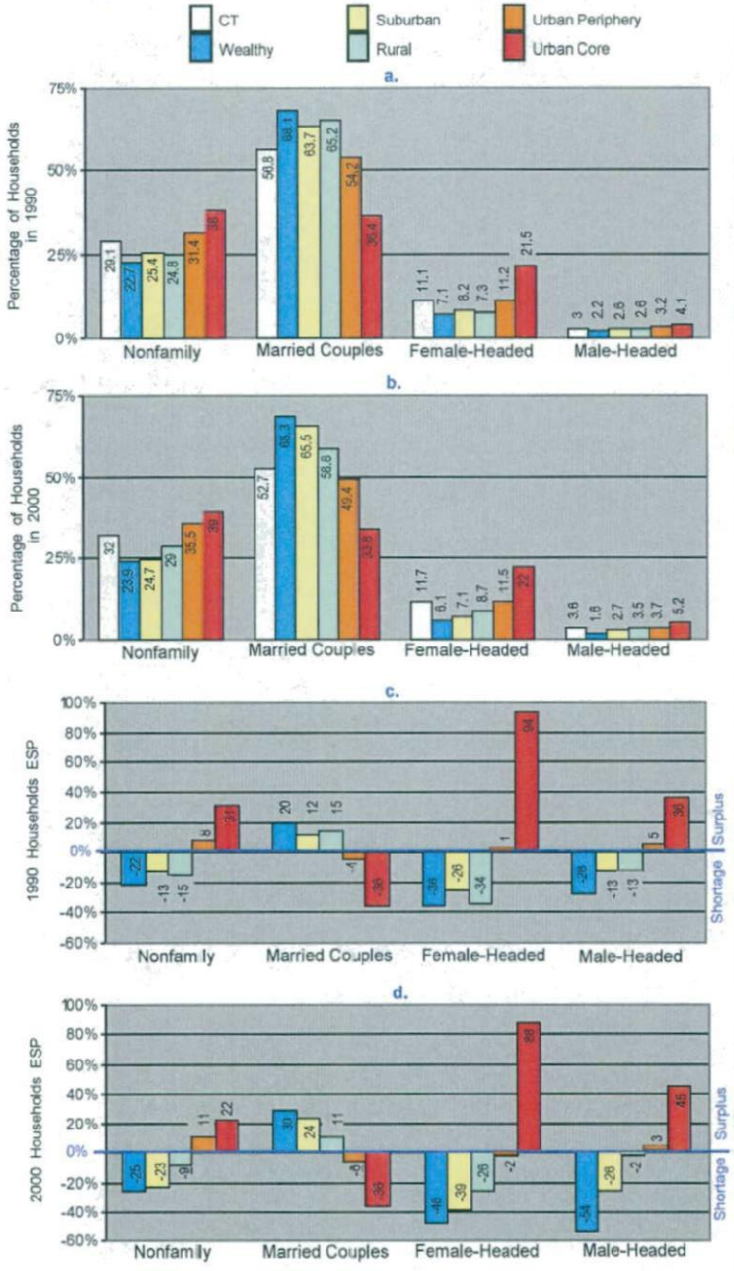
Suburban - Cheshire Type Towns

32a-b. In 1990, Suburban Connecticut households were divided into 25.4% nonfamily, 63.7% married couples, 8.2% female-headed, and 2.6% male-headed households. By 2000, Suburban Connecticut households were divided into 24.7% nonfamilies, 65.5% married couples, 7.1% female-headed, and 2.7% male-headed.

32c-d. The 1990 to 2000 ESP's indicate that the share of nonfamilies decreased from a 13% shortage to a 23% shortage; married couples increased from a 12% surplus to a 24% surplus; female-headed households decreased from a 26% shortage to a 39% shortage; and male -headed households decreased from a 13% shortage to a 26% shortage.

Between 1990 and 2000, the household trends in Suburban Connecticut were similar to that of Wealthy Connecticut. The percentage of married couple households increased. Also, there was an increase in the share of married couple households and decreases in the

Figure 32: 1990 and 2000 Household Types by Town Group



The Census defines four types of households. There are three "family type" households in which all members are related to the householder by birth, marriage or adoption. These include married couples, female-headed (no spouse present) and male-headed (no spouse present). In addition, there is the nonfamily household, which is comprised of only a single person or two or more people living together who are not related by birth, marriage or adoption.

shares of all other household types.

Rural - North Stonington Type Towns

32a-b. In 1990, Rural Connecticut households were divided into 24.8% nonfamily, 65.2% married couples, 7.3% female-headed, and 2.6% male-headed households. By 2000, Rural Connecticut households were divided into 29% nonfamilies, 58.8% married couples, 8.7% female -headed, and 3.5% male-headed.

32c-d. The 1990 to 2000 ESP's indicate that the share of nonfamilies increased from a 15% shortage to a 9% shortage; married couples decreased from a 15% surplus to an 11% surplus; female-headed households increased from a 34% shortage to a 26% shortage; and male-headed households increased from a 13% shortage to a 2% shortage.

Between 1990 and 2000, Rural Connecticut experienced a loss in the percentage of married couple families. There was a corresponding increase in the percentage of nonfamily, female-headed, and male-headed households. These trends were opposite to the Wealthy and Suburban groups.

Urban Periphery - Manchester Type Towns

32a-b. In 1990, households in the Urban Periphery of Connecticut were divided into 31.4% nonfamily, 54.2% married couples, 11.2% female-headed, and 3.2% male-headed households. By 2000, households in the Urban Periphery were divided into 35.5% nonfamilies, 49.4% married couples, 11.5% female-headed, and 3.7% male-headed.

32c-d. The 1990 to 2000 ESP's indicate that the share of nonfamilies increased from an 8% surplus to an 11% surplus; married couples decreased from a 4% shortage to a 6% shortage; female-headed households decreased from a 1% surplus to a 2% shortage; and male-headed households decreased from a 5% surplus to a 3% surplus.

In both 1990 and 2000, the distribution of household types in the Urban Periphery most resembled the statewide averages. This group also mirrored the statewide average trends of increasing nonfamily households, increasing female-headed and male-headed households, and decreasing married couple households.

Urban Core - Bridgeport Type Towns

32a-b. In 1990, households in the Urban Core of Connecticut were divided into 38% nonfamily, 36.4% married couples, 21.5% female-headed, and 4.1% male-headed households. By 2000, households in the Urban Core were divided into 39% nonfamilies, 33.8% married couples, 22% female-headed, and 5.2% male-headed.

32c-d. The 1990 to 2000 ESP's indicate that the share of nonfamilies decreased from a 31% surplus to a 22% surplus; married couples remained unchanged at a 36% shortage; female-headed households decreased from a 94% surplus to an 88% surplus; and male-headed households increased from a 36% surplus to a 45% surplus. The decrease in shares of nonfamilies and female-headed households occurred because other groups had a larger percentage increase in these household types.

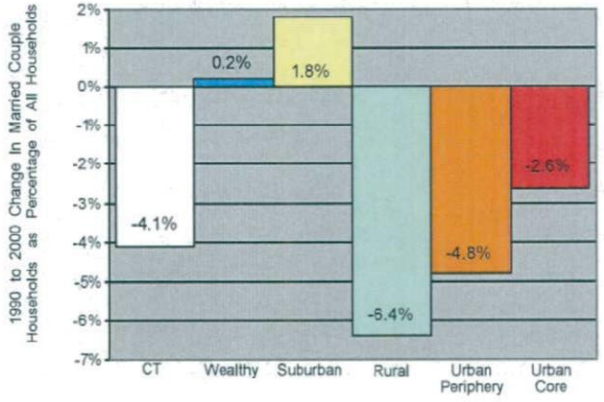
Between 1990 and 2000, household trends in the Urban Core also mirrored the statewide average trends. Furthermore, in both 1990 and 2000, the Urban Core had the largest surplus of nonfamily, female-headed, and male-headed households, as well as the largest shortage of married couple households. In 2000, 35% of all female-headed households statewide and 27% of all male-headed households statewide lived in the Urban Core, which accounted for only 19% of all households statewide.

Summary

33. The statewide averages showed a trend towards more nonfamily households. Among family households, the trend was toward more single-parent households. However, these trends were not common to all five groups. Figure 33 shows an increase in the percentage of married couple households in Wealthy Connecticut, at 0.2%, and Suburban Connecticut, at 1.8%. However, statewide there was a decrease of 4.1% in married couple households. A decline in married couple households was seen in Rural Connecticut, at -6.4%, the Urban Periphery, at -4.8%, and the Urban Core, at -2.6%.

Only the Suburban group had a decrease in the percentage of nonfamily households between 1990 and 2000. The Suburban group

Figure 33: 1990 to 2000 Percentage Change in Married Couple Households by Town Group



In 2000, 39% of all households in the Urban Core were nonfamily households. This was the highest percentage for any group.

Only the Suburban group had a decrease in the percentage of nonfamily households between 1990 and 2000.

In 2000, 35% of all female-headed households statewide and 27% of all male-headed households statewide lived in the Urban Core, which accounted for only 19% of all households statewide.

In both 1990 and 2000, the Urban Core had the largest surplus of nonfamily, female-headed, and male -headed households, as well as the largest shortage of married couple households.

The Wealthy and Suburban groups were the only groups to have an increase in the percentage of married couple households between 1990 and 2000.

also had the largest increase in the percentage of married couple households. These trends were contrary to statewide average trends.

The percentage of nonfamily households in Wealthy, Rural, the Urban Periphery, and the Urban Core did follow the statewide average trends, to varying degrees, towards more nonfamily households.

32b. The most striking trend was the pattern in the distribution of household types starting with Wealthy Connecticut and moving progressively to the Urban Core. For example, the Wealthy group had the highest percentage of married couples in 2000 at 68.3%. Moving through Suburban (65.5%), to Rural (58.8%), to Urban Periphery (49.4%), and to the Urban Core (33.8%) there was a steady decrease in the percentage of married couple families. This pattern, whether increasing or decreasing in percentages, occurred in 1990 and 2000 for all household types.

Families with Two or More Workers

In 1990, 64.3% of all families in Connecticut had two or more workers. Connecticut was then ranked 9th highest in the nation. By 2000, Connecticut had dropped to 18th highest with 60% all of families having two or more workers.

Family worker ESP's are based on the number of families in the group.

Wealthy - Westport Type Towns

34a-b. In 1990, 63.3% of families in Wealthy Connecticut had two or more workers. By 2000, 52.9% of families in this group had two or more workers.

34c-d. The 1990 to 2000 ESP's indicate that the share of families with two or more workers decreased from a 2% shortage to a 12% shortage.

Between 1990 and 2000, Wealthy Connecticut had the largest decrease in both the percentage of families with two or more workers and in the share of families with two or more workers.

Suburban - Cheshire Type Towns

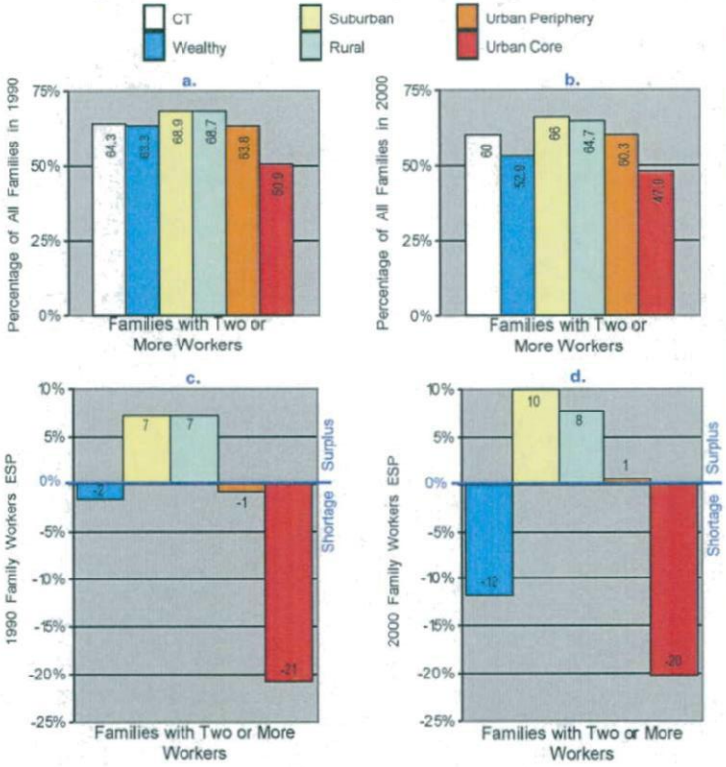
34a-b. In 1990, 68.9% of families in Suburban Connecticut had two or more workers. By 2000, 66% of families in this group had two or more workers.

34c-d. The 1990 to 2000 ESP's indicate that the share of families with two or more workers increased from a 7% surplus to a 10% surplus .

Between 1990 and 2000, Suburban Connecticut saw a decrease in the percentage of families with two or more workers. This followed the statewide trend. However, it's share of families with two or more workers increased from a 7% surplus in 1990 to a 10% surplus in 2000.

Suburban Connecticut had the highest percentage of families with two or more workers in both 1990 and 2000.

Figure 34: 1990 and 2000 Family Workers by Town Group



Rural - North Stonington Type Towns

34a-b. In 1990, 68.7% of families in Rural Connecticut had two or more workers. By 2000, 64.7% of families in this group had two or more workers.

34c-d. The 1990 to 2000 ESP's indicate that the share of families with two or more workers increased from a 7% surplus to an 8% surplus.

Between 1990 and 2000, Rural Connecticut saw a decrease in the percentage of families with two or more workers. This followed the statewide trend.

Between 1990 and 2000, Wealthy Connecticut had the largest decrease in the percentage of families with two or more workers.

Suburban Connecticut had the highest percentage of families with two or more workers in both 1990 and 2000.

The Urban Core had both the lowest percentage of families with two or more workers and largest shortage of families with two or more workers in both 1990 and 2000.

Urban Periphery - Manchester Type Towns

34a-b. In 1990, 63.8% of families in the Urban Periphery had two or more workers. By 2000, 60.3% of families in this group had two or more workers.

34c-d. The 1990 to 2000 ESP's indicate that the share of families with two or more workers increased from a 1% shortage to a 1% surplus.

Between 1990 and 2000, the Urban Periphery of Connecticut saw a decrease in the percentage of families with two or more workers. This followed the statewide trend.

Urban Core - Bridgeport Type Towns

34a-b. In 1990, 50.9% of families in the Urban Core had two or more workers. By 2000, 47.9% of families in this group had two or more workers.

34c-d. The 1990 to 2000 ESP's indicate that the share of families with two or more workers increased from a 21% shortage to a 20% shortage.

Between 1990 and 2000, the Urban Core of Connecticut saw a decrease in the percentage of families with two or more workers. This followed the statewide trend.

The Urban Core had both the lowest percentage of families with two or more workers and largest shortage of families with two or more workers in both 1990 and 2000.

Summary

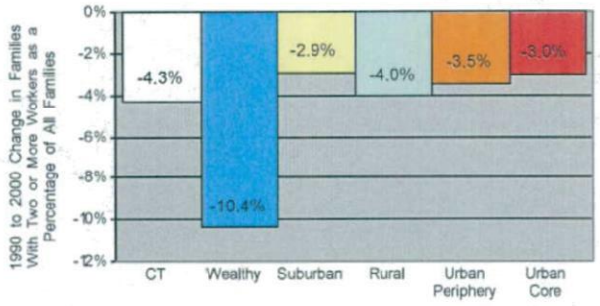
35. Between 1990 and 2000, all five groups experienced a drop in the percentage of families with two or more workers. For the Rural, Urban Periphery, and Urban Core groups, this may have been partially due to the drop in the percentage of married couple households (see Figure 33). The largest drop in the percentage of families with two or more workers was -10.4% in Wealthy Connecticut. The lowest drops were -2.9% in Suburban Connecticut and -3.0 in the Urban Core.

34d. By 2000, Wealthy Connecticut (12% shortage) and the Urban Core (20% shortage) had the two largest shortages of families with two or more workers. The Wealthy group and the Urban Core group are generally dissimilar in most aspects. However, different socioeconomic dynamics within these two groups generated similar results for families with two or more workers.

33. The Wealthy group had a slight increase, at 0.2%, in the percentage of married couple households between 1990 and 2000. This group also had a significant increase in income during this time period. The result may have been more married couple families with higher incomes from a single earner.

33. Conversely, the Urban Core had a decrease, at –2.6%, in the

Figure 35: 1990 to 2000 Percentage Change in Families with Two or More Workers by Town Group



percentage of married couple households. However, income growth in the Urban Core remained flat, or was negative, during the 1990's, which was opposite to what happened in the Wealthy group. The decrease in the percentage of families with two or more workers in the Urban Core may have been due to the decrease in married couple families, an inability to find jobs, or a combination of these and other factors. Whatever the cause, the Urban Core and Wealthy groups had a similar trend in the 1990's, but different underlying causes.

Census Income

Unless otherwise noted, when citing 1989 income this report presents 1989 income figures that have been inflation-adjusted to 1999 values. Review the Methodology section, at the end of this report, for the inflation multipliers used in calculating inflation-adjusted income.

In 1989, per capita income in Connecticut was $25,895 (in 1999 dollars), which grew by $2,871, or 11.1%, to $28,766 in 1999.

In 1989, the median household income in Connecticut was $53,513 (in 1999 dollars), which grew by $422, or 0.8%, to $53,935 in 1999.

In 1989, the median family income in Connecticut was $63,104 (in 1999 dollars), which grew by $2,417, or 3.8%, to $65,521 in 1999.

Per capita income ESP's are relative to the group's population size. Household income ESP's are relative to the number of households in the group. Family income ESP's are relative to the number of families in the group.

Wealthy - Westport Type Towns

36a-d. Per capita income in Wealthy Connecticut grew from $54,007 in 1989 to $70,910 in 1999. This was an increase of $16,903, or 31.3%, for the group and ***6 times*** the statewide increase in per capita income of $2,871. The 1989 to 1999 ESP's indicate that the share of per capita

The 1990 Decennial Census reported income based on 1989 earnings.

The 2000 Decennial Census reported income based on 1999 earnings.

Per capita income is the average income computed for every man, woman, and child in a particular area or group.

Median income is the midpoint for measuring household and family income. One-half of all households and families have incomes that are below the median/midpoint. The other half of households and families have incomes that are above the median/midpoint.

When measuring income, a family includes a householder and one or more other people living in the same household who are related to the householder by birth, marriage, or adoption.

income increased from a 109% surplus to a 147% surplus.

36a-d. Median household income in Wealthy Connecticut increased from $96,500 in 1989 to $133,493 in 1999. This was an increase of $36,993, or 38.3%, for the group and ***88 times*** the statewide increase in median household income of $422. The 1989 to 1999 ESP's indicate that the share of household income increased from a 114% surplus to a 164% surplus.

36a-d. Median family income in Wealthy Connecticut increased from $107,073 in 1989 to $155,655 in 1999. This was an increase of $48,582, or 45.4%, for the group and ***20 times*** the statewide increase in median family income of $2,417. The 1989 to 1999 ESP's indicate that the share of family income increased from a 111% surplus to a 160% surplus.

In 2000, only 5.4% of the state's population lived in Wealthy Connecticut. However, this group received 13.3% of the state's income (based on aggregate per capita income). Furthermore, income in Wealthy Connecticut may be under-reported by the U.S. Census. If so, Wealthy Connecticut had an even higher level of income than reported here. This topic is covered in more detail in the section titled *Unreported Capital Gains Income in Wealthy Connecticut.*

Suburban - Cheshire Type Towns

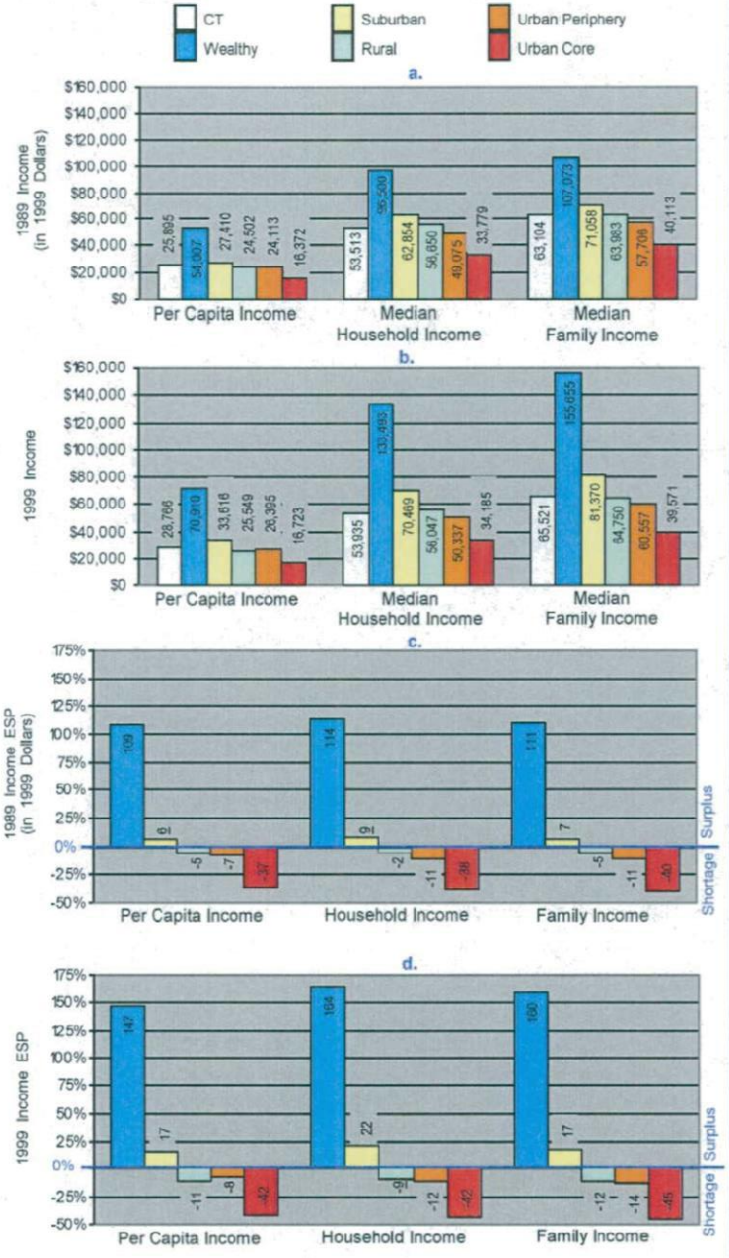
36a-d. Per capita income in Suburban Connecticut grew from $27,410 in 1989 to $33,616 in 1999. This was an increase of $6,206, or 22.6%, for the group and ***2 times*** the statewide increase in per capita income of $2,871. The 1989 to 1999 ESP's indicate that the share of per capita income increased from a 6% surplus to a 17% surplus.

36a-d. Median household income in Suburban Connecticut increased from $62,854 in 1989 to $70,469 in 1999. This was an increase of $7,615, or 12.1%, for the group and ***18 times*** the statewide increase in median household income of $422. The 1989 to 1999 ESP's indicate that the share of household income increased from a 9% surplus to a 22% surplus.

36a-d. Median family income in Suburban Connecticut increased from $71,058 in 1989 to $81,370 in 1999. This was an increase of $10,312, or 14.5%, for the group and ***4 times*** the statewide increase in median family income of $2,417. The 1989 to 1999 ESP's indicate that the share of family income increased from a 7% surplus to a 17% surplus.

In 2000, 26.3% of the state's population lived in Suburban Connecticut. This group received 30.7% of the state's income (based on aggregate per capita income). The income this group received was greater than its share but not to the same extent as in Wealthy Connecticut.

Figure 36: 1989 and 1999 Income by Town Group



Between 1989 and 1999, median household income in the Wealthy group increased by $36,993, which was 88 times the statewide median increase of $422.

Between 1989 and 1999, median household income in the Suburban group increased by $7,615, which was 18 times the statewide median increase of $422.

Between 1989 and 1999, median household income in the Rural group *decreased* by $603, which was 2 times lower than the statewide median increase of $422.

Between 1989 and 1999, median household income in the Urban Periphery increased by $1,262, which was 3 times the statewide median increase of $422.

Between 1989 and 1999, median household income in the Urban Core increased by $406, which was slightly below the statewide median increase of $422.

Rural - North Stonington Type Towns

36a-d. Per capita income in Rural Connecticut grew from $24,502 in 1989 to $25,549 in 1999. This was an increase of $1,047, or 4.3%, for the group but it was ***64% lower*** than the statewide increase in per capita income of $2,871. The 1989 to 1999 ESP's indicate that the share of per capita income decreased from a 5% shortage to an 11% shortage.

36a-d. Median household income in Rural Connecticut ***decreased*** from $56,650 in 1989 to $56,047 in 1999. This was a decrease of $603, or –1.1%, for the group and was more than ***2 times lower*** than the statewide increase in median household income of $422. The 1989 to 1999 ESP's indicate that the share of household income decreased from a 2% shortage to a 9% shortage.

36a-d. Median family income in Rural Connecticut increased from $63,983 in 1989 to $64,750 in 1999. This was an increase of $767, or 1.2%, for the group but it was ***68% lower*** than the statewide increase in median family income of $2,417. The 1989 to 1999 ESP's indicate that the share of family income decreased from a 5% shortage to a 12% shortage.

In 2000, 13.4% of the state's population lived in Rural Connecticut but this group received only 11.9% of the state's income (based on aggregate per capita income). Rural Connecticut's income growth between 1989 and 1999 lagged behind the statewide figures. Median household income dropped between 1989 and 1999 – after adjusting for inflation.

Urban Periphery - Manchester Type Towns

36a-d. Per capita income in the Urban Periphery of Connecticut grew from $24,113 in 1989 to $26,395 in 1999. This was an increase of $2,282, or 9.5%, for the group but it was ***21% lower*** than the statewide increase in per capita income of $2,871. The 1989 to 1999 ESP's indicate that the share of per capita income decreased from a 7% shortage to an 8% shortage.

36a-d. Median household income in the Urban Periphery increased from $49,075 in 1989 to $50,337 in 1999. This was an increase of $1,262, or 2.6%, for the group and was ***3 times*** the statewide increase in median household income of $422. The 1989 to 1999 ESP's indicate that the share of household income decreased from an 11% shortage to a 12% shortage.

36a-d. Median family income in the Urban Periphery increased from $57,706 in 1989 to $60,557 in 1999. This was an increase of $2,851, or 4.9%, for the group, which was ***above*** the statewide increase in median family income of $2,417. The 1989 to 1999 ESP's indicate that the share of family income decreased from an 11% shortage to a 14% shortage.

In 2000, 36% of the state's population lived in the Urban Periphery but this group received only 33% of the state's income (based on aggregate per capita income). There were mixed trends in income for the Urban Periphery, between 1989 and 1999, as income growth hovered around the statewide figures.

Urban Core - Bridgeport Type Towns

36a-d. Per capita income in the Urban Core of Connecticut grew from $16,372 in 1989 to $16,723 in 1999. This was an increase of $351, or 2.1%, for the group but it was ***88% lower*** than the statewide increase in per capita income of $2,871. The 1989 to 1999 ESP's indicate that the share of per capita income decreased from a 37% shortage to a 42% shortage.

36a-d. Median household income in the Urban Core increased from $33,779 in 1989 to $34,185 in 1999. This was an increase of $406, or 1.2%, for the group and was slightly below the statewide increase in median household income of $422. The 1989 to 1999 ESP's indicate that the share of household income decreased from a 38% shortage to a 42% shortage.

36a-d. Median family income in the Urban Core ***decreased*** from $40,113 in 1989 to $39,571 in 1999. This was a decrease of $542, or -1.4%, for the group and was ***1.2 times below*** the statewide increase in median family income of $2,417. The 1989 to 1999 ESP's indicate that the share of family income decreased from a 40% shortage to a 45% shortage.

In 2000, 18.8% of the state's population lived in the Urban Core but this group received only 11% of the state's income (based on aggregate per capita income). Median family income dropped between 1989 and 1999 – after adjusting for inflation.

The Urban Core was the poorest of the five Connecticuts and became even poorer between 1989 and 1999 - relative to income growth in the other four groups. Furthermore, U.S. Census poverty figures may undercount poverty in Connecticut (see *The Changing Demographics of Connecticut - 1990 to 2000. Part 1: Comparing Connecticut to National Averages),* which would result in the reporting of even higher poverty in this group.

Summary

Between 1990 and 2000, the population of Wealthy Connecticut decreased from 6.8% to 5.4% of the state's total population partially due to the reclassification of five towns from Wealthy to Suburban. However, the Wealthy group's share of statewide income increased disproportionately - compared to the other four groups.

The percentage of the state's population living in Suburban Connecticut decreased by only 0.6% between 1990 and 2000. However, its share of statewide income increased - but not to the same degree as was seen in the Wealthy group.

Between 1989 and 1999, median household income dropped in Rural Connecticut.

Between 1989 and 1999, median family income dropped in the Urban Core.

Between 1989 and 1999, residents of Wealthy Connecticut had an increase in per capita income of 31.3%.

Between 1989 and 1999, residents of Suburban Connecticut had an increase in per capita income of 22.6%.

Between 1989 and 1999, residents of Rural Connecticut had an increase in per capita income of 4.3%.

Between 1989 and 1999, residents of the Urban Periphery had an increase in per capita income of 9.5%.

Between 1989 and 1999, residents of the Urban Core of Connecticut had an increase in per capita income of 2.1%.

The percentage of the state's population living in Rural Connecticut decreased between 1990 and 2000. However, its share of income decreased more than its decrease in population.

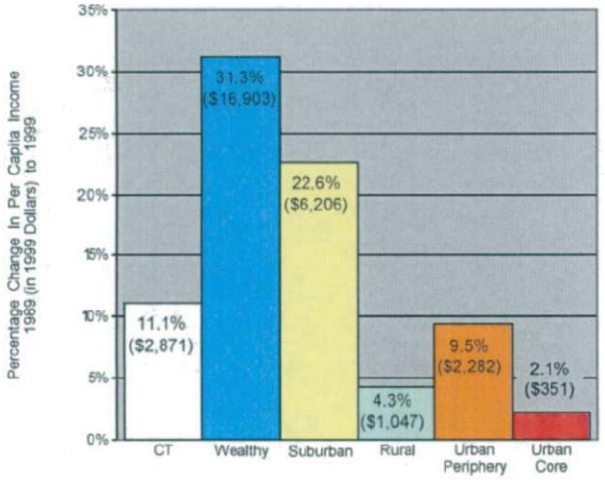
The percentage of the state's population living in the Urban Periphery grew between 1990 and 2000. However, its share of income decreased during this same period.

The percentage of the state's population living in the Urban Core increased between 1990 and 2000. It had the lowest overall income growth of the five Connecticuts and its share of income decreased.

In terms of income, towns in the Wealthy and Suburban groups fared significantly better than the rest of the state between 1990 and 2000. When looking at ESP's, Wealthy and Suburban Connecticut had ***surpluses*** in all income categories in both 1989 and 1999, while the other three groups had ***shortages*** in all income categories. Furthermore, the ESP's for the Wealthy and Suburban groups showed ***increased surpluses*** between 1989 and 1999, while the other groups had ***increased shortages***.

37. Figure 37 shows the percentage change in per capita income, by group, between 1989 (in 1999 dollars) and 1999. The statewide average was an 11.1% increase in per capita income. However, this average was misleading. Residents of Wealthy Connecticut had an increase in per capita income of 31.3%; Suburban Connecticut 22.6%; Rural Connecticut 4.3%; the Urban Periphery 9.5%; and the Urban Core 2.1%. Clearly, income growth in Connecticut during the 1990's was unevenly distributed among groups and their respective towns.

Figure 37: 1989 to 1999 Percentage Change in Per Capita Income by Town Group



Unreported Capital Gains Income In Wealthy Connecticut

The Decennial Census does not report income derived from capital gains or from the sale of non-business related property. Consequently, the Decennial Census may under-report income in towns that have significant income from capital gains.

A ***forthcoming report*** by the Connecticut State Data Center estimates that the Decennial Census does not report a significant portion of the state's income. This report uses 1999 Connecticut State personal income tax revenues to estimate town level AGI.

It is estimated that $2,252,589,711 of capital gains income, in 1999, from towns in the Wealthy group was not reported by the 2000 Decennial Census. This corresponds to an aggregate household income for the Wealthy Group of $15,250,420,211 versus the 2000 Decennial Census reported income of $12,997,830,500.

If the estimates are correct, then the 2000 Decennial Census did not report, at a minimum, ***14.8%*** of household income from Wealthy Connecticut because the Census Bureau does not define capital gains as income.

House Values and Monthly Housing Costs

Between 1990 and 2000, the percentage of owner-occupied housing units in Connecticut increased from 65.6% to 66.8% of all housing units statewide. Home ownership increased during the decade. However, the median value of an owner-occupied house dropped from $176,700 in 1990 to $166,900 in 2000. In this report, 1990 house values are not adjusted for inflation.

In 1990, the statewide median housing cost for owner-occupied units was 22.9% of median income. By 2000, owner-occupied housing costs had dropped slightly to 22.4% of median income.

In 1990, statewide median rental cost was 26.6% of median income. By 2000, median rental costs had dropped to 25.4% of median income.

Between 1990 and 2000, both owner-occupied housing costs and rental costs decreased - as a percentage of median income. However, there were different underlying causes among the five groups.

Wealthy - Westport Type Towns

38a-c. In 1990, 79.9% of housing units in Wealthy Connecticut were owner-occupied. The median value of a house was $379,300 and the median monthly cost was 22.5% of median income. Rental units comprised 20.1% of housing units with a median monthly rental cost of

In 1999, Wealthy and Suburban Connecticut accounted for 31.7% of the state's population and 44% of the state's income.

AGI: Adjusted Gross Income

The 2000 Decennial Census did not report, at a minimum, 14.8% of household income from the Wealthy Group.

The State of Connecticut does not currently release town level income statistics.

Owner-occupied housing units refer to single-family houses on less than 10 acres without a business or medical office on the property.

Between 1990 and 2000, the median house value in Wealthy Connecticut increased by $250,550, which was a gain of 27 times the statewide median loss of $9,800.

24.8% of median income.

38d-f. In 2000, 80.8% of housing units in Wealthy Connecticut were owner-occupied. The median value of a house was $629,850 and the median monthly cost was 21.8% of median income. Rental units comprised 19.2% of housing units with a median monthly rental cost of 25.5% of median income.

Between 1990 and 2000, median owner-occupied housing costs decreased from 22.5% to 21.8% of median income. This followed the statewide trend. However, the median house value in Wealthy Connecticut increased by $250,550, or 66.1%, from $379,300 to $629,850. This ***increase*** in median house value was a gain of ***27 times*** the statewide median loss of $9,800, or -5.5%. Furthermore, income in Wealthy Connecticut grew substantially in order to overcome the growth in house values and still achieve a decrease in housing cost relative to income.

Median rental housing cost increased from 24.8% to 25.5% of median income. This was opposite to the statewide trend.

Suburban - Cheshire Type Towns

38a-c. In 1990, 76.8% of housing units in Suburban Connecticut were owner-occupied. The median value of a house was $186,900 and the median monthly cost was 22.7% of median income. Rental units comprised 23.2% of housing units with a median monthly rental cost of 25% of median income.

38d-f. In 2000, 84.4% of housing units in Suburban Connecticut were owner-occupied. The median value of a house was $198,600 and the median monthly cost was 22.2% of median income. Rental units comprised 15.6% of housing units with a median monthly rental cost of 23.4% of median income.

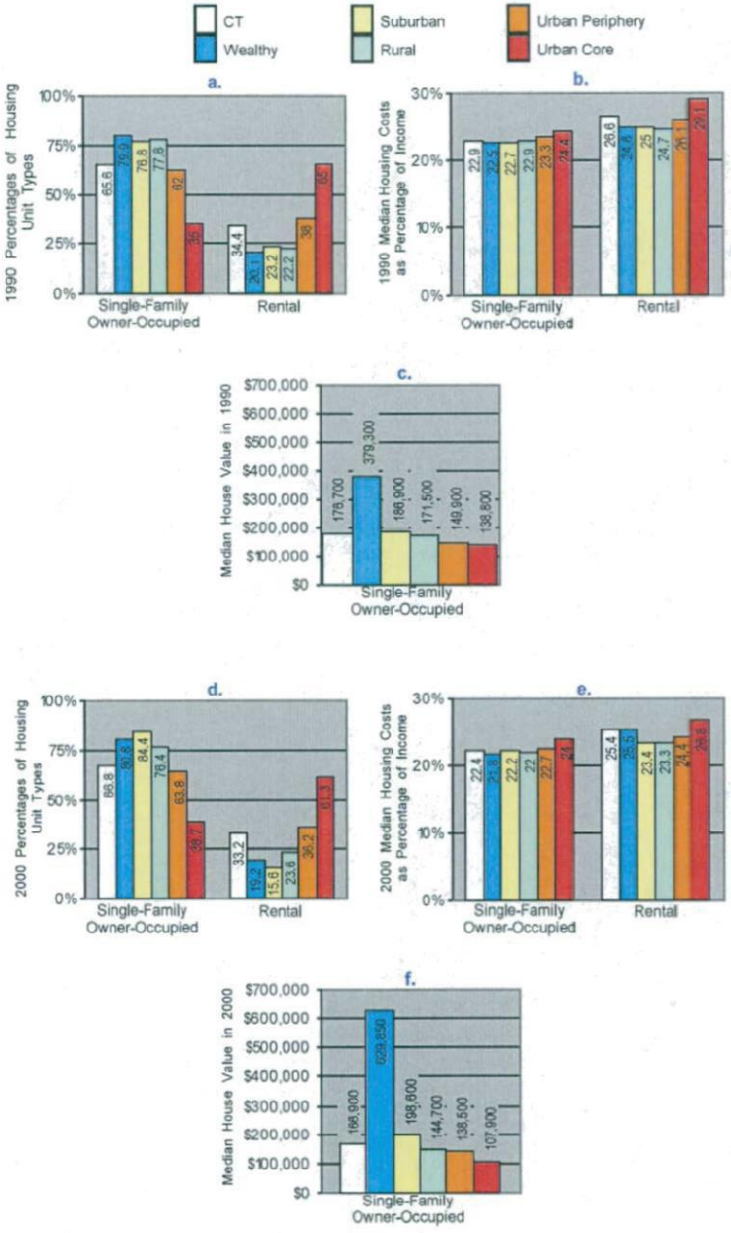
Between 1990 and 2000, the cost of housing, relative to income, dropped for this group, which followed the statewide trend. However, the median house value increased by $11,700, or 6.3%, from $186,900 to $198,600. This was opposite to the statewide trend. This ***increase*** in median house value was ***2 times*** above the statewide median loss of $9,800, or -5.5%. The percentage of rental units decreased dramatically from 23.2% to 15.6%. In short, Suburban Connecticut became even more suburban.

Median rental housing cost decreased from 25% to 23.4% of median income. This followed the statewide trend.

Rural - North Stonington Type Towns

38a-c. In 1990, 77.8% of housing units in Rural Connecticut were owner-occupied. The median value of a house was $171,500 and the median monthly cost was 22.9% of median income. Rental units comprised 22.2% of housing units with a median monthly rental cost of

Figure 38: 1990 and 2000 House Values and Housing Costs by Town Group



The 1990 Decennial Census reported housing costs based on 1989 income.

The 2000 Decennial Census reported housing costs based on 1999 income.

Owner-occupied costs include all mortgages, deeds, home equity loans, real estate taxes, insurance, and utilities.

Rental costs include the contract rent plus the estimated average monthly cost of utilities.

24.7% of median income.

38d-f. In 2000, 76.4% of housing units in Rural Connecticut were owner-occupied. The median value of a house was $144,700 and the median monthly cost was 22% of median income. Rental units comprised 23.6% of housing units with a median monthly rental cost of 23.3% of median income.

Between 1990 and 2000, median owner-occupied housing costs decreased from 22.9% to 22% of median income. This followed the statewide trend. The median house value also decreased by $26,800, or -15.6%, from $171,500 to $144,700. This ***loss*** in house value was ***3 times*** the statewide median loss of $9,800, or -5.5%.

Median rental housing cost decreased from 24.7% to 23.3% of median income. This followed the statewide trend.

Urban Periphery - Manchester Type Towns

38a-c. In 1990, 62% of housing units in the Urban Periphery were owner-occupied. The median value of a house was $149,900 and the median monthly cost was 23.3% of median income. Rental units comprised 38% of housing units with a median monthly rental cost of 26.1% of median income.

38d-f. In 2000, 63.8% of housing units in the Urban Periphery were owner-occupied. The median value of a house was $138,500 and the median monthly cost was 22.7% of median income. Rental units comprised 36.2% of housing units with a median monthly rental cost of 24.4% of median income.

Between 1990 and 2000, median owner-occupied housing costs decreased from 23.3% to 22.7% of median income. This followed the statewide trend. The median house value also decreased by $11,400, or ***-7.6%***, from $149,900 to $138,500. This ***loss*** in house value was relatively close to the statewide median loss of $9,800, or -5.5%.

Median rental housing cost decreased from 26.1% to 24.4% of median income. This followed the statewide trend.

Urban Core - Bridgeport Type Towns

38a-c. In 1990, only 35% of housing units in the Urban Core were owner-occupied. The median value of a house was $138,800 and the median monthly cost was 24.4% of median income. Rental units comprised 65% of housing units with a median monthly rental cost of 29.1% of median income.

38d-f. In 2000, 38.7% of housing units in the Urban Core were owner-occupied. The median value of a house was $107,900 and the median monthly cost was 24% of median income. Rental units comprised 61.3% of housing units with a median monthly rental cost of 26.8% of median income.

Between 1990 and 2000, median owner-occupied housing costs decreased from 24.4% to 24% of median income. This followed the statewide trend. The median house value decreased by $30,900, or -22.3%, from $138,800 to $107,900. This ***loss*** in house value was ***3 times*** the statewide median loss of $9,800, or -5.5%.

Median rental housing cost decreased from 29.1% to 26.8% of median income. This followed the statewide trend.

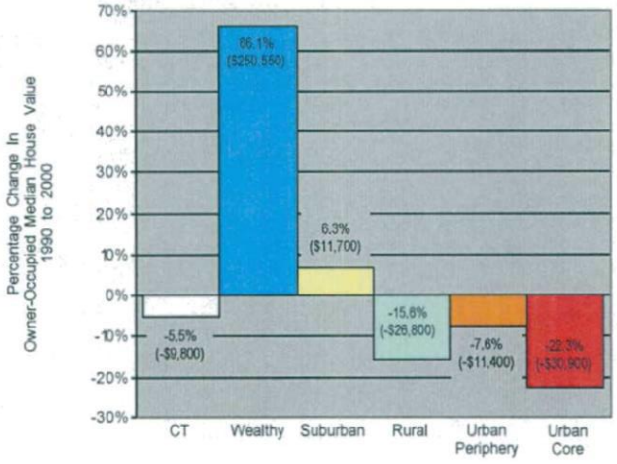
In both 1990 and 2000, the Urban Core had the ***lowest*** home ownership rates, the ***lowest*** owner-occupied house values, and the ***highest*** housing cost rates for both owner-occupied and rental housing. The drop in median house values during the 1990's was also greatest in the Urban Core, which experienced a 22.3% drop in the median value of a house.

Summary

39. As of publication of this report, house values in Connecticut had improved from values in 2000. However, this should not diminish the importance of the dissimilar trends in house values among the five Connecticuts. Figure 39 shows the percentage change in house values for the five Connecticuts between 1990 and 2000. Notice that while house values increased in both Wealthy Connecticut (66.1%) and Suburban Connecticut (6.3%), the other groups saw declines in house values. Also, Wealthy and Suburban Connecticut combined accounted for only 38% of all owner-occupied housing units statewide in 2000. Overall, there was a statewide decrease of 5.5% in house values.

During the 1990's, all five groups experienced a decrease in housing

Figure 39: 1990 to 2000 Percentage Change in Median House Values by Town Group



In both 1990 and 2000, the Urban Core had the lowest home ownership rates, the lowest owner-occupied house values, and the highest rate for housing costs.

Housing costs, relative to income, decreased in the Wealthy and Suburban groups in part due to increasing incomes. Conversely, housing costs, relative to income, decreased in the Rural group, the Urban Periphery, and the Urban Core in part due to lower house values.

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costs relative to income. However, there were different underlying causes among the groups.

Both income and house values increased in the Wealthy and Suburban groups while owner-occupied housing costs decreased. It appears that housing costs, relative to income, decreased in the Wealthy and Suburban groups in part due to increasing incomes that offset the higher house values.

In the other groups, incomes rose modestly, at best, but house values decreased. Again, the result was decreasing housing costs. Housing costs, relative to income, decreased in the Rural, Urban Periphery, and Urban Core in part due to lower house values.

In 2000, the highest percentage of owner-occupied housing was 84.4% in Suburban Connecticut. Contrast Suburban rates with the Urban Core, which had the lowest percentage of owner-occupied housing at 38.7%. Furthermore, median monthly owner-occupied housing costs were the highest in the Urban Core at 24% of median income and lowest in the Wealthy Group at 21.8%.

This pattern suggests that Connecticut residents in less affluent towns have lower home ownership rates and pay a greater percentage of their income for owner-occupied housing than residents in more affluent towns.

Education

The Adult Education Index (AEI) is an educational attainment measure developed by the Connecticut State Data Center. The AEI is used to compare the overall ***maximum*** educational attainment between different groups. A higher AEI number indicates higher overall educational attainment. See *The Changing Demographics of Connecticut - 1990 to 2000, Part 1: Comparing Connecticut to National Averages* for more information on the AEI.

Education is measured using five categories of maximum educational attainment for adults (age 25 and over). The categories are as follows:

- Not Completed High School - AEI **1.0**
- Completed High School - AEI **2.0**
- Completed Associate Degree or Some College - AEI **3.0**
- Completed Bachelor's Degree - AEI **4.0**
- Education Beyond Bachelor's Degree - AEI **5.0**

From 1990 to 2000, the statewide maximum educational attainment of Connecticut's adults increased from an AEI of 2.67 in 1990 to 2.84 in 2000. There were two underlying factors for this increase in maximum educational attainment. First, more people were completing education beyond high school. Second, the mortality of older residents is diminishing the size of a population with less formal education than more recent generations.

Statewide, school enrollment in grades 1-12 increased from 493,500 in 1990 to 590,771 in 2000. The percentage of grades 1-12 students enrolled in public schools rose from 88.1% in 1990 to 89.8% in 2000. Ninety-eight percent of the growth in enrollment was absorbed by the public school system. Between 1990 and 2000, the percentage of grades 1-12 students enrolled in Connecticut public schools increased while decreasing in private schools. This was opposite to the national trend, which saw an increasing percentage of enrollments in private schools.

Education ESP's are based on the population of adults (age 25 and over) in the group.

Wealthy - Westport Type Towns

40a. Wealthy Connecticut had the highest AEI in both 1990 and 2000. In 1990, the AEI was 3.48, which rose to 3.72 in 2000. In 2000, 66% of adults in Wealthy Connecticut had completed at least a Bachelor's degree and 30% had completed education beyond the Bachelor's degree.

40b. In 2000, the lowest ESP indicated that there was a 67% shortage in the share of adults that had Not Completed High School. The highest ESP indicated that there was a 126% surplus in the share of adults with educations Beyond Bachelor's Degree.

40c. Between 1990 and 2000, the percentage of grades 1-12 students in public schools decreased from 84.9% to 83.7% in this group. This was opposite to the statewide trend.

Parents in this group had the greatest tendency to enroll their children in private schools.

Suburban - Cheshire Type Towns

40a. In Suburban Connecticut the AEI rose from 2.81 in 1990 to 3.15 in 2000. This was the largest increase, 0.34, in AEI for any group. Over 40% of adults in this group had at least a Bachelor's degree.

40b. In 2000, the lowest ESP indicated a 42% shortage in the share of adults that had Not Completed High School. The highest education ESP indicated a 31% surplus in the share of adults who had completed a Bachelor's Degree.

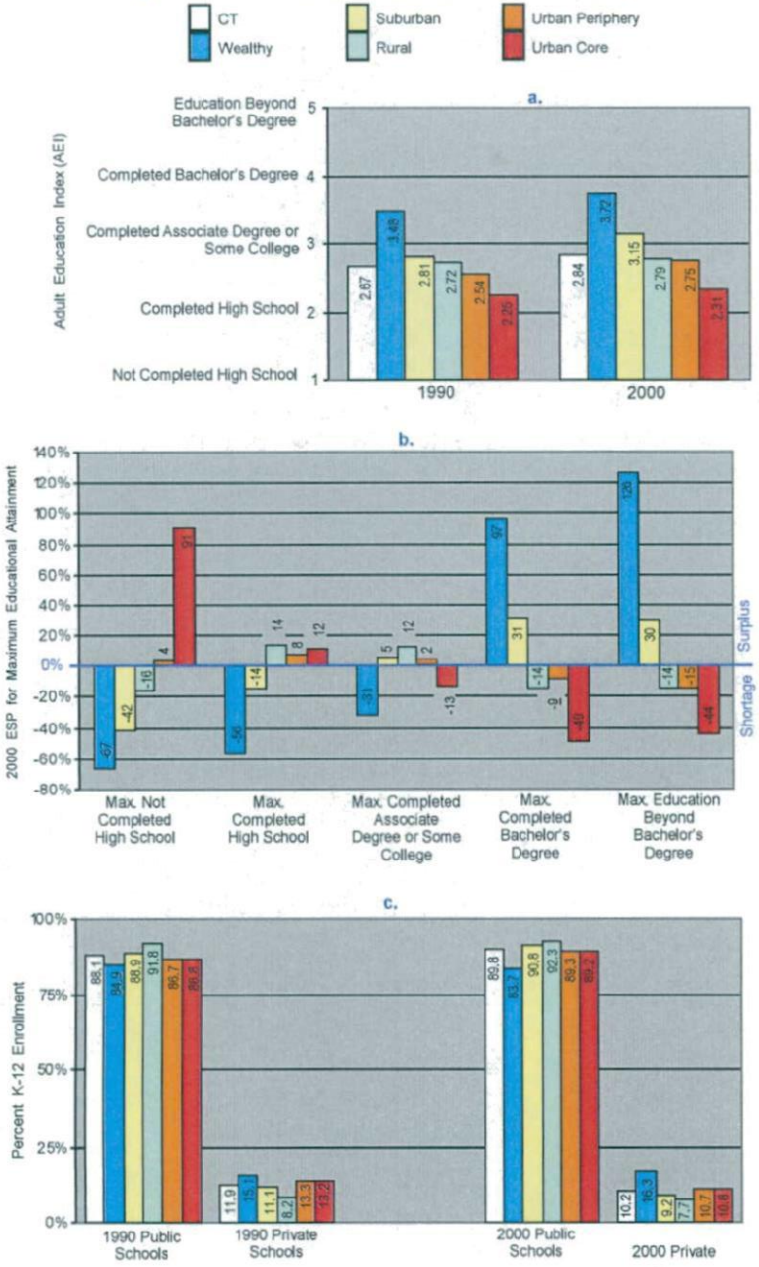
40c. Between 1990 and 2000, the percentage of grades 1-12 students in public schools increased from 88.9% to 90.8% in this group. This followed the statewide trend.

Parents in this group continued to send their children to public schools, which differed from the Wealthy Group where the trend was toward private schooling.

The AEI (Adult Education Index) is a statistic used to compare the total maximum educational attainment of adults from different geographic areas. A higher AEI value indicates that the adult population has completed higher levels of education.

In 2000, 66% of the population age 25 and over in Wealthy Connecticut had completed at least a Bachelor's degree and 30% had completed education beyond the Bachelor's degree.

Figure 40: 1990 and 2000 Education by Town Group



Rural - North Stonington Type Towns

40a. In 1990, Rural Connecticut had an AEI of 2.72, which was higher than the statewide average of 2.67. However, in 2000 the AEI was 2.79, which was below the statewide average of 2.84. This was the 2nd smallest increase, 0.07, in AEI for any group.

40b. In 2000, the lowest ESP indicated a 16% shortage in the share of adults that had Not Completed High School. The highest education ESP indicated a 14% surplus in the share of adults who had Completed High School.

40c. Between 1990 and 2000, the total number of students in Rural grades 1-12 schools dropped by 15,600 from 95,544 to 79,944. This was partially due to the reclassification of 28 towns from Rural to Suburban in 2000. The rate of public school enrollment, in the Rural group, increased from 91.8% to 92.3% during this same period.

The demographics of grades 1-12 enrollment between 1990 and 2000 was somewhat mixed for the Rural group. In short, Rural Connecticut lost total population as towns were reclassified as Suburban in 2000. This resulted in a drop in grades 1-12 enrollment associated with Rural Connecticut. The percentage of children in Rural Connecticut did not decrease (see Figures 30a-b). But the number of towns in Rural Connecticut did decrease. However, the remaining grades 1-12 population favored public schools.

Rural Connecticut lost ground in educational attainment during the 1990's. The increase in AEI of 0.07 was the 2nd lowest increase of any group (the Urban Core had the lowest increase of 0.06) and lagged the national increase of 0.17. The group AEI in 2000 was 2.79, which was below the state AEI of 2.84, but still above the national average AEI of 2.65.

Urban Periphery - Manchester Type Towns

40a. In the Urban Periphery the AEI rose from 2.54 in 1990 to 2.75 in 2000. However, the AEI's for this group were still below the statewide averages in both 1990, at 2.67, and 2000, at 2.84.

40b. In 2000, the lowest ESP indicated a 15% shortage in the share of adults with educations Beyond Bachelor's Degree. The highest education ESP indicated an 8% surplus in the share of adults who had Completed High School.

40c. Between 1990 and 2000, the percentage of grades 1-12 students in public schools increased from 86.7% to 89.3%. This followed the statewide trend.

In 1990 and 2000, this group had the largest number of grades 1-12 students (public and private combined). In 2000, nearly one-third, 32.6%, of all children statewide attended grades 1-12 schools in the Urban Periphery. The Urban Periphery had an increase in grades 1-12 enrollment of 47,062 students, or 32.3%, between 1990 and 2000. This

In 1990, the Rural Group had an AEI that was above the statewide average. By 2000, this group's AEI had fallen below the statewide average.

In both 1990 and 2000, the AEI's for the Urban Periphery were above the national average but below the statewide average.

In both 1990 and 2000, the Urban Core had AEI's that were below both the statewide and national averages.

Wealthy and Suburban Connecticut widened their lead in AEI during the 1990's.

was the largest increase in enrollment in absolute numbers of any group.

Although the group's AEI increased by 0.21 from 2.54 in 1990 to 2.75 in 2000, the group's AEI was still below the statewide average of 2.84 in 2000. However, the group did exceed the national average AEI of 2.65 in 2000.

Urban Core - Bridgeport Type Towns

40a. In the Urban Core the AEI rose by 0.06 from 2.25 in 1990 to 2.31 in 2000. This was the smallest increase for any group. The AEI's for the Urban Core were the lowest of any group in both 1990 and 2000.

40b. In 2000, the lowest ESP indicated a 49% shortage in the share of adults with a Bachelor's Degree. The highest education ESP indicated a 91% surplus in the share of adults who had Not Completed High School.

40c. Between 1990 and 2000, the percentage of grades 1-12 students in public schools increased from 86.8% to 89.2% in the Urban Core. This followed the statewide trend.

In 1990, 17.3% of all grades 1-12 students (public and private combined) in Connecticut were enrolled in Urban Core school systems. By 2000, that percentage had increased to 20.4% of all of grades 1-12 students statewide. Enrollment in Urban Core schools increased by 35,056, or 41%, between 1990 and 2000. This was the largest percentage increase of any group.

The Urban Core was very different from all other groups in terms of educational attainment. This group experienced the largest percentage growth in grades 1-12 enrollment. However, improvement in educational attainment lagged both state and national averages. In both 1990 and 2000, the Urban Core had AEI's that were below both the statewide and national averages.

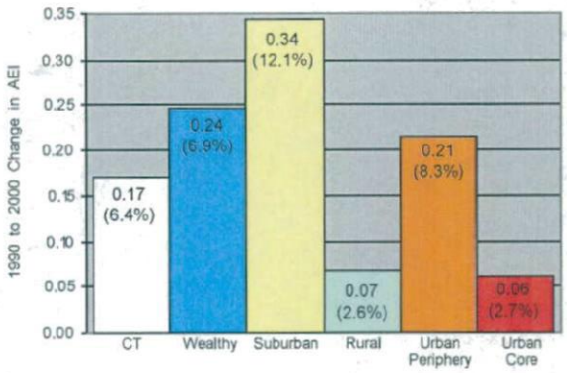
Summary

In both 1990 and 2000, Wealthy and Suburban Connecticut had a lopsided share of higher educational attainment.

41. Between 1990 and 2000, the increase in maximum educational attainment, as measured by the AEI, was uneven among the five groups. The Wealthy (increase of 0.24 AEI) and Suburban (increase of 0.34 AEI) groups widened their lead during the 1990's. The Urban Periphery (increase of 0.21 AEI) had an increase that was above the statewide and national increase of 0.17 AEI. However, the Rural Group (increase of 0.07 AEI) and the Urban Core (increase of 0.06 AEI) fell behind both the statewide and national increases in maximum educational attainment.

The Urban Core experienced the largest percentage growth in grades 1-12 enrollment and continued to have the lowest educational attainment of any group. Educational attainment in the Urban Core was also below the national averages in both 1990 and 2000.

Figure 41: 1990 to 2000 Increase in AEI by Town Group



Poverty

The percentage of the population living in poverty in Connecticut increased, between 1990 and 2000, going from 6.6% to 7.6% of the statewide population. The number of people in poverty increased by 42,167 from 217,347 to 259,514. This was opposite to the national trend of decreasing poverty during the 1990's.

The percentage of the population in extreme poverty increased, between 1990 and 2000, going from 2.8% to 3.7% of the statewide population. The number of people in extreme poverty increased by 34,770 from 92,304 to 127,074.

Families in poverty increased, between 1990 and 2000, going from 5% to 5.6% of all families statewide. The number of families in poverty increased by 6,018 from 43,965 to 49,983.

The percentage of children (age 17 and under) in poverty decreased slightly, between 1990 and 2000, going from 10.7% to 10.4% of children statewide. Although the percentage of children in poverty decreased, the number of children in poverty still increased by 6,888 from 79,020 to 85,908. This was due to an increase in the percentage of children (age 17 and under) in Connecticut's population (see Figures 30a-b).

These statistics were initially presented in *The Changing Demographics of Connecticut - 1990 to 2000, Comparing Connecticut to National Averages*, previously published by the Connecticut State Data Center. This report noted that the poverty threshold calculated by the U.S. Census Bureau is a national average statistic that fails to consider regional differences in costs-of-living. Given Connecticut's higher cost-of-living, it is possible that census data understates poverty in Connecticut.

Population poverty ESP's are based on the total population in the group. Family poverty ESP's are based on the number of families in the

Suburban Connecticut had the largest increase in AEI of any group between 1990 and 2000.

Poverty is measured based upon 1989 and 1999 income.

Extreme poverty is when income falls below 50% of the poverty threshold.

Poverty status is determined by the U.S. Census using income thresholds that are "... the same for all parts of the country - they are not adjusted for regional, state or local variations in the cost of living."

Poverty may be under-reported in Connecticut as Census poverty thresholds do not take regional cost-of-living into account.

Poverty status is determined only for families and the general population - not households.

group. Child poverty ESP's are based on the number of children (age 17 and under) in the group.

Wealthy - Westport Type Towns

42a-d. The percentage of residents living in poverty in Wealthy Connecticut increased from 2.4% in 1990 to 2.9% in 2000. The ESP's indicate that the share of poverty increased slightly from a 63% shortage to a 62% shortage.

The percentage of residents living in extreme poverty increased from 1.1% in 1990 to 1.7% in 2000. The ESP's indicate that the share of extreme poverty increased from a 59% shortage to a 54% shortage.

The percentage of families in poverty in Wealthy Connecticut increased from 1.4% in 1990 to 1.7% in 2000. The ESP's indicate that the share of families in poverty increased from a 73% shortage to a 70% shortage.

The percentage of children in poverty increased from 2.2% in 1990 to 2.7% in 2000. The ESP's indicate that the share of children in poverty increased from an 80% shortage to a 74% shortage.

Between 1990 and 2000, poverty increased slightly in Wealthy Connecticut but was limited in extent.

Suburban - Cheshire Type Towns

42a-d. The percentage of residents living in poverty in Suburban Connecticut decreased from 3.1% in 1990 to 2.7% in 2000. The ESP's indicate that the share of poverty decreased from a 52% shortage to a 64% shortage.

The percentage of residents living in extreme poverty remained unchanged at 1.3% of the population. The ESP's indicate that the share of extreme poverty decreased from a 53% shortage to a 66% shortage.

The percentage of families in poverty in Suburban Connecticut decreased from 2.1% in 1990 to 1.7% in 2000. The ESP's indicate that the share of families in poverty decreased from a 59% shortage to a 70% shortage.

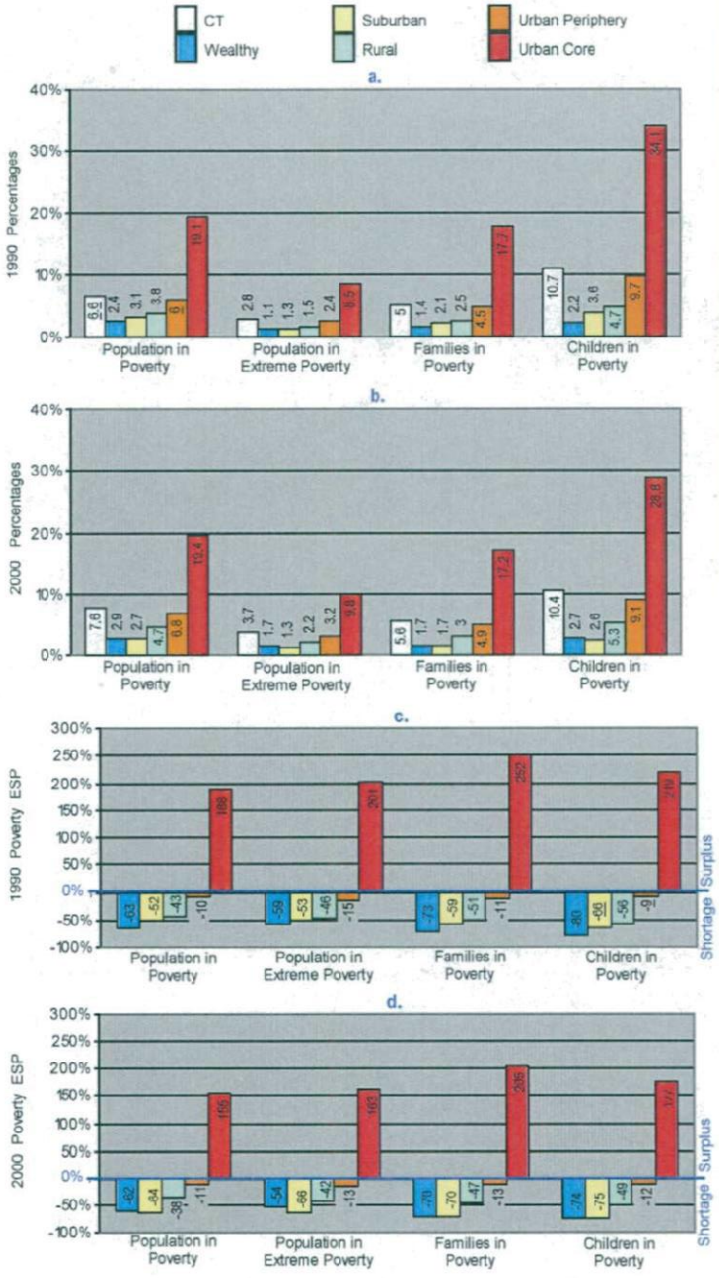
The percentage of children in poverty decreased from 3.6% in 1990 to 2.6% in 2000. The ESP's indicate that the share of children in poverty decreased from a 66% shortage to a 75% shortage.

Poverty was limited in Suburban Connecticut in the 1990's and decreased during the decade. This followed the national trend but was opposite to the statewide trend of increasing poverty.

Rural - North Stonington Type Towns

42a-d. The percentage of residents living in poverty in Rural Connecticut increased from 3.8% in 1990 to 4.7% in 2000. The ESP's indicate that the share of poverty increased from a 43% shortage to a 38% shortage.

Figure 42: 1990 and 2000 Poverty by Town Group



Only the Suburban group had a decrease in poverty between 1990 and 2000.

In 2000, the rate of poverty in the Urban Core was 1.6 times the national average; extreme poverty was 1.8 times the national average; the rate of families in poverty was 1.9 times the national average; the rate of children in poverty was 1.7 times the national average.

In 2000, ***41%*** of children in Hartford lived in poverty. This was the highest percentage among the 169 towns in Connecticut.

The percentage of residents living in extreme poverty increased from 1.5% in 1990 to 2.2% in 2000. The ESP's indicate that the share of extreme poverty increased from a 46% shortage to a 42% shortage.

The percentage of families in poverty in Rural Connecticut increased from 2.5% in 1990 to 3% in 2000. The ESP's indicate that the share of families in poverty increased from a 51% shortage to a 47% shortage.

The percentage of children in poverty increased from 4.7% in 1990 to 5.3% in 2000. The ESP's indicate that the share of children in poverty increased from a 56% shortage to a 49% shortage.

Between 1990 and 2000, poverty increased in Rural Connecticut but rates remained below statewide and national averages. The overall trend in this group paralleled the statewide trend of increasing poverty.

Urban Periphery - Manchester Type Towns

42a-d. The percentage of residents living in poverty in the Urban Periphery of Connecticut increased from 6% in 1990 to 6.8% in 2000. The ESP's indicate that the share of poverty decreased from a 10% shortage to an 11% shortage. This does not mean that poverty decreased in the Urban Periphery. These seemingly contradictory figures indicate that other groups had increases for the population living in poverty.

The percentage of residents living in extreme poverty increased from 2.4% in 1990 to 3.2% in 2000. The ESP's indicate that the share of extreme poverty increased from a 15% shortage to a 13% shortage.

The percentage of families in poverty in the Urban Periphery increased from 4.5% in 1990 to 4.9% in 2000. The ESP's indicate that the share of families in poverty decreased from an 11% shortage to a 13% shortage. This does not mean that poverty decreased in the Urban Periphery. These seemingly contradictory figures indicate that other groups had increases for families living in poverty.

The percentage of children in poverty decreased from 9.7% in 1990 to 9.1% in 2000. The ESP's indicate that the share of children in poverty decreased from a 9% shortage to a 12% shortage.

Between 1990 and 2000, poverty trends in the Urban Periphery were mixed. The rate of poverty, extreme poverty, and family poverty increased. However, the rate of children in poverty decreased. Poverty trends in the Urban Periphery paralleled the statewide trends but rates were still below the statewide averages.

Urban Core - Bridgeport Type Towns

42a-d. The percentage of residents living in poverty in the Urban Core of Connecticut increased from 19.1% in 1990 to 19.4% in 2000. The ESP's indicate that the share of poverty decreased from a 188% surplus to a 155% surplus. This does not mean that poverty decreased in the Urban Core. These seemingly contradictory figures indicate that other groups had increases for the population living in poverty.

The percentage of residents living in extreme poverty increased from 8.5% in 1990 to 9.8% in 2000. The ESP's indicate that the share of extreme poverty decreased from a 201% surplus to a 163% surplus. This does not mean that poverty decreased in the Urban Core. These seemingly contradictory figures indicate that other groups had increases in the population living in extreme poverty.

The percentage of families in poverty in the Urban Core decreased from 17.7% in 1990 to 17.2% in 2000. The ESP's indicate that the share of families in poverty decreased from a 252% surplus to a 205% surplus.

The percentage of children in poverty decreased from 34.1% in 1990 to 28.8% in 2000. The ESP's indicate that the share of children in poverty decreased from a 219% surplus to a 177% surplus.

Like the Urban Periphery, the Urban Core had mixed trends between 1990 and 2000. The rate of poverty and extreme poverty increased. However, the rate of families in poverty and children in poverty decreased. This should not overshadow the large amount of poverty that was still present in the Urban Core.

In 1990, ***45%*** of all Connecticut residents who lived in poverty lived in the Urban Core. By 2000, nearly one-half, ***48%***, of all Connecticut residents who lived in poverty lived in the Urban Core. Poverty was much more prevalent in the Urban Core than in the other four groups.

Summary

The distribution of poverty in Connecticut was a tale of extremes. Wealthy and Suburban Connecticut had negligible poverty. Poverty increased in Rural Connecticut while the Urban Periphery experienced mixed trends in poverty. However, poverty rates remained below state and national averages in both the Rural and Urban Periphery groups.

In Connecticut, poverty was concentrated in the Urban Core where poverty rates exceeded the national averages. In 2000, the rate of poverty in the Urban Core was ***1.6 times*** the national average. Extreme poverty in the Urban Core was ***1.8 times*** the national average. The rate of families in poverty was ***1.9 times*** the national average. And the rate of children in poverty was ***1.7 times*** the national average.

42c-d. A review of the ESP's shows that only the Urban Core had surpluses in poverty in both 1990 and 2000. The other four groups, to different extents, had shortages in poverty.

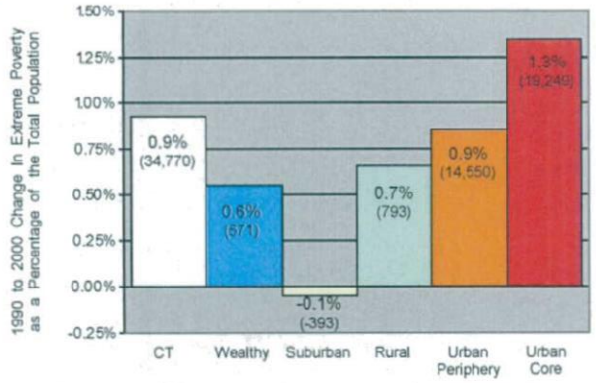
The most striking changes in poverty in Connecticut during the 1990's was the growth in extreme poverty from 2.8% to 3.7%. While the percentage increase of 0.9% may seem small, it should be taken into account that, on average, poverty decreased nationwide during this same period. Also, as previously noted, poverty may be undercounted in Connecticut.

43. Only Suburban Connecticut had a decrease in the rate of

In 2000, the Urban Core accounted for only 18.8% of the state's population but 48% of the state's population living in poverty.

There was significant poverty in Connecticut in the 1990's but it was highly concentrated in the Urban Core.

Figure 43: 1990 to 2000 Change in Extreme Poverty by Town Group



extreme poverty between 1990 and 2000. Suburban Connecticut had a decrease of 0.1%, or 393 fewer residents, in extreme poverty. Wealthy Connecticut had an increase of 0.6%, or 571 additional residents, in extreme poverty. Rural Connecticut had an increase of 0.7%, or 793 additional residents, in extreme poverty. The Urban Periphery had an increase of 0.9%, or 14,550, additional residents in extreme poverty. The largest increase in extreme poverty was in the Urban Core, which had an increase of 1.3%, or 19,249 additional residents, in extreme poverty.

There was significant poverty in Connecticut in the 1990's but it was ***highly concentrated*** in the Urban Core.

What Does It All Mean?

It is misleading to quote Connecticut's statewide average or median demographic and socioeconomic statistics. The state has too much ***concentrated disparity*** to be viewed in average terms. There were five distinctly different groups of towns in Connecticut - Wealthy, Suburban, Rural, the Urban Periphery, and the Urban Core. These groups were present in 1990 and 2000. They will most likely be present in 2010.

The socioeconomics of Wealthy Connecticut were an extreme in the state. The Urban Core was the other extreme. However, in 2000, Wealthy Connecticut represented only 5.4% of the state's population while the Urban Core accounted for 18.8% of the state's population.

44. Figure 44 is a summary of the basic statistics presented in this report. The ESP is provided for the five variables that are best at distinguishing among the five groups.

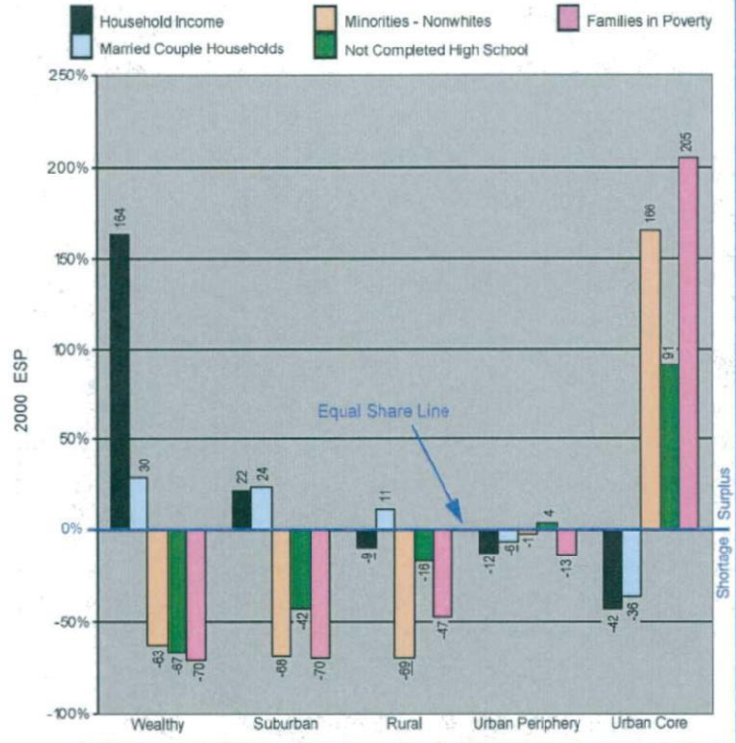
Notice that the trends for the Wealthy, Suburban, and Rural groups were similar. Income best differentiated between these three groups.

Wealthy Connecticut was significantly different from any other part of the state.

The Urban Periphery lacked extremes in socioeconomics and most resembled the typical Connecticut with 36% of the state's residents living there in 2000.

Finally, the Urban Core was extremely stressed. The socioeconomics of the Urban Core were the direct opposite of Wealthy Connecticut in most respects.

Figure 44: Summary of 2000 ESP's



	Wealthy	Suburban	Rural	Urban Periphery	Urban Core
Percentage of Statewide Population	5.4%	26.3%	13.4%	36%	18.8%
Surplus	-Income -Married Couple Households	-Income -Married Couple Households	-Married Couple Households	-Not Completed High School	-Minorities -Not Completed High School -Poverty
Shortage	-Minorities -Not Completed High School -Poverty	-Minorities -Not Completed High School -Poverty	-Income -Minorities -Not Completed High School -Poverty	-Income -Married Couple Households -Minorities -Poverty	-Income -Married Couple Households

It is misleading to quote Connecticut's statewide average or median demographic and socioeconomic statistics.

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Methodology

Credits

The following individuals made contributions to this report:

Don Levy, Research Assistant
Orlando Rodriguez, Data Manager
Wayne Villemez, Ph.D., Director

Data Sources

Data for 1990 came from the 1990 Decennial Census STF1 and STF3. Data for 2000 came from the 2000 Decennial Census SF1 and SF3. Data from STF1 and SF1 are 100 percent data. Data from STF3 and SF3 are sample data.

1990 and 2000 Town Grouping Methodology

45-46. Towns were grouped separately for 1990 and 2000. A combination of factor analysis, cluster analysis, and discriminate analysis were used for classification. The steps were as follows:

1. Factor Analysis of variables for 169 towns.
   a. Household Income
   b. Family Income
   c. Per Capita Income
   d. Educational Attainment using AEI
   e. Percentage of Families in Poverty
   f. % of Female-Headed Families in Poverty
   g. Percentage of Population Below 100% Poverty
   h. Percentage of Population Below 50% Poverty
   i. Percentage English as Primary Language
2. Three factors were created and a score generated for each town.
   a. SES (Social Economic Status) Factor
      i. Household Income
      ii. Family Income
      iii. Per Capita Income
      iv. Educational Attainment using AEI
   b. Poverty Factor
      i. % Families in Poverty
      ii. % Population Below 100% Poverty
      iii. % Population Below 50% Poverty
      iv. % Female-Headed Families in Poverty
      v. % English as Primary Language
   c. Factor created for Population Density based on the log of population density.
3. Generated five clusters applying K-Means clustering to individual factors and then ranking.
   a. SES: 1=Least, 5=Most
   b. Poverty: 1=Most, 5=Least
   c. Population Density: 1=Most, 5=Least
4. Generated five clusters by applying K-Means clustering to 169 towns using factor ranks from step 3.
5. Selected variables for discriminant analysis using Pearson's correlation.
   a. Family Income
   b. % of Population Below 100% Poverty
   c. Population Density
6. Ran discriminant analysis using cluster number from step 4 as the dependent variable and the variables from step 5 as independent variables.
7. Classified towns into groups based on results of discriminant analysis. Borderline outliers were adjusted as necessary. Noted that cluster centers had moved between 1990 and 2000.

For references on methodology see:

Semple, Keith R., and Milford B. Green. 1984. Classification in Human Geography. Spatial Statistics and Models: 55-79

Hill, Edward W., and John F. Brennan. 2000. A Methodology for Identifying the Drivers of Industrial Clusters: The Foundation of Regional Competitive Advantage. Economic Development Quarterly 14 (February): 65-96

Inflation Adjustments

Income dollars from 1989 were adjusted for inflation in Connecticut to 1999 dollars using an inflation multiplier of 1.28263 (Connecticut Center for Economic Analysis).

Income dollars from 1990 were adjusted for inflation in Connecticut to 2000 dollars using an inflation multiplier of 1.267 (Connecticut Center for Economic Analysis).

Group Median Values

The median values for each group were calculated as the median of the medians of all towns in the group. This applies to income, housing values, and housing costs.

For income, the Equal Share Percentages (ESP) were calculated using the aggregate income of all towns in a group. The income ESP's are not based on median income.

Medians were not used in any ESP calculation.

Software

All data was downloaded from the U.S. Census website. The data was then imported into Microsoft® Access for analysis and reporting. SPSS was used for statistical analysis. Charts were created using Microsoft® Excel.

All components were then compiled into a single report using Microsoft® Publisher.

Figure 45: 1990 Town Clusters

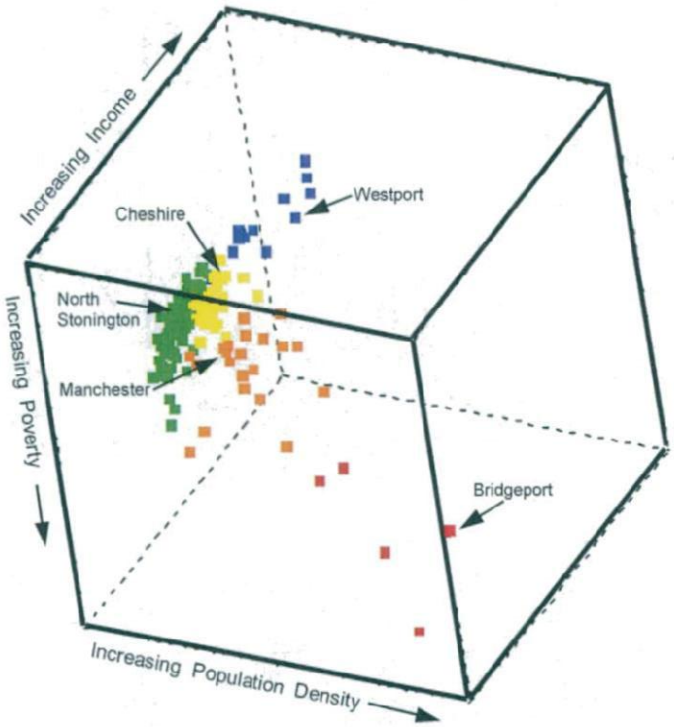
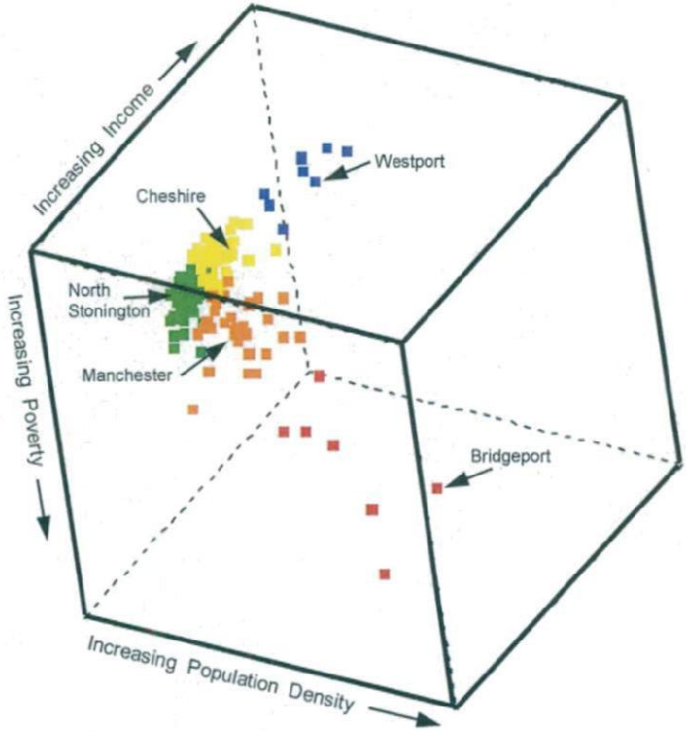


Figure 46: 2000 Town Clusters



Wealthy - Westport Type Towns
Suburban - Cheshire Type Towns
Rural - North Stonington Type Towns
Urban Periphery - Manchester Type Towns
Urban Core - Bridgeport Type Towns

1008

EXHIBIT 20

State of Connecticut

Department of Public Health

Office of Health Care Access

Select Filings in the Matter of :

An Application for a Certification of Need filed pursuant to Section 19a-638, C.G.S., by Lawrence & Memorial Hospital

Docket No. 12-31768-CON

Agreed Settlement adopted February 4, 2013

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2013, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
East Lyme	1			1
Essex		1	1	2
Groton	2	1		3
Leydard	2	1		3
Mystic	1			1
New London	4	1	1	6
Niantic	2			2
Norwich	2	1		3
Oakdale		1		1
Old Lyme	1			1
Portsmouth, RI	1			1
Preston	2			2
Riverside, RI	2			2
Stonington		1		1
Waterbury	1			1
Waterford	2	2		4
Westerly, RI	2			2
Total PCI Procedures	25	9	2	36

*Assumed to be inpatient procedures

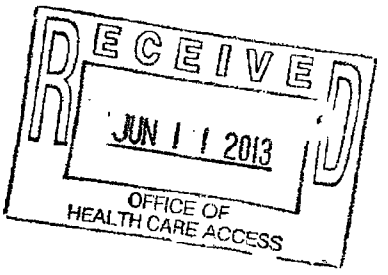
** All towns in Connecticut unless otherwise noted

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

July 11, 2013

Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308



RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2013 Quarter 3 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2012Q4

If you have any questions or concerns regarding this filing, please contact me at (860) 442-0711 x. 5185 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2013, Quarter 3

Reports 1. a. and 1. b (combined)

Town	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI	1			1
Bozrah	1			1
Broad Brook	1			1
Cumberland, RI	1			1
East Lyme		2		2
Gales Ferry	2		1	3
Groton		3		3
Hope Valley, RI	1			1
Hopkinton, RI	1			1
Johnston, RI	1			1
Leydard		1		1
Mystic	2			2
New London	5	3	2	10
Niantic	1		3	4
North Stonington		1		1
Norwich	1	1		2
Oakdale		1		1
Salem	1	1		2
Stonington			1	1
Waterford	2			2
West Warwick, RI		1		1
Westerly, RI			1	1
Total PCI Procedures	21	14	8	43

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2013, Quarter 3

There were 0 transfers for cardiac surgery in FY 2013, Quarter 3

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

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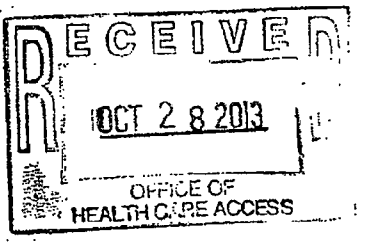

October 28, 2013

Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2013 Quarter 4 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2013Q2

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2013, Quarter 4

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI			1	1
Altoona , PA	1			1
Bradford, RI	2			2
Charleston, RI	1			1
East Haven	1			1
East Long Meadow, MA	1			1
East Lyme	1	2		3
Gales Ferry	1			1
Groton	3	3	3	9
Ledyard	1	1	1	3
Lyme	1	1		2
Milford	1			1
Mystic	3	2		5
New London	2	1	1	4
Newington	1			1
Niantic			1	1
North Stonington	1			1
Norwich	3	1		4
Oakdale	1			1
Ponta Gurda, FL	1			1
Quaker Hill		2		2
Salem	1			1
Sandy Hook	1			1
Saratoga, NY	1			1
Southwick, MA	1			1
Uncasville			1	1
Waterford	2	1		3
Westerly, RI	1			1
Wethersfield	1			1
Total PCI Procedures	34	14	8	56

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2013, Quarter 4

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Primary PCI procedure; non-urgent transfer to Yale for further treatment; operator was unable to cross lesion of STEMI patient due to chronic total occlusion	9/22/2013 00:23	9/22/2013 01:15	Yale operator unable to open culprit lesion; angioplasty with stent performed on another vessel: 9/22/2013 16:01
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

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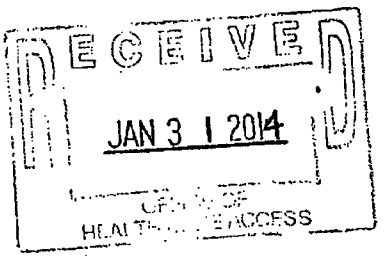
January 30, 2014



Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2014 Quarter 1 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2014, Quarter 1

Reports 1. a. and 1. b (combined)

Town	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Charleston, RI	1			1
Colchester			1	1
East Lyme		1		1
Groton	2	2		4
Jewett city			1	1
Ledyard	1			1
Middle Island, NY	1			1
Mystic	1	1	1	3
New London	2	2		4
Niantic		1		1
Norwich	1	1		2
Oakdale	2	1		3
Pawcatuck	2			2
Stonington			1	1
Uncasville		1		1
Waterford			1	1
Westerly, RI	1	1		2
Total PCI Procedures	14	11	5	30

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Note: Between 11/27/13 and 12/19/13, L+M's emergent PCI program was suspended due to the nursing/tech strike. Per the strike contingency plan provided to CT DPH, "emergent Percutaneous Coronary Intervention (PCI) will not be performed during strike."

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 1

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	None				
2					
3					
4					
5					
6					
7					
8					
9					
10					

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April 29, 2014

Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2014 Quarter 2 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2014, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Bristol	1			1
Brook Neal, VA	1			1
East Lyme	1		1	2
Essex	1			1
Gales Ferry		1	1	2
Groton	4	2	1	7
Ledyard	1			1
Mystic	2		1	3
New London	1	1	2	4
Niantic	2			2
Norwich			2	2
Pawcatuck	3			3
Plainfield			1	1
Quaker Hill		1	1	2
Sterling			1	1
Stonington		1		1
Uncasville			1	1
Waterford	3	2		5
Westerly, RI	5			5
Willimantic		1		1
Total PCI Procedures	25	9	12	46

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Elective PCI procedure; non-urgent transfer to Yale for further treatment; operator was unable to cross partially chronic lesion in a SV graft. Patient transferred via routine ambulance. Case not included in elective PCI volume numbers.	2/28/2014 11:52	2/28/2014 12:44	Elective PCI 2/28/2014 12:50
2	Yale-New Haven Hospital	Primary PCI procedure; unable to accommodate as lab was busy with an unstable PCI patient. Both patients presented within 5 minutes of each other. Patient was not a candidate for thrombolytics. Transferred case not included in primary PCI volume numbers.	3/31/2014 11:03	3/31/2014 11:52	PCI 3/31/2014 11:53
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

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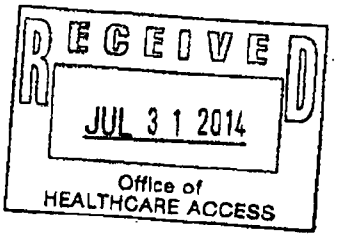

July 24, 2014

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2014 Quarter 3 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2014Q1

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2014, Quarter 3

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Bozrah			1	1
Bradford, RI	1			1
East Lyme			1	1
Gales Ferry	1	1		2
Groton	2	1	1	4
Lady Lake, FL		1		1
Lebonan			1	1
Ledyard		2		2
Lyme	1			1
Mystic	2	2	1	5
New London	5	1	1	7
New Rochelle, NY	1			1
Niantic	1	1		2
North Franklin		2	1	3
Norwich			1	1
New York, NY			1	1
Oakdale	1			1
Old Lyme	1			1
Ponce, PR	1			1
Preston	1			1
Quaker Hill	1	1	1	3
Roxbury	1			1
Sarasota, FL	1			1
Stonington			1	1
Uncasville		1		1
Waterford	4	2	2	8
Westerly, RI	4			4
Total PCI Procedures	29	15	13	57

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 3

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Emergent PCI procedure: post-successful-stenting of difficult LAD lesion, patient proactively transferred via Helicopter with IABP to monitor more closely for any potential complications.	5/18/2014 7:14	5/18/2014 8:00	Not applicable; no procedure administered
2					
3					
4					
5					
6					
7					
8					
9					
10					

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October 31, 2014

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2014 Quarter 4 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):				
Federal Fiscal Year 2014, Quarter 4				
Reports 1. a. and 1. b (combined)				
Town	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI	2			2
Charleston, RI	2			2
East Lyme			1	1
Gales Ferry	3		1	4
Groton	3	2	1	6
Jewett City			1	1
Ledyard	1			1
Lyme		2		2
Mystic	2	1	2	5
New London	2	4	1	7
Niantic	1		1	2
North Franklin			1	1
Norwich			1	1
Old Lyme	2			2
Pawcatuck	1		1	2
Quaker Hill			1	1
Stonington	2		1	3
Waterford	4	5	2	11
West Warwick, RI	1			1
West Harford	1			1
Woonscoket, RI	1			1
Guilderland, NY	1			1
Voluntown		1	0	1
Danielson			1	1
Griswold			1	1
Brewster		1		1
Total PCI Procedures	29 ✓	16 ✓	17 ✓	62 ✓
*Assumed to be inpatient procedures				
** All towns in Connecticut unless otherwise noted				

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 4

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Elective PCI procedure: unable to cross lesion, patient transferred for complex PCI	9/22/2014 12:22	9/22/2014 14:35	PCI procedure: 9/23/2014 11:10
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

Huber, Jack

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Monday, January 26, 2015 12:31 PM
To: Huber, Jack
Subject: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)
Attachments: FY 2015 Q1 Compliance Format for 12-31768-CON (L+M Hospital).xlsx

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

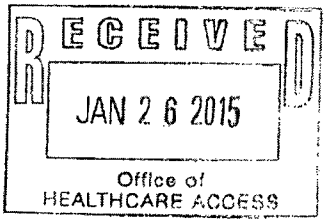
- Fiscal Year 2015 Quarter 1 PCI Volume by Patient's Town of Residence

We have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex before January 31st.

The ACC-NCDR Data Report for 2014Q3 will be sent separately, once the report is released to L+M.

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email.

Thank you,
Shraddha Patel



Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

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Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 1

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Baltic	1			1
Coventry, RI	1			1
Griswold	1			1
Groton	7	1		8
Ledyard	1	1	2	4
Moodus	1		1	2
Mystic	2	1	2	5
New London	1	2		3
Niantic	2	2	2	6
North Franklin			1	1
Norwich	2			2
Oakdale		1	2	3
Old Lyme	1			1
Pawcatuck	3	1		4
Philadephia, PA	1			1
Preston		2		2
Quaker Hill			1	1
Sargus, MA	1			1
Seymore	1			1
Stonington	1		2	3
Taftville			1	1
Uncasville	1			1
Upper Marlboro	1			1
Waterford	2		2	4
Total PCI Procedures	31	11	16	58

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 1

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Patient had successful opening of culprit artery at L+M (via emergent PCI), but required further treatment (CABG) at YNHH for remaining disease.	10/19/2014 11:16	10/19/2014 14:13	10/20/2014 16:00
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

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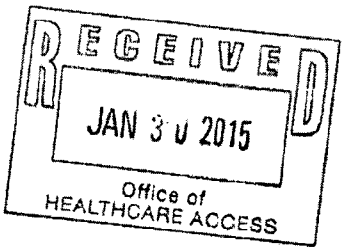
365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

January 28, 2015



Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2015 Quarter 1 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 1

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Baltic	1			1
Coventry, RI	1			1
Griswold	1			1
Groton	7	1		8
Ledyard	1	1	2	4
Moodus	1		1	2
Mystic	2	1	2	5
New London	1	2		3
Niantic	2	2	2	6
North Franklin			1	1
Norwich	2			2
Oakdale		1	2	3
Old Lyme	1			1
Pawcatuck	3	1		4
Philadephia, PA	1			1
Preston		2		2
Quaker Hill			1	1
Sargus, MA	1			1
Seymore	1			1
Stonington	1		2	3
Taftville			1	1
Uncasville	1			1
Upper Marlboro	1			1
Waterford	2		2	4
Total PCI Procedures	31	11	16	58

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 1

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Patient had successful opening of culprit artery at L+M (via emergent PCI), but required further treatment (CABG) at YNHH for remaining disease.	10/19/2014 11:16	10/19/2014 14:13	10/20/2014 16:00
2					
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9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

Huber, Jack

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Thursday, April 30, 2015 10:50 AM
To: Huber, Jack
Subject: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)
Attachments: FY 2015 Q2 Compliance Format for 12-31768-CON (L+M Hospital).xlsx

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

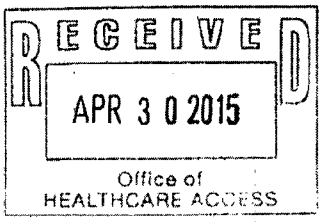
- Fiscal Year 2015 Quarter 2 PCI Volume by Patient's Town of Residence
- Patient transfer information

We have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex early next week.

The ACC-NCDR Data Report for 2014Q4 will be sent separately, once the report is released to L+M.

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email.

Thank you,
Shraddha Patel



Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

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RECEIVED
APR 30 2015
Office of
HEALTHCARE ACCESS

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI	1			1
Baltic	1			1
Centerfield, MA	1			1
East Lyme		1		1
Gales Ferry		1		1
Groton	6			6
Hope Valley, RI		1		1
Jewett City	2			2
Ledyard	3	1		4
Mystic		1	1	2
New London	5	2		7
Niantic		1		1
Noank		2		2
North Stonington	1			1
Norwich	3	1		4
Oakdale		2	2	4
Pawcatuck	1			1
Preston	1	1		2
Quaker Hill	1			1
Stonington	1	1		2
Uncasville	1			1
Verona, VA	1			1
Voluntown	1			1
Waterford	2		3	5
Westerly, RI	1			1
Westport	1			1
Total PCI Procedures	34	15	6	55

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

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APR 30 2015
Office of
HEALTHCARE ACCESS

Federal Fiscal Year 2015, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Elective PCI on patient with high grade lesion in LAD and RCA. Patient had a successful elective PCI on LAD system. When attempting to cross the RCA lesion with a wire, there was some difficluty in crossing the lesion and subsequent angiography showed what apeared to be a small dissection and reduced flow. Patient remained hemodynamically stable. Procedure aborted and Yale consulted. Decision to transfer to Yale for further treatment on this complex lesion. At Yale they were also unable to open artery.	1/15/2015 11:48	1/15/2015 12:46	Attempt at RCA PTCA was unscuccessful and patient was successfully managed medically. 1/15/2015 13:12
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*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

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MAY - 4 2015
Office of
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April 29, 2015

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2015 Quarter 2 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
Karen Buck
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI	1			1
Baltic	1			1
Centerfield, MA	1			1
East Lyme		1		1
Gales Ferry		1		1
Groton	6			6
Hope Valley, RI		1		1
Jewett City	2			2
Ledyard	3	1		4
Mystic		1	1	2
New London	5	2		7
Niantic		1		1
Noank		2		2
North Stonington	1			1
Norwich	3	1		4
Oakdale		2	2	4
Pawcatuck	1			1
Preston	1	1		2
Quaker Hill	1			1
Stonington	1	1		2
Uncasville	1			1
Verona, VA	1			1
Voluntown	1			1
Waterford	2		3	5
Westerly, RI	1			1
Westport	1			1
Total PCI Procedures	34	15	6	55

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Elective PCI on patient with high grade lesion in LAD and RCA. Patient had a successful elective PCI on LAD system. When attempting to cross the RCA lesion with a wire, there was some difficluty in crossing the lesion and subsequent angiography showed what apeared to be a small dissection and reduced flow. Patient remained hemodynamically stable. Procedure aborted and Yale consulted. Decision to transfer to Yale for further treatment on this complex lesion. At Yale they were also unable to open artery.	1/15/2015 11:48	1/15/2015 12:46	Attempt at RCA PTCA was unscuccessful and patient was successfully managed medically. 1/15/2015 13:12
2					
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*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

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860.442.0711 | lmhospital.org

RECEIVED
JUL 30 2015
Office of
HEALTHCARE ACCESS

July 28, 2015

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2015 Quarter 3 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2015Q1

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
J. Goldberg
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 3

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Canterbury	1			1
East Lyme		1		1
Gales Ferry	1	1		2
Groton	5	2	2	9
Jewett City			1	1
Kutztown, PA	1			1
Ledyard	1			1
Mystic	2		2	4
New London	2	6	1	9
Niantic	1		2	3
Oakdale	1	1		2
Old Lyme	2	1		3
Old Mystic	1			1
Quaker Hill	1	2	1	4
Troy, NY	1			1
Uncasville		1		1
Waterford			1	1
Total PCI Procedures	20	16	10	45

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

AUG. 12. 2015 4:00PM NO. 220 P. 3

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 3

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
	NONE				

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

AUG. 12. 2015 4:00PM NO. 220 P. 4

EXHIBIT 21

Backus Hospital
A Hartford HealthCare Partner

ED CARD STEMI Transfer Order Set

Department of Emergency Medicine

Guidelines
Transfer STEMI patients except those with advanced dementia or palliative care
If recent surgery, stroke or active bleeding, discuss with cardiology before Plavix, or Heparin

Nursing
☑ Nursing Chest Pain Protocol
☑ Oxygen Nasal Cannula Titrate [Start at 2 L/min, titrate (max 6L total) to maintain O2 Sat >= to 94%]
[Add'l O2 Orders: For COPD patients, titrate to keep O2 Sat to 90%]
☑ ED Saline Lock IV
☑ ED 2nd Saline Lock IV

Quality/Safety Measures
☐ ASA Contraindicated

Laboratory
☑ ED Troponin POC
☐ TROPONIN-STAT
☑ COMPLETE BLOOD COUNT (CBC) – STAT
☑ BASIC CHEM PROFILE (BCP, BMP) – STAT
☑ PROTHROMBIN TIME PT INR – STAT
☐ PT INR POC PLAINFIELD ONLY

Cardiology
☑ EKG – STAT [Reason for Exam: Chest Pain]

Diagnostic Imaging
☑ XRAY CHEST PORTABLE 1 VIEW – STAT [Reason for Exam: Chest Pain]
☐ XRAY CHEST PA & LAT- STAT

Medications
☐ 0.9% Saline 1000 ml IV at 2000 mls/hr ONCE
☐ 0.9% Saline 1000 ml IV at 150 mls/hr ONCE
☑ Aspirin (ASA) 324 mg chew PO ONCE (unless allergy or already given)
☑ Aspirin (ASA) 300 mg PR ONCE PRN unable to take PO (unless allergy or already given)
☑ Clopidogrel (Plavix) 600 mg PO ONCE (Do not use if giving thrombolytics)
☑ Metoprolol (Lopressor) 25 mg PO ONCE (if no concern for shock and SBP > 100mmHg)
☑ Heparin 0 units IVP ONCE (No heparin drip)
Patient Weight: < 50 KG = 3000 units
>= 50 KG = 4000 units
☑ Atorvastatin (Lipitor) 80 mg PO ONCE
☑ Ondansetron (Zofran) 4 mg IV ONCE PRN Nausea
☐ Nitroglycerin 0.4 mg SL every 5 min PRN Chest Pain x 3 doses (Hold for SBP < 90mmHg)
☐ Morphine 2 mg IVP every 5 min PRN Chest Pain x 3 doses (if not pain free with nitroglycerin)
☐ Tenecteplase IV Kit (TNKase) (High Risk) 0 mg IV ONCE Per Protocol (If time to transfer will be delayed)

Patient Weight (kg)	TNKase™ (mg)	Reconstituted TNKase™ (mL)
< 60	30	6
≥ 60 to < 70	35	7
≥ 70 to < 80	40	8
≥ 80 to < 90	45	9
≥ 90	50	10

Signature _____ Date: __/__/____ Time: _____

MRDOCORD

Affix Patient Label Here

Backus Hospital
A Hartford HealthCare Partner

ED CARD STEMI Transfer Order Set

Department of Emergency Medicine

Consultation

☑ Contact LifeStar for transfer immediately. If unavailable, contact ground transport.
☐ Cardiologist on Call
☐ Yale Cardiologist on Call 203-785-4129
☐ Hartford Hospital Cardiologist on Call 860-545-2975

Signature _____ Date: ___/___/_____ Time: _____

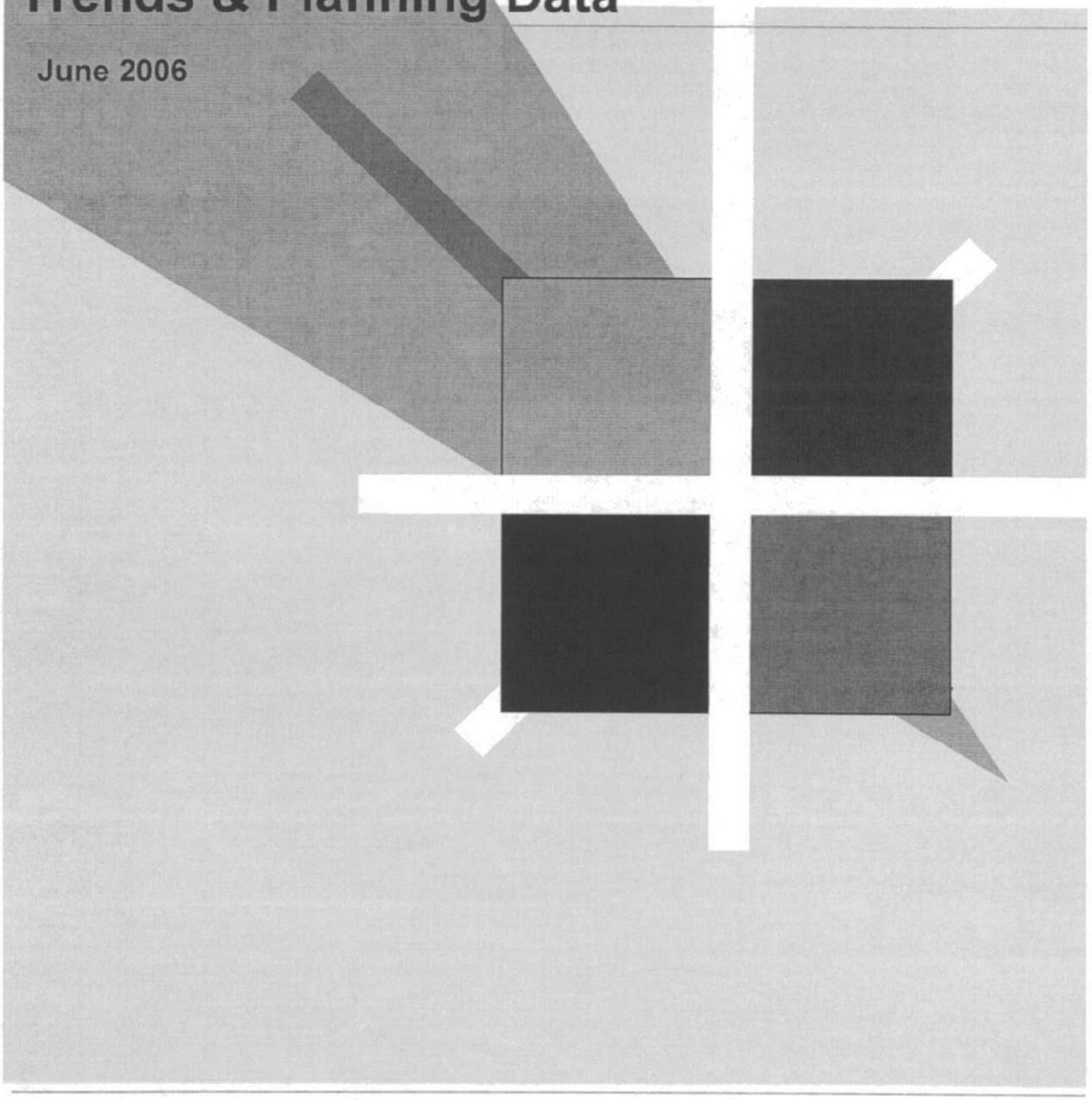
MRDOCORD

Affix Patient Label Here

EXHIBIT 22

Transportation in Connecticut:
Trends & Planning Data

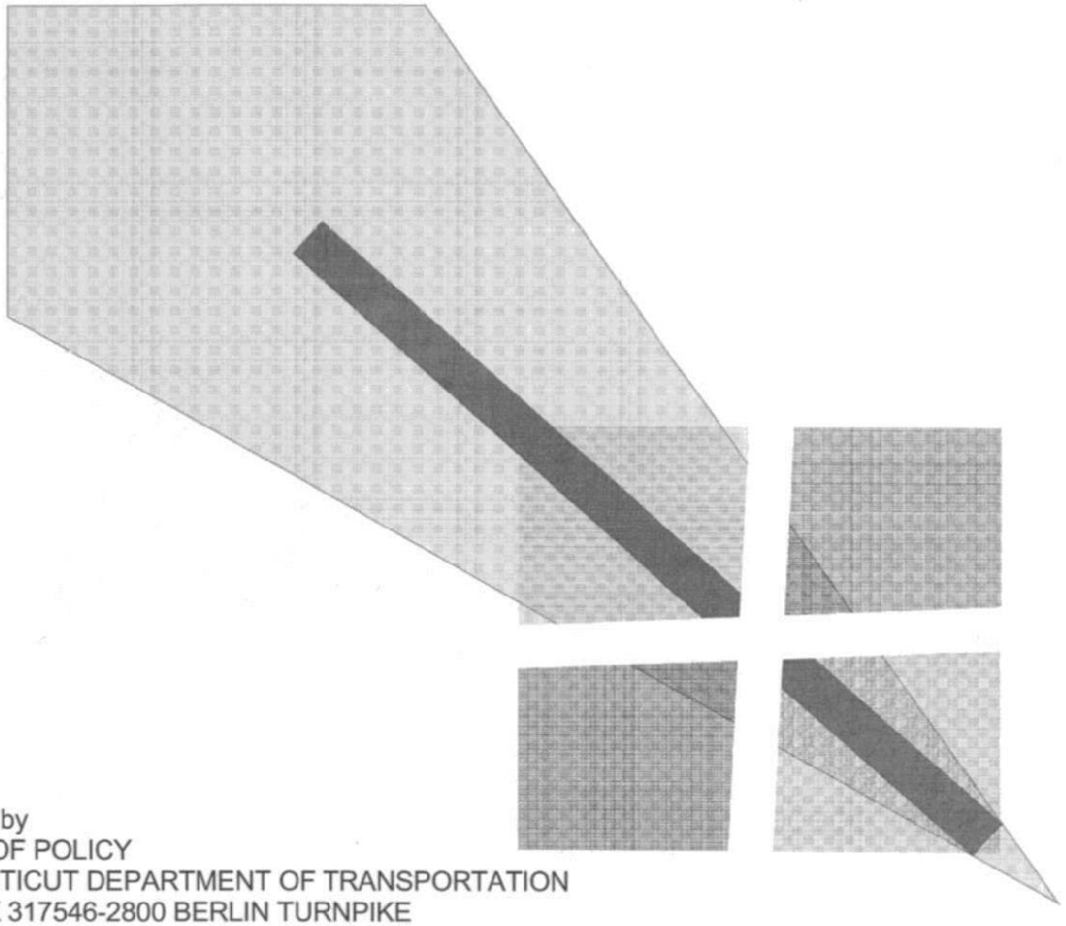
June 2006



State of Connecticut

Department of Transportation

Transportation in Connecticut: Trends & Planning Data



Prepared by
OFFICE OF POLICY
CONNECTICUT DEPARTMENT OF TRANSPORTATION
P.O. BOX 317546-2800 BERLIN TURNPIKE
NEWINGTON, CONNECTICUT 06131-7546

In cooperation with the
U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL HIGHWAY ADMINISTRATION

With assistance from the Connecticut Department of Transportation's Division of Systems Information, Division of Intermodal Planning, Office of Maintenance & Highway Operations, Office of Transit and Ridesharing, and Bureau of Aviation and Ports, the Connecticut Department of Revenue Services, the Connecticut Labor Department, the New York State Department of Transportation, the Rhode Island Department of Transportation, the Massachusetts Department of Transportation and the Pioneer Valley Regional Planning Agency

June 2006

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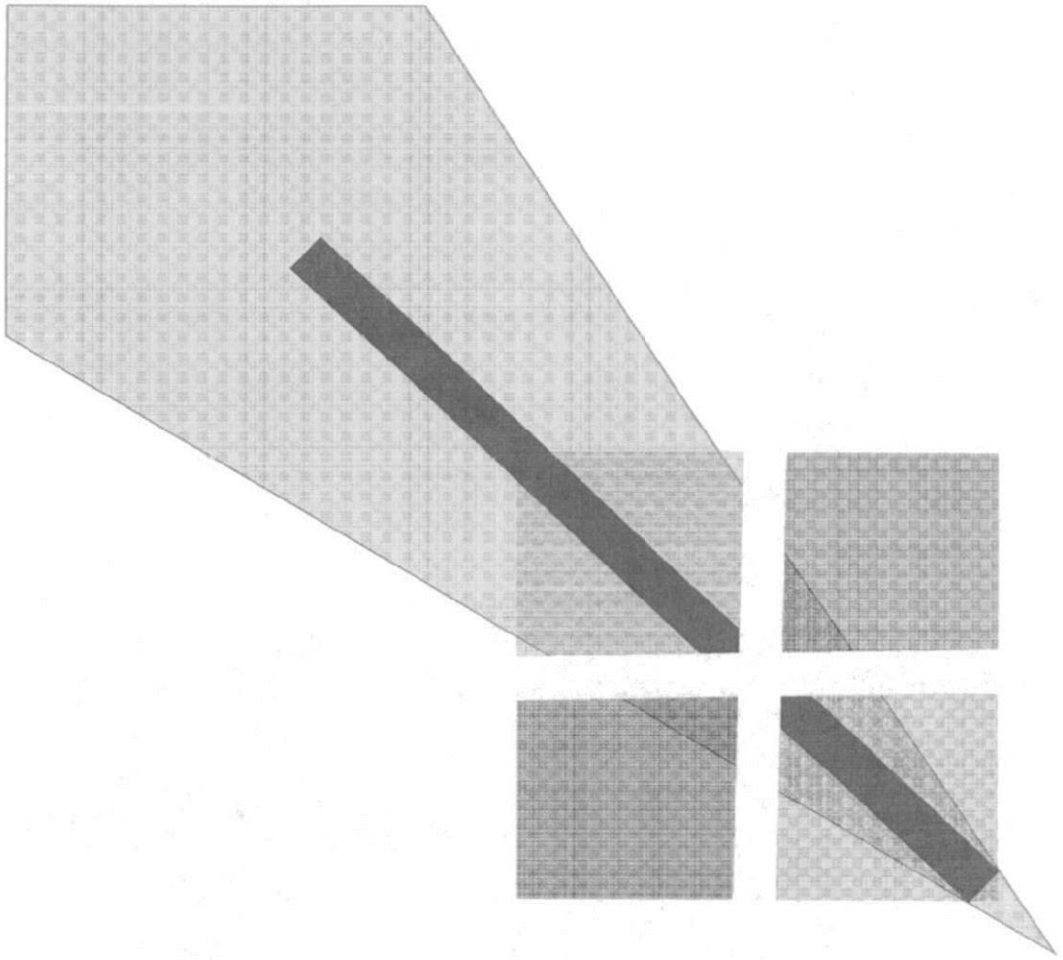


TRENDS & PLANNING DATA

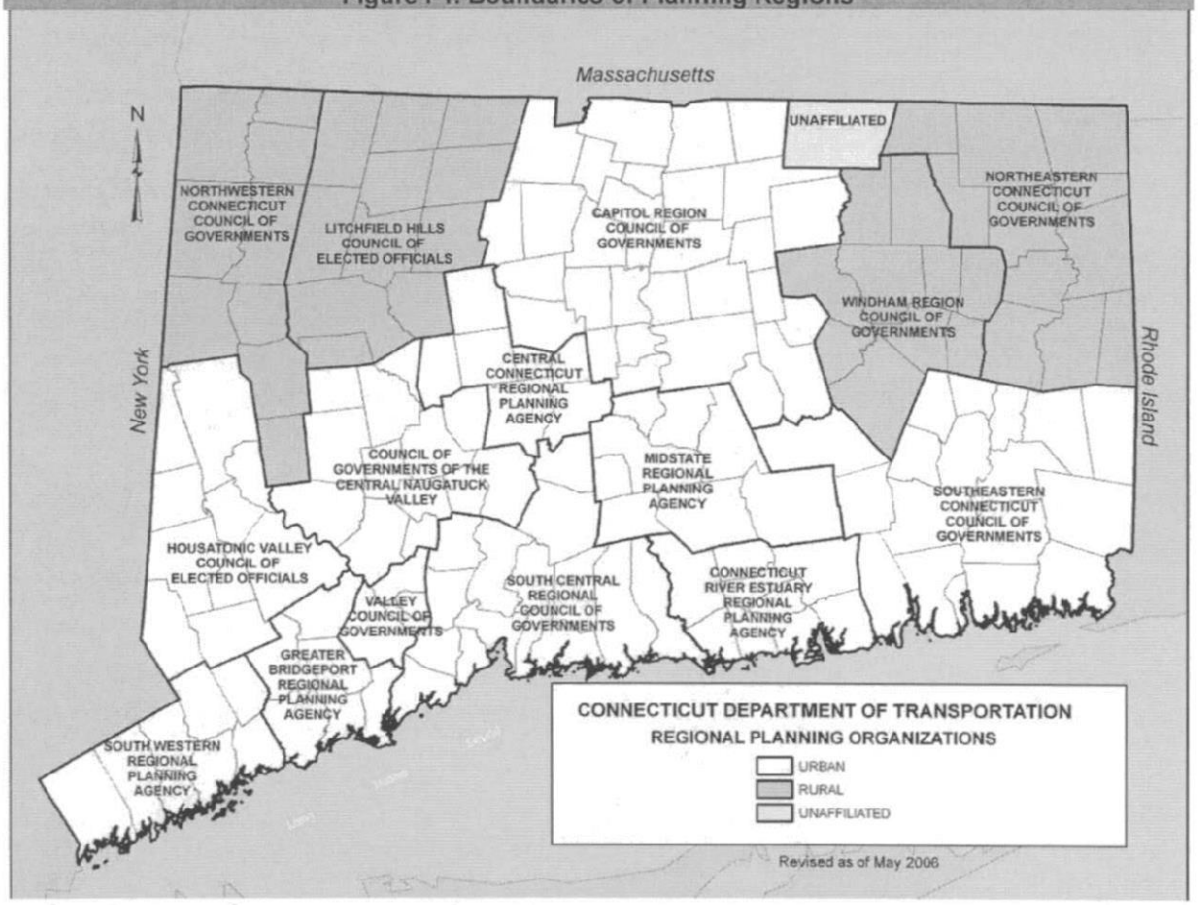
Chapter I of this document contains information on relevant trends, factors and other information used or considered by Connecticut Department of Transportation engineers and transportation planners to forecast and address travel demands in the State of Connecticut. Past and projected demographic trends such as population, employment, housing and vehicle ownership are presented because they provide a general basis, along with land use, economic and other factors, for understanding the underlying variables that effect changes in travel. Commuting patterns, mode of commuting, traffic accident statistics, congestion levels, traffic volumes and safety in critical travel corridors, and developments and trends in the movement of goods, transportation-related security, and federal and state revenue trends are discussed to give an overview of travel patterns and conditions that more directly affect the transportation network.

Chapter II contains information on the long-range transportation plans and major current and anticipated transportation projects and studies in the adjacent states of Massachusetts, Rhode Island and New York that may be relevant to Connecticut.

I. DEMOGRAPHIC TRENDS & PLANNING DATA FOR CONNECTICUT

In this chapter demographic information and planning data is provided for the State of Connecticut and for the individual planning regions. As shown in Figure I-1, in Connecticut, there are eleven urban planning regions, four rural planning regions and one unaffiliated town, the town of Stafford. Previously, the town of Union was also unaffiliated. However, in 2002, the town of Union became a member of the Northeastern Connecticut Council of Governments. For purposes of discussion, comparisons are made amongst the planning regions, separate from the unaffiliated town(s). Reference tables that contain data organized by planning region are included in Appendix B; the tables provide detail for much of the data presented graphically in this chapter.

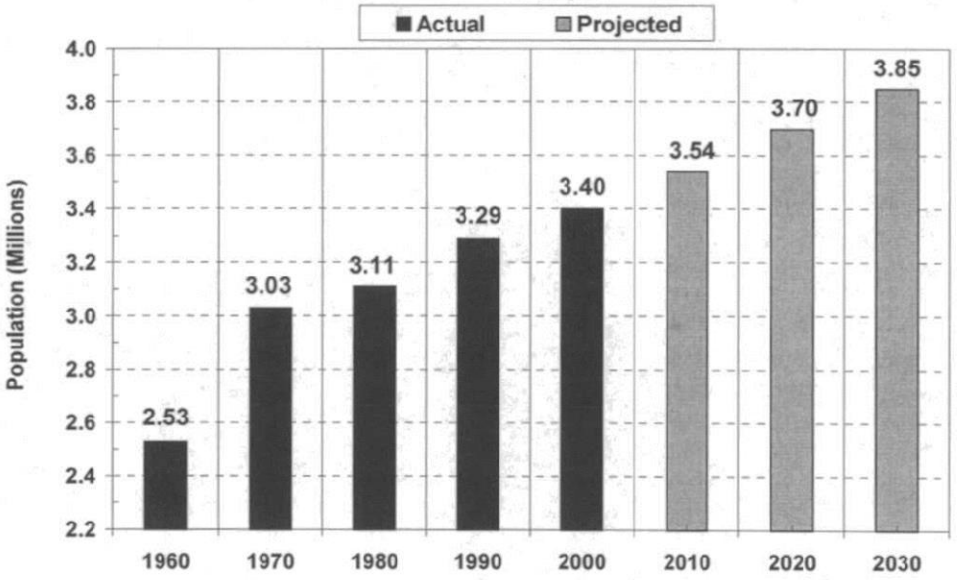
Figure I-1. Boundaries of Planning Regions



A. POPULATION

As presented in Figure I-2, from 1990 to 2000, the state's population increased by 3.6 percent from 3,287,116 to 3,405,545 persons. During this period the average annual growth rate was 0.36 percent. In 2000, the state averaged 665 persons per square mile. Modified state population projections from the Connecticut Office of Policy and Management call for an 8.5 percent increase in total state population from 3,405,545 in 2000 to 3,696,560 by 2020. The current forecast of an average annual growth rate of 0.42 percent for the period of 2000 to 2020 indicates that this trend of slow steady growth will continue. Connecticut's population is projected to increase to an estimated 3.8 million by 2030.

Figure I-2. Population Growth in Connecticut



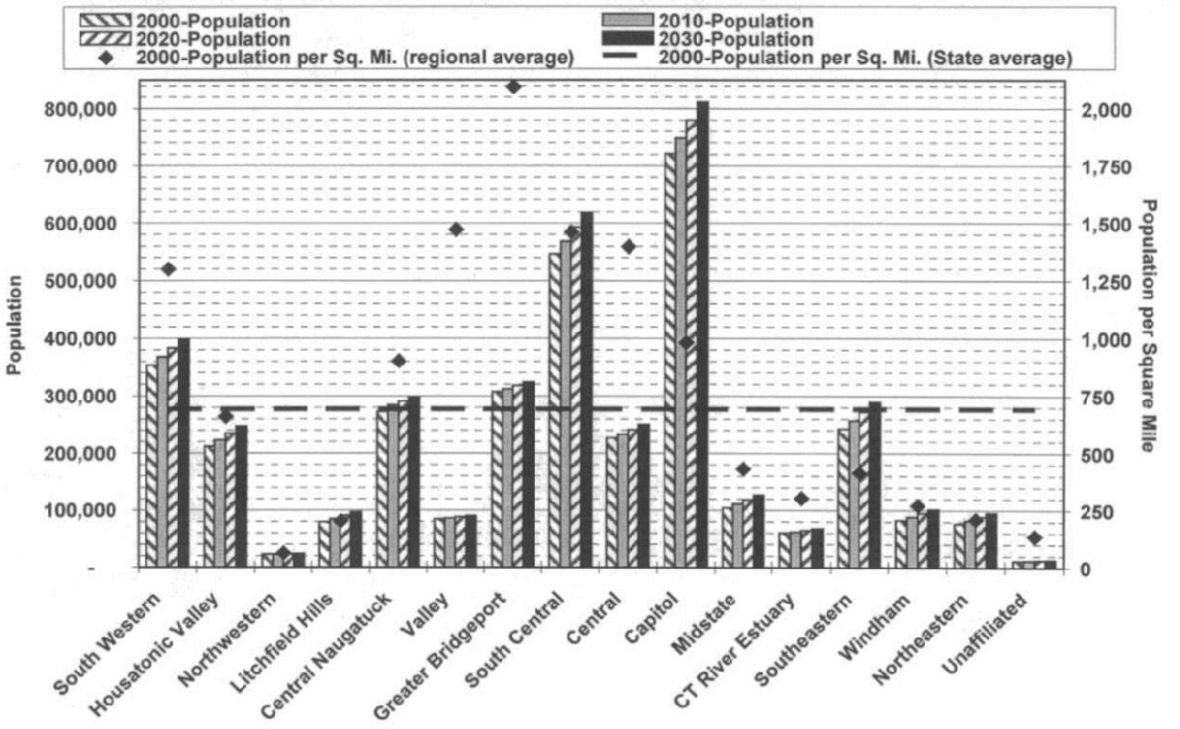
Source: 1960 Census, 1970 Census, 1980 Census, 1990 Census, 2000 Census, and ConnDOT Series 27B Landuse Projections. Data for years following 2000 is projected. Graphics revised as of August 2004.

Within the state, actual and projected populations and rates of growth vary among the 15 planning regions and for the unaffiliated town(s). Between 1990 and 2000, as presented in Figure I-3, the population increased in 14 of the 15 planning regions and decreased in 1. The Housatonic Valley Planning Region and the Connecticut River Estuary Planning Region experienced the highest growth rates: 13.0 percent and 9.8 percent, respectively. The Central Connecticut Planning Region experienced a population decrease of 0.4 percent.

In 2000, the Capitol Region, comprising 29 towns with a total area of 761 square miles, had the largest population with 721,320 persons. The Northwestern Region, comprising nine towns with a total area of 361.0 square miles and 62 persons per square mile, had the smallest population (22,655). In 2000, 56.65 percent (1,929,275 persons) of the state's population lived in four regions: the Capitol Region, the South Central Region, the South Western Region, and the Greater Bridgeport Region.

In 2000, the Greater Bridgeport Region had the largest number of persons per square mile: 8,721. Four additional regions had more than 1,000 persons per square mile. These were the Valley Region (1,444 persons per square mile); the South Central Region (1,408 persons per square mile), the Central Region (1,362 persons per square mile), and the South Western Region (1,683 persons per square mile). The Northwestern Region, with 63 persons per square mile, had the lowest population density in the state. A comparison of Census data for population sizes and densities among the planning regions is presented in Figure I-3 and listed in Table B-1 in Appendix B.

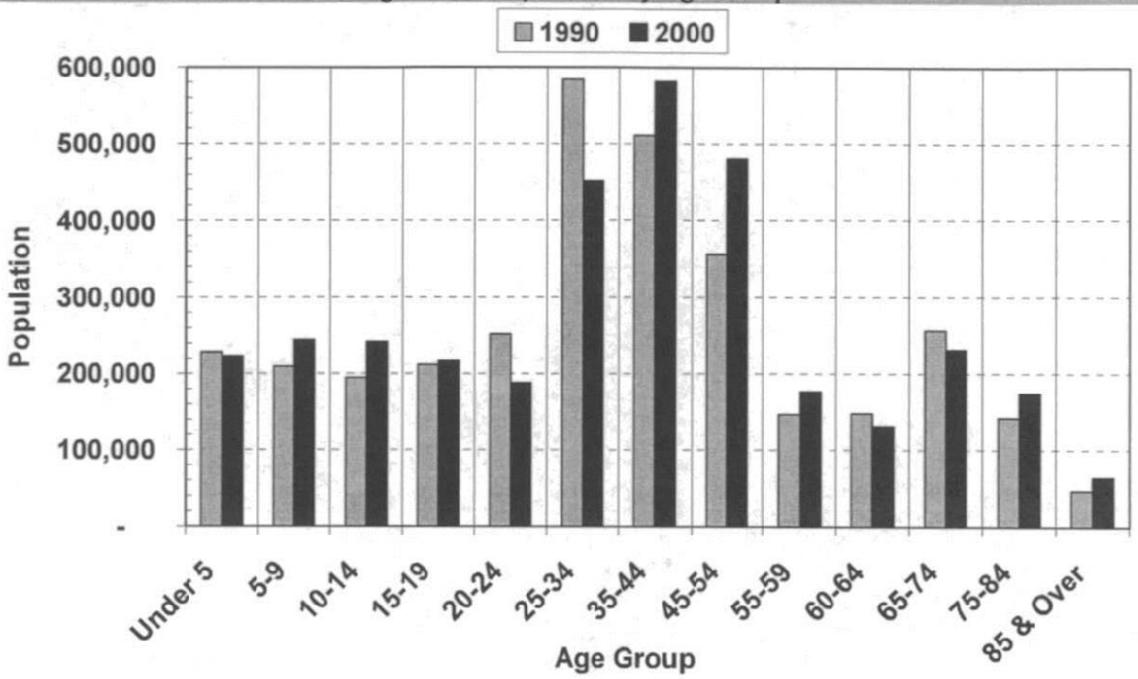
Figure I-3. Population Data by Planning Region



Source: 1990 Census, 2000 Census, and ConnDOT Series 27B Landuse Projections. Data for years following 2000 is projected. Graphics revised as of August 2004.

For the period 2000 through 2030, the populations of all 15 planning regions are projected to increase by percentages ranging from 3.1 percent in the Northwestern Region to 23.2 percent in the Windham Region. The Northeastern Region is projected to increase by 24.9 percent during this period, but a portion of this increase is due to the town of Union having become a new member in 2002. Population projections for each planning region and for the unaffiliated town(s) are presented graphically in Figure I-3 and listed in Table B-1 in Appendix B.

Figure I-4. Population by Age Group

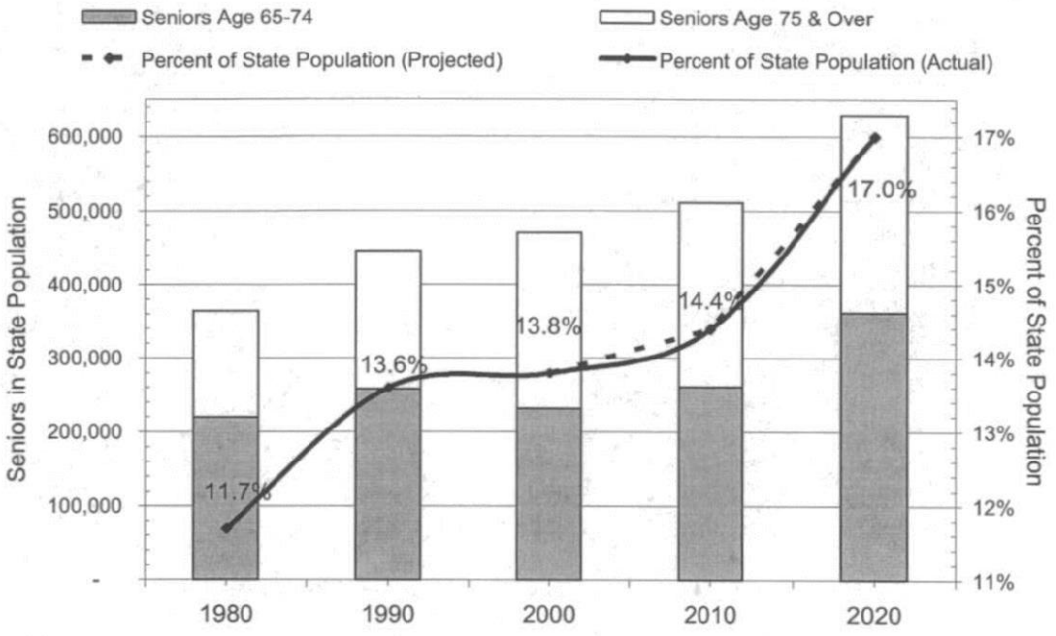


Source: 1990 Census and 2000 Census. Projections for years following 2000 not available.
Graphics revised as of August 2004.

Connecticut's total population is not projected to change drastically during the next 20 years. However, changes in the makeup and location of the population will affect the character of the state and demands on public and private services. The composition, by age group, of Connecticut's population is presented graphically in Figure I-4. The figure shows that much of Connecticut's population in 2000 was in the 35-44 and 45-54 age groups. The persons previously distributed in the 45-54 age groups during the 2000 census will likely comprise a large portion of Connecticut's senior population in 2020. As Figure I-5 illustrates, the population in the senior demographic group, persons age 65 and over, has been on the rise since 1980 in Connecticut and is anticipated to continue this trend.

The number of persons in the senior population is growing rapidly; this is in contrast to the slow growth of the overall state population. As presented in Figure I-5, the number of persons age 65 and older was 11.7 percent of the total state population in 1980, 13.6 percent in 1990 and 13.8 percent of the total state population in 2000. From 2000 to 2020, the population of persons over 65 is projected to grow more than 33.0 percent, from 470,183 to 629,000, increasing in proportion from 13.8 percent to 17 percent of the total state population; the largest increase will be during the period 2010 to 2020. Of the senior demographic group, the proportion of those 75 years or older, is projected to increase by almost 11.9 percent, from 238,618 in 2000 to 267,000 in 2020, increasing this group's share of total state population from 7.0 percent to 7.2 percent. This age group comprises 50.7 percent of the total elderly statewide population.

Figure I-5. Seniors (Age 65 & Over) in State Population

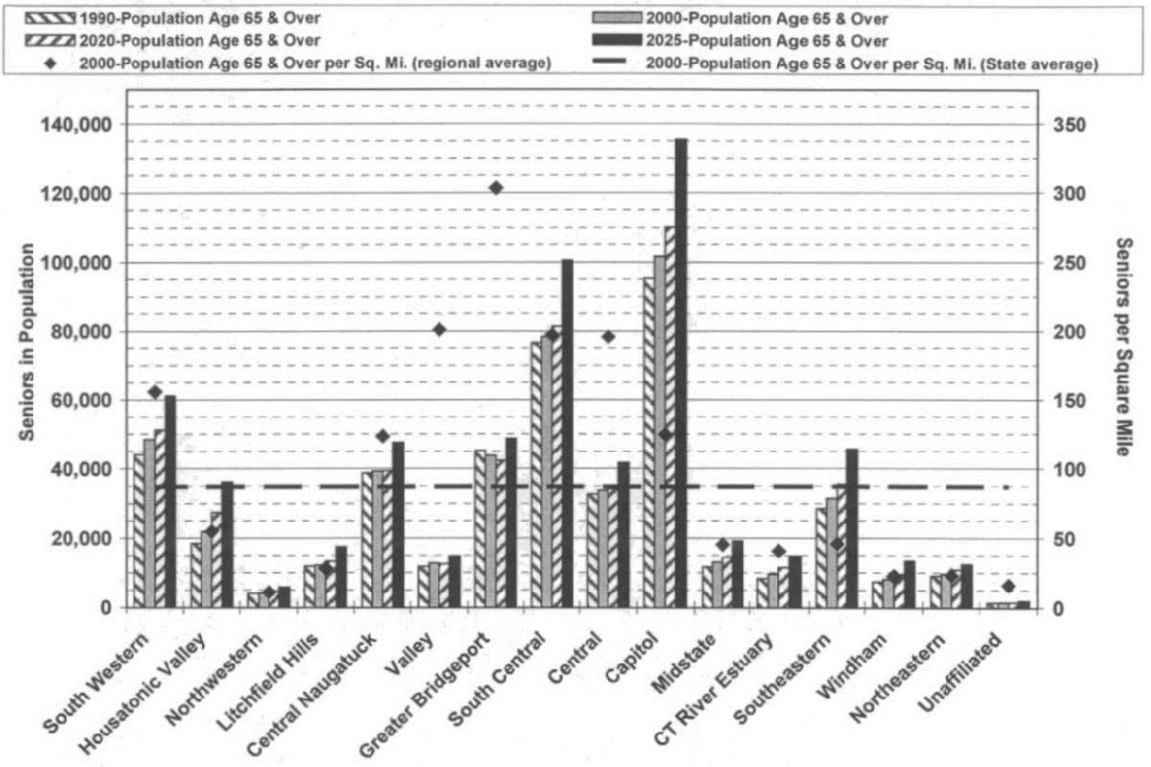


Source: 1980 Census, 1990 Census, and 2000 Census. Projections are Modified OPM Projections. Data for years following 2000 is projected. Graphic revised as of May 2006.

On a regional level, as shown in Figure I-6 and listed in Appendix Table B-2 in 2000 the Capitol Region, followed by the South Central Region, had the largest numbers of seniors. The Capitol Region had 101,665 or 21.6 percent of the state's senior population and the South Central Region had 78,455 or 16.7 percent. For the period 2000 through 2025, projected increases in persons 65 years of age and older range from 11.3 percent in the Greater Bridgeport Region to 65.7 percent in the Housatonic Valley Region.

These figures illustrate the continuing increase in both the numbers and proportion of the older population segments of society; a phenomenon often referred to as the "aging" of U.S. society. Because seniors represent a segment with specific needs and habits, the continuing expansion of this demographic group is exerting a growing influence on the future shape of society. A transportation-related consequence of this trend will be an increased demand for the expansion of paratransit (i.e. "dial a ride") and other transportation services designed to meet the needs of this demographic group. Another consequence will be the need to change components of highway, bus, rail, and air transportation systems to address the safety and mobility needs of older drivers and pedestrians.

Figure I-6. Senior (Age 65 & Over) Data by Planning Region



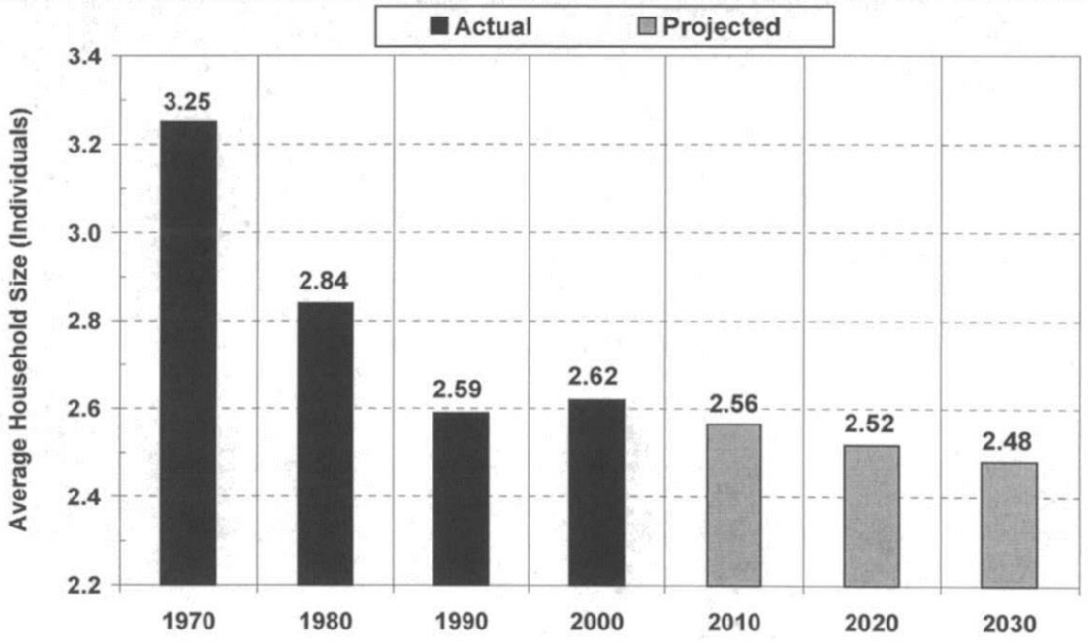
Source: 1990 Census, 2000 Census, and ConnDOT Series 27B Landuse Projections. Data for years following 2000 is projected. Projections for years following 2025 not available. Graphics revised as of August 2004.

Minority populations are the fastest growing populations in the State of Connecticut. Between 1980 and 1990, the overall state population increased by 5.8 percent, whereas, the Asian population increased by 16.3 percent, Hispanics by 71.2 percent, Afro-Americans by 26.1 percent in contrast to an increase in Whites of 2.1 percent. Between 1990 and 2000, these minority populations continued to increase as a percent of the overall state population, however, differences in the race categories used in the 2000 Census make it impossible to accurately compare 1990 Census data with 2000 Census data.

B. HOUSEHOLDS

ConnDOT estimated that between 1990 and 2000, the number of households in Connecticut increased by 5.8 percent, from 1,230,243 households to 1,301,670 households. In 2000, the state had an average number of 254 households per square mile. During the period 2000 to 2030, the number of households in the state is projected to increase by 12.8 percent, to 1,467,999 households. While the number of households has been increasing, the average number of people per household in the state has been decreasing.

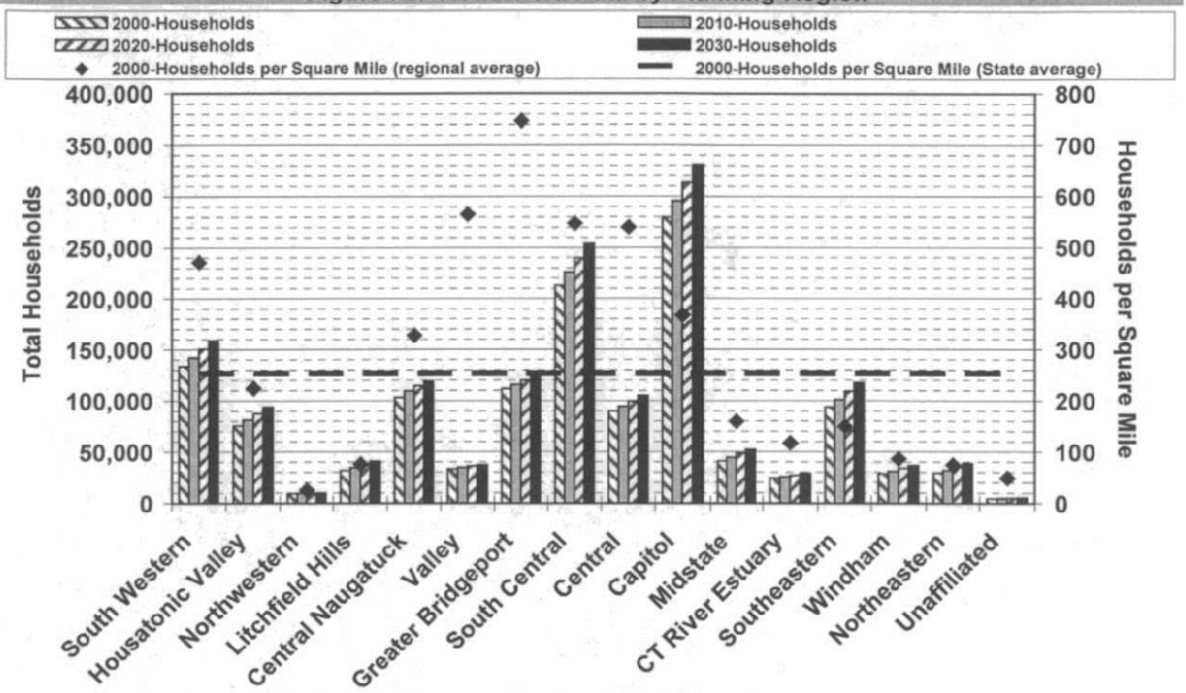
Figure I-7. Average Household Size in Connecticut



Source: 1970 Census, 1980 Census, 1990 Census, 2000 Census, and ConnDOT Series 27B Landuse Projections. Based on population divided by number of households. Data for years following 2000 is projected. Graphic revised as of August 2004.

As presented in Figure I-7, since 1970, there has been a decrease in household size in the State of Connecticut. In 1970, the average household size was 3.25. The average household size dropped successively to 2.84 in 1980, 2.59 in 1990, and then increased to 2.62 in 2000. It is projected that the average household size will decrease to 2.56 in 2010 and continue to decline through the year 2030, to an average of 2.48 persons. This trend of decreased household size is related to the overall increase in the number of households, and is not unique to Connecticut.

Figure I-8. Household Data by Planning Region



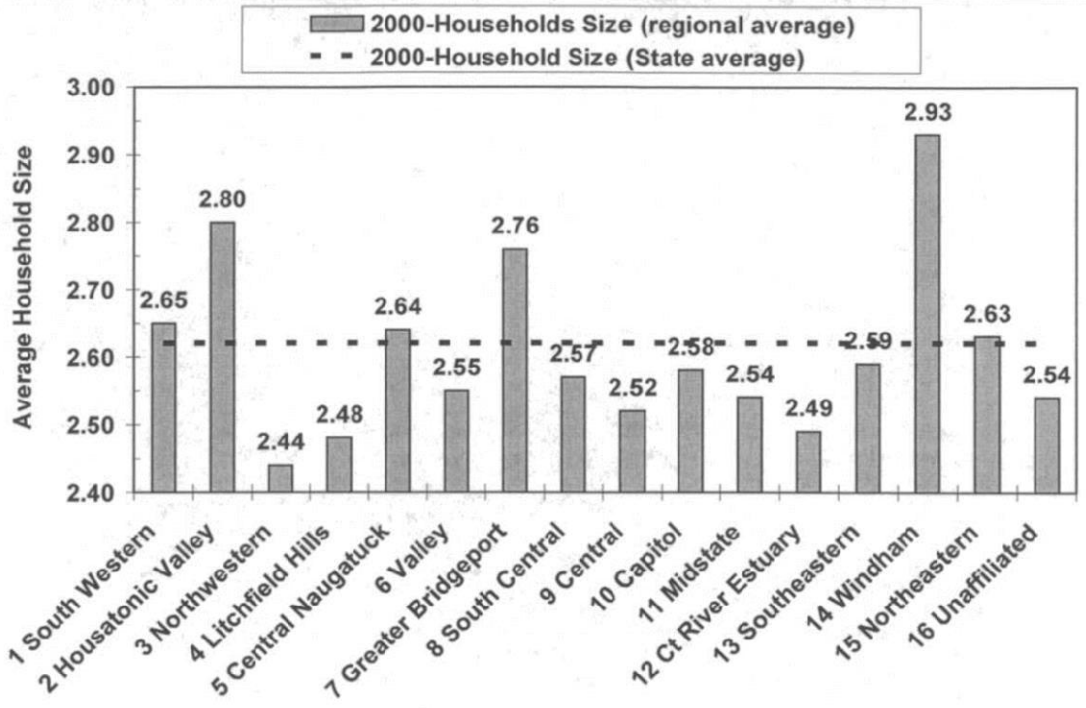
Source: 1990 Census, 2000 Census, and ConnDOT Series 27B Landuse Projections. Data for years following 2000 is projected. Graphic revised as of August 2004.

Higher rates of separation and divorce, the aging of the population and a trend toward delayed marriages by younger people have resulted in more younger and older people living alone, more single parent households, and more couples without children than in the past. These changing social patterns contribute to the decreasing number of people per household unit and the increasing number of non-family households.

Regional information on households is presented graphically in Figure I-8 and presented in Table B-3 in Appendix B. Between 1990 and 2000, increases in the number of households ranged from 1.3 percent in the Northwestern Region to 18.3 percent in the South Central Region. During the same period, two regions experienced a decrease in the number of households: the Midstate Region had a 25 percent decrease in the number of households and the Connecticut River Estuary Region had a 43.6 percent decrease.

In 2000, as presented in Figure I-8, the Capitol and South Central regions had the largest numbers of households, 279,871 and 212,894, respectively. The Northwestern Region had the smallest number: 9,290. Figure I-9 shows that the average household size ranged from 2.44 persons in the Northwestern Region to 2.93 persons in the Windham Region with six of the fifteen planning regions having an average household size greater than the overall state average of 2.5 persons per household.

Figure I-9. Average Household Size by Planning Region



Source: 2000 Census. Graphic revised as of August 2004.

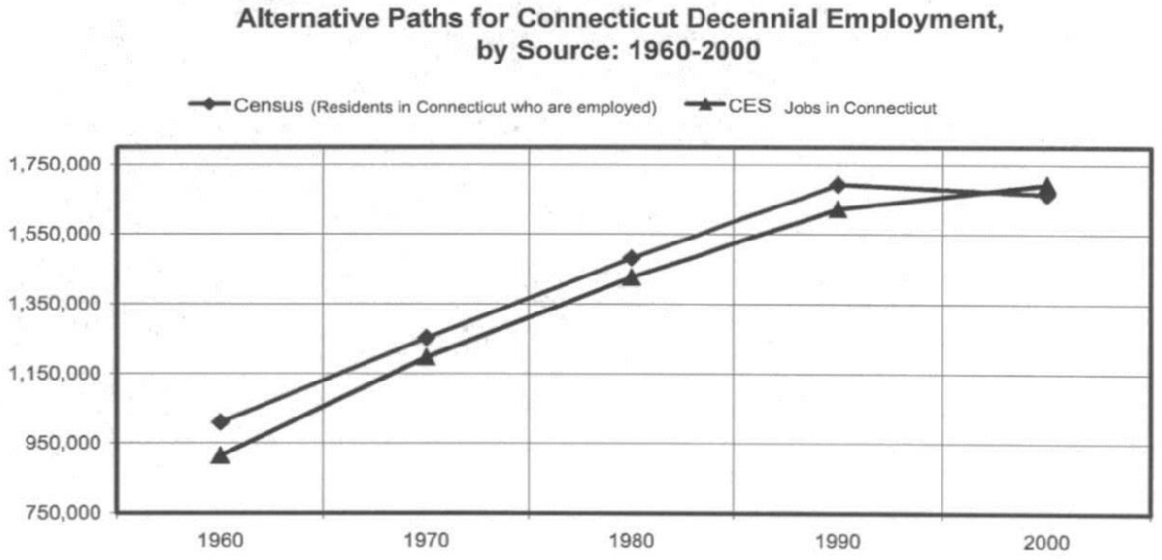
For the period 2000 through 2030, it is projected that the number of households in all 15 regions will increase. The projected increases range from 5.74 percent in the Northwestern Region to 20.02 percent in the Windham Region. The number of households is projected to increase by 10 percent or more in 12 of the 15 regions; the exceptions are the Northwestern, Valley, and Greater Bridgeport regions. Additional data on households is presented in Appendix B in Table B-3.

In 2000 the number of households per square mile, ranged from a low of 26 households per square mile in the Northwestern Region to a high of 748 households per square mile in the Greater Bridgeport Region.

C. EMPLOYMENT

Employment trends, annual fluctuations in employment, and employment projections are presented and discussed in this section. This information is important because it provides insights into changes in growth in Connecticut, people's travel patterns and, hence, current and future mobility needs and issues. The Connecticut Department of Transportation (ConnDOT) obtains data on existing employment from the Connecticut Department of Labor (DOL) and develops 20-year statewide and regional projections of future employment to use as variables in its transportation modeling process. Employment estimates are a key part of determining the number of work trip attractions to a traffic analysis zone (TAZ) in the generative phase of the Department's travel model. Employment at any given time depends heavily on the state of the economy.

Figure I-10. Connecticut Decennial Employment by Data Source



Source: Daniel Kennedy Ph.D, Senior Economist, Office of Reseach,Connecticut Department of Labor. January 2006

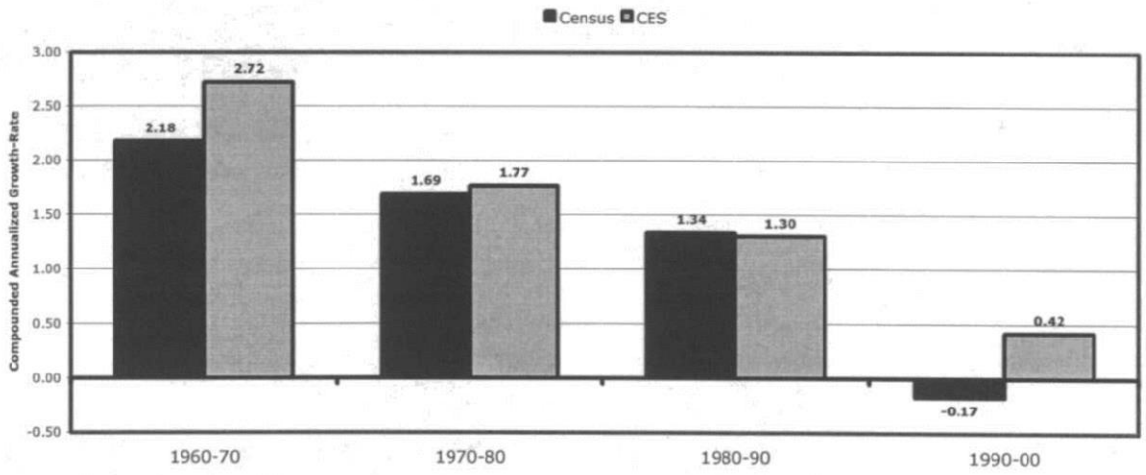
Figure I-10 depicts employment trends in Connecticut from 1960 through 2000. It shows the levels and changes in Connecticut employment based on data from two kinds of surveys: 1) an establishment-based Current Employment Statistics (CES) survey, which counts non-farm jobs in the State of Connecticut; and 2) the decennial census employment survey (Census), a household survey that counts people living in Connecticut who are employed.

The CES data on jobs, which is obtained from a survey of 5,000 Connecticut businesses, provides information on non-farm jobs in Connecticut, regardless of whether the workers live in Connecticut or another state. The data obtained from the Census survey provides information on labor market status of residents of Connecticut who are employed, regardless of whether they work in Connecticut or out-of-state. Summary information explaining the differences in concepts between the two surveys of HOUSEHOLD (labor force) vs. ESTABLISHMENT (jobs) is included in Appendix C in Table C-1 and Table C-2

Figure I-10 shows that employment increased steadily from 1960 through 1990. For that time period, both the Census and the CES data show increases (1.3 percent) and (1.25 percent), respectively, in the employment population. For 2000, the household-based Census data indicate that from 1990 to 2000 there was a 1.71 percent decline in employment. However, the CES data, which counts jobs in Connecticut, indicate that there was a 4 percent increase in non-farm jobs in Connecticut during this period.

Figure I-11, Annual Compounded Employment Growth Rates in Connecticut, shows the levels and changes in the growth rates of employment (based on an annual compounded growth-rate) in Connecticut from 1960 through 2000 (in decennial intervals) based on data from the Census and the CES surveys. It shows that over the past forty years, from 1960 through 2000, the rate of growth in employment in Connecticut declined. From 1960 through 1970, the rate of growth in employment was 2.18 percent based on Census data and 2.72 percent based on CES data. From 1970 through 1980, the rate of growth in employment was 1.69 percent based on the Census data and 1.77 percent based on the CES data. From 1980 through 1990, the rate of growth was 1.34 percent based on the Census data and 1.30 percent based on the CES data. From 1990 through 2000, however, the Census data, which reflects the employment based on persons living in households in Connecticut, not the state(s) in which these individuals work, indicate a negative rate of employment growth (-0.17 percent). The CES data, which reflect the rates of growth in non-farm jobs located in Connecticut, indicate that, although the rate of growth from 1990-2000 was significantly lower than it was from 1980-1990; there was a positive rate of employment growth (0.42 percent) during this period.

Figure I-11. Annual Compounded Employment Growth Rates in Connecticut,1960-2000

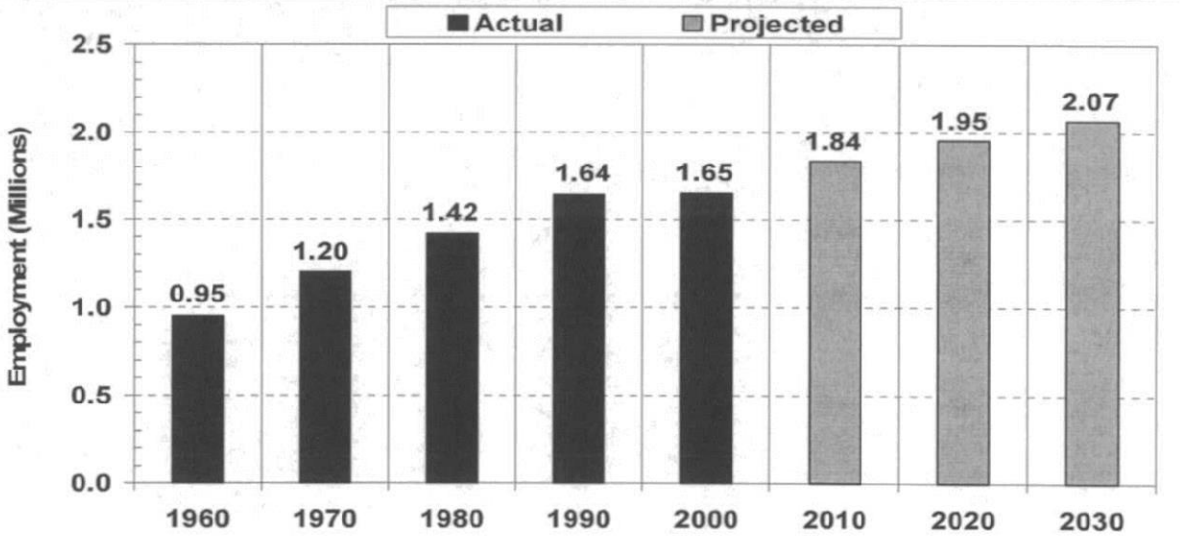


Source: Daniel Kennedy Ph.D, Senior Economist, Office of Reseach, Connecticut Department of Labor. January 2006

The data presented in Figure I-10 and Figure I-11 for the period 1990-2000 show the impact of either the loss of out-of state jobs and/or the decrease in travel to out-of-state job by Connecticut residents. It suggests that a certain percentage of Connecticut residents use Connecticut's transportation system to travel to jobs located in other states or countries and that there was a decrease in either the number of out-of-state jobs held by Connecticut residents or in work-related travel to out-of-state locations.

Figure I-12 presents actual employment data for the State of Connecticut in ten-year intervals from 1960 through 2000 and projected employment growth for ten-year intervals from 2010 through 2030. It shows that employment grew from .95 million in 1960 to 1.20 million in 1970, 1.42 million in 1980, 1.64 million in 1990 and 1.65 million in 2000. From 2000 to 2030 ConnDOT is forecasting a moderate rate of growth in employment. Using the Census Transportation Planning Package, which takes into account in-state and out-of-state travel to places of employment, the Department has projected that employment in Connecticut will increase at a slow, annual growth rate of 0.91 percent from the 2000 employment level to 1.95 million in 2020 and 2.07 million in 2030. This represents a 25.3 percent increase in employment from 2000 to 2030.

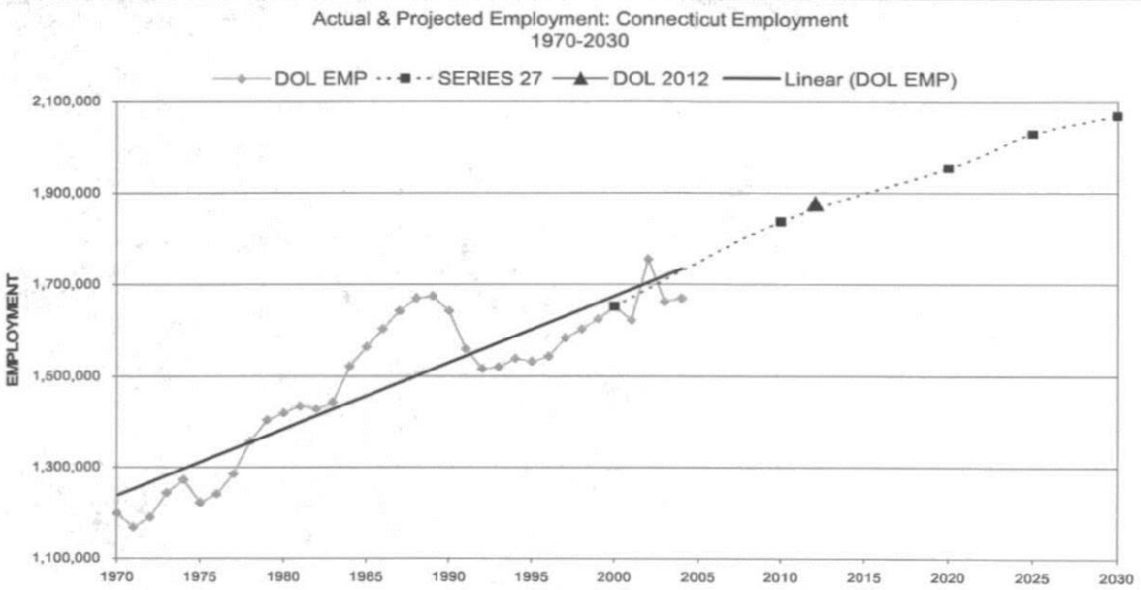
Figure I-12. Employment in Connecticut, 1960-2030



Source: 1960 Census, 1970 Census, 1980 Census, 1990 Census, 2000 Census, and ConnDOT Series 27B Landuse Projections as well as data from the Connecticut Department of Labor. Data for years following 2000 is projected. Graphic revised as of August 2004.

Figure I-13 presents annual employment data obtained from the Connecticut Department of Labor (DOL) and ConnDOT's projections of future employment. This graph demonstrates the volatile nature of employment. Even on a statewide basis, the employment varies considerably. The DOL employment is shown annually due to the variation in employment from year to year. The Series 27 projections are a trend line based on the DOL reports on employment. As shown on the graph, the DOL's 2012 statewide projection is on ConnDOT's trend line. The near-term employment between 2001 and 2004 is somewhat below the Department's projections.

Figure I-13. Actual and Projected Employment in Connecticut



Source: Developed by the ConnDOT Division of Systems Information, from the Connecticut Department of Labor reports with 2012 projection and Series 27B Connecticut Department of Transportation Land Use Projections. Graphic revised as of March 2006.
Note: Figures beyond 2005 are projected.

The fluctuations in employment are due to various trends and events. The rate of growth during the period 1970 and 2000 was fueled to some degree by the large increase in the number of women entering the work force and a robust economy which absorbed the influx of workers. During the 1980's there was substantial employment growth in the State of Connecticut. Between 1980 and the peak year, 1989, the state's total non-farm employment grew by 255,510 to 1,676,180 jobs.[1] From 1990 to 1992, however, employment declined. The state lost approximately 150,000 jobs, with employment sinking to a low of 1,516,700 in 1992.[2] This figure put employment back roughly to its 1984 level. In the early 1990's, the state was recovering from the economic recession of 1989-1992 when employment declined from its peak to a level consistent with the mid-80's. From 1990 to 2000, new jobs were created at a slow but steady pace. During this period, statewide employment grew by only 0.6 percent, or an average annual increase of 0.06 percent.

Between 2001 and 2004, the actual employment was below ConnDOT's projections due to a recession during that period. After early 2001, the economy saw a slight decline. The state economy suffered an additional setback after the September 11, 2001, terrorist attacks on the World Trade Center and the Pentagon. A decline in air travel resulted in the loss of jobs in travel-related fields. However, from 2001 to 2005 air passenger traffic gradually increased on an annual basis. From 2000 to 2004 air traffic increased by 7.53 percent.[3] As of October 2005, the year-to-date air passenger traffic had increased 4.1 percent from the same period the previous year.[4]

[1] Connecticut Department of Labor.

[2] Ibid.

[3] "Passenger Traffic Report – 2005", Bureau of Aviation & Ports, ConnDOT.

[4] "The Connecticut Economic Digest", December 2005, Volume 10, Number 12, Page 7.

Regional Employment

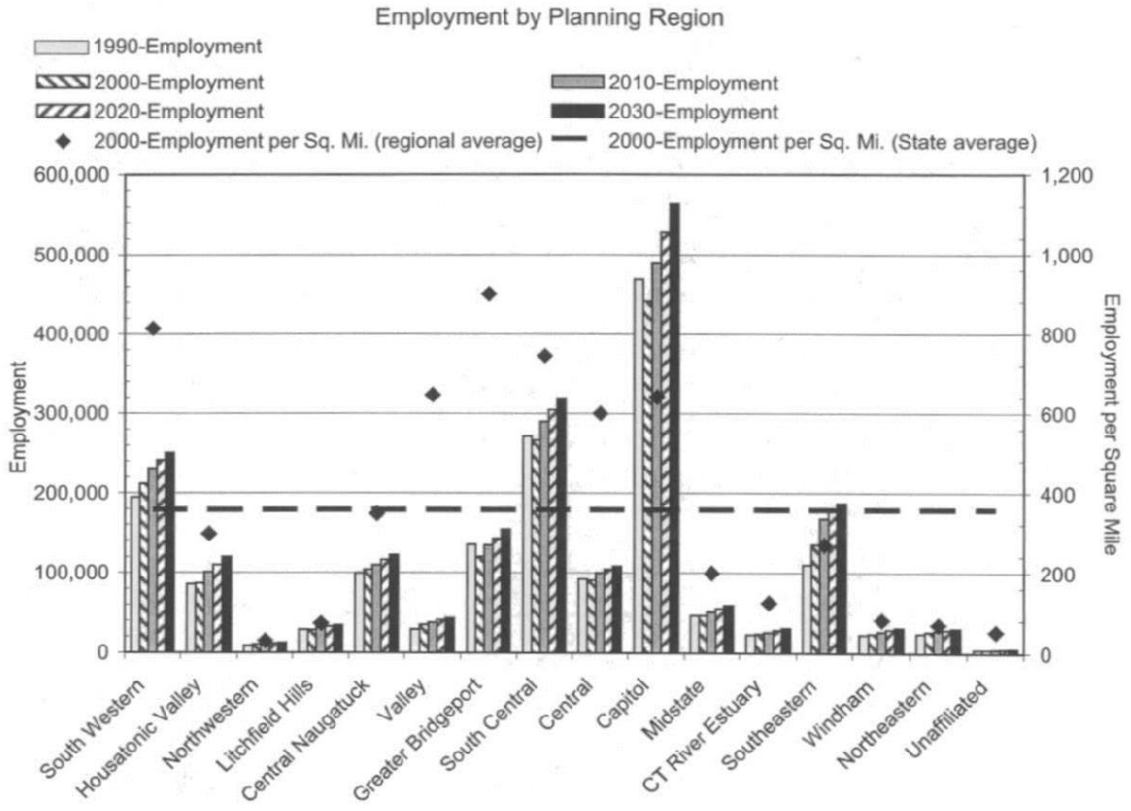
Figure I-14 presents actual and projected Connecticut employment data from 2000 through 2030 by planning region. It shows that from 1990 to 2000, employment increased in nine regions and decreased in six planning regions. The increases in employment ranged from highs of 20.7 percent and 22.9 percent, respectively, in the Valley and Southeastern regions to a low of 1.5 percent in the Housatonic Valley Region. The decreases in employment ranged from 0.6 percent in the Midstate region to 11.1 percent in the Greater Bridgeport Region. Six regions experienced an average annual decline. The largest decline in employment occurred in the Greater Bridgeport Region, which had an average annual decline of 1.11 percent. The other five regions that experienced a negative annual growth rate were Litchfield Hills, South Central, Central, Capitol and Midstate. The average annual growth of employment ranged from a low of 0.15 percent in the Housatonic Valley Region to a high of 2.29 percent in the Southeastern Region.

In 2000, the Capitol, South Central, and South Western regions had the greatest numbers of jobs: 441,290, 266,580, and 211,480, respectively. The total employment in these regions represented 55.6 percent of the state's total employment in 2000. The Northwestern Region had the lowest number of jobs: 9,900. With respect to employment density in 2000, the South Western and Greater Bridgeport regions had greater than 700 jobs per square mile. The Northwestern Region, comprising nine towns, had the lowest number of jobs per square mile (27) of the planning regions in 2000. The state had an average employment of 323 jobs per square mile.

ConnDOT has projected employment increases in all planning regions through 2030. The Capitol Region is projected to experience the highest growth in employment followed by South Central, Southwestern, Southeastern Connecticut, and Greater Bridgeport. The lowest employment growth is projected in the following regions: Litchfield Hills, Northeastern Connecticut, Windham, Connecticut River Estuary, and Northwestern Connecticut. Additional employment data for each of the regions is presented in Appendix B Table B-4 and in Figure B-1, Figure B-2 and Figure B-3.

A long-term factor that could make this growth optimistic is the aging of Connecticut's population which could lower the overall growth of the labor force in Connecticut. The increased average age is a nationwide trend with the large group of "baby boomers" approaching retirement age. However, changes in the Social Security system and in companies' pension plans and health benefits could result in more workers remaining in the workforce for longer periods of time. This situation could result in increased demand to modify and improve transportation systems to accommodate the mobility needs of older workers.

Figure I-14. Employment Data by Planning Region, 1990-2030



Source: 1990 Census, 2000 Census, and ConnDOT Series 27B Landuse Projections. Data for years following 2000 is projected. Graphic revised as of February 2006.

Trends in Types of Employment in Connecticut

With respect to types of employment, trends in Connecticut are mixed. Employment in the state has been slowly returning to its previous peak; however, there has been a shift in the types of jobs created. Within the last 30 years, there has been a shift of jobs from the manufacturing sector to the service sector. In general, the base industries in Connecticut have shifted to other areas, with many jobs being relocated outside of the country. However, there is still a component of high end, aeronautical manufacturing in the state with Pratt and Whitney and companies such as Sikorsky. Electric Boat has about half its peak employment of 14,000, but still has a substantial work force.[5] This shift in employment from manufacturing to service employment does not affect ConnDOT's travel modeling because the type of employment is not part of the travel model inputs except for retail employment. The shift from manufacturing does, however, affect the distribution of employment in the state in that employment is more spread out in the state.[6]

[5] Herman Lehlbach, unpublished paper, "Connecticut Employment Projections," Division of Systems Information, Connecticut Department of Transportation, February 2006.

[6] Ibid.

Growth and trends with respect to types of employment differ from region to region. A recent trend in the Hartford area of the Capitol Region is the loss of insurance and finance jobs due to the consolidation of large companies such as Travelers and Aetna.[7] In the southeastern part of the state, more than 20,000 jobs have been created as a result of the development and expansion of the Native American Casinos. In Ledyard, the Foxwoods Resort and Casino, which is owned and operated by the Mashantucket Pequot Tribal Nation, has undergone several successive expansions including the construction of two large tourist hotels. Tribal and Foxwoods officials were scheduled to break ground in November 2005 on a $700 million development project that will provide Foxwoods' customers with more gaming, more entertainment and additional resort amenities, including more convention and meeting space at a single site than any other casino on the east coast. The project will add 2,300 permanent jobs at Foxwoods, bringing total employment to more than 13,500 people.[8] The Mohegan Sun Casino, which is owned and operated by the Mohegan Tribal Nation, is also located in southeastern Connecticut in the town of Montville. Nearly 10,000 people are employed at this casino.[9] These jobs replace some of the manufacturing jobs lost but at a reduced level of compensation. The casinos have brought in many persons from foreign countries.

Casinos have had and are continuing to have a significant impact on tourism, transportation, and related development, particularly in the southeastern part of the state.[10] They are growth centers that contrast sharply with rural surroundings and may foster new land use patterns over a broad area. These impacts, both positive and negative, make cooperative planning efforts among state, regional, municipal and tribal officials a vital and continuing obligation.[11]

A major addition in the southeastern part of the state is the building of the Pfizer Research Center in New London. This research center supplements Pfizer's existing facilities in Groton.

The southwestern part of the state, notably Greenwich, Stamford, and to a lesser extent, Norwalk, have become employment centers developed as corporate parks due to the relocation of companies from New York to the 'suburbs'. Much of this type of development has slowed because of the high cost of housing and the infrastructure. Interstate 95 is at or over capacity and there is little likelihood of relief any time in the near future. In any case, the further development of office space will be limited by the capacity of the transportation system and any future attempts to increase it. Less expensive housing is also related to the transportation deficiencies. As people move further away from urban and suburban areas to obtain affordable housing they put even greater strain on the transportation system. Cities such as Danbury are growing at a fast rate, but there is limited north-south access within the southwestern part of Connecticut by auto, and the rail service on the Danbury Line is one track with passing sidings. In any case, the potential for further growth in the southwestern part of the state will be limited by transportation. Cities such as New Haven have a solid base of employment with some potential for further growth out of New York. This has not occurred up to now but may in the future.[12]

[7] Ibid.

[8] Foxwoods Resort Casino, "THE MASHANTUCKET PEQUOT TRIBAL NATION TO BEGIN $700 MILLION FOXWOODS DEVELOPMENT PROJECT," Press Release on November 3, 2005, <http://www.foxwoods.com/Home/PressCenter/PressReleases.aspx#> (30 November 2005)

[9] Mohegan Sun Casino & Entertainment, "Look up Frequently Asked Questions under Employment section," http://www.mohegansun.com/common/faq.jsp, copyright 2005 (30 November 2005)

[10] *Conservation and Development Policies Plan for Connecticut, 1998-2003*, State Office of Policy and Management, last modified October 31, 2001.

[11] "Planning for Connecticut's Future," *Conservation and Development Policies Plan Connecticut, 1998-2003*, p. 6, State Office of Policy and Management, last modified October 31, 2001.

[12] Lehlbach, "Connecticut Employment Projections," Connecticut Department of Transportation, February 2006.

In 2000, of the 1.65 million jobs in Connecticut, 273,561 (16.6 percent) were in retail and wholesale trade sectors; the remaining 1.38 million jobs (83.4 percent) were in other sectors.[13] ConnDOT has projected that, of the estimated available jobs in the year 2020, 325,340 are projected to be in retail and wholesale trade sectors, and 1.63 million are anticipated to be in other sectors.

As of March 2006 there were nine industry clusters in Connecticut: Aerospace, Agriculture, Bioscience, Insurance and Financial Service, Maritime, Metal Manufacturing, Plastics, Software and Information Technology, and Tourism. Of these industry clusters, Financial and Insurance Services, which comprises 8% of our employment population, is the largest. The smallest growing industry cluster is Plastics, which comprises 0.5% of our employment population.

Other Relevant Employment Data

Unemployment rates for Afro-Americans and Hispanics are significantly higher than those of the overall labor force, despite growing representation of these groups' in the labor force. The impacts of minority unemployment are felt most in the larger cities as minority populations tend to be concentrated in these areas and the growth in jobs increasingly has been in the suburbs. These employment patterns, coupled with the population trends previously discussed, indicate that there is a continuing need for state, regional and local agencies to work together to develop and encourage land use and transportation strategies that address the employment and mobility needs of the state's minority populations.

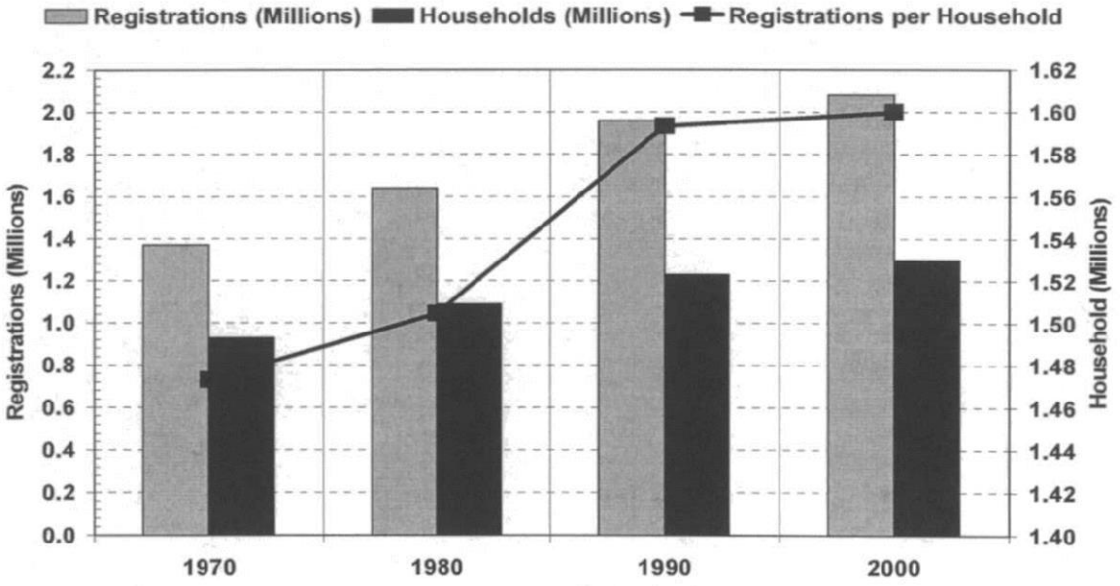
[13] Division of Information Systems, Connecticut Department of Transportation, March 2006.

D. MOTOR VEHICLE OWNERSHIP

From 1990 to 2000, Connecticut's population increased 3.6 percent from 3,287,116 in 1990 to 3,405,545 in 2000. During this same period, motor vehicle ownership, as reflected by the number of passenger vehicles registered in the state's cities and towns, increased by over 5.9 percent from 1,963,809 to 2,080,612.

The average number of vehicles available per household has been increasing. As shown in Figure I-15, the ratio of registered passenger vehicles to population steadily increased from 1.47 vehicles per household in 1970 to 1.59 vehicles per household in 1990. From 1990 to 2000, the ratio of vehicles per household increased slightly from 1.59 to 1.60.

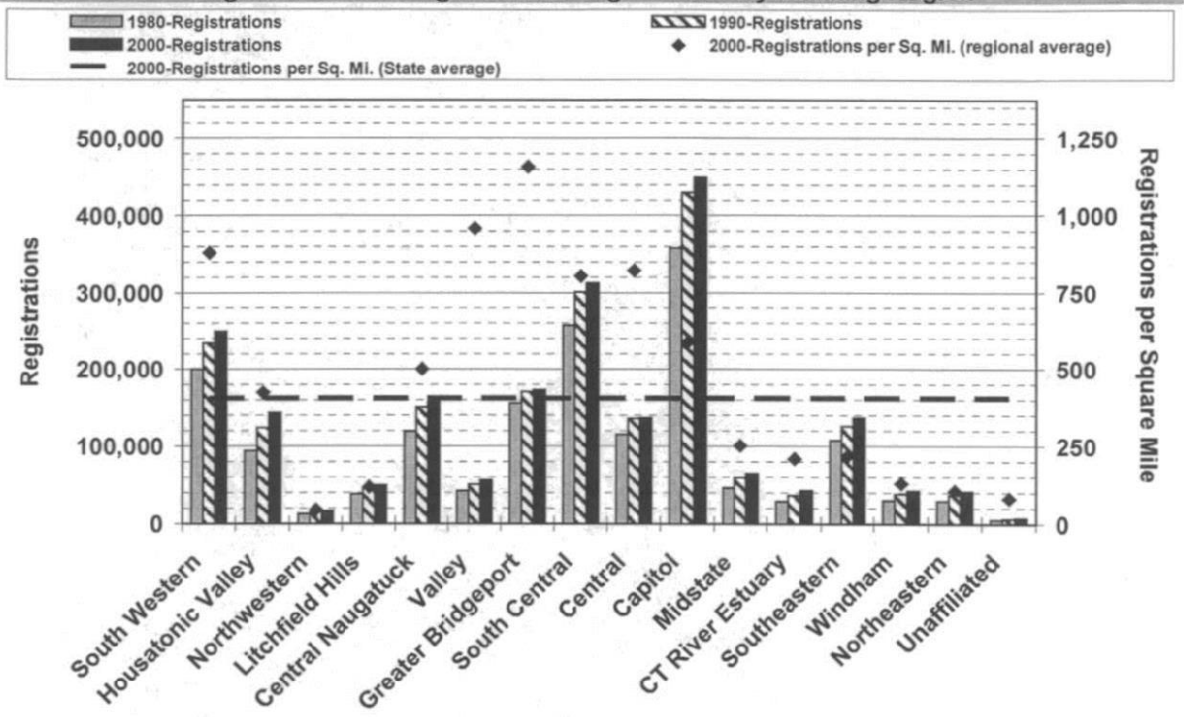
Figure I-15. Comparison of Passenger Vehicle Registrations to Households



Source: 1970 Census, 1980 Census, 1990 Census, 2000 Census, and Connecticut Department of Motor Vehicles. Graphic revised as of April 2006

From 1990 to 2000, passenger vehicle ownership increased more than 10 percent in the following regions: Connecticut River Estuary, Housatonic Valley, Northeastern, Windham, Valley and Northwestern. In 2000, passenger vehicle ownership was the highest in the Capitol and South Central regions and the lowest in the Northwestern Region. Additional information on passenger vehicle registrations in Connecticut is presented in Figure I-16 and Table B-5 in Appendix B.

Figure I-16. Passenger Vehicle Registrations by Planning Region



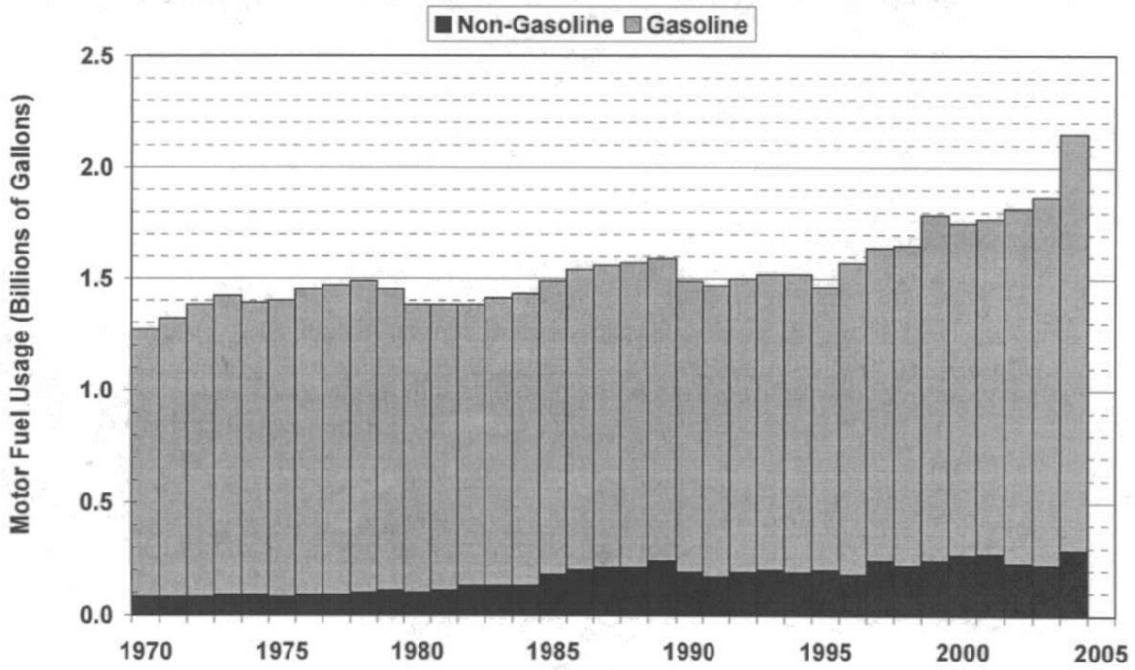
Source: Connecticut Department of Motor Vehicles - Class 1 Auto Registrations (Passenger Cars). Projections for years following 2000 is not available. Graphic revised as of August 2004.

Comparatively, the greatest numbers of vehicles per square mile in 2000 were found in the Greater Bridgeport (1,159) and Valley (960) regions. The Northwestern Region averaged the lowest number of passenger vehicles per square mile (46) in 2000. The statewide average for vehicles per square mile in 2000 was 406. These demographic trends form the foundation for assessing future transportation needs and for developing a transportation program that will meet those needs.

E. AUTO USAGE

Transportation requires a massive amount of energy, and, except in the cases of bicycling and walking, this energy is provided by one of the various types of transportation fuels. The term "motor fuel" applies to gasoline and all other fuels that are used for transportation. In Connecticut, fuel vendors record the amounts of fuels sold and submit this information to the state for tax purposes. Figure I-17 below presents historic motor fuel usage in Connecticut, including data comparing gasoline to non-gasoline fuel alternatives. This recorded fuel sales volume also serves as a measure of vehicle use.

Figure I-17. Motor Fuel Usage in Connecticut



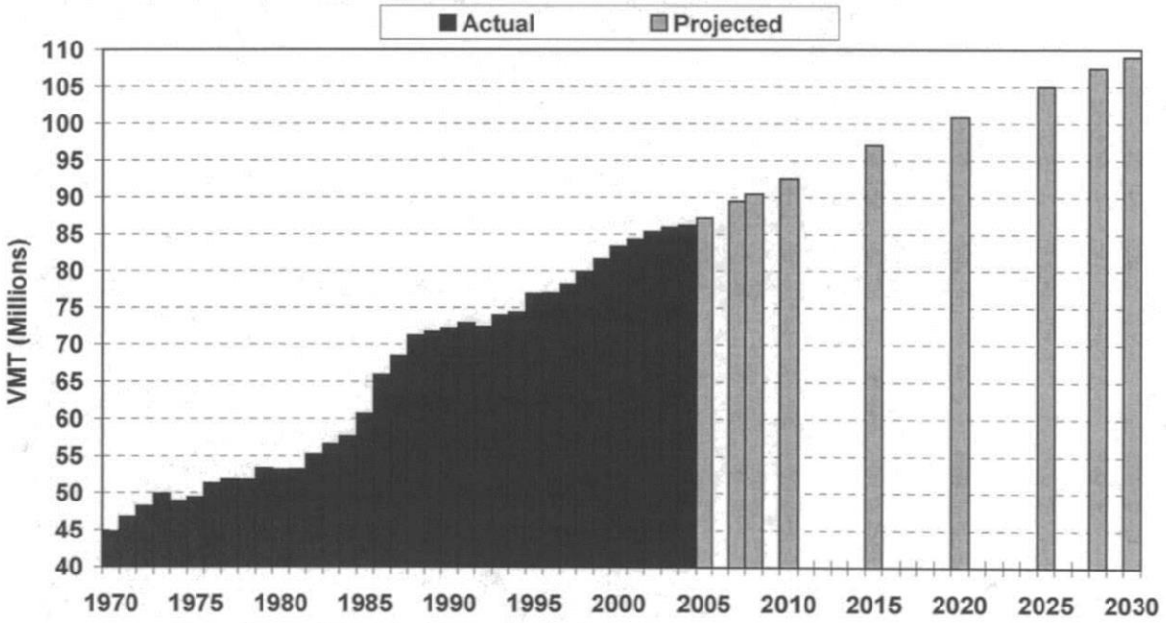
Source: Highway Statistics Table MF-21. Data following 2004 not yet available. Graphic revised as of April 2006.

Special Notes: As a result of revised estimation procedures, data from one year to another may not be comparable.

Despite technological advances in fuel efficiency, which considerably reduced the amount of fuel needed by vehicles, the overall trend during the 1970's and 1980's was an increase in the volume of motor fuel sold. An exception to this trend was the period of the energy crisis in the mid-1970's and early 1980's whereby significant dips in fuel use were observed across the nation. Motor fuel usage in Connecticut reached a high in 1989; this was due primarily to the rapid increase in the number of vehicles and growth in the number of vehicle miles traveled (VMT) in the state. Motor fuel consumption decreased slightly in 1990 and 1991 during the Gulf War. Since 1992, motor fuel consumption has been increasing gradually with a slight decrease again in 1995. Since 1995, motor fuel consumption in Connecticut has been increasing, with a peak of 1.79 billion gallons sold in 1999. In 2001, motor fuel consumption dropped slightly to 1.78 billion gallons.

The transportation industry has traditionally relied upon fuels that are inexpensive and readily available. Petroleum has dominated the fuel market during the past century, and despite growing concerns about pollution, it will no doubt continue to play a major role as a transportation fuel for many years to come. At the present time, significant amounts of time and money are being spent on research to develop alternative fuels, which are cleaner and less expensive than those presently in use. Environmental concern over the pollution caused by the use of traditional fossil-based fuels is the driving force behind this research. Three technologies that hold promise are hybrid, fuel cells, and electric vehicles. As cleaner and less expensive fuels make their way into the marketplace, the transportation industry will no doubt adapt to make use of them as it has in the past.

Figure I-18. Vehicle Miles Traveled (VMT) in Connecticut

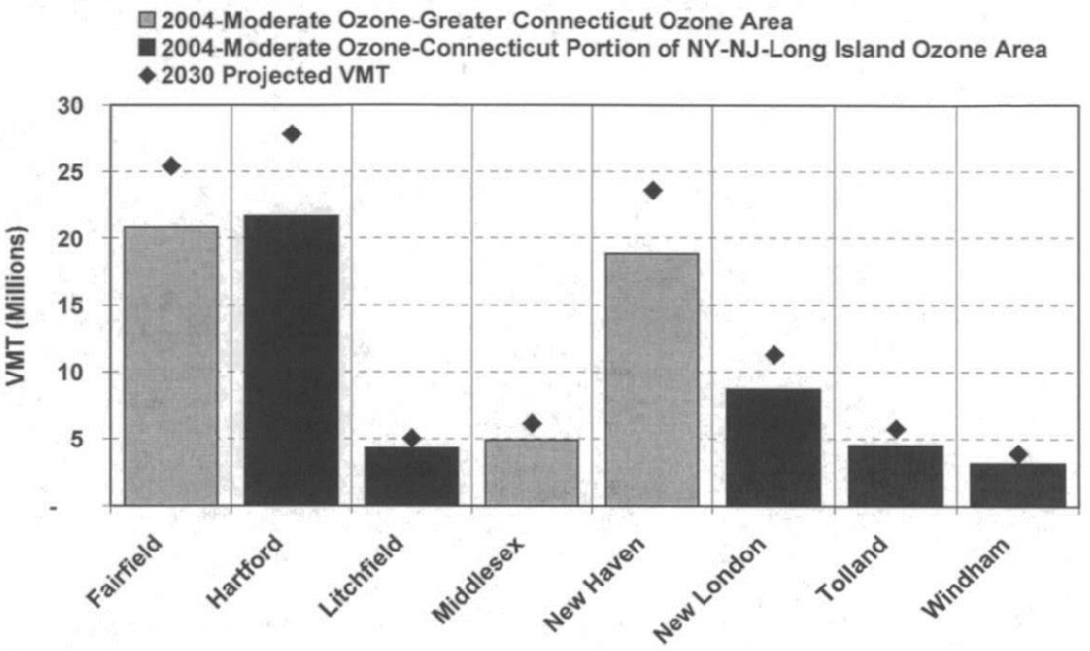


Source: Years 1970 to 1977 derived from statewide fuel usage data; years 1978 to 2004 from Highway Performance & Monitoring System Data; years greater than 2004 are projected with ConnDOT Travel Model (Series 28). Graphic revised in October 2005.

Special Notes: Data represents the average daily vehicle miles of travel. Some years are leap years. Model projections do not include Worchester UA VMT.

Another index of vehicle use is Daily Vehicle Miles of Travel, or VMT. As Figure I-18 illustrates, daily VMT in Connecticut has been growing steadily since 1970. However, during the period from 1990 to 2000, the rate of growth was approximately 17.4 percent over the ten-year period, compared to an approximate 36 percent from 1980 to 1990. In 2000, the total VMT in Connecticut was 83.4 million miles. Future projections call for continued slow growth in VMT as both the state and the economy continue to grow. In 2030, the statewide VMT is anticipated to be 109 million miles. This represents an increase of 25.6 million miles or a 30.7 percent increase from the VMT in 2000.

Figure I-19. Vehicle Miles Traveled (VMT) by County



Source: ConnDOT Travel Model (Series28). Graphic revised as of April 2006.

Special Notes: Data represents the Average Daily vehicle miles of travel. Graph shows June 2004 ozone non-attainment designations.

On a county level, in 2004, as illustrated in Figure I-19, Hartford County had the most vehicle miles traveled in the state: 21.7 million miles or 24.9 percent of the average daily miles traveled. Comparatively, Windham County had the fewest with slightly less than 3.2 million miles or 3.7 percent, of the statewide average daily VMT.

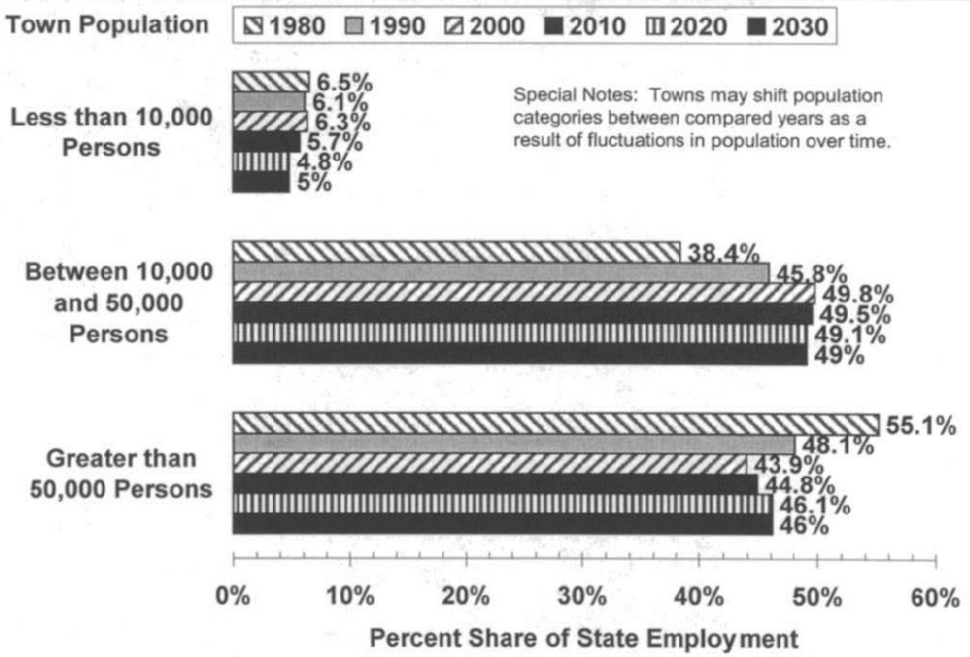
In 2004 all of the counties in Connecticut were designated as Moderate Ozone Non-attainment areas. As shown in Figure 1-19, the three counties with the highest VMT in 2004: Fairfield County, Hartford County and New Haven County, are projected to have the largest increases in VMT in 2030.

F. COMMUTING

Getting people from their homes to their place of employment puts a critical demand on the transportation network. Increases in suburban employment have resulted in special separation between home and worksite. This has resulted in increases in suburban travel, which has placed added strain on the transportation system beyond the urban center. Figure I-20 shows that from 1990 to 2000, the percentage of total state employment located in towns with populations greater than 50,000 had decreased by 4 percent from 48 percent to 44 percent of the total state employment. During the same period, the percentage of total jobs located in towns with populations between 10,000 and 50,000 increased 4 percent from 46 percent to 50 percent; the employment share of towns with populations less than 10,000 remained virtually unchanged at 6 percent. It should be noted that during compared years, populations in any given town can fluctuate; this potentially leads to a shifting of towns between the population categories from one year to another.

From 2000 through 2030, ConnDOT has projected a 2 percent increase (from 44 percent to 46 percent) in the percentage of total state employment located in towns with populations greater than 50,000, an insignificant increase (less than 1 percent) for towns with populations between 10,000 and 50,000 persons, and a small decrease (less than 2 percent) for towns with less than 10,000 persons.

Figure I-20. Employment Share by Town Size



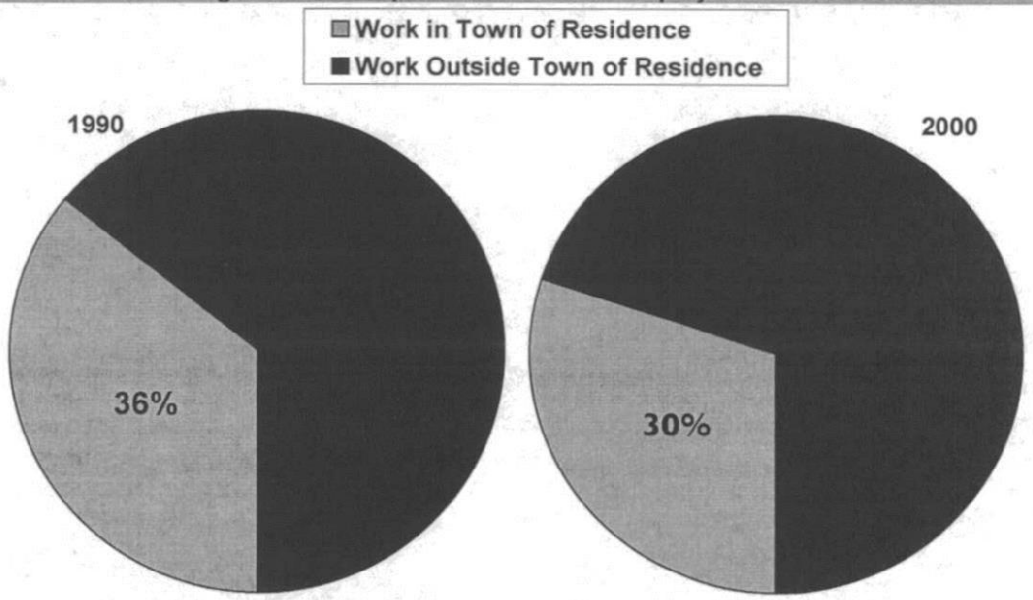
Source: 1980 Census, 1990 Census, 2000 Census, and ConnDOT Series 27B Landuse Projections. Data for years following 2000 is projected. Graphic revised as of August 2004.

During the period 1980 through 2000, the shift of employment from central cities to suburban towns has been accompanied by an increase in the percentage of Connecticut's work force commuting to employment sites outside their towns of residence. Figure I-21, shows that the number of workers who commuted to a job located outside their towns of residence increased overall by approximately 6 percent statewide from 1,071,800 in 1990 to 1,147,898 in 2000.

During the same period, the number of workers living in Connecticut whose place of employment was located within their town of residence decreased by 18.1 percent from 601,642 to 492,925.

The aforementioned demographic changes have affected the amount of time it takes commuters to make trips. The average state wide commute increased 13.74 percent from 21.1 minutes in 1990 to 24.4 minutes in 2000.

Figure I-21. Comparison of Place of Employment to Residence



Source: 1990 Census and 2000 Census. Projections not available.
Graphic revised as of August 2004.

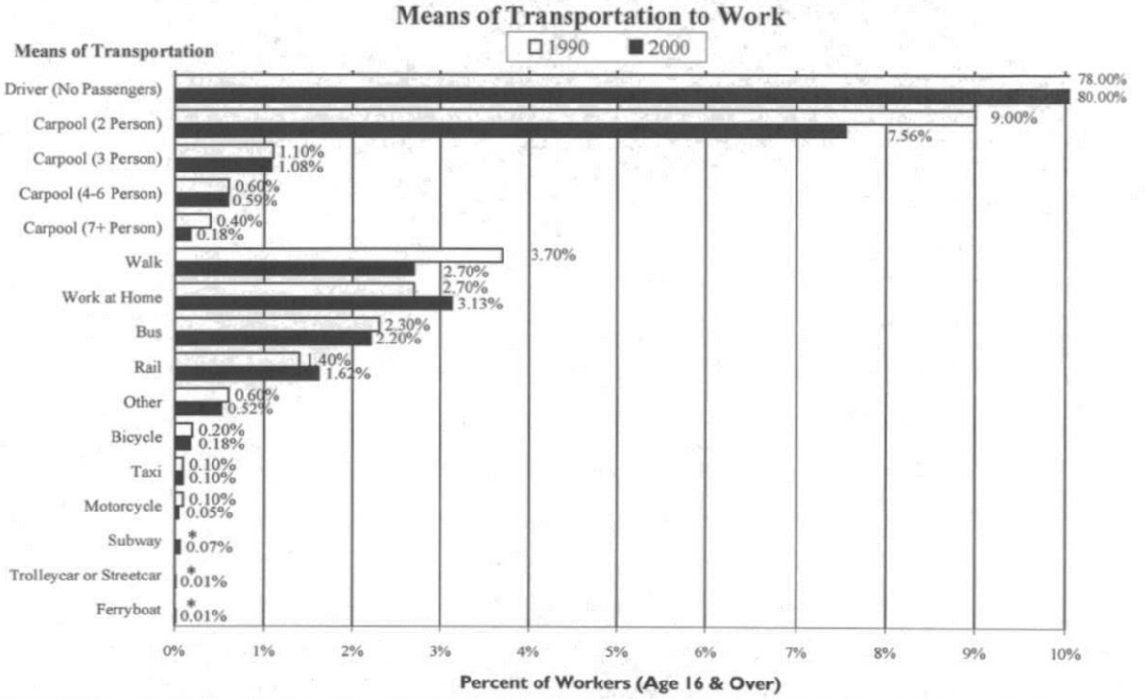
Information on the means by which persons in Connecticut travel to work is presented in Figure I-22. This figure presents 1990 Census and 2000 Census data on means of transportation to work for Connecticut workers who are age 16 and over. In 1990 the private automobile was the primary means of transportation to work. Of the workers commuting to work in a private automobile, 78 percent of the workers drove to work alone, 9 percent participated in 2-person carpools, 1.10 percent participated in 3-person carpools, .60 percent participated in 4-6 person carpools and .40 percent participated in carpools of 7 or more persons. After the private automobile, "Walking" was the next largest category (3.70 percent) followed by "Work at Home" (2.70 percent), "Bus" (2.30 percent), "Rail" (1.40 percent), "Other"(.60 percent) "Bicycle" (.20 percent), "Taxi" (.10 percent), and "Motorcycle" (.10 percent).

In 2000, 80 percent of workers drove to work alone, 7.56 percent traveled in 2-person carpools, 1.08 percent traveled in 3-person carpools, .59 percent participated in 4-6 person carpools, and .18 percent traveled in a carpool of 7 or more persons. After the private automobile, "Work at Home" was the next largest category (3.13 percent) followed by "Walking" (2.70 percent), "Bus" (2.20 percent), "Rail" (1.62 percent), "Other" (.52 percent), "Bicycle" (.18 percent), "Taxi" (.10 percent), and "Motorcycle" (.05 percent). Additionally, in 2000, .07 percent of workers used a subway to get to work, .01 percent used a trolley car or streetcar, and .01 percent used a ferryboat to get to work. "Subway", "Trolley car or Streetcar", and "Ferryboat" are new Means-to-Work categories that were listed in the 2000 Census.

A comparison of the 1990 to 2000 Means to Work census data indicates that in 2000, the private automobile continued to be the primary means of transportation to work. However, there was an

increase (2 percent) in the percentage of workers driving alone and a decrease (1.69 percent) in the percentage of workers using carpools as a means of transportation to work. There also were increases in the percentage of workers working at home and traveling by rail and decreases in the percentages of workers riding the bus and walking to work.

Figure I-22. Means of Transportation to Work in 1990 and 2000



Source:1990 Census, and 2000 Census Supplemental Survey. * The following categories: Trolley, Subway and Ferryboat were not available in the1990 census. The Census allows a person to select only one category as a means of transportation to work. It does not account for dual-mode trips to work. Data updated as of January 2006

The increase in the percentage of workers driving alone and the decrease in the percentages of workers who carpool, ride the bus and walk to work have contributed to the growth in traffic volumes on Connecticut roads.

The increase in the number of commuters driving alone to work occurred despite the higher cost compared with carpooling and transit. The continuing dispersion of employment and other services into the suburbs is a contributing factor to this behavior. Another significant and somewhat related factor is the increasing number of women, particularly women with young children, in the labor force. Women now make more trips, by all modes, than men do and they are more likely to "trip-chain" - to link together a series of trips for different purposes in one outing. The increase in "trip-chaining" associated with providing childcare and managing a household is directly related to the increase in the number of commuters driving alone.

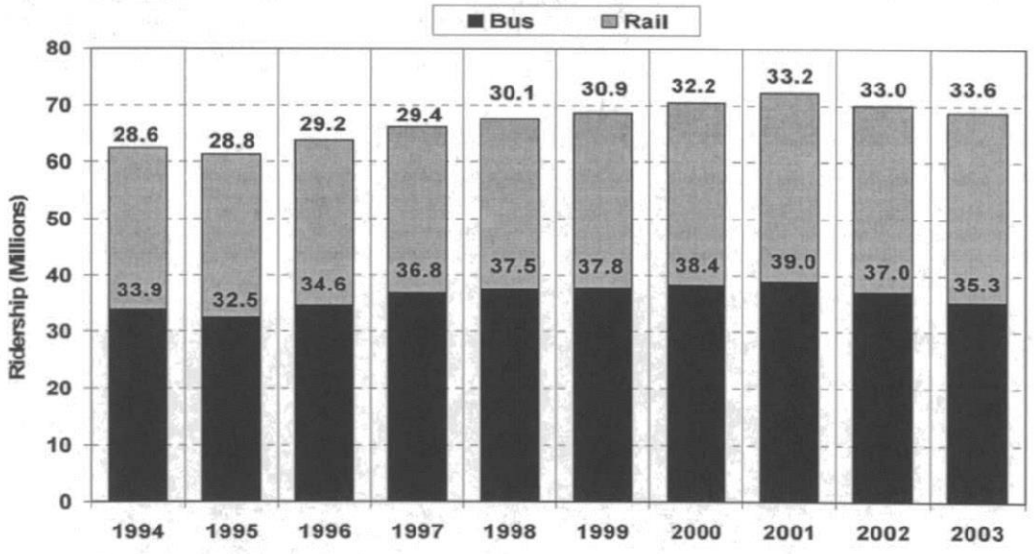
Reducing the number of single occupancy vehicles has proved to be a difficult objective. Several factors contribute directly to a successful carpool. These include a large employer that serves as a "magnet", a long commuting distance (greater than 10 miles), and a work location where free parking is not readily available. Another factor which has been observed in other areas of the country and that may start affecting Connecticut commuters is the decision to avoid congestion and decrease travel times during the peak period by using High Occupancy Vehicle (HOV) lanes. Connecticut now has approximately 38 miles of HOV lanes in operation on I-84, I-384 and I-91 extending northward and eastward from Hartford. These lanes carry approximately 7,100 commuters toward Hartford during the morning peak period.

Local bus service tends to be centered on urban areas. Express bus service primarily connects suburban towns with urban centers. While rail ridership has increased during the past ten years, bus ridership has declined overall. The Capitol Region (Greater Hartford Area) has the heaviest use of bus service in the state. Bus ridership in the Capitol Region accounts for nearly 35 percent of the total bus ridership in the state. The median household income for bus riders is lower than any other mode of transportation, and many bus riders have limited access to automobiles. Low household income and lack of auto availability continue to be significant factors in the use of bus service.

Rail commuters in Connecticut historically have been destined mainly for New York City. Data, however, indicates that the number of people traveling in the reverse commute direction (New York to Connecticut) and within Connecticut is increasing. The most heavily traveled segment of rail line in Connecticut is between Norwalk and Greenwich, the area of residence for the majority of the state's rail commuters who work in Manhattan. Rail service provides the most convenient means of traveling to Manhattan, and it captures most of the commuter market to that destination. Rail ridership between Connecticut towns is increasing, and, although it still remains a small percentage of total rail ridership, it represents a growth component that is a priority for the state.

The relative share of transit passengers carried by bus and by rail in 1994 through 2003 is shown in Figure I-23. The figure compares annual passenger volumes for bus and rail for SFY1994 through SFY2003. It shows that bus passenger volumes decreased from 33.9 million in SFY1994 to 32.5 million in SFY1995, increased annually from 32.5 million in SFY1995 to 39 million in SFY2001, and then decreased to 37 million in SFY2002 and to 35.3 million in SFY2003. In comparison, rail passenger volumes increased annually during this period from 28.6 million in SFY1994 to 33.6 million in SFY2003.

Figure I-23. Comparison of Annual Passenger Volumes for Transit Modes (SFY1994-SFY2003)



Source: ConnDOT Bureau of Public Transportation's "Operations Statistics". Graphic Revised as of September 2004.

The advent of the Information Age has brought about a multitude of technological advances that are gradually changing the face of the world and how communications and business transactions are conducted today. Personal computers, modems and fax machines have made possible a growing employment trend, telecommuting. With telecommuting, information transfer is used as a substitute for the traditional journey to work on either a part-time or a full-time basis. Telecommuting programs provide multiple benefits because they allow greater schedule flexibility and reduce commuting times to zero for the participants, while at the same time they save fuel and reduce congestion for society at large. In 2003, 3 percent of the state's labor force worked at home, up from 1.5 percent in 1980 and 2.70 percent in 1990. Because of the continuing development of communications technology and increasing costs of fuel, this mode of employment will play a growing role in addressing the demand for transportation services.

Additional demographic information on commuters and their work trips is published in the Connecticut Department of Transportation's March 2005 publication, *Connecticut Census Review: A Look at Demographic & Transportation-Related Statistics for Connecticut from 1990 - 2000.*

G. TRAFFIC ACCIDENT STATISTICS

The Connecticut Department of Transportation (ConnDOT) obtains data on motor vehicle traffic accidents from police accident reports provided by investigating police agencies and analyzes it to determine accident dynamics, causal factors and accident location of each accident. This information is entered into ConnDOT's traffic accident database, which is constantly updated and verified to ensure its accuracy. The traffic accident database is used by highway engineers and transportation planners to identify and prioritize safety needs, and to develop strategies, programs and projects to improve safety on highways in Connecticut.

Current accident statistics and trends, which are based on reported traffic accidents included in ConnDOT's traffic accident database, are presented in *CONNECTICUT TRAFFIC ACCIDENT FACTS,* which is published every two years by Department's Office of Policy and Systems Information. This report includes statistics and trends for the following categories of traffic accidents: all reported accidents, reported accidents involving alcohol, reported accidents involving a tractor-trailer, reported accidents involving a pedestrian, and reported accidents involving a motorcycle. For all of these categories, a breakdown of accidents resulting in injuries versus fatalities is provided. Tables and graphs are used to highlight various accident attributes such as severity of accident, time of occurrence, day of the week, month of the year, route classification, environmental conditions, town and county of occurrence, age and sex of drivers, and contributing factors. The most recent report, *CONNECTICUT TRAFFIC ACCIDENT FACTS 2004,* was published in April 2006.

Highway traffic accident trends and an analysis of changes in traffic accident data from year to year are published annually in the Department's *CONNECTICUT HIGHWAY SAFETY STRATEGIC PLAN.* This strategic plan, which identifies problems, performance measures, performance goals, performance objectives and planned countermeasures for impaired driving, police traffic services, vehicle occupant protection, roadway safety, motorcycle safety, traffic records, hazard elimination and other areas and factors, is developed using data obtained from the ConnDOT's traffic accident database.

Traffic accident data compiled by ConnDOT is also provided to the National Highway Safety Administration (NHTSA), which compiles and analyzes traffic data collected from all state transportation agencies. Information on national traffic safety statistics and trends for 2004 was published by NHTSA's National Center for Statistics and Analysis in *TRAFFIC SAFETY FACTS 2004: A Compilation of Motor Vehicle Crash Data from the Fatality Analysis Reporting System and the General Estimates System.* General information on highway traffic accident statistics also is available at web site www.nhtsa.dot.gov/people/ncsa, which includes the following annual NCSA fact sheets: *Overview, Alcohol, Occupant Protection, Older Population, Speeding, Children, Young Drivers, Pedestrians, Pedacyclists, Motorcycles, Large Trucks, School Transportation-Related Crashes, State Traffic Data, and State Alcohol Estimates.*

H. GOODS MOVEMENT

The freight transportation industry in the United States has undergone dramatic changes in the last twenty years. Developments in "containerization," shifts in the manufacturing industry to "just-in-time" delivery; the deregulation of the rail, trucking and aviation industries, and the development of new trading patterns in a global economy have led to consolidation and restructuring within, and partnerships between, all freight transportation modes.

The development of an extensive cross-country expressway network, the trend toward larger and heavier trucks, steady fuel prices, more time-sensitive shipping requirements, increasing competition, and railroad branch line reductions have contributed to the trucking industry attracting a large market share of goods movements. However, while the number of truck trips is increasing, the length of such trips is decreasing. Many shippers are using more cost-effective rail, air, or water transport for the long-haul portion of freight delivery, with trucking firms supplying the pick-up and delivery portion of trips rather than supplying end-to-end service. Thus, truck/intermodal traffic has increased dramatically in recent years and is expected to continue to increase.

Connecticut can expect to continue to experience primarily the truck portions of intermodal freight trips, however. This is attributable to its small geographic area and close proximity to some of the nation's largest ports, intermodal rail facilities, and airports.

Table I-1 Freight Shipments To, From, and Within Connecticut 1998, 2010, and 2020, presents information on freight shipments that have either an origin or a destination in Connecticut. As shown in Table I-1, trucks move a large percentage of the tonnage and value of shipments, followed by water and rail tonnage and air value.

Table I-1 Freight Shipments To, From, and Within Connecticut 1998, 2010, and 2020

CONNECTICUT	Tons (millions)			Value (billions $)		
	1998	2010	2020	1998	2010	2020
State Total	117	165	200	80	154	248
By Mode						
Air	<1	<1	<1	8	18	30
Highway	89	126	155	67	127	205
Other*	2	3	3	<1	<1	1
Rail	12	17	22	2	4	7
Water	15	19	20	2	4	5
By Destination/Market						
Domestic	95	129	151	64	120	188
International	22	36	49	16	35	60

Note: Modal numbers may not add to totals due to rounding. * The "Other" category includes international shipments that moved via pipeline or by an unspecified mode.

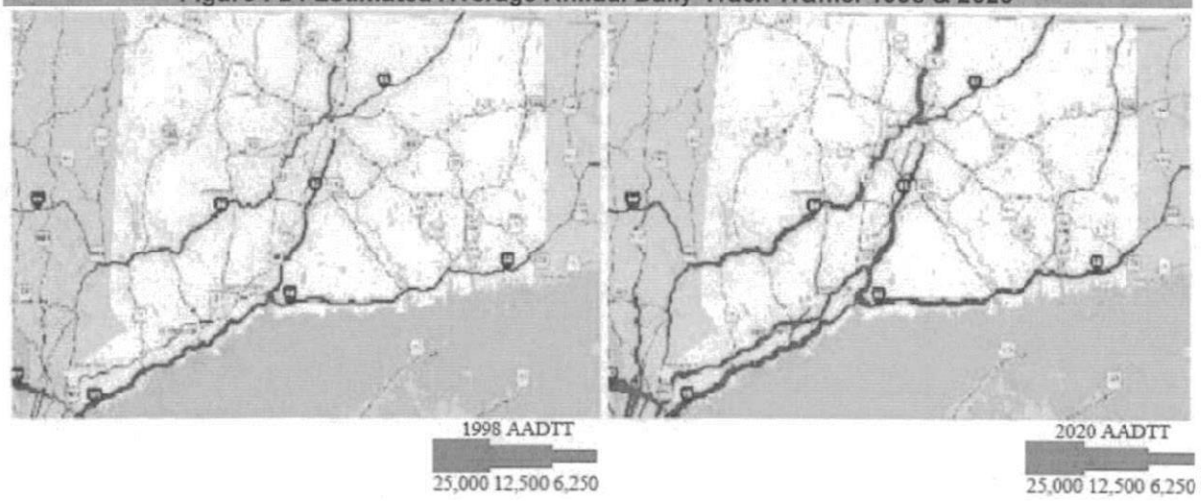
Source: Office of Freight Management Operations, Federal Highway Administration, *Freight Transportation Profile—Connecticut Freight Analysis Framework,* November 2002

Data from the United States Department of Transportation (USDOT) show that trucks currently carry approximately 76 percent of the traffic in Connecticut. This share is projected to grow to 77.5 percent by the year 2020, even as rail traffic grows from a 10.3 percent share to 11 percent. Although all modes will experience a growth in volume, it is anticipated that trucking will provide the majority of service, regardless of state policies and programs. In 2005 and 2006, however, fuel prices increased due to oil shortages resulting from the war in Iraq and damage to oil refineries caused by Hurricane Katrina. The extent to which significant increases in fuel prices will impact trucking and other freight transportation modes is unknown at this time.

The Interstate highway system carries the most interstate truck movements. Of these corridors, Interstate 95 (I-95) between the New York state line and New Haven carries the greatest volume. I-91, especially from Meriden to Hartford, carries a high volume because a portion of the I-84 east-west movement joins with the north-south movement. Other routes, for example U.S. 6, U.S. 7, CT 2, and CT 8, provide regionally important truck accessibility.

As shown in Figure I-24 much of the growth in truck traffic will occur in urban areas and on the Interstate highway system. Truck traffic moving to and from Connecticut has accounted for 6 percent of the average annual daily truck traffic (AADTT) on the Freight Analysis Framework (FAF) road network. Approximately 5 percent of truck traffic involved in-state shipments, and 14 percent involved trucks traveling across the state to other markets. About 75 percent of the AADTT were not identified with a route-specific origin or destination. [14]

Figure I-24 Estimated Average Annual Daily Truck Traffic: 1998 & 2020



Source: US Department of Transportation, Federal Highway Administration, Office of Freight Management and Operations

[14] Office of Freight Management and Operations, Federal Highway Administration, U.S. Department of Transportation, "Freight Transportation Profile-"Connecticut" Freight Analysis Framework" *FREIGHT NEWS*, FHWA-OP-03-054, EDL 13742, November 2002.

Additional information such as freight flow maps for states, modes, and gateways; detailed databases on traffic flows and commodity movements; information on the methodologies used to develop FAF, and forecast assumptions is available on the following web site: *http://www.ops.fhwa.dot.gov/freight*.

Table I-2 shows the top five commodity groups shipped to, from, and within Connecticut by all modes. The top commodities by weight are nonmetallic minerals and petroleum or coal products. By value, the top commodities are chemicals or allied products and secondary traffic. Secondary traffic is defined as freight flows to or from distribution centers or through intermodal facilities. No commodities are assigned to this intermediate step in the transportation process.

Table I-2 Top Five Commodities Shipped To, From, and Within Connecticut

Commodity	Tons (millions)		Commodity	Value (billions $)	
	1998	2020		1998	2020
Nonmetallic Minerals	24	27	**Chemicals/Allied Products**	14	45
Petroleum/Coal Products	21	31	**Secondary Traffic**	7	25
Chemicals/Allied Products	11	22	**Food/Kindred Products**	6	25
Farm Products	10	18	**Primary Metal Products**	6	12
Clay/Concrete/Glass/Stone	10	20	**Machinery**	6	20

Source: Office of Freight Management and Operations, Federal Highway Administration, U.S. Department of Transportation, "Freight Transportation Profile—Connecticut Freight Analysis Framework," *FREIGHT NEWS*, November 2002, FHWA-OP-03-054, EDL 13742

The 1996 Connecticut Intermodal Management System report concluded that due to the concentration of truck trip generation and truck traffic in some of the state's most congested urban core areas, such as the I-95 corridor, intermodal planning must be coordinated with congestion management planning.

Toward this end, the Department is currently developing projects that will help to adequately monitor truck service while maintaining the flow of traffic. The "Weigh in Motion" (WIM) equipment and pre-clearance system installed at the truck weigh station in Union, Connecticut enable inspectors to check the credentials and the gross the weight of commercial vehicles while the vehicles are traveling at highway speeds. Vehicles that possess the required credentials and are of proper weight are allowed to bypass the weigh station; non compliant vehicles are required to stop for an examination. WIM equipment and a pre-clearance system may also be installed on I-95 in Greenwich, Connecticut. Installation of these systems will enable inspectors to concentrate on identified scofflaws.

In addition, the U.S. DOT is developing an Intelligent Transportation System (ITS) that will cover many aspects of highway travel and navigation. One element of this ITS is the Commercial Vehicle Information Systems and Network (CVISN). Connecticut is playing a lead role in the implementation of CVISN. This system will allow states to share information on commercial vehicles and operations including taxing, licensing, special permitting, insurance, operating authorities, etc. An important piece of this information sharing will allow inspectors to identify commercial vehicles that have passed a previous inspection and do not need to be inspected again. This will allow for smoother trips and eliminate unnecessary side trips and paperwork.

I. TRANSPORTATION-RELATED SECURITY

Since the September 11, 2001, terrorist attacks, homeland security has been a national and state priority. In general, efforts to improve security at national, state and local levels have entailed greater coordination and information sharing within and among governmental agencies and with organizations that are involved in responding to emergencies. ConnDOT responded to the need to increase security for users and providers of transportation services and facilities in Connecticut by instituting a variety of changes to address emergency management procedures and preparedness and by developing Emergency Response Plans that outline ConnDOT's Homeland Security Advisory System. The plans were established in accordance with the five threat levels of risk established under the Federal Homeland Security Advisory System. These plans are based on the responsibilities of each of ConnDOT's bureaus and are continually being updated and modified.

ConnDOT established a Homeland Security Task Force to review and address needs for increased coordination between ConnDOT's bureaus to respond to any natural disaster and/or terrorist events. Each bureau is tasked to review its current emergency response plans and to identify areas that need to be updated. ConnDOT has developed a resource document and contact list to address resource management objectives. Each bureau, as part of the planning process, has submitted a Security and Emergency Preparedness Plan to respond to incidents, natural disasters or terrorists to protect life, property and service to residents of the State of Connecticut. In addition, the Task Force has become involved in the planning process for future homeland security activities and exercises and is developing action plans regarding emergency response, protection of critical infrastructure elements, and other homeland security and emergency response issues. A strategic emergency operations response, mitigation, recovery and continuity plan will be developed and submitted to Connecticut's Department of Emergency Management and Homeland Security.

The following are some of the transportation-related security changes that have been implemented in Connecticut:

- ***Airports.*** Bradley International Airport was among the first airports in the U.S. to experience implementation of the Federal Transportation Security Administration's Federal Security Director (FSD) program. Since August 2002, Bradley has had the FSD on site and has had a full federal work force of employee passenger screeners in place. While Bradley still has mandated responsibilities for security in accordance with Federal Aviation Regulations, the September 11, 2001, attacks resulted in the airport receiving many new resources, primarily in the form of federal personnel, to perform many of the functions for which Bradley and/or the airlines were previously responsible. Since September 11, 2001, all state-owned general aviation airports in Connecticut have undergone extensive security enhancements.
- ***Ports.*** ConnDOT continues to work closely with the United States Coast Guard (USCG) on the security of the ports in Connecticut. There has been a concerted effort to develop better communication links, and the USCG is reaching out to local and state entities. The Coast Guard, in accordance with the Homeland Security Alert System condition (blue, green, yellow, orange or red), sets Maritime Security (MARSEC) levels (one, two, or three). Coincident with the MARSEC level, the Coast Guard may issue MARSEC directives to provide additional mandatory security requirements and/or detail to existing security requirements. Facility owners or operators must comply with these requirements. Their facilities were required to operate in compliance with 33 CFR Part 105, including the implementation of the security measures in an approved Facility Security Plan by July 1, 2004.

- ***Rail Services and Facilities.*** Amtrak, Metro-North Railroad and ConnDOT have been excellent partners in exchanging information. All aspects of security issues pertaining to commuters and inter-city trains are being addressed. Periodic meetings are held among representatives from both the railroads and ConnDOT to review any unusual incidents, upcoming special train movements and potential security issues.
- ***Bus Services.*** After September 11, 2001, a security plan was developed for Connecticut's state-owned bus operations. Connecticut Transit was the first transit system in the country to receive an FTA-sponsored security review after September 11. The results indicated that the system was generally well-positioned to provide secure environments for employees, customers and assets.
- ***Highways.*** ConnDOT's Office of Maintenance and Highway Operations has a *Homeland Security Advisory System Response Plan*. This plan implements appropriate protective measures and identifies assets for which maintenance field and office staff is responsible at each level. It is consistent with the Federal Homeland Security Advisory System. Prior to September 11, 2001, ConnDOT had in place Radiological Response Plans and Procedures using a traffic management plan for a Millstone Nuclear Power Station disaster event. Implementation plans for various impacts had been coordinated and developed with the Connecticut State Police, Office of Emergency Management and ConnDOT. Diversion plans for incidents on limited access highways (along I-95, I-395, I-91, I-84, and Route 8) had been developed in cooperation with local and state police, first elected officials, the permanent Statewide Incident Management Task Force and ConnDOT field personnel.

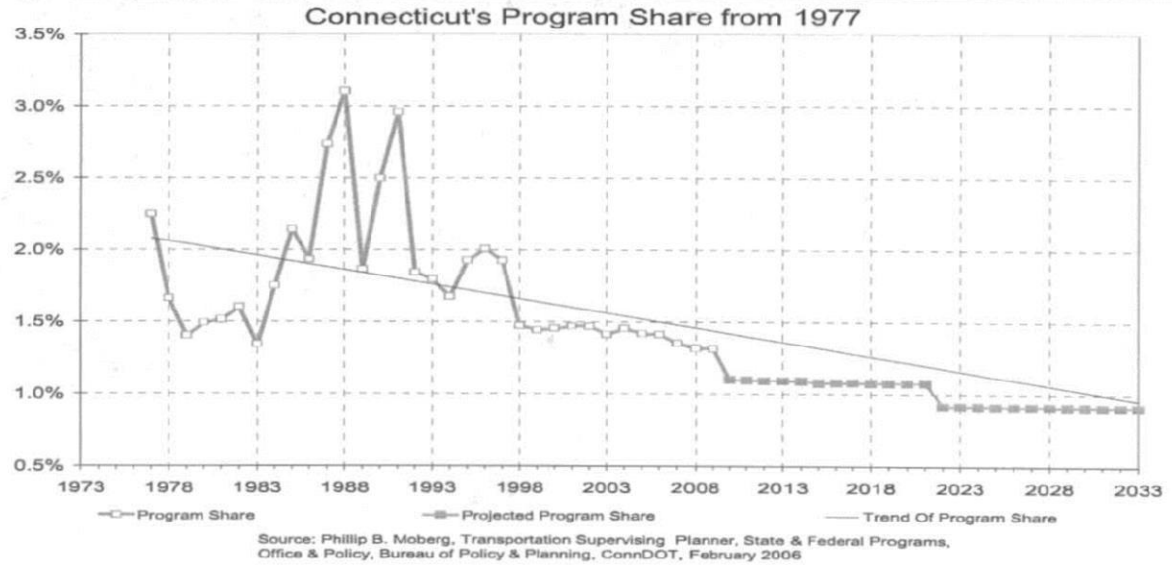
J. FEDERAL AND STATE REVENUE TRENDS

This section presents information on some revenue trends of interest to transportation planners and policy makers. It includes historical data and projections and an analysis of Connecticut's share of the Federal-Aid Highway Program; identifies the sources and amounts of state revenue collected by the Connecticut Department of Revenue Services for SFY2000–SFY2005; and identifies the sources, amounts of revenue and revenue trends for Connecticut's Special Transportation Fund and the Bradley International Airport Enterprise Fund.

A. FEDERAL-AID HIGHWAY PROGRAM FUNDING [15]

Figure I-25 presents the State of Connecticut's historic and projected share of the Federal-Aid Highway Program from 1997 through 2033. It shows that Connecticut's share of the Federal-Aid Highway program was 2.250 percent in 1977, that it peaked at 3.109 percent in 1988, and that it has been declining since then. In 2006, the State's program share was 1.414 percent.

Figure I-25. State of Connecticut's Share of the Federal-Aid Highway Program



Source: Phillip B. Moberg, Transportation Supervising Planner, State & Federal Programs, Office & Policy, Bureau of Policy & Planning, ConnDOT, February 2006

The decrease in the program share is primarily due to three reasons, the first and most important of which is that the state's highway system had largely matured by that time, while many other states' systems were experiencing considerable growth. The second reason has to do with the restructuring of the program, beginning with the passage of the *Intermodal Surface Transportation Act of 1991* (ISTEA). This act acknowledged that many states' highway systems had either reached or were approaching maturity, and that future effectiveness of the system was dependent on its ability to incorporate the strengths of other modes as an integral part of a larger system. A change in the basic approach to funding apportionment was necessary to

[15] Phillip B. Moberg, unpublished analysis of Federal-Aid Highway Program Funding, State & Federal Programs Unit, Bureau of Policy and Planning, Connecticut Department of Transportation, January 2006.

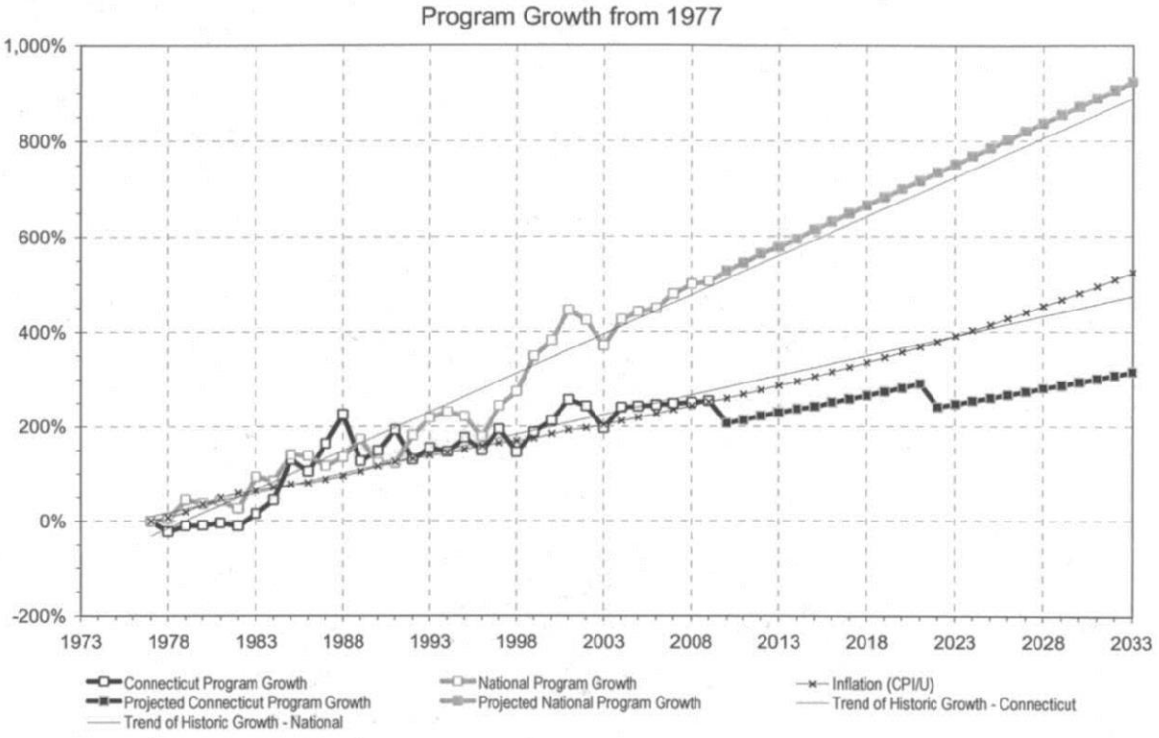
implement this change in direction. As a result of these changes, Connecticut's share of the total program became more stable than in prior years, but also began a steady, gradual decline.

The third reason involves a philosophical change in the basis of funding that began with the passage of the *Transportation Equity Act for the 21st Century* (TEA-21). While this act maintained the program structure and direction of ISTEA, each state's funding became dependent on a weighted ratio of its share of contributions to the Highway Trust Fund to its share of Federal-Aid Highway funding. The practical effect of this was to produce a back-loaded funding structure in which most states' total funding was dependent upon the Minimum Guarantee categories. This hurt a number of states (Connecticut being among them) so badly that it was necessary to grow the total program at an unprecedented rate in order to keep these states from incurring funding losses in real terms. This rate of growth ultimately proved untenable when the out years' Highway Trust Fund contributions in the "out" years badly lagged the original projections.

With the passage of the *Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users* (SAFETEA-LU), this ratio was set to be gradually de-weighted to more directly approach the direct ratio of the two shares. As a consequence, six states, including Connecticut, do not receive sufficient funding from either the formulas or the equity adjustments to prevent a loss in real terms. A similar attempt was made to grow the program to compensate those states, as well as others hurt by the equity adjustments, but this failed early in the reauthorization process. These states are guaranteed a specified percentage increase in total funding for each year. Connecticut's share of the Federal-Aid Highway Program is projected to drop to just over 1.3 percent by the end of SAFETEA-LU.

Figure I-26 presents historic and projected Federal-Aid Highway Program growth rates and trends from 1977 through 2033 for both the national program and the State of Connecticut's program. The percent of inflation during this period is also shown. The data and projections, which were developed by ConnDOT's Office of Policy, are based on the assumption that a program similar to the current Federal-Aid Highway Program would remain in place for the foreseeable future. As shown in Figure I-26, the national growth rate tracked its trend line consistently until TEA-21, and tracked it very closely for the projected years of SAFETEA-LU. Since this appeared to demonstrate the established political consensus, and since there appeared to be no compelling arguments to the contrary, the future national program total was developed based on a rolling six-year projection of the last six years of historic and enacted funding. This, too, closely tracked the historic trend line, growing at a slightly higher rate. The figure also shows that when inflation was plotted using the Consumer Price Index/Urban (CPI/U), this tracked Connecticut's historic trend to an amazingly close degree. Future inflation rates used to create this plot were developed from a rolling twelve-year projection of historic data for the CPI/U.

Figure I-26. Historic & Projected Federal-Aid Highway Program Growth Rates (1977-2033)



Source: Phillip B. Moberg, Transportation Supervising Planner, State & Federal Programs, Office & Policy, Bureau of Policy & Planning, ConnDOT, February 2006

Figure I-26 also shows that the growth rate of Connecticut's program did not track its trend line consistently until the advent of ISTEA, and after that, tracked it closely with one exception. This situation made the projection of the State's program slightly more complicated. Because the changes to the funding formulas enacted with TEA-21 and SAFETEA-LU had effectively decoupled Connecticut from formula funding, and Connecticut's share has been steadily decreasing, a simple projection of historic data would have been unrealistic. The threshold provision of SAFETEA-LU was used as the basis of the rationale for two-stage change in the future development of funding totals for Connecticut.

The first stage, beginning at the end of SAFETEA-LU, was projected by projecting growth in core-program totals on essentially the same basis as that used for the national program, and using a back-loaded adjustment to keep Connecticut's totals consistent with inflation. For the second stage, the back-loaded inflation adjustment was eliminated and, the core programs were grown at the same rate as the national program. It should be noted that the national growth rate, that far out, was lagging projected inflation, and this is why Connecticut's totals were driven by the national rate.

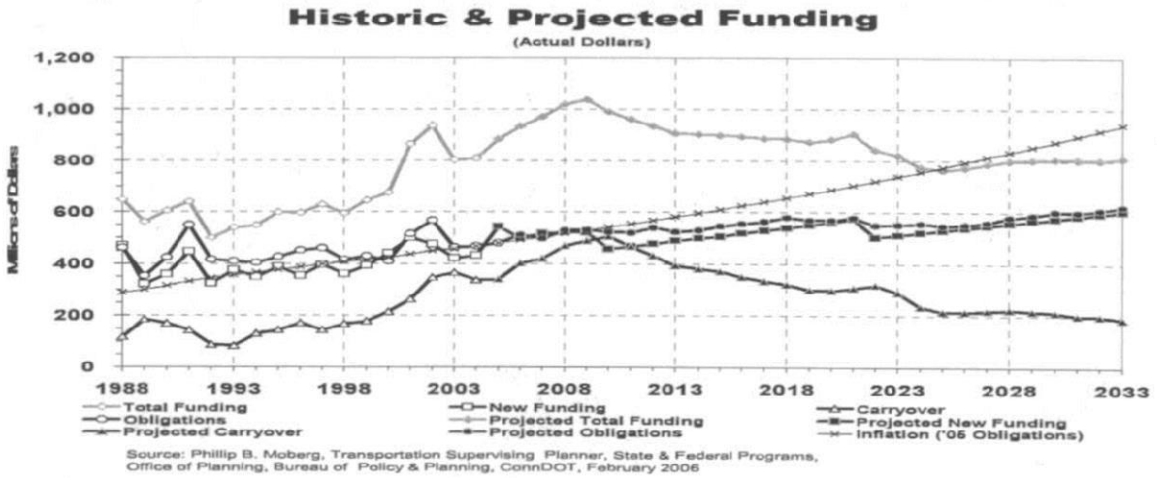
The result of these assumptions produced two twelve-year steps down in Connecticut's share of the program, mimicking the twelve-year pattern of current historic and enacted funding. With the exception of the one year of unusually high revenue-aligned budget authority (RABA) under TEA-21, this also appears to mimic the historic and enacted growth rate for the same period.

All forecasts, and especially economic forecasts, are speculative to some extent. The future direction of the federal program is by no means clear, given that there have been serious proposals to restructure it in various ways since the development of TEA-21, and since there have been an increasing number of policy makers willing to consider these seriously. In

addition, there is a broad range of economic, demographic, technological and other factors driving transportation needs, and therefore the definition of what sort of program would be most effective to meet them. This being the case, the driving factor with respect to the total program size will be the extent to which program growth is politically tenable. The original growth target for the current program was effectively a non-starter. It took over two years to develop a sufficient consensus for the program that was enacted, and once enacted, it was roundly criticized for the high level of earmark and other designated funding.

Figure I-27 presents Connecticut's historic and projected Federal-Aid Highway Program funding, obligations and inflation from 1988, the earliest year for which sufficient detail was available, through 2033. It shows historic and projected trends in total program funding, new program funding, and carryover funding in relation to historic and projected trends in program obligations and inflation. In 1988 the State of Connecticut's total program funding was $648.4 million and it increased to $937.1 million in 2002. The State's total program funding is projected to increase to $1.04 billion in 2009 and decline thereafter. New funding in 1989 was $322.7 million, it increased to $550.1 million in 1991, and it dropped to $325.4 million in 1992, and has ranged from $350.4 million to $545.6 million from 1994 through 2005. New funding is projected to range from $499.2 in 2006 to $605.8 million in 2033. Inflation, expressed in terms of 2005 total obligations ($481.3 million), is shown as steadily and consistently increasing during this time period from $289.5 million in 1998 to $940.4 million in 2033.

Figure I-27. Connecticut's Historic & Projected Federal Highway Program Funding[16]



These historic and projected trends have significant implications regarding the size and type of a program that could be sustained by Connecticut under these circumstances. The results of this

[16]These projections were made by Phillip Moberg, ConnDOT, Office of Policy, in January 2006. They were applied to a set of spreadsheets previously developed for the Quarterly Financial Report, and expanded to 2033 for the purposes of this analysis. These spreadsheets made future calculations by program category for each future year. Un-obligated funds, if any, were carried over to the following year. In the case of over programmed categories, these spreadsheets assigned excess balanced to equity funding categories where appropriate and possible, or rolled over the un-obligated balance to the subsequent year's program.

The spreadsheets used for the analysis are based on data going back to 1988, the earliest year for which sufficient detail is available. The projected program was developed by program category based primarily on a demonstrated record of obligation at that level. Ideally, this involved a rolling five-year projection, but aberrations in prior years' obligations generated many exceptions to this in the case of ongoing programs. New programs were initially developed based on a percentage of apportionments to establish a trend, and then projected. Retired programs were usually based on a percentage of carryover, typically thresholded at $250,000 unless the program itself was smaller. The object of the projected program was to keep projected lapses at a negligible level.

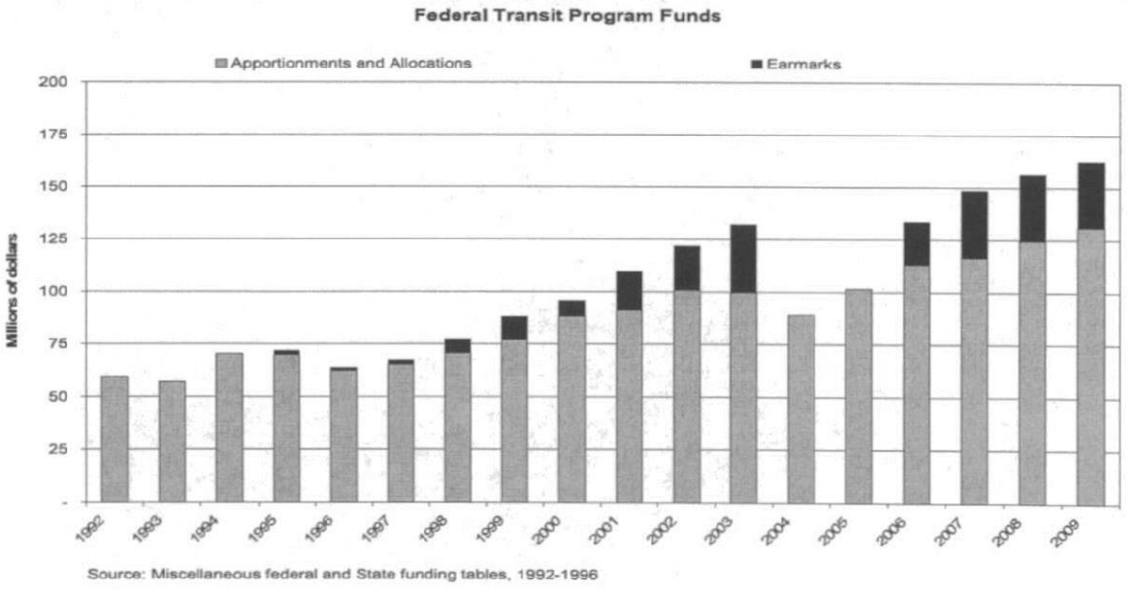
effort produced obligations ranging from around $525 million/year in 2010 to around $625 million/year in 2033. Plotted against this was the 2005 obligations adjusted for the historic or projected CPI/U for each respective year. The future program would significantly lag projected inflation. In fact growth would be nearly flat over the over a quarter of a century. It would only be sustainable at that level if Connecticut (and other states at the threshold level) receives some relief from ceiling (obligation limitation) and access to a portion of the considerable un-obligated balance accumulated as a result of ceiling. In the event no such relief is forthcoming, such states' programs would necessarily sustain a declining program in current dollar terms.

The policy implications are clear for Connecticut and other threshold states. Real growth in program is now unlikely, everything else being equal. A change of federal policy with respect to obligation limitation and un-obligated balances will be necessary for states at the bottom of the program to maintain a safe and reasonably effective highway system in good repair. In addition to this, federal policies governing direct user fees and alternate funding sources will need to be re-examined and revised to allow threshold states the means to sustain their programs to the level of inflation, as a minimum.

B. FEDERALTRANSIT PROGRAM FUNDING

Figure I-28 shows trends in Connecticut's net Federal Transit Program funding from FFY1992 through FFY2009. Under ISTEA, in FFY1992 the State of Connecticut's net FTA program funding was $59,210,519 and it increased to $67,324,409 in FFY1997. Under TEA-21, the State's total program funding increased to $77,377,135 in FFY1998 and to $132,102,965 in FFY2003. Under SAFETEA-LU, Connecticut's net FTA program funding was $101,557,000 in FFY2005, $133,643,000 in FFY2006, and will increase to $148,578,000 in FFY2007, to $156,346,000 in FFY2008, and to $162,797,000 in FFY2009.

Figure I-28 Federal Transit Program Funds



Source: Miscellaneous federal and State funding tables, 1992-1996

C. STATE OF CONNECTICUT REVENUE

State of Connecticut revenue is derived from various categories of taxes and fees which are primarily collected by the Connecticut Department of Revenue Services (DRS), and the Department of Motor Vehicles (DMV). Other revenue is derived from Unemployment Compensation tax, which is collected by the Connecticut Department of Labor; franchise tax, which is collected by the Secretary of the State; and professional license permits and fees, which are collected by a number of other Connecticut state agencies. Sales taxes and fees collected through other agencies are not counted in DRS collections.

Total State of Connecticut Revenues for Calendar Years 2004 and 2005 are presented in Table I-3. From 2004 to 2005 total state revenues increased by 11 percent. The categories with the largest increases were Corporate Tax (13.03 percent) followed by Personal Income Tax (11.84 percent) and Real Estate Conveyance Tax (13.95 percent).

Table I-3 Total State Revenues for Calendar Year 2004 and 2005

Millions of Dollars	Monthly Comparison			Calendar Year Comparison		
	June 2004	June 2005	% Change	2004	2005	% Change
Total All Revenues *	977.4	1,078.8	10.37	10,685.3	11,820.2	10.62
Corporate Tax	97.6	118.9	21.82	627.1	708.8	13.03
Personal Income Tax	465.3	520.1	11.78	5,103.2	5,707.2	11.84
Real Estate Conveyance. Tax	17.5	19.5	11.43	189.2	215.6	13.95
Sales and Use Tax	252.7	266.4	5.42	3,203.6	3,333.5	4.05
Indian Gaming Payments **	33.5	34.1	1.79	411.4	421	2.33

Source: Connecticut Department of Revenue Services; Division of Special Revenue
Special Notes: *Includes all sources of revenue; only selected sources are displayed. Most July receipts are credited to the prior fiscal year and are not shown. ** Indian Gaming Payments are amounts received by the State as a result of the slot compact with the two federally-recognized tribes in Connecticut, which calls for 25 percent of net slot receipts to be remitted to the State. Indian Gaming Slots are the net revenues from slot machines only received by two federally-recognized Indian Tribes.

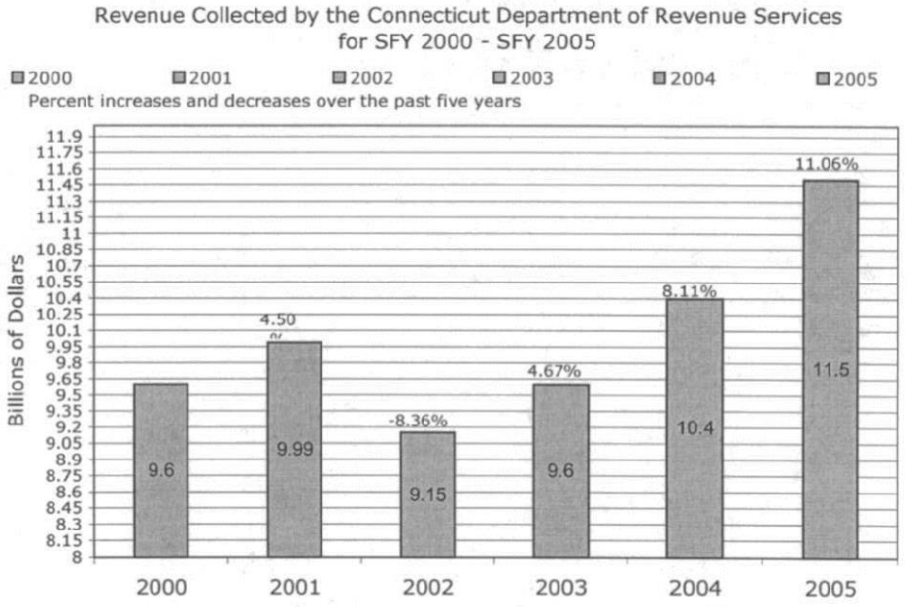
The DRS collects the revenue from fourteen categories. These categories are listed in Table 1-4. For State Fiscal Year (SFY) 2000; $9,556,347,998 in State revenue was derived from these categories. As shown in, Figure I-29, from SFY2000 to SFY2001 the revenue was up 4.5 percent, from SFY2001 to SFY2002 the revenue was down 8.36 percent, from SFY2002 to FY2003 the revenue was up 4.67 percent, from FY2003 to FY2004 the revenue was up 8.11 percent, and from FY2004 to FY2005 the revenue increased 11.6 percent. Since FY2000, State

revenue from these categories of taxes and fees has been increasing. From FY2000 to FY2005, revenues collected by DRS increased by 20 percent. [17]

Table I-4 Department of Revenue Services Revenue Categories

- Personal Income Tax
- Sales & Use Tax
- Corporation and Business Entity Taxes
- Public Service Corps.
- Real Estate Conveyance
- Admissions & Dues
- Licenses
- Gift and Estate Tax
- Insurance Taxes
- Cigarettes and Tobacco Taxes
- Alcoholic Beverages
- Petroleum Gross Earnings
- Motor Fuel Tax
- Miscellaneous Taxes

Figure I-29. Revenue Collected by the Connecticut Department of Revenue Services for SFY2000-SFY2005



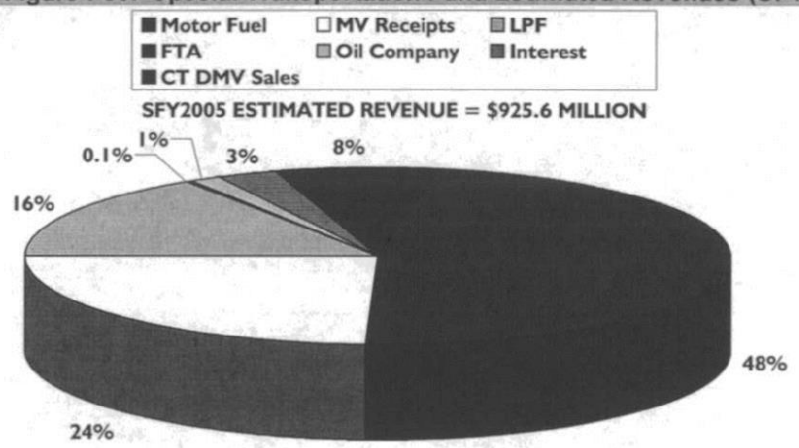
Source: State of Connecticut, Department of Revenue Services Monthly Comparative Statement of Tax Revenue, SFY June 2000, June 2001, June 2001-2002, June 2002-2003, June 2003-2004 (SFY 2003-04 Sales and Use Tax Do Not Include Taxes Collected by other State Agencies), and June 2005-2006

[17] "STATE OF CONNECTICUT, DEPARTMENT OF REVENUE SERVICES MONTHLY COMPARATIVE STATEMENT OF TAX REVENUE," October 2005/2004 <http://www.ct.gov/drs/lib/drs/research/o5comparstate/mon_stmt_oct_2005.pdf, copyright 2005

D. SPECIAL TRANSPORTATION FUND

Revenues from Motor Fuel Taxes collected by the DRS are pledged to the State of Connecticut's Special Transportation Fund (STF). The STF is a dedicated fund for financing investments in the State's transportation system and covering the costs of ConnDOT's operations and services, excluding support of Bradley International Airport. As shown in Figure I-30, the Motor Fuels Tax accounted for 48 percent of the STF estimated revenues for State Fiscal Year (SFY) 2005. Other sources of STF revenues are License Permit and Fee (LPF) Income and Motor Vehicle Use Taxes, which are collected by the State Department of Motor Vehicles; Federal Transit Administration (FTA) Operating Grants; Interest Income and General Fund (GF) Transfers.

Figure I-30. Special Transportation Fund Estimated Revenues (SFY2005)

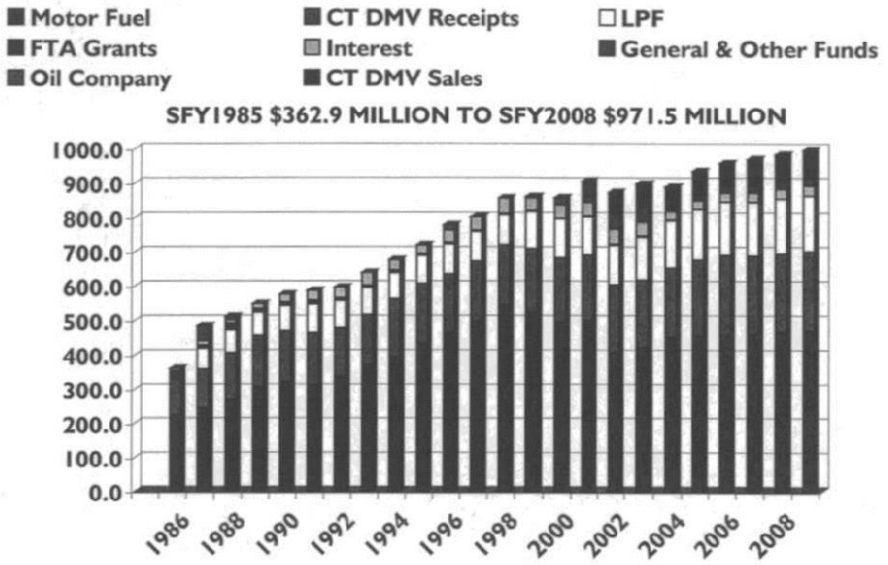


Source: Bureau of Finance & Administration. Data based on State Fiscal Year. Graphic revised as of December 2004.

A unique feature of the STF was that when it was established, not only were existing revenues from certain taxes and fees dedicated to the STF, but rate increases scheduled throughout a ten-year future period were also enacted. This ensured that the pledged revenues would be sufficient to sustain the substantial transportation investments that were planned, as well as meet the operational needs of ConnDOT and cover the costs associated with the various services provided by ConnDOT. This multi-year philosophy has been continued in all the revenue changes that have been enacted.

As shown in Figure I-31, revenues have grown from $362.9 million in SFY1985, the first year of the STF, to an estimated $925.6 million for SFY2005; this is an increase of $562.7 million, or 155 percent over the period. Revenues are anticipated to reach $971.5 million in SFY2008.

Figure I-31. Special Transportation Fund Revenues (SFY1985-SFY2008)



Source: Bureau of Finance & Administration. Data based on State Fiscal Year. Values for years following 2004 are projected. Graphic revised as of December 2004.

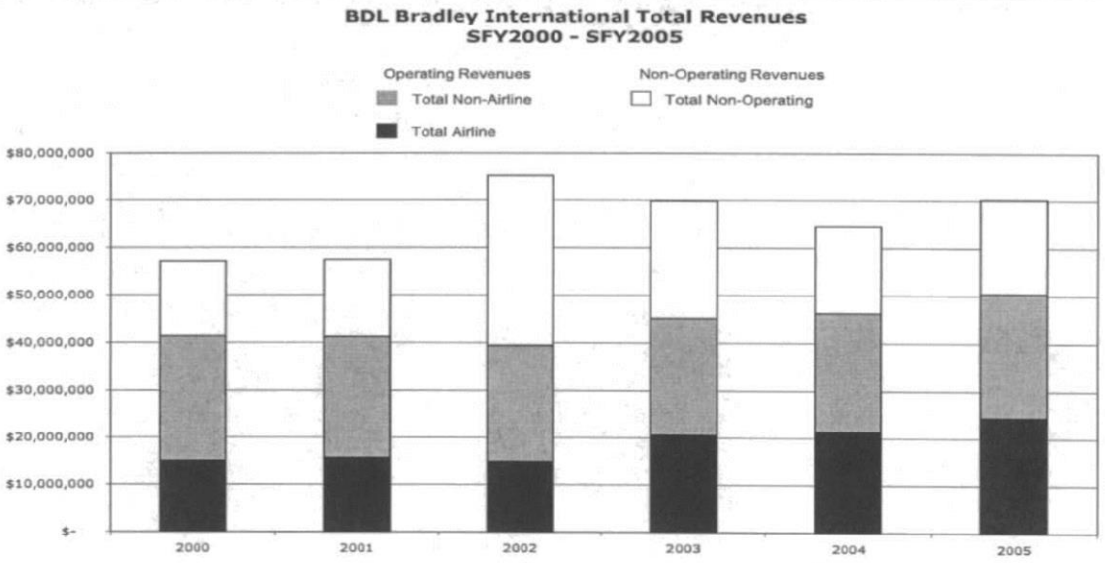
Special Note: Transfers of revenues to the Transportation Strategy Board were made and are anticipated to be made as follows: 2003 - $60.5M; 2004 - $22.9M; 2005 - $31.0M; 2006 - $29.3M; 2007 - $24.3M; and 2008 - $24.3M.

More comprehensive information on the STF is published in the Department's biennial master transportation plans, which are published on or before January 1 of each odd-numbered year.

E. BRADLEY INTERNATIONAL AIRPORT ENTERPRISE FUND

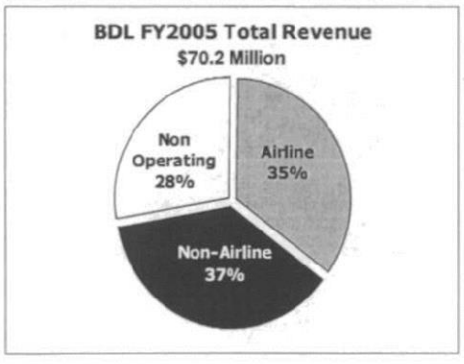
Bradley International Airport is an enterprise fund of the State of Connecticut, operated by the Department of Transportation. This means that all of the operations, maintenance and development expenses of the airport are funded through user charges and the capital financing mechanisms available to the airport. The airport generates revenue from operating and non-operating sources. Operating revenues are generated through user charges that are categorized in terms of airline and non-airline revenues. Non-operating revenues include investment income, passenger facility charges and capital contributions. As shown in Figure I-32, total operating and non-operating revenues increased from $57.2 million in SFY2000 to $70.2 million in SFY2005.

Figure I-32. Trends in Total BDL Revenue



Source: Connecticut Department of Transportation, Bureau of Aviation and Ports, Office of Fiscal and Administrative Services, January 2006.

Figure I-33. BDL SFY 2005

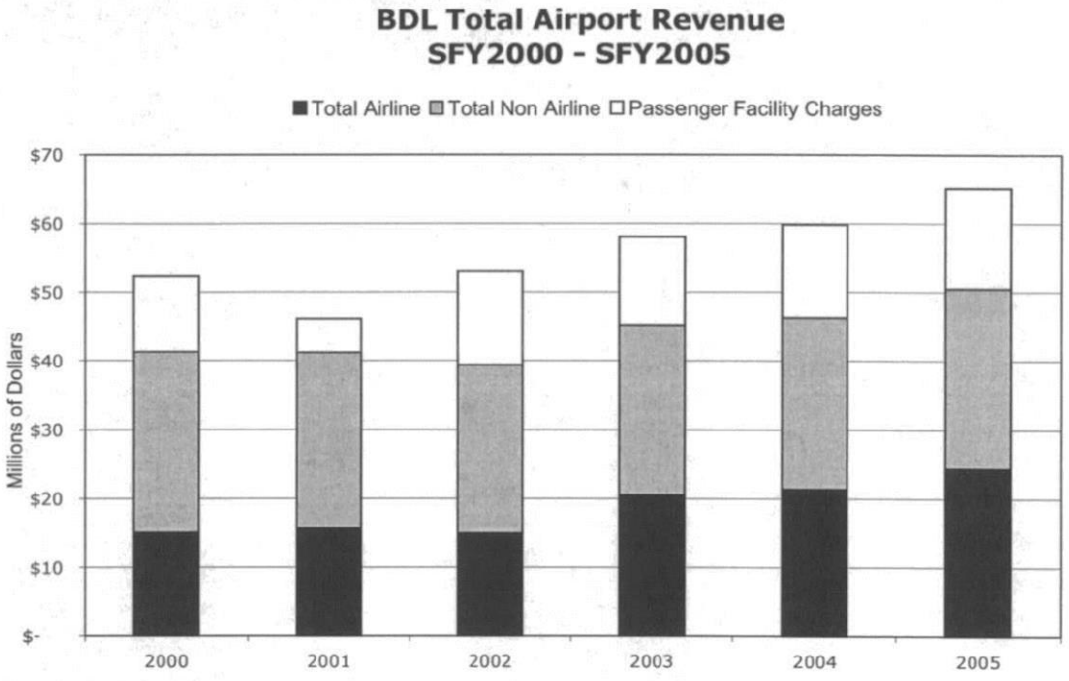


In SFY2005, as shown in Figure I-33, 28 percent of BDL's total revenue was derived from non-operating sources and 72 percent was derived from airline (35 percent) and non-airline (37 percent) operating sources.

Operating Revenue

Operating revenues are derived from airline and non-airline sources. As shown in Figure I-34, Bradley International Airport's Total Operating Revenues have increased from $41.3 million in FY2000 to $50.5 million in FY2005, an increase of 22.2 percent.

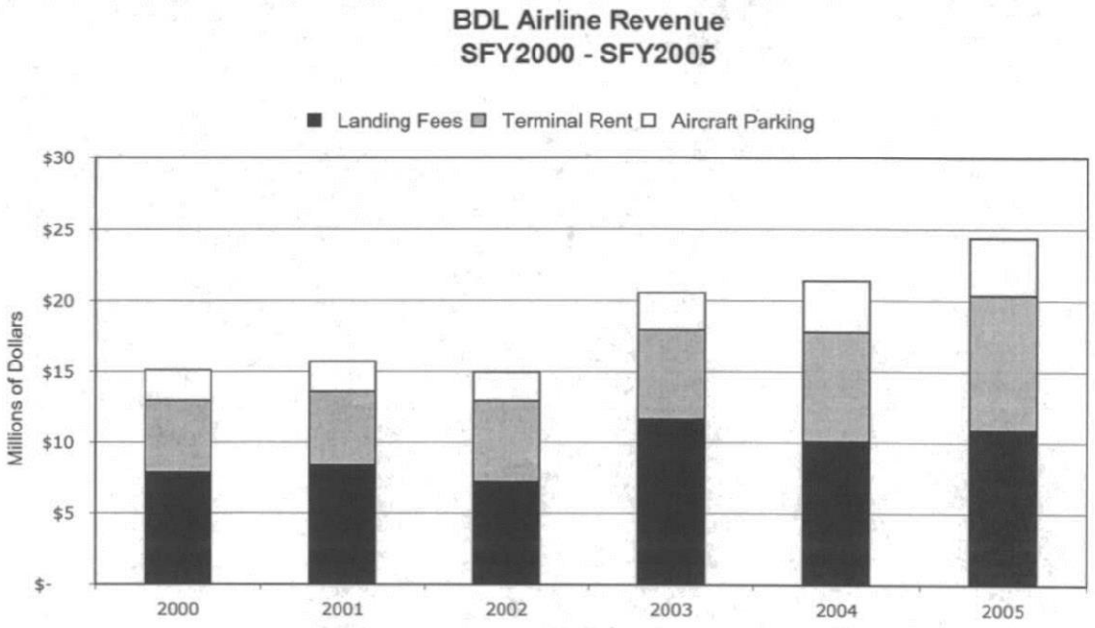
Figure I-34. Trends in BDL Airport Revenue



Source: Connecticut Department of Transportation, Bureau of Aviation and Ports, Office of Fiscal and Administrative Services, January 2006.

To generate revenue from the airlines serving the airport, the airport uses what is known as a "compensatory" system of setting airline rates and charges. In a compensatory system, operating and non-operating expenses attributable to airline use of the airport are allocated to airline cost centers. These cost centers include the terminal building, aircraft parking apron and landing area, and the airlines pay terminal building rent, aircraft parking and landing fees equivalent to the allocated costs. As shown in Figure I-35, Airline Revenues have increased from $15.1 million in SFY2000 to $24.4 million in SFY2005 or 61.7 percent. This increase is attributable to increased operating expenses and increased debt service associated with the Terminal Expansion and Improvement Program underway at the airport.

Figure I-35. Trends in BDL Airline Revenue



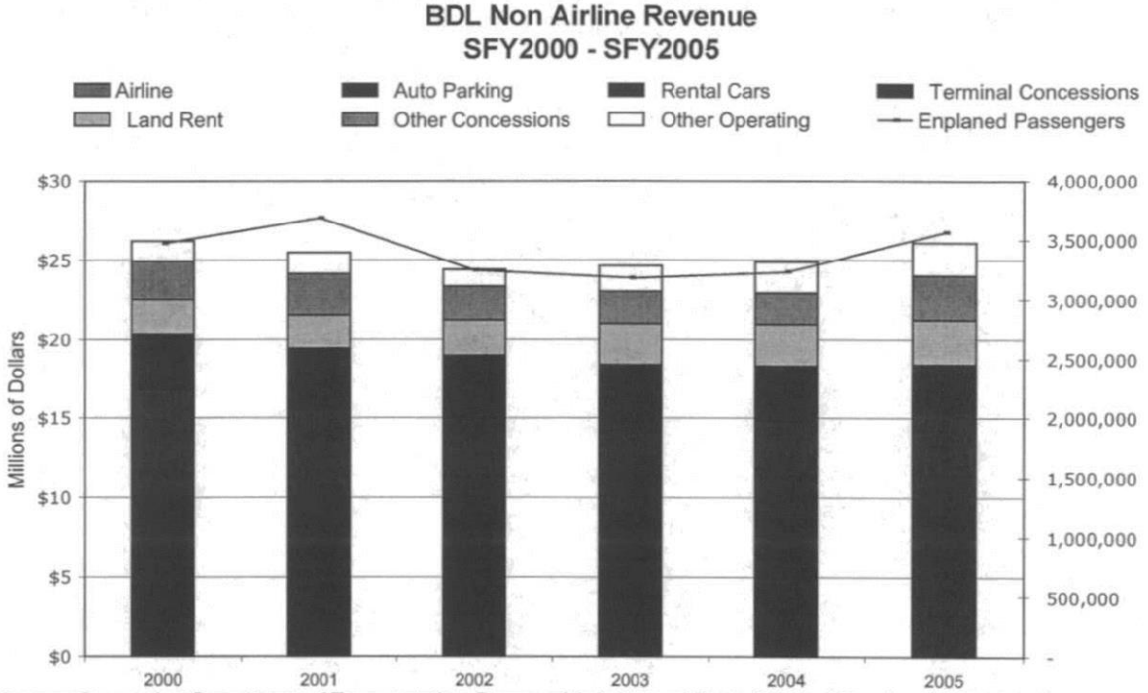
Source: Connecticut Department of Transportation, Bureau of Aviation and Ports, Office of Fiscal and Administrative Services, January 2006.

Bradley International Airport's non-airline revenues are generally market driven, and considering the compensatory nature of airline revenues as discussed above, all airport operating income is derived from non-airline sources. Non-airline revenues include auto parking, rental cars, terminal concessions, land rent, other concessions and other operating revenue. As shown in Figure I-36, non-airline revenues have declined from $26.2 million to $26.1 million from FY2000 to FY2005. A number of factors have contributed to the decline and rebounding of the airport's non-airline revenue. Passenger traffic declined significantly following the September 11, 2001, terrorist attacks. Enplaned passengers declined 11.9 percent from FY2001 to FY2002, and declined another 1.9 percent from SFY2002 to SFY2003. Overall, enplaned passengers increased only 2.6 percent from SFY2000 to SFY2005. Passenger traffic affects a variety of non-airline revenues such as terminal concession sales, rental car sales, on and off airport vehicle parking.

The airport entered into a new master food and beverage concession agreement focusing on investment in new facilities and improved customer service and satisfaction in connection with its terminal expansion and improvement program. This initiative required lower minimum annual guaranteed revenue to the airport from food and beverage concessions. The airport's new terminal and concourse opened in April of 2003, and the terminal improvement program continues with refurbishment of Terminal A, which is expected to be completed in the fall of 2007.

The airport entered into a new agreement with the on-airport parking facility operator providing for the financing, construction and operation of a new parking garage at the Airport in connection with the terminal expansion. This initiative, together with declining traffic, also resulted in lower revenue to the airport from the parking concession.

Figure I-36. Trends in BDL Non-Airline Revenue



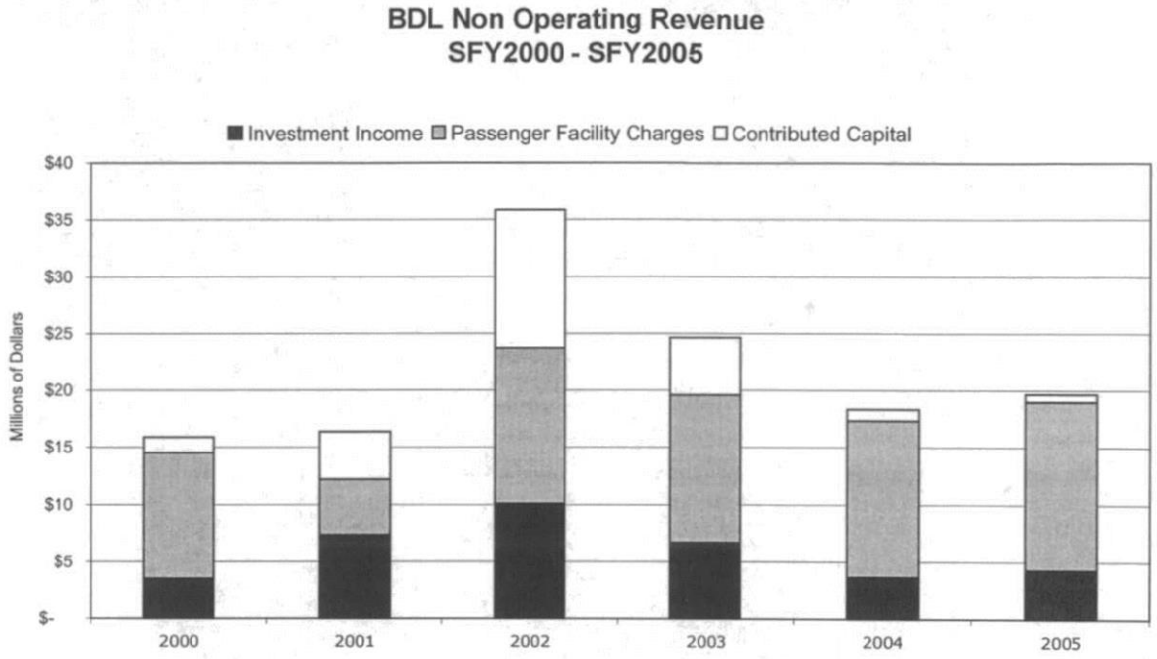
Source: Connecticut Department of Transportation, Bureau of Aviation and Ports, Office of Fiscal and Administrative Services, January 2006.

Non-Operating Revenues

As shown in Figure I-37, the airport's Non-Operating Revenues increased from $15.9 million in SFY2000 to $19.7 million in SFY2005, an increase of 23.9 percent. Non-Operating Revenues include Investment Income, Passenger Facility Charges and Capital Contributions.

The airport generates relatively significant Investment Income from the various accounts maintained within the Airport Enterprise Fund. Total Investment Income over the past six years was $35.7 million, ranging from a low of $3.6 million in SFY2000 to a high of $10.1 million in SFY2002. The major accounts within the Enterprise Fund generating Investment Income include the Construction Fund for the terminal expansion program, the Improvement Fund for the airport share of other capital projects, debt service reserves and general reserve funds. These funds are typically invested in the State's Short-Term Investment Fund (STIF) and in long-term Guaranteed Investment Contracts (GICs). The annual level of Investment Income is directly related to the balances maintained within these accounts and the interest rates being earned on the STIF and GICs.

Figure I-37.Trends in BDL Non-Operating Revenue



Source: Connecticut Department of Transportation, Bureau of Aviation and Ports, Office of Fiscal and Administrative Services, January 2006.

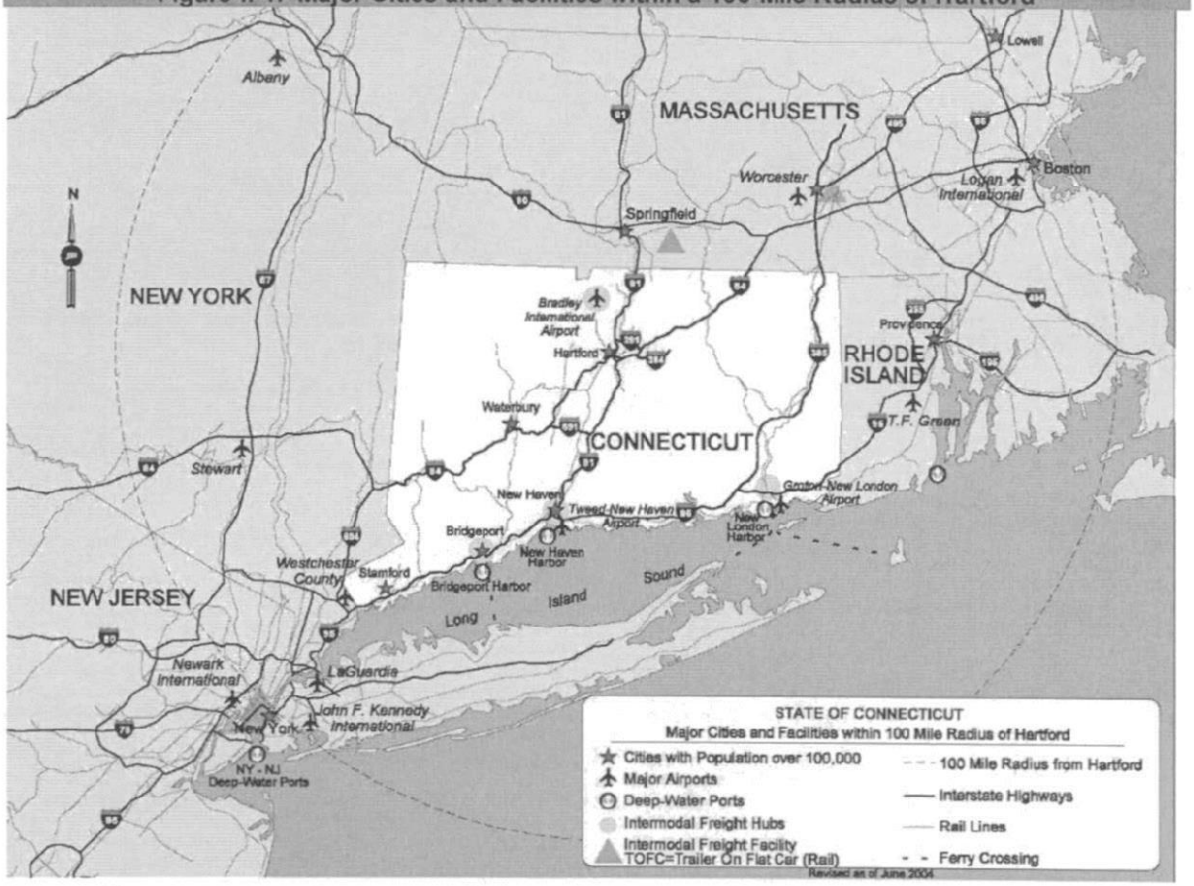
A major source of capital financing available to the BDL is at its Passenger Facility Charges (PFCs). PFCs are collected by airlines as part of the fare charged for passenger air travel. The PFC is then remitted to the airport authorized to impose the charge. Authorization to impose PFCs is administered and granted through the Federal Aviation Administration (FAA). Collection authorization may only be granted for the eligible costs of approved projects. BDL has requested and been granted authority to collect $302 million in PFCs, the majority of which represents debt service associated with eligible portions of the current terminal expansion and improvement program. As of September 30, 2005, the airport had collected $111 million of its authorized collections leaving a balance to be collected of $191 million. As shown in Figure I-37, PFC revenue over the past six years has ranged from a low of $4.9 million in SFY2001 to a high of $14.7 million in SFY2005, which is directly related to the airport's authority to impose the charge, the level of the charge itself and passenger traffic at the airport.

Another major source of capital financing available to BDL is its federal grants. Grants are received from the FAA under its Airport Improvement Program (AIP), and from the Federal Highway Administration for eligible roadway work undertaken in connection with the terminal expansion program. As indicated on Exhibit A, total Contributed Capital (grants) over the past six years is $24.4 million and ranged from a low of $0.7 million in SFY2005 to a high of $12.2 million in SFY2002. The annual level of Contributed Capital is directly related to the cost of eligible projects being undertaken and the funding limits of the grant programs themselves, which for the FAA's AIP program, varies when PFCs are and are not authorized.

II. LONG-RANGE PLANS OF ADJACENT STATES

This chapter contains information on the transportation priorities, plans and projects of the adjacent states of Rhode Island, Massachusetts and New York. To facilitate efforts to ensure the connectivity of Connecticut's transportation planning efforts with those of adjacent states, staff of the state transportation departments in these states were contacted to obtain information on the status of their long range plans and their current and anticipated efforts to improve, upgrade or expand their system, particularly in the vicinity of Connecticut's borders. In addition, information on transportation plans and projects was obtained from each of the state's web sites and from agency staff. The transportation activities listed in this chapter have been identified by the states of Rhode Island, Massachusetts and New York as major transportation-related policies, projects and/or studies that the states have undertaken and/or will be implementing. For reference purposes, Figure II-1 shows the major cities and transportation facilities within a 100-mile radius of Hartford.

Figure II-1. Major Cities and Facilities within a 100-Mile Radius of Hartford



A. RHODE ISLAND

The Rhode Island Statewide Planning Program, in cooperation with other agencies, prepares a long-range (20-year) transportation plan that sets state policy to guide the public and private decisions involving transportation. This plan is part of the State Guide Plan, which is a collection of plans and policy documents adopted by the State Planning Council to address the social, economic and physical development of the state.

In 2004, a major update of the long-range transportation plan, entitled *Transportation 2025: Long Range Plan Transportation 2004*, was completed, and the planning horizon was extended to the year 2025. Transportation planning in Rhode Island is based on a common vision that recognizes transportation as "a core function that threads through other elements of society to connect the state with global and regional economies, the home with the workplace, and the individual with the community, and all of us with another. It must equally benefit all communities." The plan presents recommendations around the 14 topic areas listed in the bullets below:

- Bicycle
- Design
- Economic Development
- Emergency Response
- Environment
- Equity
- Finance
- Highway
- Intermodal
- Land Use and Corridors
- Planning
- Safety
- Transit
- Pedestrian

Within each topic, there is an overall goal, followed by objectives, policies, strategies and performance measures, collectively referred to as "recommendations." The following project descriptions were downloaded in full or in part from a web site maintained by the State of Rhode Island (July 2005).

Relocation of Interstate 195 (I-195) – This project includes the following improvements: one mile of new I-195, one and one-half miles of resurfaced and realigned I-95, new interchange with I-95 and I-395, 15 new bridges to be constructed including numerous ramp bridges and a 50-foot wide pedestrian bridge at India Point Park; various highway access and city traffic flow improvements; an intermodal transportation and visitors center; a multi-use path for pedestrians and bicycles (both sides of river); boat ramps; and dredging of the Providence River to allow passage of larger vessels. The relocated I-195 should be partially open to traffic in 2007 and fully operational by 2009.

Rhode Island South County Commuter Rail – Rhode Island Department of Transportation completed a planning study (2001) to evaluate the feasibility of extending the current MBTA Boston, Massachusetts - Providence, Rhode Island commuter rail service over 43.8 miles of Amtrak's Northeast Corridor between Providence and Westerly, Rhode Island. The state is currently pursuing the plan's Initial Phase, with the extension of MBTA service to Warwick and Wickford Junction. This includes a multimodal transportation facility at Warwick intermodal train station, with parking, rental car, intercity bus, taxi/limousines, intercity and commuter rail, and direct access to T.F. Green Airport. RIDOT has initiated a further study (2006) in consideration of a Future Phase, further extension of the service to Westerly, Rhode Island, and possibly New London, Connecticut.

T. F. Green Airport Improvements – T. F. Green Airport currently serves over five million passengers per year and growth is anticipated to increase to 11 million passengers by 2020. The airport currently has approximately 250 daily operations and this is also expected to increase significantly (630 by 2020). Updating of the airport master plan has been underway since 2001. An environmental impact statement is being prepared for major projects proposed

as part of the master plan update. Additionally, other projects that are pending at the T. F. Green Airport include initiation of a surface-marking project, runway repavement, development of an intermodal station, and initiation of a 4th floor building project at the airport. Information on T.F. Green Airport will be updated in the New England Regional Airport System Plan as part of a Federal Aviation Administration Regional Project.

B. MASSACHUSETTS

The State of Massachusetts released its draft 20-year long-range transportation plan, entitled *A Framework for Thinking–A Plan for Action: Transportation in the Commonwealth of Massachusetts,* in June 2005. The information that follows has been taken in full or in part from digital files of this plan as downloaded from the Massachusetts Executive Office of Transportation (EOT) web site in June 2005.

Transportation in Massachusetts is at a crossroads. For the first time in nearly two decades, the Central Artery/Tunnel project is no longer the centerpiece of the transportation agenda. In the soon-to-be post Big Dig era, Massachusetts transportation officials are extremely cognizant of the need to promote greater geographic equity in transportation planning and funding decisions. The Romney Administration, in partnership with the Massachusetts Legislature, has made sustainability—the advancement of policies that protect the natural environment, support healthy communities, and promote economic prosperity in harmony with livability—a centerpiece of the agenda for the Commonwealth.

The policies of the Romney Administration, including *Fix-It-First* and *Communities First*, encourage planning that strengthens the existing transportation network, respects local landscapes and community character, provides multiple transportation options, enhances intermodal connections, and promotes equity of investment across the Commonwealth. The *Fix-It-First* policy of the Romney Administration emphasizes the importance of preserving and improving existing infrastructure before we elect to build or purchase new facilities. This policy is relevant for all of the transportation agencies, regardless of mode, and will provide a guide for the transportation investments of the next several decades. The Romney Administration and the Legislature have also emphasized the streamlining of the internal processes of the Massachusetts transportation agencies. *An Act Restructuring the Transportation Systems of the Commonwealth* (Chapter 196 of the Acts of 2004) initiated the reform of the transportation agencies, introducing new inter-agency efficiencies and promoting cost-savings.

Following the release of *A Framework for Thinking—a Plan for Action*, the Executive Office of Transportation will undertake a statewide process to solicit public comment and secure broad public participation in the further development of the document. The further development of the document will include a discussion of how best to deal with the major infrastructure projects currently proposed for the Commonwealth.

The following is a listing by geographic region of large, high priority transportation projects in Massachusetts that may be relevant to or of interest to Connecticut. These are termed "mega" projects, defined as those projects that have a cost that exceeds, or are expected to exceed, one hundred percent of each of the Metropolitan Planning Organization's annual regional target amount, excluding bridges.

a. Berkshire Region

Pittsfield Airport ($24m) – This project will increase runway length and make other associated safety improvements to allow aircraft to land in all weather conditions and permit corporate jets to fly non-stop to and from the west coast. The project was recommended by the Regional Competitive Council (RCC) as key to the region's efforts to attract businesses interested in locating in the Berkshires.

b. Central Massachusetts Region

Commuter rail improvements (cost not available) – Increased commuter rail service to Worcester has been a top priority for the City and was recommended by the RCC. The MBTA has conducted several studies and is discussing feasibility and costs with CSX. The goal is to increase the service to 20 round trips a day. Expansion of this line should be coupled with capacity improvements at South Station.

c. Franklin Region

Northern ITS (6.25m) – This project would extend the Interstate 91 ITS project to the Vermont border to provide a communication backbone for the region, with the potential through the Wiring Massachusetts Initiative to substantially improve broadband availability. The Regional Plan recommended more ITS in this region and the RCC identified this connection as a cornerstone infrastructure improvement necessary for regional economic development.

d. Northern Middlesex Region

Improvements to Interstate 495 (I-495) (cost not available) - The majority of the section of I-495 that runs through the region is congested at peak periods. I-495 functions as a major link both within the Commonwealth and to other states via direct connections to I-90, I-93, I-95, Route 2, and Route 3. With this critical role in inter-regional and interstate mobility, I-495 provides a vital function in the movement of people and goods. The Regional Plan highlighted this corridor as one that needed further attention. Opportunities for strategic and multimodal improvements may be identified in a study that MassHighway and the MPO are about to begin. A full range of alternatives, including interchange, highway, and non-highway improvements as well as multimodal options, will be developed and analyzed as the study progresses. A recommended plan of future transportation improvements (both short-term and long-term), based on the alternatives analysis, will be the end product of this study.

e. Metropolitan Boston Region

Silver Line III ($756m) – This phase of the Silver Line project would create an underground link between South Station and Boylston Street and connect the two phases that have already been built—namely the Washington Street service and the service to the Seaport District and Airport. In February 2005, the MBTA was recommended for further funding at a level of 60 percent federal funds/40 percent non-federal funds through the New Starts program. This project is scheduled to be completed in 2013.

f. Pioneer Valley Region

Interstate 91 (I-91) ITS ($8m) – This project would provide ITS capability along I-91 from the Connecticut border to the Vermont border and provide a communication backbone for the region, with the potential through the Wiring Massachusetts Initiative to substantially improve broadband availability. Supported by the Regional Plan and recommended by the RCC, this initiative has received a Congressional earmark.

Julia Buxton (South End) Bridge Reconstruction ($70m) – Still in preliminary conceptual stages, this project would consist of the upgrade of the existing four lane bridge between

Springfield and Agawam. In addition, this could consist of improvements to the Interstate 91 corridor between exits 1-5 to address the existing lane reductions from three to two travel lanes.

Agawam, Route 5/57 ($10m) – This project involves the creation of direct access from the west end of the Connecticut River Bridge to Route 57 (westbound) a heavy traffic movement due to recent development in southeast Agawam. The project was recommended by both the Regional Plan and the RCC.

Route 57 Phase II - Route 187 to Southwick Town Line ($34m) – This project consists of the construction of a limited access highway (two lanes in each direction) from the Route 57/187 interchange in Agawam to the Agawam/Southwick line.

Improvements to Union St. Rail Underpass in Merrick Neighborhood ($15m) – A major recommendation of the Merrick-Memorial Neighborhood Redevelopment Plan was to upgrade the existing Union Street railroad underpass in West Springfield. This underpass currently provides only 12 feet of vertical clearance. Given its current configuration, the Union Street Underpass significantly limits the number of entry points for heavy-vehicle traffic serving the existing industrial areas in the Merrick and Memorial neighborhoods, and in particular, the Merrick Industrial Area, which is home to more than 169 industries, including the CSX freight rail operations. The upgrade of the Union Street Underpass will create a new truck route into the Merrick Industrial Area using Route 147 (Memorial Avenue). This will allow trucks to enter the industrial area from Interstate 91 via the Memorial Bridge and Route 5/147 rotary, as opposed to the North End Bridge and Route 5/20 rotary.

Improvements to Route 5 Access Ramps ($5m) – Another major recommendation of the Merrick-Memorial Neighborhood Redevelopment Plan was to upgrade an existing roadway to allow truck access from Route 5 into the industrial areas of West Springfield. Currently, large trucks must negotiate between the Route 5/20 rotary or the Route 5/147 rotary to access the industrial areas. Existing ramps on Route 5 in Agawam provide access to "M" Street which serves the Bondi's Island Wastewater Treatment Plant and Springfield Landfill. The enhancement of these existing ramps would allow large trucks to enter and exit the industrial areas of West Springfield via Union Street Extension to Agawam Avenue to Route 5.

Route 5 Traffic Signal Improvements – Based on the recommendation of a congestion management study conducted by the PVPC, this study would address the feasibility of widening Route 5 in Longmeadow to provide additional capacity from Forest Glen Road to Converse Street. In addition, the feasibility of upgrading and coordinating the existing traffic signals along Route 5 would also be addressed.

Commuter Rail - Springfield to New Haven ($30m) – This project consists of the implementation of commuter rail service between Springfield, Massachusetts and Hartford and New Haven, Connecticut. The service would operate on the existing 62-mile Amtrak owned Springfield Line connecting the three cities. The rail corridor crosses the MA/CT border in Longmeadow and continues to Union Station in Springfield. Union Station would be the primary station located in Massachusetts with the possibility of another station located in downtown Springfield.

Interstate 91 (I-91)/Connecticut River Corridor Passenger Rail Study – This Passenger Rail Study will consider the options for providing a phased implementation strategy for passenger rail service between Springfield, Massachusetts and White River Junction, Vermont. It is intended that this project will build on the existing planning efforts by CDOT for New Haven-Hartford-Springfield and support implementation of commuter rail service to Springfield.

Route 10/202 Resurface: Westfield CL to CT SL ($5.5m) – This project consists of the rehabilitation of the Route 10/202 corridor in Southwick. It may include spot widening for turning lanes as warranted and the improvement of existing traffic signals along the corridor.

Southwick Rails to Trails Bike path along Penn. Central Line ($2.6m) – This bike path project will consist of the construction of a multiuse facility with a proposed connection to Farmington Valley Greenway.

Great River Bridge: Construction: BR# W-25-010 over the Westfield River ($20m) – The Great River Bridge spans the Westfield River in Westfield and is part of Route 10/202. This bridge serves as the main corridor to the Massachusetts Turnpike and points north of the city. The project will include reconstruction and widening of the existing bridge, with the addition of a sister span along the east side of the existing bridge. The existing bridge will contain three one-way southbound travel lanes and the sister span will contain three one-way northbound travel lanes. Redesign of the roadways north of the bridge is also included in the project.

g. Southeast Massachusetts Region

Commuter rail to New Bedford and Fall River ($670m) – While both capital and operating costs would be a challenge, the local studies now going forward are a model of the corridor studies that are recommended as a precursor to any major expansion project. The RCC recommended the project. This project, as with several other expansion proposals, are prime candidates for corridor financing mechanisms such as District Improvement Financing. Any such expansion of commuter rail service south of Boston should be coupled with an expansion of the tracks at South Station to add the necessary capacity.

C. NEW YORK

The New York State Department of Transportation's (NYSDOT) mission is to ensure that its customers–those who live, work, and travel in New York State–have a safe, balanced, and environmentally sound transportation system. It is recognized that the transportation system, which is essential to the efficient movement of people and goods, is vitally important to commerce and industry.

In December 2005, the NYSDOT published a preliminary draft long-range transportation plan, *Transportation Strategies for a New Age: New York's Transportation Plan for 2030*. This preliminary draft plan states that New York State is transforming its approach to providing transportation.

This transformation recognizes that transportation's customers—those who use the transportation system for travel or to ship goods—do not care who owns or operates individual transportation facilities. These customers do care that transportation is seamless and that it effectively responds to their needs in the ever changing global economy. They care that transportation operators can appropriately prioritize among potential investments, can successfully measure the success or failure of their efforts to improve the systems operation, and can, therefore, be held accountable for their investment of public funds. [18]

The state will build on its many accomplishments to respond to the changing global economy, travel demands and customers needs.

New York State's vision for transportation in 2030 is of a seamless system in which travelers can conveniently shift between modes and operators to complete trips that meet their individual and business needs. Future transportation investments will be customer-driven. A system to measure how well the investment performs will help ensure accountability. Priorities will be determined within major transportation corridors which serve the predominate customers of the system. [19]

The draft plan provides a "broad policy road map" that will underlie the State's efforts to achieve this vision. It identifies the following five Priority Result Areas:

- Mobility and Reliability
- Environmental Conditions
- Security
- Economic Sustainability
- Safety

This draft Plan also outlines nine important strategies to achieve desired outcomes within these Priority Result Areas. These strategies, which follow, "will underpin future transportation investments." They are discussed in greater detail throughout NYSDOT's draft plan. The plan states that, notwithstanding the uncertainty of future transportation revenue sources and funding levels, each of these Priority Result Areas must be addressed through an integrated capital and operating plan. The highest priorities in New York State will be largely determined by examining the needs of designated corridors and their component facilities.

[18] New York State Department of Transportation, "New York State's Transportation Plan: Strategic Policies for 2005-2030," New York State Department of Transportation, <http://www.dot.state.ny.us/transplan/index.html> (4 January 2006)

[19] Ibid.

	Strategies to Achieve Desired Outcomes within the Priority Result Areas
1	To implement effective integrating mechanisms for improving coordination among the State's transportation operators
2	To focus investments on meeting customer needs within the designated travel corridors;
3	To promote improved safety through altering the travel behaviors of vehicle operators posing the highest risk to transportation safety;
4	To increase the compatibility between existing and desired land uses and transportation;
5	To use state-of-the-art transportation asset management principles to make future investment decisions;
6	To emphasize state-of-the-art operational techniques, including advanced technologies, to meet customer expectations for mobility and reliability;
7	To adopt comprehensive performance management practices to ensure progress within the Priority Result Areas;
8	To place customers in the "driver's seat" in determining investment priorities, and
9	To play a leadership role in promoting sound environmental and energy policies in all transportation investments

In its draft plan, New York recognizes the "importance of overcoming the adverse impacts of governmental and other institutional fragmentation that defines the transportation sector in New York State today. The following impacts were identified: insufficient comprehensive planning, difficulty in attaining consensus on major investments to be advanced, traffic tie-ups resulting from simultaneous construction on two or more highways within the same travel corridor, missed connections between train and bus, or commuter rail and subway, and other operational issues that prevent a seamless trip from origin to destination.

The plan for 2030 foresees a far more collaborative approach to planning and investment decision making. This plan states that the Commissioner of the NYSDOT, utilizing existing and statutory authority, will integrate transportation policy development among operators throughout the state to ensure greater policy coherence and consistency. The creation of the Transportation Federation in 2004, comprised of the NYSDOT, the New York Thruway Authority and the New York State Bridge Authority, under the overall direction of the State Transportation Commissioner, will promote improved policy and programmatic coordination upstate and represents only the first step in this effort. Similarly, the Chairman of the Metropolitan Transportation Authority will play a leading role in the downstate region promoting improved integration and coordination between the transportation operators.

The plan further states that "as NYSDOT continues to reorganize to meet the challenges of the 21st century, it is anticipated that the Commissioner's transportation integrating role will be strengthened in order to achieve the policy objectives identified in this plan."

At the forefront of planning activities in the New York portion of the NY-NJ-CT urbanized (transportation management) area is the New York Metropolitan Transportation Council

(NYMTC). It is the council of regional governments that serves as the metropolitan planning organization (MPO) for the New York City, Long Island, and the Lower Hudson Valley to oversee transportation-planning activities in the region.

- NYMTC's Mid-Hudson South Transportation Coordinating Committee is an advisory member of the South Western Regional MPO and this agency is also an advisory member of NYMTC's MHSTCC.

- Further, NYMTC joins ten other MPOs, including Orange County Transportation Council, some of Connecticut's MPOs as well as others from New Jersey, in the multi-state air quality non-attainment area for fine particulate matter (PM2.5) and must jointly determine conformity with them until new State Implementation Plans for air quality are adopted.

- NYMTC's Best Practice Model covers twenty-eight counties in the NY-NJ-CT region, which includes nine other MPOs, and results in commonality among analytical tools, many areas of data collection, and socio-economic/demographic forecasting, e.g. 1997/98 household travel survey.

- In the NY-NJ-CT region, NYMTC joins up with other MPOs in various advisory working groups, such as the Regional Transportation Planning Coalition, the Freight Transportation Working Group, the Forecasting Working Group, the Metropolitan Mobility Network, the Long Island Sound Ferry Coalition, etc. Participation in these groups has led to specific multi-MPO studies and projects, such as the Long Island Sound Waterborne Transportation Plan, and supplemental coordination on major regional projects such as I-287/Tappan Zee Bridge Environmental Assessment.

The Poughkeepsie-Dutchess County Transportation Council PDCTC) and Orange County Transportation Council (OCTC) are the MPOs of the Mid-Hudson Valley area which borders Connecticut. NYSDOT and the Metropolitan Transportation Authority are also members of these councils as well as of NYMTC.

Following are brief descriptions of projects underway or planned to be undertaken in the State of New York. This information was obtained from the web sites of the New York State Thruway Authority, the New York State Metropolitan Transit Authority, and the Port Authority of New York and New Jersey.

a. Highways

The information that follows on highway projects and studies being undertaken by the State of New York has been taken in full or in part from the New York State Thruway Authority's web site (April 2005) or provided by NYSDOY's Region 8 office.

I-84/I-87 Interchange Project – The NYS Thruway (I-87) and I-84 are major interstate highways providing important connections between population and commercial centers of the northeastern United States. The two highways intersect in the Town of Newburgh, Orange County, New York. Currently, there are no direct connections between I-87 and I-84. In recent years, local and interstate traffic volumes have increased significantly, resulting in increased congestion, longer travel times, and safety problems on the Interchange roadways. The purpose of this project is to reconstruct the I-84/I-87 Interchange, to provide direct access between the two interstates, and to relieve traffic congestion from the local roads, through the use of cost effect measures and with minimal impact to the community and the environment. This project will include higher speed E-ZPass lanes that allow customers to pass through the barrier at speeds up to 40 miles per hour. http://www.thruway.state.ny.us/projects/i84-i87/about.html# rollover image Phase 1

was completed on October 12, 2004, at a cost of $5.5 million. Phase 2 was awarded at the end of 2005. As of mid February 2006, Phase 3 letting was in the process of being scheduled.

New England Thruway (I-95) Capacity Project - New England Thruway (I-95) Capacity Project – From Milepost 14.0 to the Connecticut Line for 2012. In addition, the NYS Thruway Authority plans to do a corridor study of the entire New England Thruway post 2010.

The NYS Thruway Authority has also begun a study to investigate the potential of changing the current Thruway toll collection system to an open road toll system. Preliminary results of the study are expected to be available by the end of the year.

Long-Term Needs Assessment and Alternative Analysis I-287/Tappan Zee Bridge Corridor In late 1997, Governor Pataki formed the I-287 Task Force to recommend alternatives to a high occupancy vehicle lane on the Cross Westchester Expressway and to address the transportation issues in the lower Hudson Valley. The Task Force was chaired by E. Virgil Conway of the Metropolitan Transportation Authority and also included Ambassador Charles Gargano, Chairman of the Empire State Development Corporation, Joseph Boardman, the Commissioner of the Department of Transportation, John Cahill, the Commissioner of the Department of Environmental Conservation and John Platt, Executive Director of the Thruway Authority. The Task Force retained an outside consultant team to perform a preliminary study of such alternatives. This report provides the technical foundation for the Task Force to consider in making recommendations regarding those alternatives and the long-term needs. The following study builds on the work of the Task Force.

Tappan Zee Bridge/I-287 Environmental Review – The New York State Thruway Authority (NYSTA) and MTA Metro-North Railroad, in coordination with and subject to the review and acceptance by the Federal Highway Administration (FHWA) and the Federal Transit Authority (FTA), will prepare an Alternatives Analysis (AA) and then an Environmental Impact Statement (EIS) for the I-287 Corridor in Westchester and Rockland Counties, which includes the Tappan Zee Bridge. Congestion in the corridor is anticipated to continue to worsen, and the structural needs of the Tappan Zee Bridge must be addressed. Although the bridge is safe, due in large part to a detailed program of maintenance and inspection, it is nearing the end of its expected service life. The purpose of the study is to identify and evaluate alternative proposals to address the transportation needs of the Tappan Zee Bridge/I-287 Corridor. The environmental review process for the Tappan Zee Bridge/I-287 Corridor will be carried out in two stages: Stage 1 is an alternatives analysis (AA) and the initial environmental review process and Stage 2 consists of the Environmental Impact Statement (EIS).

Tappan Zee Bridge Deck Replacement – The New York State Thruway Authority (NYSTA) is going to expand service and ensure safety by replacing a significant portion of the deck of the Tappan Zee Bridge. Construction is expected to begin in the summer 2006 and be completed by the fall of 2008.

Access To Stewart International Airport – This project provides a direct link from I-84 to Stewart International Airport in Orange County. A new diamond interchange will be constructed at Drury Lane, and a new access road will be constructed from Drury Lane into the airport. Drury Lane will also be improved. The project was awarded in November 2005.

Conversion of Route 17 to I-86 – The conversion of Route 17 to I-86 is underway. Sections in western New York State have already been designated I-86. The sections in Orange County should be converted over the next five years. The conversion consists of updating the roadway section, clearances, and access to Interstate standards.

Route 22 from I-84 to County Road 65 – This project, which was in the DEIS phase in February 2006, would widen Route 22 in Putnam County to a four-lane divided highway. Traffic congestion and safety would be improved. Route 22 provides commuting access for commuters

in both New York and western Connecticut. It also has heavy recreational use on Fridays and Sundays. Concerns about New York City watershed impacts have affected the project schedule.

I-84 from I-684 to Connecticut State Line – This section of I-84 and the I-684 interchange experience congestion. NYSDOT would like to partner with ConnDOT to complete the planning requirements to allow widening to six lanes and the reconstruction of the I-84/I-684 interchange.

I-84 Repaving – I-84 is being repaved from the Pennsylvania state line to Connecticut. It is being done in stages over the next five years. Sections in Dutchess and Putnam Counties have been completed. Two remaining sections that finish Putnam County to the Connecticut state line will be under construction in 2006.

I-287 Reconstruction – The NYSDOT has been reconstructing I-287 from the Tappan Zee Bridge to Route 120 in Westchester County. The reconstruction is generally complete from the Tappan Zee Bridge to the Bronx River Parkway. The next section through the City of White Plains was scheduled to be let in April 2006. The following section from Bloomingdale Road to Route 120 is scheduled to be let in 2008. The section from Route 120 to I-95 is to be repaved in either 2006 or 2007.

Intelligent Transportation Systems – The NYSDOT has opened its Transportation Management Center for the Hudson Valley Region located in Hawthorne, Westchester County. ITS equipment is being installed on I-287 as part of its reconstruction. A number of VMS signs on major highways have also been installed. The ITS system will be extended along the limited access highways in Westchester County over the next five years. An extensive motorist assistance program, HELP, has been operating for a number of years providing peak hour, weekday coverage on limited access highways in Westchester, Putnam, Dutchess, and Rockland Counties.

I-684 – I-684 is being reconstructed from I-287 to I-84. The section from I-287 to Harris Road south of the Saw Mill River Parkway is complete or under construction except for Exit 2 at the Westchester County Airport. Exit 2 is scheduled to be let in 2007 and will eliminate congestion at the interchange and incorporate extensive water quality mitigations due to the proximity of the Kensico Reservoir. Harris Road to the Saw Mill River Parkway is scheduled for 2008. The I-684/Saw Mill River Parkway/Route 35 interchange will be studied beginning in 2006 to determine needed improvements. I-684 from Route 35 to Hardscrabble Road has been improved. The section from Hardscrabble Road to I-84 is scheduled to be repaved in 2009.

Trailways – NYSDOT, in cooperation with Westchester, Putnam, Dutchess, and Columbia Counties, has been developing a regional trailway system. The North County Trailway in Westchester County is complete from central Westchester to the Putnam line. The South County Trailway is being built in stages south from the North County Trailway to New York City. The Putnam Trailway from the North County Trailway to Brewster in Putnam County is open to Carmel and the segments to Brewster are in design. Putnam County is also designing the Maybrook Trailway which parallels Metro-North's Beacon-Danbury Line from Brewster to the Dutchess County line. Dutchess County is designing another portion of the Maybrook Trailway from Hopewell Junction to the Hudson River in Poughkeepsie. Dutchess County is also extending the Harlem Valley Rail Trail into Columbia County. Columbia County and the New York State Office of Parks and Historic Preservation are working on extending the rail trail in Columbia County.

b. Public Transportation

The following information on public transportation projects and studies being undertaken by the State of New York was taken in full or in part from the New York State Metropolitan Transit Authority's web site. All of these projects are being built by MTA Capital Construction, which was formed in July 2003 by the MTA's Board of Directors to manage the design and construction of the MTA's network expansion projects.

East Side Access MTA Long Island Rail Road - Grand Central Connection – The East Side Access (ESA) project will connect the Long Island Rail Road's (LIRR) Main and Port Washington lines in Queens to a new LIRR terminal beneath Grand Central Terminal in Manhattan. The new connection will increase the LIRR's capacity into Manhattan, dramatically shorten travel time for Long Island commuters, provide a new commuter rail station in Sunnyside Queens—and much more. Metropolitan New York is home to the nations most extensive—and most used—rail transit network, serving nearly 6 million riders per day. Because the network is operating at or near capacity and is not fully interconnected, millions of travelers are delayed by indirect routing and/or overcrowding. When completed in 2012, the East Side Access project—the largest construction project ever undertaken by the Metropolitan Transit Authority (MTA)—will carry more customers than all but four other commuter railroads in the country, and will profoundly affect the lives not only of Long Island commuters but also of transit users, motorists and residents throughout the New York metropolitan region. The ESA project will stimulate regional growth and development in a variety of ways, including enabling easy transfers at Grand Central between Long Island and Metro-North destinations in the Bronx, Westchester, Hudson Valley and Connecticut.

Second Avenue Subway – The Second Avenue Subway will reduce overcrowding and delays on the Lexington Avenue Line, improving travel for both city and suburban commuters, and improving access to mass transit for residents of the Far East Side of Manhattan. A Federal Environmental Impact Statement has been completed that addresses questions and comments rose during the hearing process. The Federal Transit Administration issued a Record of Decision (ROD) in July 2004, which states that, the requirements of the National Environmental Policy Act of 1969 (NEPA) have been satisfied for the Second Avenue Subway Project. The MTA completed Preliminary Engineering (PE) work on the full-length subway line. The MTA plans to begin construction of Phase I of the Second Avenue Subway in 2006.

No. 7 Subway Extension – Hudson Yards Rezoning and Development Program - The Metropolitan Transportation Authority, MTA Capital Construction and the City of New York Department of City Planning propose to promote the transit-oriented redevelopment of the Hudson Yards area ("the Hudson Yards"), which extends generally from West 28th Street on the south, Eighth Avenue on the east, West 43rd Street on the north and the Hudson River Park on the west. The proposed action includes construction and operation of an extension of the No. 7 Subway Line to serve the Hudson Yards; adoption of zoning map and text amendments to the New York City Zoning Resolution and related land use actions to permit the development of the Hudson Yards as a mixed-use community; other public actions, including work on the nearby convention center; construction of new exhibition space and a new hotel, and new or replaced transportation facilities for pedestrian movement, vehicle storage and other public purposes. Final design is scheduled to be completed in December 2006.

Fulton Street Transit Center – The new Fulton Street Transit Center in the general vicinity of Fulton Street and Broadway, incorporating six existing Lower Manhattan subway stations is under construction. The $785 million project will improve access to and connections between 12 subway lines for hundreds of thousands of daily commuters and Lower Manhattan residents and visitors, and will link New York City Transit facilities with PATH service and the World Trade Center site. The Final Environmental Impact Statement was published on September 29, 2004.

This project was under construction as of February 2006 and is expected to be completed in July 2009.

South Ferry Terminal – An improved South Ferry Terminal for the No. 1 and No. 9 subway lines, to be located underneath Peter Minuit Plaza in Lower Manhattan, adjacent to Battery Park and the Staten Island Ferry Terminal was under construction as of mid February 2006. The $451 million project will correct existing physical and operating deficiencies which limit train capacity and reduce subway reliability for millions of customers each year. The new station will reduce customer travel times, provide additional station entrances with ADA accessibility, and will offer a new free transfer between the No. 1 and No. 9 subway lines and the "R" and "W" lines at Whitehall Street. The Federal Transit Administration has issued a *Finding of No Significant Impact for the South Ferry Terminal Project*. Preliminary construction work on the South Ferry Terminal is being undertaken by the New York State Department of Transportation as part of the completion of the new Staten Island Ferry Terminal. Full construction was underway as of February 2006 and the project is scheduled to be completed by December 2007.

c. Waterborne Transportation

The following information is from the web site of the New York Metropolitan Transportation Council (NYMTC), the metropolitan planning organization for the New York portion of the metropolitan area.

NYMTC explored the potential for expanded use of the Long Island Sound and its tributaries for waterborne and freight transportation in the Long Island Sound Waterborne Transportation Plan (LISWTP). This plan was jointly sponsored by the NYMTC, the Greater Bridgeport Regional Plan Agency (GBRPA) and the South West Regional Planning Agency (SWRPA) and identifies a regional program of feasible, beneficial, and sustainable marine transportation improvements and services that reduce the region's reliance on highways. The intent was to develop a plan for waterborne transportation in the 2002 to 2025 period which would include strategies through which ferries can handle a greater share of the region's transportation demand and offer increased emergency response capability. The LISWTP was adopted for inclusion in the NYMTC Regional Transportation Plan on September 8, 2005.

d. Port of New York and New Jersey

The following information on the Port Authority of New York and New Jersey's $1 billion improvement program for the Port of New York and New Jersey was taken in full or in part from the Port Authority of New York and New Jersey's web site.

Channel and Berth Deepening – The Port Authority has been working with the U.S. Army Corps of Engineers to fund and implement crucial channel deepening projects in the harbor necessary to accommodate the demand for international cargo through our region. The agency is also working with its container terminal operator partners to deepen selected berths as part of the various port improvements in progress. The Port Authority and the Corps are currently working on several critical channel deepening projects in the New York/New Jersey harbor.

Terminal Improvement Projects – The Port Authority of New York and New Jersey, in conjunction with its marine terminal operator partners, is in the midst of a significant improvement program at the Port of New York and New Jersey. As part of this program, terminal improvements will be undertaken. When the terminal reconfiguration projects are

completed, the Port of New York and New Jersey will have the capacity to meet the projected rise in demand for international cargo to the region.

Inland Access Improvements – A number of projects have been identified to improve the rail movement of cargo via the on-dock Express Rail System. In addition, a Port Authority Bistate Rail Freight Initiative and a Port Inland Distribution Network (PIDN) are planned. Future plans include completing a New Jersey Department of Transportation's (NJDOT) Portway International Intermodal Corridor and a Comprehensive Port Improvement Plan (CPIP). The Portway is a decade-long program that includes the phased development of various projects designed to improve truck access and road safety. The CPIP will assess the costs and benefits of planned improvements to accommodate forecasted growth (by 2040) in cargo at the port.

e. Rail Freight

The following information was obtained from the New York City Economic Development Corporation's web site on the Cross Harbor Study.

Cross Harbor Freight Movement Project –The Cross Harbor Freight Movement Project is a joint Federal Highway Administration Federal Railroad Administration (FRA) and the New York City Economic Development Corporation (NYCEDC) effort to examine the way freight is transported in the New York metropolitan region area. The project includes an analysis of rail alternatives to address the current regional goods mobility problem and enhance the capacity, reduce congestion and costs, and improve reliability and strategic redundancy of the freight system. The project focuses specifically on investments that enable robust rail service in the East-of-the-River; namely, improvements to the two key East-Hudson rail lines–the Bay Ridge Branch in Brooklyn and Queens and the Montauk Branch in Queens, rail yards and other supporting facilities, and an improved connection to the national freight rail network in northern New Jersey. The study effort began in 1998 when NYCEDC commissioned the *Cross Harbor Freight Movement Major Investment Study* (MIS) to identify and evaluate strategies for improving freight movement throughout the entire region's rail freight network. At the conclusion of the MIS in 2000, the following project alternatives were identified: 1) No Action Alternative, 2) Transportation System Management (TSM) Alternative, 3) Expanding Float Operation Alternative, and 4) Rail Freight Tunnel Alternative. In 2001, NYCEDC, in cooperation with the FHWA and the FRA, began work on a Draft Environmental Impact Statement (DEIS) to further examine these initial alternatives, in conformance with the National Environmental Policy Act of 1969. In the DEIS, which was published in April 2004, the Tunnel Alternative was deemed to be the preferred alternative because it would produce significantly greater benefits with respect to the project goals and objectives than the other three alternatives. A New Jersey alignment of the Tunnel Alternative was identified by the NYCEDC as the Preferred Alternative. Work on the study was suspended prior to the completion of a Final EIS.

The project was undertaken because the metropolitan tri-state region, including portions of southern New York, northern New Jersey, and southwestern Connecticut, is facing a major urban freight mobility challenge. The region's economic prosperity has fueled a tremendous demand for goods movement but the freight transportation system east of the Hudson River has not kept pace with this growth in goods movement. The freight system in the East-of-the-Hudson region has failed to evolve with changing freight patterns and technology. Instead, the concentration of port, rail and air freight facilities needed to sustain the region's economic link to the rest of the world has developed largely in the West-of-the-Hudson region. The only direct connection from this freight hub to the heavily populated region east of the Hudson River is via truck. Currently, trucks move almost 80 percent of all goods. Because the demand for goods movement in the metropolitan region is expected to grow roughly 70 percent above existing

levels by 2025, the freight system needs to be substantially upgraded to prevent traffic congestion from constraining economic growth. [20]

Additional information on this project is available on the following web site: http://www.crossharborstudy.org/.

[20] New York City Economic Development Corporation, *Cross Harbor Freight Movement Project Draft Environmental Impact Statement,* April 2004 <http:www.crossharborstudy.org> May 23, 2006.

Appendix A
List of Acronyms

APPENDIX A. LIST OF ACRONYMS

A	
AA	Alternatives Analysis
ADA	Americans with Disabilities Act
AIP	Airport Improvement Program
B	
BLS	Bureau of Labor Statistics
BRT	Bus Rapid Transit
C	
CES	Current Employment Statistics
ConnDOT	Connecticut Department of Transportation
CPIP	Comprehensive Port Improvement Plan
CPI / U	Consumer Price Index / Urban
CPS	Current Population Survey
CSX	Chessie Seaboard Multiplier (railroad transportation company)
CVISN	Commercial Vehicle Information Systems and Networks
CTDECD	Connecticut Department of Economic and Community Development
D	
DEP	Department of Environmental Protection
DGEIS	Draft Generic Environmental Impact Statement
DIF	District Improvement Financing
DMV	Department of Motor Vehicles
DOL	Department of Labor
DRS	Department of Revenue Services
E	
EIS	Environmental Impact Statement
EOT	Executive Office of Transportation
ESA	East Side Access
F	
FAA	Federal Aviation Administration
FEIS	Final Environmental Impact Study
FHWA	Federal Highway Administration
FSD	Federal Security Director
FTA	Federal Transit Administration
G	
GA	General Aviation
GBRPA	Greater Bridgeport Regional Planning Agency
GCF	Glycol Collection Facility
GF	General Fund
GICs	Guaranteed Investment Contracts
GIS	Geographic Information System
GO	General Obligation

G

GCIDA	Greene County Industrial Development Agency
GON	Groton-New London Airport
GPS	Global Positioning System
GTI	Guilford Transportation Industries
GVW	Gross Vehicle Weight

H- I

HOV	High Occupancy Vehicle
ISTEA	Intermodal Surface Transportation Act
ITS	Intelligent Transportation Systems

J- L

LAUS	Labor Area Unemployment Statistics
LPF	License Permit and Fee
LRTA	Lowell Regional Transit Authority
LIRR	Long Island Rail Road
LISWTP	Long Island Sound Waterborne Transportation Plan

M

MARSEC	Maritime Security
MHSTCC	Mid-Hudson South Transportation Coordinating Committee
MPO	Metropolitan Planning Organization
MTA	Metropolitan Transportation Authority
MBTA	Massachusetts Bay Transit Authority
MVRTA	Merrimack Valley Region Transit Authority

N

NEPA	National Environmental Policy Act
NJDOT	New Jersey Department of Transportation
No.	Number
NYMTC	New York Transportation Metropolitan Transportation Council
NYS	New York State
NYSDOT	New York State Department of Transportation
NYSTA	New York State Transit Authority

O- P

OCTC	Orange County Transportation Council
PDCTC	Poughkeepsie-Duchess County Transportation Council
PE	Preliminary Engineering
PFCs	Passenger Facility Charges
PIDN	Port Inland Distribution Network

Q-R

QCEW	Quarterly Census of Employment and Wages
RABA	Revenue-Aligned Budget Authority
RCC	Regional Competitive Council
RIDOT	Rhode Island Department of Transportation
ROD	Record of Decision
RTP	Regional Transportation Plan

S	
SAFETEA-LU	Safe, Accountable, Flexible, Efficient Transportation Equity Act – A Legacy for Users
SEIS	Supplemental Environmental Impact Statement
SFY	State Fiscal Year
SIP	State Implementation Plan
STF	Special Transportation Fund
STIF	Short Term Investment Fund
SWRPA	South West Regional Planning Agency
T	
TAZ	Traffic Analysis Zone
TEA-21	Transportation Equity Act for the 21st Century
TSE	Truck Stop Electrification
U	
UI	Unemployment Insurance
USCG	United States Coast Guard
USDOT	United States Department of Transportation
V-Z	
VMT	Vehicle Miles of Travel
WIM	Weigh in Motion

Appendix B
Demographic Data & Trends
By Planning Regions

APPENDIX B. DEMOGRAPHIC DATA & TRENDS BY PLANNING REGION

Table B-1. Population Data by Planning Region

Regional Planning Organization	Square Miles	2000	2010	2020	2030	Persons per Square Mile 2000	Average Annual Growth 2000-2010
South Western	283.0	353,556	368,220	383,380	398,200	1,301	0.41%
Housatonic Valley	337.0	212,248	223,000	234,790	247,540	662	0.51%
Northwestern	360.8	22,654	22,810	23,020	23,360	63	0.07%
Litchfield Hills	416.9	79,188	84,600	90,450	96,440	203	0.68%
Central Naugatuck Valley	314.3	272,594	283,870	290,920	298,030	903	0.41%
Greater Bridgeport	58.5	84,500	86,200	88,070	89,970	1,474	0.20%
South Central	149.1	307,607	312,620	318,170	324,040	2,097	0.16%
Central	388.4	546,799	568,420	593,300	618,700	1,463	0.40%
Capitol	166.5	226,695	232,950	241,660	250,530	1,399	0.28%
Midstate	761.0	721,320	748,340	779,800	811,500	983	0.37%
CT River Estuary	257.0	104,442	111,490	119,110	126,850	434	0.67%
Southeastern	204.0	60,051	62,070	65,040	68,090	304	0.34%
Windham	619.4	242,759	256,770	272,050	288,740	415	0.58%
Northeastern	325.7	82,580	88,600	95,090	101,740	272	0.73%
Unaffiliated	390.3	76,572	82,260	88,830	95,660	211	0.74%
	88.6	12,000	12,160	12,880	13,610	137	0.13%
State Total	**5,120.5**	**3,405,565**	**3,544,380**	**3,696,560**	**3,853,000**	**692**	**0.41%**

Source: 1990 Census, 2000 Census, and ConnDOT Series 27B Land use Projections. Data for years following 2000 is projected. Graphics revised in August 2004.

Table B-2 Senior (65 & Older) Population Data by Planning Region

Regional Planning Organization	Square Miles	1990	2000	2010	2020	Persons per Square Mile 2000	Average Annual Growth 2000-2010
South Western	283.0	44,109	48,545	51,300	61,200	156	0.57%
Housatonic Valley	337.0	18,588	21,901	27,500	36,300	55	2.56%
Northwestern	360.8	4,001	4,083	4,500	6,000	11	1.02%
Litchfield Hills	416.9	11,884	12,194	13,300	17,600	29	0.91%
Central Naugatuck	314.3	38,859	39,278	39,400	47,600	124	0.03%
Valley	58.5	11,774	12,823	12,500	14,900	201	-0.25%
Greater Bridgeport	149.1	45,274	43,858	42,400	48,800	304	-0.33%
South Central	388.4	76,751	78,455	81,400	100,600	198	0.38%
Central	166.5	32,657	33,779	34,200	41,800	196	0.12%
Capitol	761.0	95,299	101,665	110,200	135,500	125	0.84%
Midstate	257.0	11,725	13,055	14,500	19,200	46	1.11%
CT River Estuary	204.0	8,380	9,671	11,500	14,900	41	1.89%
Southeastern	619.4	28,611	31,469	35,600	45,700	46	1.31%
Windham	325.7	7,397	8,215	9,600	13,400	23	1.69%
Northeastern	390.3	9,146	9,702	10,900	12,400	23	1.23%
Unaffiliated	88.6	1,452	1,490	1,500	2,000	16	0.07%
State Total	5,120.5	445,907	470,183	500,300	617,900	87	0.64%

Source: 1990 Census, 2000 Census, and ConnDOT Series 27A Land use Projections. Data for years following 2000 is projected. Projections for years following 2025 not available. Graphics revised in August 2004.

Special Notes: After 2001, the municipality of Union (previously considered unaffiliated) became a part of the Northeastern Planning Region. Also, the procedure used to calculate square mileage in 2000 differed from the procedure used in 1990. Specifically, the methodology regarding water area was revised.

Table B-3 Household Data by Planning Region

Regional Planning Organization	Square Miles	1990	2000	2010	2020	2030	Household Size	Households per Square Mile 2000	Average Annual Growth 2000-2010
South Western	283.0	125,410	133,575	142,033	150,707	158,856	2.65	472	0.63%
Housatonic Valley	337.0	69,542	75,729	81,474	87,486	93,753	2.80	225	0.76%
Northwestern	360.8	9,172	9,290	9,543	9,823	10,120	2.44	26	0.27%
Litchfield Hills	416.9	30,144	31,871	34,695	37,821	40,907	2.48	76	0.89%
Central Naugatuck	314.3	99,057	103,155	109,580	114,364	118,910	2.64	328	0.62%
Valley	58.5	30,209	33,104	34,475	35,944	37,287	2.55	566	0.41%
Greater Bridgeport	149.1	108,093	111,459	115,671	119,983	124,065	2.76	748	0.38%
South Central	388.4	179,919	212,894	225,717	239,882	253,897	2.57	548	0.60%
Central	166.5	79,907	89,997	94,344	99,690	104,929	2.52	541	0.48%
Capitol	761.0	259,795	279,871	295,809	313,656	331,010	2.58	368	0.57%
Midstate	257.0	54,775	41,077	44,595	48,365	52,118	2.54	160	0.86%
CT River Estuary	204.0	42,737	24,076	25,385	27,102	28,807	2.49	118	0.54%
Southeastern	619.4	84,165	93,577	100,976	108,951	117,379	2.59	151	0.79%
Windham	325.7	25,764	28,220	30,900	33,869	36,904	2.93	87	0.95%
Northeastern	390.3	27,260	29,422	31,970	35,194	38,475	2.63	75	0.87%
Unaffiliated	88.6	4,294	4,353	4,780	5,161	5,542	2.54	49	0.98%
State Total	**5,120.5**	**1,230,243**	**1,301,670**	**1,381,947**	**1,467,998**	**1,552,959**	**2.62**	**254**	**0.62%**

Source: 1990 Census, 2000 Census, and ConnDOT Series 27B Land use Projections. Data for years following 2000 is projected. Graphic revised in August 2004.

Special Notes: After 2000, the municipality of Union (previously considered unaffiliated) became a part of the Northeastern Planning Region. Also, the procedure used to calculate square mileage in 2000 differed from the procedure used in 1990. Specifically, the methodology regarding water area was revised.

Table B-4 Employment Data by Planning Region

Regional Planning Organization	Square Miles	2000	2010	2020	2030	Employment per Square Mile 2000	Average Annual Growth 2000-2010
South Western	283.0	211,482	230,670	241,430	250,490	815	0.91%
Housatonic Valley	337.0	86,950	100,470	109,690	119,680	298	1.55%
Northwestern	360.8	9,900	10,730	11,330	11,960	30	0.84%
Litchfield Hills	416.9	28,130	30,700	32,510	34,370	74	0.91%
Central Naugatuck Valley	314.3	103,750	109,690	116,060	122,000	349	0.57%
Greater Bridgeport	58.5	35,160	37,900	40,590	43,200	648	0.78%
South Central	149.1	120,270	134,490	142,700	154,530	902	1.18%
Central	388.4	266,580	289,850	304,740	318,960	746	0.87%
Capitol	166.5	90,320	100,090	104,390	108,280	601	1.08%
Midstate	761.0	441,290	489,240	527,710	563,470	643	1.09%
CT River Estuary	257.0	46,410	51,480	55,370	58,940	200	1.09%
Southeastern	204.0	23,653	25,640	28,130	30,700	126	0.84%
Windham	619.4	135,190	167,830	177,260	186,900	271	2.41%
Northeastern	325.7	23,880	26,760	28,980	31,350	82	1.21%
Unaffiliated	390.3	26,020	27,610	28,810	30,290	71	0.61%
	88.6	3,940	4,660	5,060	5,470	53	1.83%
State Total	5,120.5	1,652,925	1,837,810	1,954,760	2,070,590	359	1.12%

Source: 1990 Census, 2000 Census, and ConnDOT Series 27B Land use Projections. Data for years following 2000 is projected. Graphic revised in August 2004.

Special Notes: After 2000, the municipality of Union (previously considered unaffiliated) became a part of the Northeastern Planning Region. Also, the procedure used to calculate square mileage in 2000 differed from the procedure used in 1990. Specifically, the methodology regarding water area was revised.

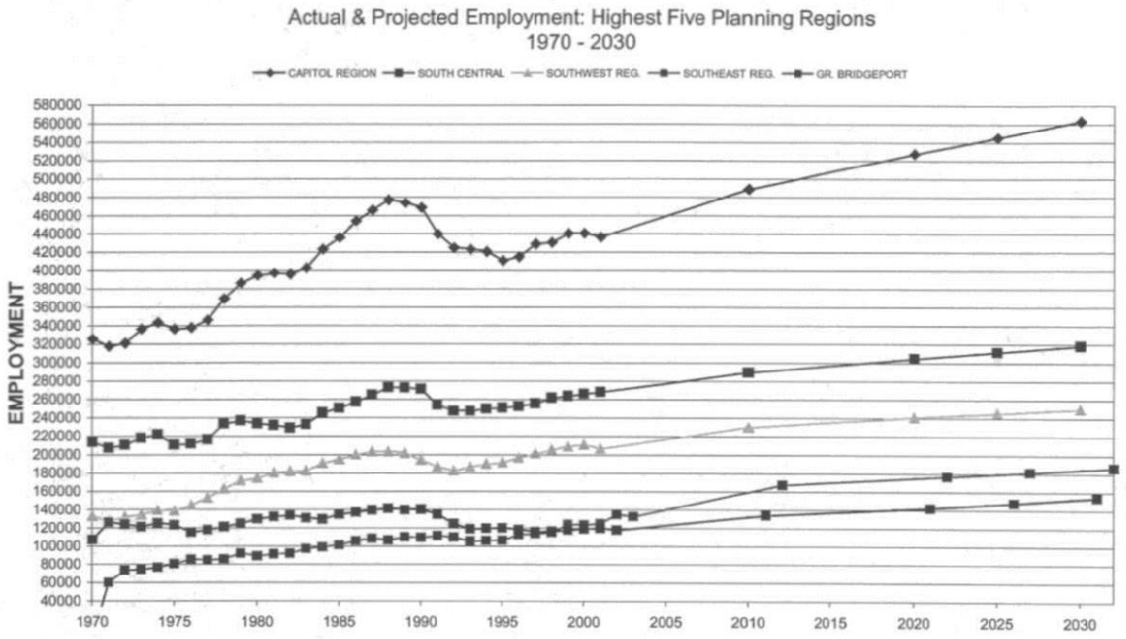
Table B-5 Passenger Vehicle Registration Data by Planning Region

Regional Planning Organization	Square Miles	1980	1990	2000	Registrations per Square Mile 2000	Average Annual Growth 1990-2000
South Western	283.0	200,077	233,988	249,307	881	0.65%
Housatonic Valley	337.0	94,297	124,137	143,247	425	1.54%
Northwestern	360.8	12,611	14,943	16,507	46	1.05%
Litchfield Hills	416.9	38,074	46,433	49,689	119	0.70%
Central	314.3	119,643	150,769	157,546	501	0.45%
Naugatuck Valley	58.5	42,345	50,645	56,173	960	1.09%
Greater Bridgeport	149.1	156,224	170,489	172,863	1,159	0.14%
South Central	388.4	257,220	301,237	312,598	805	0.38%
Central	166.5	115,358	136,077	136,975	823	0.07%
Capitol	761.0	357,766	430,186	449,338	590	0.45%
Midstate	257.0	46,580	59,618	64,907	253	0.89%
CT River Estuary	204.0	29,342	36,863	42,983	211	1.66%
Southeastern	619.4	107,814	126,176	136,831	221	0.84%
Windham	325.7	30,483	38,199	42,654	131	1.17%
Northeaster	390.3	29,766	37,272	41,694	107	1.19%
Unaffiliated	88.6	5,257	6,777	7,300	82	0.77%
State Total	**5,120.5**	**1,642,857**	**1,963,809**	**2,080,612**	**406**	**0.59%**

Source: Connecticut Department of Motor Vehicles - Class 1 Auto Registrations (Passenger Cars). Projections for years following 2000 are not available. Graphic revised in August 2004.

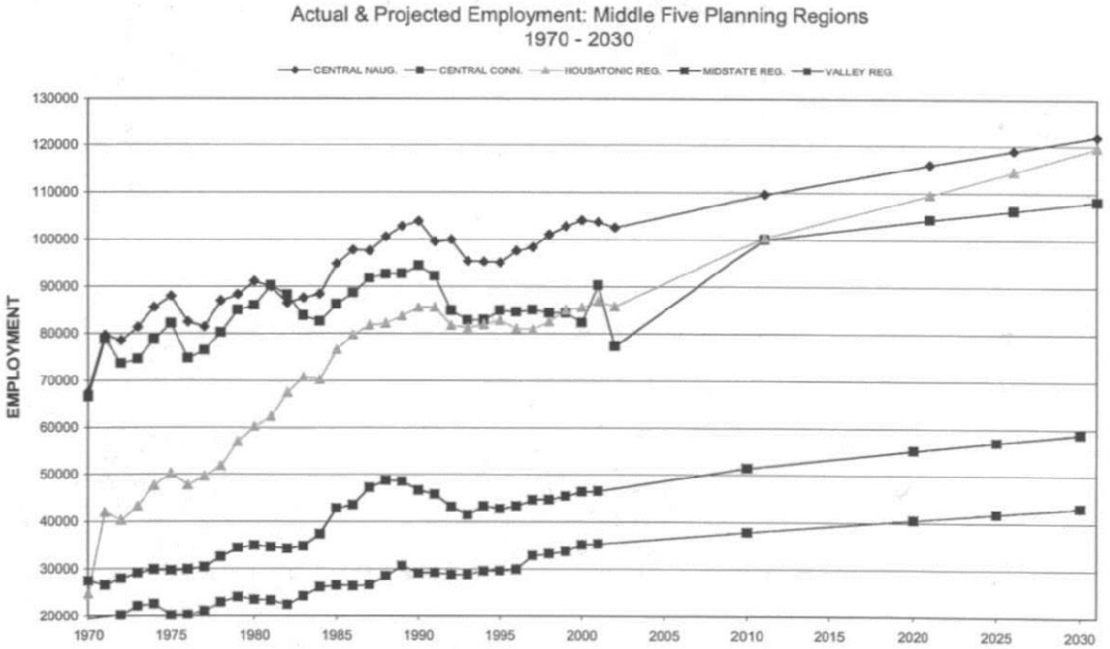
Special Notes: After 2000, the municipality of Union (previously considered unaffiliated) became a part of the Northeastern Planning Region. Also, the procedure to calculate square mileage in 2000 differs from 1990; specifically the methodology regarding water area was revised.

Figure B-1 Employment Growth: Highest Five Planning Region



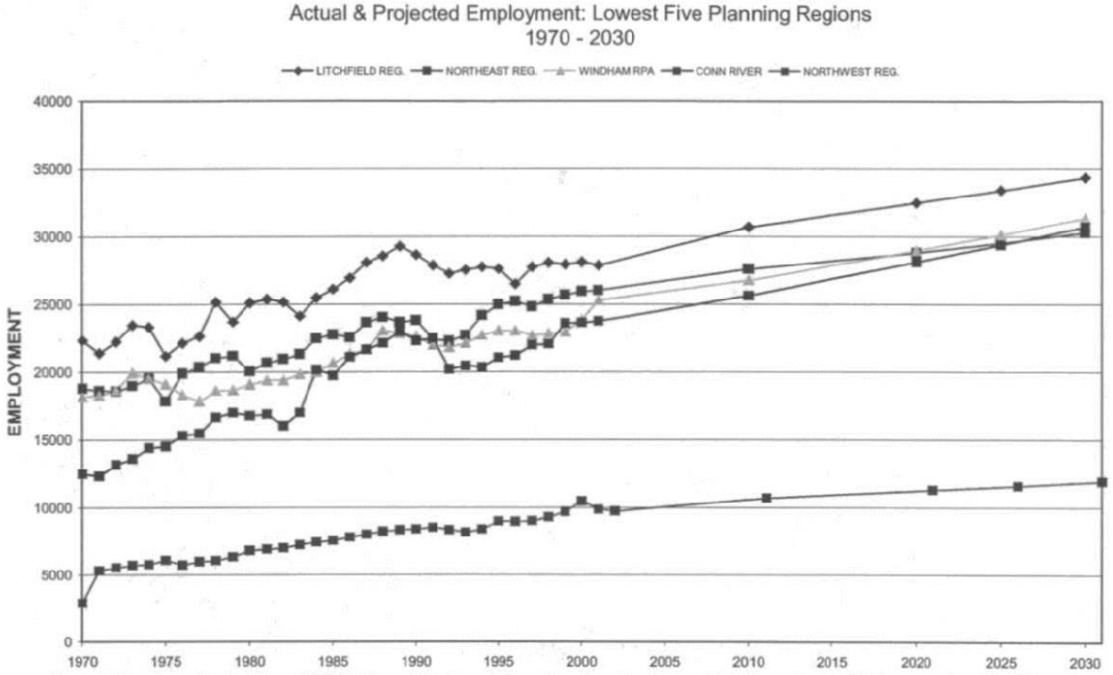
Source: Developed by the ConnDOT Division of Systems Information from the Connecticut Department of Labor reports with 2012 projection and Series 27B Connecticut Department of Transportation Land Use Projections. Graphic revised as of March 2006.
Note: Figures beyond 2005 are projected.

Figure B-2 Employment Growth: Middle Five Planning Regions



Source: Developed by the ConnDOT Division of Systems Information from the Connecticut Department of Labor reports with 2012 projection and Series 27B Connecticut Department of Transportation Land Use Projections. Graphic revised as of March 2006.
Note: Figures beyond 2005 are projected.

Figure B-3 Employment Growth: Lowest Five Planning Regions



Source: Developed by the ConnDOT Division of Systems Information from the Connecticut Department of Labor reports with 2012 projection and Series 27B Connecticut Department of Transportation Land Use Projections. Graphic revised as of March 2006.
Note: Figures beyond 2005 are projected.

Appendix C
Household vs. Establishment Series

APPENDIX C. HOUSEHOLD VS. ESTABLISHMENT SERIES

Table C-1 Household vs. Establishment Series

ITEM	CPS (Household Survey)	CES (Establishment Survey)
BASIC UNIT	Household	Business Establishment
SURVEY METHOD	Interviewers	Mail Out/ Telephone
SURVEY AGENCY	Census Bureau for BLS	SESA's* and BLS
TARGET POPULATION	Persons 16 yrs. and older	UI Covered Establishments
SAMPLE	1,200 CT Households	5,000 CT Establishments
SURVEY PERIOD	Calendar week including the 12th of the month.	Workers, full- or part-time who receive pay during the payroll period that includes the 12th of the month.
DATA COLLECTED	Comprehensive data on the labor force, the employed and unemployed classified by age, sex, race, family relationship, marital status, occupation, and industry attachment.	Industry information on non-farm wage and salary employment, average weekly hours, average hourly earnings, and average weekly earnings for the nation, states, and metropolitan areas.

SOURCE: U.S. Bureau of Labor Statistics (BLS), and CTDOL-Research.

*SESA = State Employment Statistical Agency.

NOTES to Table 1

1. Data from the Current Population Survey (CPS) and the Current Employment Statistics (CES) Survey complement one another, each providing significant types of information that the other cannot suitably supply. Population characteristics, for example, are obtained only from the Household Survey (CPS), whereas detailed industrial classifications are much more reliably derived from Establishment (CES) Reports.

2. Data from these two sources differ from each other because of variations in definitions and coverage, source of information, methods of collection, and estimating procedures. Sampling variability and response errors are additional reasons for discrepancies. The major factors which have a differential effect on the levels and trends of the two series are presented in Table C-2.

Table C-2 Household vs. Establishment Series II

ITEMS	CPS (Household Survey)	CES (Establishment Survey)
COVERAGE	The definition of **employment** comprises *wage and salary workers* (including domestics and other private household workers), self-employed persons, and unpaid workers who worked 15 hours or more during the reference week in family-operated enterprises. Employment in both agricultural and nonagricultural industries is included.	Covers only wage and salary employees on the payrolls of non-farm establishments.
MULTIPLE JOBHOLDING	Provides information on the work status of the population without duplication, since each person is classified as *employed, unemployed*, or *not in the labor force*. Employed persons holding more than one job are only counted once.	Persons who worked in more than one establishment during the reporting period are counted *each time* their names appear on payroll.
UNPAID ABSENCES FROM JOBS	Included among the employed are *all civilians* who had jobs but were not at work during the reference period (i.e., they had jobs, but were not working because they were temporarily absent due to illness, vacation, bad weather, child-care problems, labor-management disputes, or because they were taking time off for various other reasons, even if they were not paid by their employers for their time off.	Persons on leave paid for by the company are included, but those on leave without pay for the entire payroll period are not.

SUMMARY NOTES [21]

Note 1. For each state, the District of Columbia, and U.S. Territories, their Current Employment Statistics (CES) Programs produce monthly estimates of Non-Farm Employment. For the U.S., the U.S. Bureau of Labor Statistics (BLS) produces the national estimates of monthly Non-Farm Employment, based on a national sample of 400,000 establishments. The CES Unit in the Office of Research at the Connecticut Department of Labor produces Connecticut's employment series. The CES takes a probability sample of approximately 5,000 Connecticut business establishments from the population of approximately 100,000 establishments that report wage and employment information to the State. It is stored in the Unemployment Insurance (UI) Tax-Reporting database called the Quarterly Census of Employment and Wages (QCEW), formally known as the ES-202 Program. The CES is a voluntary survey, which is conducted around the

[21] Summary notes were provided by Daniel W. Kennedy, Ph. D., Senior Economist, Office of Research, Connecticut Labor Department, February 2006.

12th of every month. Every March, the CES benchmarks their sample of establishments to the QCEW population frame to account for any changes in the information that occurred between the time the sample was drawn and administered, and when new or updated data was reported and recorded in the UI Tax database. This year's benchmark was more significant than usual. This affected the last Short-Term forecast of Connecticut Employment. This is not unusual when the economy enters a turning point in the business cycle. In fact, many states were affected.

SOURCE NOTE: The texts for Notes 2 and 3, below, are from two articles written by Salvatore A. DiPillo, Research Analyst Supervisor, at CTDOL-Research, and they originally appeared in the ***Connecticut Economic Digest***, and can also be accessed from the CTDOL Web site. The following was obtained from the CT DECD Web site.

Note 2. The redesigned estimation methodology is planned to be implemented with labor force, employment and unemployment estimates for January 2005 to be published in March 2005. Historical series from January 1976 forward will be replaced with estimates based on the redesigned models. Additionally, revised data from 2000 forward will reflect Census population estimates updated to account for changes in births, deaths and migration that have occurred since the decennial Census.

Each month, statistics on the labor force, the employed, and the unemployed are developed as part of the Labor Area Unemployment Statistics (LAUS) program. A major component of the LAUS methodology is data from the Current Population Survey (CPS). The CPS provides information on the labor force status (whether people are employed, unemployed or not in the labor force) of the civilian non-institutional population 16 years of age and over. The CPS is collected each month from a probability sample of between 500 and 600 Connecticut households[22]. The survey period is a calendar week including the 12th day of the month. Each employed person is counted only once, even if they hold more than one job. Multiple jobholders are counted in the job at which they worked the greatest number of hours during the reference week.

The CPS sample includes categories of workers entirely or partly excluded from the ES-202 program: among these are the self-employed, employees of certain nonprofit organizations, and railroad workers. The household survey counts a person only once, and classifies him or her according to the major activity, while the payroll data (CES and ES-202) counts a person who is employed by two or more establishments at each place of employment. As a household survey, the CPS's focus is on individuals, whereas the CES and ES-202 focus on jobs. When providing geographic information, the CPS program tabulates data by the location of the residence; the CES and ES-202 programs provide State and labor market area data by the location of the job. Both labor force and nonfarm employment data are released within one month of the reference period; ES-202 data become available several months after the reference quarter.

The household survey also provides much information on the demographic characteristics (sex, age, and race) of the labor force. (These are available for Connecticut as annual averages in the Bureau of Labor Statistics' publication, Geographic Profile of Employment and Unemployment.) The establishment data provide limited information on personal characteristics of workers;

[22] The Connecticut sample has been doubled to 1,200 households (see Note 3 below).

however, they are excellent sources for detailed industrial and geographic data. In addition, they provide hours and earnings information, which relates directly to the employment figures. The payroll and household surveys thus complement each other.[23]

Note 3. In September 2000, the U.S. Census Bureau expanded the monthly sample for the CPS to meet the requirements of the State Children's Health Insurance Program (SCHIP) legislation. This legislation requires that the Census Bureau improve state estimates of the number of children who live in low-income families and lack health insurance. The expansion of the monthly CPS sample was one part of the Census Bureau's plan for strengthening the SCHIP estimates. The monthly CPS sample was increased in 31 states and the District of Columbia, and the total number of households eligible for the survey rose from about 50,000 nationally to about 60,000. In Connecticut, the CPS sample doubled, from approximately 600 to about 1,200. The additional households were introduced into the survey over a 3-month period beginning in September 2000.

The Bureau of Labor Statistics (BLS) which develops national labor force data and under whose direction the states develop state and local area labor force data, determined that it would not use the additional sample to produce the official labor force estimates prior to the release of July 2001 data in August. This delay would allow for sufficient time to evaluate the differences, if any, between estimates obtained from the current and the expanded household sample. BLS evaluated the monthly data for the nation and states from the two samples and found no statistically significant differences in estimates, nor any unusual effects due to the CPS expansion. The expanded sample results in reductions in the estimated standard deviations for the CPS and model estimates and in actual model prediction errors. Thus, for both national and subnational estimation, the expanded sample will be used beginning with July 2001 estimates. National data is set for release on August 3; Connecticut's data will be available August 17.

With the release of July estimates, revised June state and sub-state labor force estimates also will reflect the expanded sample data. This will allow for the analysis of over-the-month change on a consistent basis. The state and area labor force estimates for January through May will not be revised at that time. Rather, the January - May expanded sample will be incorporated into the labor force estimates as part of the annual benchmarking of 2001 data. These data will be made available in March 2002.

Based on results for the early months of the year, the larger CPS sample in Connecticut is likely to produce higher unemployment rates than originally estimated for those months, with the number of residents employed somewhat lower and the number of unemployed higher. The experience of the other affected states was mixed, some with higher rates and others with lower rates or no change. It is important to keep in mind that the revised labor force estimates for June 2001 and following months at both state and substate levels will not be directly comparable to

[23] DiPillo, Salvatore A., ***Defining Employment*** (May 1999), CT Department of Economic and Community Development Website (http://www.ct.gov/ecd/cwp/view.asp?A=1106&Q=250976), Accessed January 19, 2006

those of earlier periods; comparisons should not be made without acknowledging the potential effect the differing sample sizes may have on the data[24].

Note 4. Since the U.S. Census carries out the Decennial Census on April 1st, the employment levels for the decennial years are the result of averaging together the employment levels for March and April, one month on either side of April 1st. Both the establishment-based Non-Farm Employment Series and the household-based residence employment series calculate average annual employment by summing the 12 months' levels of employment, and then dividing by 12.

[24] DiPillo, Salvatore A., ***Expanded Current Population Survey and its Effect on Labor Force Data Estimates*** (August 2001), CT Department of Economic and Community Development Web site (http://www.ct.gov/ecd/cwp/view.asp?A=1106&Q=250976), Accessed Janu19, 2006.

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Staff Contact:

Roxane M. Fromson

Transportation Supervising Planner

roxane.fromson@po.state.ct.us

EXHIBIT 23

Obesity Education Initiative

Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults

The Evidence Report

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NATIONAL INSTITUTES OF HEALTH
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

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Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults

The Evidence Report

NIH Publication
No. 98-4083
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National Institutes of Health

National Heart, Lung, and Blood Institute in cooperation with The National Institute of Diabetes and Digestive and Kidney Diseases

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NHLBI Obesity Education Initiative Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults

F. Xavier Pi-Sunyer, M.D., M.P.H.
Chair of the Panel
Chief, Endocrinology, Diabetes, and Nutrition
Director, Obesity Research Center
St. Luke's/Roosevelt Hospital Center
Professor of Medicine
Columbia University College of Physicians and Surgeons
New York, NY

Diane M. Becker, Sc.D., M.P.H.
Director
Center for Health Promotion
Associate Professor
Department of Medicine
The Johns Hopkins University
Baltimore, MD

Claude Bouchard, Ph.D.
Professor of Exercise Physiology
Physical Activity Sciences Laboratory
Laval University
Sainte Foy, Quebec
CANADA

Richard A. Carleton, M.D.
Professor of Medicine
Brown University School of Medicine
Pawtucket, RI

Graham A. Colditz, M.D., Dr.P.H.
Associate Professor of Medicine
Harvard Medical School
Channing Laboratory
Boston, MA

William H. Dietz, M.D., Ph.D.
Director
Division of Nutrition and Physical Activity
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Atlanta, GA

John P. Foreyt, Ph.D.
Professor of Medicine and Director
Nutrition Research Clinic
Baylor College of Medicine
Houston, TX

Robert J. Garrison, Ph.D.
Associate Professor
Department of Preventive Medicine
University of Tennessee, Memphis
Memphis, TN

Scott M. Grundy, M.D., Ph.D.
Director
Center for Human Nutrition
University of Texas
Southwestern Medical Center at Dallas
Dallas, TX

Barbara C. Hansen, Ph.D.
Professor of Physiology
Director of Obesity and Diabetes Research Center
University of Maryland School of Medicine
Baltimore, MD

Millicent Higgins, M.D.
Department of Epidemiology
School of Public Health
University of Michigan
Ann Arbor, MI

Archive for Historical Reference Only

James O. Hill, Ph.D.
Associate Director of Research
Center for Human Nutrition
University of Colorado Health Sciences Center
Denver, CO

Barbara V. Howard, Ph.D.
President
Medlantic Research Institute
Washington, DC

Robert C. Klesges, Ph.D.
Professor
University of Memphis Prevention Center
University of Memphis
Memphis, TN

Robert J. Kuczmarski, Dr.P.H., R.D.
Nutrition Analyst
National Center for Health Statistics
Centers for Disease Control and Prevention
Hyattsville, MD

Shiriki Kumanyika, Ph.D., R.D., M.P.H.
Professor and Head
Department of Human Nutrition and Dietetics
The University of Illinois at Chicago
Chicago, IL

R. Dee Legako, M.D.
Prime Care Canyon Park Family Physicians, Inc.
Edmond, OK

T. Elaine Prewitt, Dr.P.H., R.D.
Assistant Professor
Department of Preventive Medicine and Epidemiology
Loyola University Medical Center
Maywood, IL

Albert P. Rocchini, M.D.
Chief of Cardiology
University of Michigan Medical Center
Ann Arbor, MI

Philip L. Smith, M.D.
Professor of Medicine
Division of Pulmonary and Critical Care Medicine
The Johns Hopkins Asthma and Allergy Center
Baltimore, MD

Linda G. Snetselaar, Ph.D., R.D.
Associate Professor
Head of Preventive Nutrition Education
Department of Preventive Medicine
University of Iowa
Iowa City, IA

James R. Sowers, M.D.
Professor of Medicine and Physiology
Director
Division of Endocrinology, Metabolism, and Hypertension
Wayne State University School of Medicine
University Health Center
Detroit, MI

Michael Weintraub, M.D.
Director
Office of Drug Evaluation V
Food and Drug Administration
Rockville, MD

David F. Williamson, Ph.D., M.S.
Epidemiologist
Division of Diabetes Translation
Centers for Disease Control and Prevention
Chamblee, GA

Archive
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G. Terence Wilson, Ph.D.
Oscar K. Buros Professor of Psychology
Director, Rutgers Eating Disorders Clinic
Piscataway, NJ

Ex-Officio Members

Clarice D. Brown, M.S.
Project Manager
CODA Research, Inc.
Silver Spring, MD

Karen A. Donato, M.S., R.D.*
Executive Director of the Panel
Coordinator
NHLBI Obesity Education Initiative
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, MD

Nancy Ernst, Ph.D., R.D.*
Nutrition Coordinator
Office of the Director
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, MD

D. Robin Hill, Ph.D.*
Social Science Analyst
Behavioral Medicine Branch
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, MD

Michael J. Horan, M.D., Sc.M.*
Director
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, MD

Van S. Hubbard, M.D., Ph.D.
Director, NIH Division of Nutrition Research Coordination
Chief, Nutritional Sciences Branch
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, MD

James P. Kiley, Ph.D.*
Director
Airway Biology and Disease Program
Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, MD

Eva Obarzanek, Ph.D., R.D., M.P.H.*
Research Nutritionist
Prevention Scientific Research Group
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, MD

Consultant

David Schriger, M.D., M.P.H., F.A.C.E.P.
Associate Professor
UCLA Emergency Medicine Center
University of California at Los Angeles
School of Medicine
Los Angeles, CA

San Antonio Cochrane Center

Elaine Chiquette, Pharm.D.
V.A. Cochrane Center at San Antonio
Audie L. Murphy Memorial Veterans Hospital
San Antonio, TX

* NHLBI Obesity Education Initiative Task Force Members

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Cynthia Mulrow, M.D., M.Sc.
V.A. Cochrane Center at San Antonio
Audie L. Murphy Memorial Veterans Hospital
San Antonio, TX

Staff

Adrienne Blount, B.S.
R.O.W. Sciences, Inc.
Rockville, MD

Maureen Harris, M.S., R.D.
R.O.W. Sciences, Inc.
Rockville, MD

Anna Hodgson, M.A.
R.O.W. Sciences, Inc.
Rockville, MD

Pat Moriarty, M.Ed., R.D.
R.O.W. Sciences, Inc.
Rockville, MD

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The panel acknowledges the assistance of Dr. Rashid Chotani, Johns Hopkins University; Dr. Robert Klesges, University of Memphis; Dr. Walter Pories, East Carolina University; Dr. Ivan Baines, NHLBI; Dr. Christine Kelly, NHLBI; Glen Bennett, NHLBI; Dr. Fred Heydrick, BioReview; Debbie Lurie, Prospect Associates; Estelle Schwalb, Prospect Associates; Lori McCray, R.O.W. Sciences, Inc.; and Niyati Pandya, R.O.W. Sciences, Inc.

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FOREWORD

In 1995, the National Obesity Education Initiative of the National Heart, Lung, and Blood Institute (NHLBI), in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), convened the first Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults to develop clinical practice guidelines for primary care practitioners.

The impetus for these guidelines was the recognition that the prevalence of overweight and obesity in the United States is increasing, and that practitioners need to be alerted to the accompanying health risks. According to the latest statistics from the third National Health and Nutrition Examination Survey, 97 million Americans are overweight or obese. Excess weight is often accompanied by high blood pressure, high blood cholesterol, type 2 diabetes, coronary heart disease, and other health problems. The total costs attributable to obesity-related disease approach $100 billion annually in the United States.

The panel used the principles of evidence-based medicine, including an evidence model and evidence categories. It was the first time a panel thoroughly examined the scientific evidence for risks associated with overweight and obesity, and their treatments, and developed clinical practice recommendations based on their conclusions.

The panel was headed by Dr. F. Xavier Pi-Sunyer, of St. Luke's/Roosevelt Hospital Center in New York City. He and the other 23 panel members methodically and critically examined a vast amount of published scientific evidence. The panel also obtained scientific input from approximately 115 outside reviewers. The result was *The Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report.* Dr. David Schriger of the University of California at Los Angeles, who is a methodologist consultant in the area of evidence-based practice guidelines, and Dr. Elaine Chiquette of the San Antonio Cochrane Center in Texas, who developed the evidence tables, served as key advisors to the panel.

Evidence examined by the panel included: research on the relationship of overweight and obesity to high blood pressure, high blood cholesterol, type 2 diabetes, stroke, congestive heart failure, coronary heart disease, various cancers, osteoarthritis, and sleep apnea; risks associated with the distribution and amount of body fat; and various treatment strategies, including diet, physical activity, behavior therapy, pharmacotherapy, and surgery. The resulting guidelines document how different treatment strategies affect weight loss and how weight control affects the major risk factors for heart disease and stroke.

The guidelines have been reviewed and endorsed by many professional organizations. In fact, because of the associated risks between high blood pressure and high blood cholesterol and overweight and obesity, the document represents

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the first clinical practice guidelines to be reviewed and endorsed by members of the coordinating committees of both the National Cholesterol Education Program and the National High Blood Pressure Education Program which comprise approximately 52 professional societies, government agencies, and consumer organizations. Two additional groups endorsing the guidelines are the North American Association for the Study of Obesity and the NIDDK National Task force on the Prevention and Treatment of Obesity.

The report, the evidence model and its accompanying evidence tables, and a body mass index calculator are available on the NHLBI website at the following location: http://www.nhlbi.nih.gov./nhlbi/cardio/obes/prof/guidelns/ob_home.htm

An abbreviated version of the evidence report is being prepared and will be distributed to primary care physicians, nurses, registered dietitians and nutritionists, and other health care practitioners.

It is our hope that these clinical guidelines will not only help the health care practitioner understand the importance of weight management but also provide them with the tools to assess and treat their patients more effectively. Equally important, we hope that the guidelines lead to a greater public understanding of obesity and a greater appreciation for the persistent efforts of millions of people to lose weight.

Claude Lenfant, M.D.
Director
National Heart, Lung, and Blood Institute

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Evidence Report Endorsements

NATIONAL CHOLESTEROL EDUCATION PROGRAM (NCEP)

Coordinating Committee Member Organizations

Theodore G. Ganiats, M.D., *American Academy of Family Physicians,* Gary Graham, M.D., *American Academy of Insurance Medicine,* Ronald Kleinman, M.D., *American Academy of Pediatrics,* Ann Smith, R.N., C.O.H.N.-S., *American Association of Occupational Health Nurses,* Richard C. Pasternak, M.D., F.A.C.C., *American College of Cardiology,* Gerald T. Gau, M.D., *American College of Chest Physicians,* Ruth Ann Jordan, M.D., *American College of Occupational and Environmental Medicine,* Thomas E. Nolan, M.D., *American College of Obstetricians and Gynecologists,* Alan J. Garber, M.D., Ph.D., *American Diabetes Association, Inc.,* Linda Van Horn, Ph.D., R.D., *American Dietetic Association,* Scott Grundy, M.D., Ph.D., *American Heart Association,* Sandra Cornett, R.N., Ph.D., *American Hospital Association,* Yank D. Coble, Jr., M.D., *American Medical Association,* Joan Watson, R.N., Ph.D., F.A.A.N., *American Nurses' Association,* Michael Clearfield, D.O., *American Osteopathic Association,* Joanne Mitten, M.H.E., *Association of State and Territorial Health Officials,* Gerald J. Wilson, M.B.A., *Citizens for Public Action on Blood Pressure and Cholesterol, Inc.,* Linda Burnes-Bolton, Dr.P.H., R.N., *National Black Nurses' Association, Inc.,* Luther T. Clark, M.D., *National Medical Association,* Darlene Lansing, M.P.H., R.D., *Society for Nutrition Education*

Associate Member Coordinating Committee Organizations

Stanley Wallach, M.D., *American College of Nutrition,* Donald O. Fedder, Dr.P.H., M.P.H., *Society for Public Health Education*

Federal Agency Liaison Coordinating Committee Representatives

Yvonne L. Bronner, Sc.D., R.D., L.D., *NHLBI Ad Hoc Committee on Minority Populations,* Francis D. Chesley, M.D., *Agency for Health Care Policy and Research,* William H. Dietz, M.D., Ph.D., *Centers for Disease Control and Prevention,* Thomas M. Lasater, Ph.D., *Coordinating Committee for the Community Demonstration Studies,* Alanna Moshfegh, M.S., R.D., *Department of Agriculture,* Col. Michael Parkinson, M.D., M.P.H., *Department of Defense,* Pamela Steele, M.D., *Department of Veterans Affairs,* Celia Hayes, M.P.H., R.D., *Health Resources and Services Administration,* Clifford Johnson, M.P.H., *National Center for Health Statistics,* Linda Meyers, Ph.D., *Office of Disease Prevention and Health Promotion*

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM (NHBPEP)

Coordinating Committee Member Organizations

Lee A. Green, M.D., M.P.H., *American Academy of Family Physicians,* Jack P. Whisnant, M.D., *American Academy of Neurology,* Barry N. Hyman, M.D., F.A.C.P., *American Academy of Ophthalmology,* Lisa Mustone-Alexander, M.P.H., P.A., *American Academy of Physician Assistants,* Henry Guevara, B.S.N., R.N., C.O.H.N.-S., *American Association of Occupational Health Nurses,* Edward D. Frohlich, M.D., *American College of Cardiology,* Sheldon G. Sheps, M.D., *American College of Chest Physicians,* Ron Stout, M.D., *American College of Occupational and Environmental Medicine,* Jerome D. Cohen, M.D., *American College of Physicians,* Carlos Vallbona, M.D., *American College of Preventive Medicine,* James R. Sowers, M.D., *American Diabetes Association, Inc.,* Mary C. Winston, Ed.D., R.D., *American Dietetic Association,* Daniel W. Jones, M.D., *American Heart Association,* Roxane Spitzer, Ph.D., F.A.A.N., *American Hospital Association,* Nancy Houston Miller, B.S.N., *American Nurses' Association,* Linda Casser, O.D., *American Optometric Association,* William A. Nickey, D.O., *American Osteopathic Association,* Raymond W. Roberts, Pharm.D., *American Pharmaceutical Association,* Pamela J. Colman, D.P.M., *American Podiatric Medical Association,* Nancy McKelvey, M.S.N., R.N., *American Red Cross,* Barry L. Carter, Pharm.D., F.C.C.P., *American Society of Health-System Pharmacists,* Norman M. Kaplan, M.D., *American Society of Hypertension,* Jackson T. Wright, M.D., Ph.D., *Association of Black Cardiologists,* Gerald J. Wilson, M.B.A., *Citizens for Public Action on Blood Pressure and Cholesterol, Inc.,* Joseph L. Izzo, Jr., M.D., *Council on Geriatric Cardiology,* James W. Reed, M.D., F.A.C.P., F.A.C.E., *International Society on Hypertension in Blacks,* Rita Strickland, Ed.D., R.N., *National Black Nurses' Association, Inc.,* William Manger, M.D., Ph.D., *National Hypertension Association, Inc.,* Murray Epstein, M.D., *National Kidney Foundation, Inc.,* Otelio S. Randall, M.D., F.A.C.C., *National Medical Association,* Edwin Marshall, O.D., M.P.H., *National Optometric Association,* Harold W. "Pete" Todd, *National Stroke Association,* Kathryn M. Kolasa, Ph.D., R.D., L.D.N., *Society for Nutrition Education*

Federal Agency Liaison Coordinating Committee Representatives

Keith Ferdinand, M.D., F.A.C.C., *NHLBI Ad Hoc Committee on Minority Populations,* Francis D. Chesley, M.D., *Agency for Health Care Policy and Research,* H. Mitchell Perry, Jr., M.D., *Department of Veterans Affairs,* Jay Merchant, M.H.A., *Health Care Financing Administration,* Vicki Burt, R.N., Sc.M., *National Center for Health Statistics,* Elizabeth H. Singer, M.S., *National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)*

NIDDK NATIONAL TASK FORCE ON THE PREVENTION AND TREATMENT OF OBESITY

NORTH AMERICAN ASSOCIATION FOR THE STUDY OF OBESITY (NAASO)

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Executive Summary

Introduction

An estimated 97 million adults in the United States are overweight or obese, a condition that substantially raises their risk of morbidity from hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and endometrial, breast, prostate, and colon cancers. Higher body weights are also associated with increases in all-cause mortality. Obese individuals may also suffer from social stigmatization and discrimination. As a major contributor to preventive death in the United States today, overweight and obesity pose a major public health challenge.

Overweight is here defined as a body mass index (BMI) of 25 to 29.9 kg/m^2 and obesity as a BMI of ≥ 30 kg/m^2. However, overweight and obesity are not mutually exclusive, since obese persons are also overweight. A BMI of 30 is about 30 lb overweight and equivalent to 221 lb in a 6'0" person and to 186 lb in one 5'6". The number of overweight and obese men and women has risen since 1960; in the last decade the percentage of people in these categories has increased to 54.9 percent of adults age 20 years or older. Overweight and obesity are especially evident in some minority groups, as well as in those with lower incomes and less education.

Obesity is a complex multifactorial chronic disease that develops from an interaction of genotype and the environment. Our understanding of how and why obesity develops is incomplete, but involves the integration of social, behavioral, cultural, physiological, metabolic and genetic factors.

While there is agreement about the health risks of overweight and obesity, there is less agreement about their management. Some have argued against treating obesity because of the difficulty in maintaining long-term weight loss and of potentially negative consequences of the frequently seen pattern of weight cycling in obese subjects. Others argue that the potential hazards of treatment do not outweigh the known hazards of being obese. The intent of these guidelines is to provide evidence for the effects of treatment on overweight and obesity. The guidelines focus on the role of the primary care practitioner in treating overweight and obesity.

Evidence-Based Guidelines

To evaluate published information and to determine the most appropriate treatment strategies that would constitute evidence-based clinical guidelines on overweight and obesity for physicians and associated health professionals in clinical practice, health care policy makers, and clinical investigators, the National Heart, Lung, and Blood Institute's Obesity Education Initiative in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases convened the Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults in May 1995. The guidelines are based on a systematic review of the published scientific literature found in MEDLINE from January 1980 to September 1997 of topics identified by the panel as key to extrapolating the data related to the obesity evidence model.

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Evidence from approximately 394 randomized controlled trials (RCTs) was considered by the panel.

The panel is comprised of 24 members, 8 ex-officio members, and a methodologist consultant. Areas of expertise contributed to by panel members included primary care, epidemiology, clinical nutrition, exercise physiology, psychology, physiology, and pulmonary disease. There were five meetings of the full panel and two additional meetings of the executive committee comprised of the panel chair and four panel members.

The San Antonio Cochrane Center assisted the panel in the literature abstraction and in organizing the data into appropriate evidence tables. The center pretested and used a standardized 25-page form or "Critical Review Status Sheet" for the literature abstraction. Ultimately, 236 RCT articles were abstracted and the data were then compiled into individual evidence tables developed for each RCT. The data from these RCTs served as the basis for many of the recommendations contained in the guidelines.

The panel determined the criteria for deciding on the appropriateness of an article. At a minimum, studies had to have a time frame from start to finish of at least 4 months. The only exceptions were a few 3-month studies related to dietary therapy and pharmacotherapy. To consider the question of long-term maintenance, studies with outcome data provided at approximately 1 year or longer were examined. Excluded were studies in which self-reported weights by subjects were the only indicators used to measure weight loss. No exclusions of studies were made by study size. The panel weighed the evidence based on a thorough examination of the threshold or magnitude of the treatment effect. Each evidence statement (other than those with no available evidence) and each recommendation is categorized by a level of evidence which ranges from A to D. Table ES-1 summarizes the categories of evidence by their source and provides a definition for each category.

- **Who is at Risk?** All overweight and obese adults (age 18 years of age or older) with a BMI of ≥25 are considered at risk for developing associated morbidities or diseases such as hypertension, high blood cholesteral, type 2 diabetes, coronary heart disease, and other diseases. Individuals with a BMI of 25 to 29.9 are considered overweight, while individuals with a BMI ≥30 are considered obese. Treatment of overweight is recommended only when patients have two or more risk factors or a high waist circumference. It should focus on altering dietary and physical activity patterns to prevent development of obesity and to produce moderate weight loss. Treatment of obesity should focus on producing substantial weight loss over a prolonged period. The presence of comorbidities in overweight and obese patients should be considered when deciding on treatment options.
- **Why Treat Overweight and Obesity?** Obesity is clearly associated with increased morbidity and mortality. There is strong evidence that weight loss in overweight and obese individuals reduces risk factors for diabetes and cardiovascular disease (CVD). Strong evidence exists that weight loss reduces blood pressure in both overweight hypertensive and nonhypertensive individuals; reduces serum triglycerides and increases high-density lipoprotein (HDL)-cholesterol; and generally produces some reduction in total serum cholesterol and low-density lipoprotein (LDL)-cholesterol. Weight loss reduces blood glucose levels in overweight and obese persons without diabetes; and weight loss also reduces blood glucose levels and HbA_{1c} in some patients with type 2 diabetes. Although there have been no prospective trials to show changes in mortality with weight loss in obese patients, reductions in risk factors would suggest that develop-

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Table ES-1:

Evidence Categories

Evidence Category	Sources of Evidence	Definition
A	Randomized controlled trials (rich body of data)	Evidence is from endpoints of well-designed RCTs (or trials that depart only minimally from randomization) that provide a consistent pattern of findings in the population for which the recommendation is made. Category A therefore requires substantial numbers of studies involving substantial numbers of participants.
B	Randomized controlled trials (limited body of data)	Evidence is from endpoints of intervention studies that include only a limited number of RCTs, post hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, and the trial results are somewhat inconsistent, or the trials were undertaken in a population that differs from the target population of the recommendation.
C	Nonrandomized trials Observational studies	Evidence is from outcomes of uncontrolled or nonrandomized trials or from observational studies.
D	Panel Consensus Judgment	Expert judgment is based on the panel's synthesis of evidence from experimental research described in the literature and/or derived from the consensus of panel members based on clinical experience or knowledge that does not meet the above-listed criteria. This category is used only in cases where the provision of some guidance was deemed valuable but an adequately compelling clinical literature addressing the subject of the recommendation was deemed insufficient to justify placement in one of the other categories (A through C).

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ment of type 2 diabetes and CVD would be reduced with weight loss.

- **What Treatments Are Effective?** A variety of effective options exist for the management of overweight and obese patients, including dietary therapy approaches such as low-calorie diets and lower-fat diets; altering physical activity patterns; behavior therapy techniques; pharmacotherapy*; surgery; and combinations of these techniques.

Clinical Guidelines

Treatment of the overweight or obese patient is a two-step process: assessment and treatment management. Assessment requires determination of the degree of overweight and overall risk status. Management includes both reducing excess body weight and instituting other measures to control accompanying risk factors.

Assessment: When assessing a patient for risk status and as a candidate for weight loss therapy, consider the patient's BMI, waist circumference, and overall risk status. Consideration also needs to be given to the patient's motivation to lose weight.

- **Body Mass Index.** The BMI, which describes relative weight for height, is significantly correlated with total body fat content. The BMI should be used to assess overweight and obesity and to monitor changes in body weight. In addition, measurements of body weight alone can be used to determine efficacy of weight loss therapy. BMI is calculated as weight (kg)/height squared (m^2). To estimate BMI using pounds and inches, use: [weight (pounds)/height (inches)^2] x 703. Weight classifications by BMI, selected for use in this report, are shown in Table ES-2. A conversion table of heights and weights resulting in selected BMI units is provided in Table ES-3.
- **Waist Circumference.** The presence of excess fat in the abdomen out of proportion to total body fat is an independent predictor of risk factors and morbidity. Waist circumference is positively correlated with abdominal fat content. It provides a clinically acceptable measurement for assessing a patient's abdominal fat content before and during weight loss treatment. The sex-specific cutoffs noted on the next page can be used to identify

TABLE ES-2:

CLASSIFICATION OF OVERWEIGHT AND OBESITY BY BMI

	Obesity Class	BMI (kg/m^2)
Underweight		< 18.5
Normal		18.5 – 24.9
Overweight		25.0 – 29.9
Obesity	I	30.0 – 34.9
	II	35.0 – 39.9
Extreme Obesity	III	≥ 40

* As of September 1997, the Food and Drug Administration (FDA) requested the voluntary withdrawal from the market of dexfenfluramine and fenfluramine due to a reported association between valvular heart disease and the use of dexfenfluramine or fenfluramine alone or combined with phentermine. The use of these drugs for weight reduction, therefore, is not recommended in this report. Sibutramine is approved by FDA for long-term use. It has limited but definite effects on weight loss and can facilitate weight loss maintenance (Note: FDA approval for orlistat is pending a resolution of labeling issues and results of Phase III trials.)

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HIGH RISK

Men > 102 cm (> 40 in)

Women > 88 cm (> 35 in)

increased relative risk for the development of obesity-associated risk factors in most adults with a BMI of 25 to 34.9 kg/m^2:

These waist circumference cutpoints lose their incremental predictive power in patients with a BMI ≥ 35 kg/m^2 because these patients will exceed the cutpoints noted above. Table ES-4 adds the disease risk of increased abdominal fat to the disease risk of BMI. These categories denote *relative* risk, not *absolute* risk; that is, relative to risk at normal weight. They should not be equated with absolute risk, which is determined by a summation of risk factors. They relate to the need to institute weight loss therapy and do not directly define the required intensity of modification of risk factors associated with obesity.

- **Risk Status.** Assessment of a patient's absolute risk status requires examination for the presence of:

  Disease conditions: established coronary heart disease (CHD), other atherosclerotic diseases, type 2 diabetes, and sleep apnea; patients with these conditions are classified as being at very high risk for disease complications and mortality.

  Other obesity-associated diseases: gynecological abnormalities, osteoarthritis, gallstones and their complications, and stress incontinence.

  Cardiovascular risk factors: cigarette smoking, hypertension (systolic blood pressure ≥ 140 mm Hg or diastolic blood pressure ≥ 90 mm Hg, or the patient is taking antihypertensive agents), high-risk LDL-cholesterol (≥ 160 mg/dL), low HDL-cholesterol (< 35 mg/dL), impaired fasting glucose (fasting plasma glucose of 110 to 125 mg/dL), family history of premature CHD (definite myocardial infarction or sudden death at or before 55 years of age in father or other male first-degree relative, or at or before 65 years of age in mother or other female first-degree relative), and age (men ≥ 45 years and women ≥ 55 years or postmenopausal). Patients can be classified as being at high absolute risk if they have three of the aforementioned risk factors. Patients at high absolute risk usually require clinical management of risk factors to reduce risk.

  Patients who are overweight or obese often have other cardiovascular risk factors. Methods for estimating *absolute risk* status for developing cardiovascular disease based on these risk factors are described in detail in the National Cholesterol Education Program's *Second Report of the Expert Panel on the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* (NCEP's ATP II) and the *Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC VI). The intensity of intervention for cholesterol disorders or hypertension is adjusted according to the absolute risk status estimated from multiple risk correlates. These include both the risk factors listed above and evidence of end-organ damage present in hypertensive patients. Approaches to therapy for cholesterol disorders and hypertension are described in ATP II and JNC VI, respectively. In overweight patients, control of cardiovascular risk factors deserves equal emphasis as weight reduction therapy. Reduction of risk factors will reduce the risk for cardiovascular disease whether or not efforts at weight loss are successful.

  Other risk factors: physical inactivity and high serum triglycerides (> 200 mg/dL). When these factors are present, patients can

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Table ES-3:

Selected BMI Units Categorized by Inches (cm) and pounds (kg)

	Body weight in pounds (kg)		
Height in inches (cm)	BMI 25 kg/m²	BMI 27 kg/m²	BMI 30 kg/m²
58 (147.32)	119 (53.98)	129 (58.51)	143 (64.86)
59 (149.86)	124 (56.25)	133 (60.33)	148 (67.13)
60 (152.40)	128 (58.06)	138 (62.60)	153 (69.40)
61 (154.94)	132 (59.87)	143 (64.86)	158 (71.67)
62 (157.48)	136 (61.69)	147 (66.68)	164 (74.39)
63(160.02)	141 (63.96)	152 (68.95)	169 (76.66)
64 (162.56)	145 (65.77)	157 (71.21)	174 (78.93)
65 (165.10)	150 (68.04)	162 (73.48)	180 (81.65)
66 (167.64)	155 (70.31)	167 (75.75)	186 (84.37)
67 (170.18)	159 (72.12)	172 (78.02)	191 (86.64)
68 (172.72)	164 (74.39)	177 (80.29)	197 (89.36)
69 (175.26)	169 (76.66)	182 (82.56)	203 (92.08)
70 (177.80)	174 (78.93)	188 (85.28)	207 (93.89)
71 (180.34)	179 (81.19)	193 (87.54)	215 (97.52)
72 (182.88)	184 (83.46)	199 (90.27)	221 (100.25)
73 (185.42)	189 (85.73)	204 (92.53)	227 (102.97)
74 (187.96)	194 (88.00)	210 (95.26)	233 (105.69)
75 (190.50)	200 (90.72)	216 (97.98)	240 (108.86)
76 (193.04)	205 (92.99)	221(100.25)	246 (111.58)

Metric conversion formula = weight (kg)/height (m)²

Example of BMI calculation:
A person who weighs 78.93 kilograms and is 177 centimeters tall has a BMI of 25:

weight (78.93 kg)/height (1.77 m)² = 25

Non-metric conversion formula = [weight (pounds)/height (inches)²] x 703

Example of BMI calculation:
A person who weighs 164 pounds and is 68 inches (or 5' 8") tall has a BMI of 25:

[weight (164 pounds)/height (68 inches)²] x 703 = 25

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be considered to have incremental absolute risk above that estimated from the preceding risk factors. Quantitative risk contribution is not available for these risk factors, but their presence heightens the need for weight reduction in obese persons.

- **Patient Motivation.** When assessing the patient's motivation to enter weight loss therapy, the following factors should be evaluated: reasons and motivation for weight reduction; previous history of successful and unsuccessful weight loss attempts; family, friends, and work-site support; the patient's understanding of the causes of obesity and how obesity contributes to several diseases; attitude toward physical activity; capacity to engage in physical activity; time availability for weight loss intervention; and financial considerations. In addition to considering these issues, the health care practitioner needs to heighten a patient's motivation for weight loss and prepare the patient for treatment. This can be done by enumerating the dangers accompanying persistent obesity and by describing the strategy for clinically assisted weight reduction. Reviewing the patients' past attempts at weight loss and explaining how the new treatment plan will be different can encourage patients and provide hope for successful weight loss.

Evaluation and Treatment: The general goals of weight loss and management are: (1) at a minimum, to prevent further weight gain; (2) to reduce body weight; and (3) to maintain a lower body weight over the long term. The overall strategy for the evaluation and treatment of overweight and obese patients is presented in the Treatment Algorithm on the next page. This algorithm applies only to the assessment for overweight and obesity and subsequent decisions

Table ES-4:

CLASSIFICATION OF OVERWEIGHT AND OBESITY BY BMI, WAIST CIRCUMFERENCE AND ASSOCIATED DISEASE RISK*

			Disease Risk* Relative to Normal Weight and Waist Circumference	
	BMI (kg/m²)	Obesity Class	Men ≤ 102 cm (≤ 40 in) Women ≤ 88 cm (≤ 35 in)	> 102 cm (> 40 in) > 88 cm (> 35 in)
Underweight	<18.5		—	—
Normal+	18.5 –24.9		—	—
Overweight	25.0 – 29.9		Increased	High
Obesity	30.0 – 34.9	I	High	Very High
	35.0 – 39.9	II	Very High	Very High
Extreme Obesity	≥40	III	Extremely High	Extremely High

* Disease risk for type 2 diabetes, hypertension, and CVD.

\+ Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

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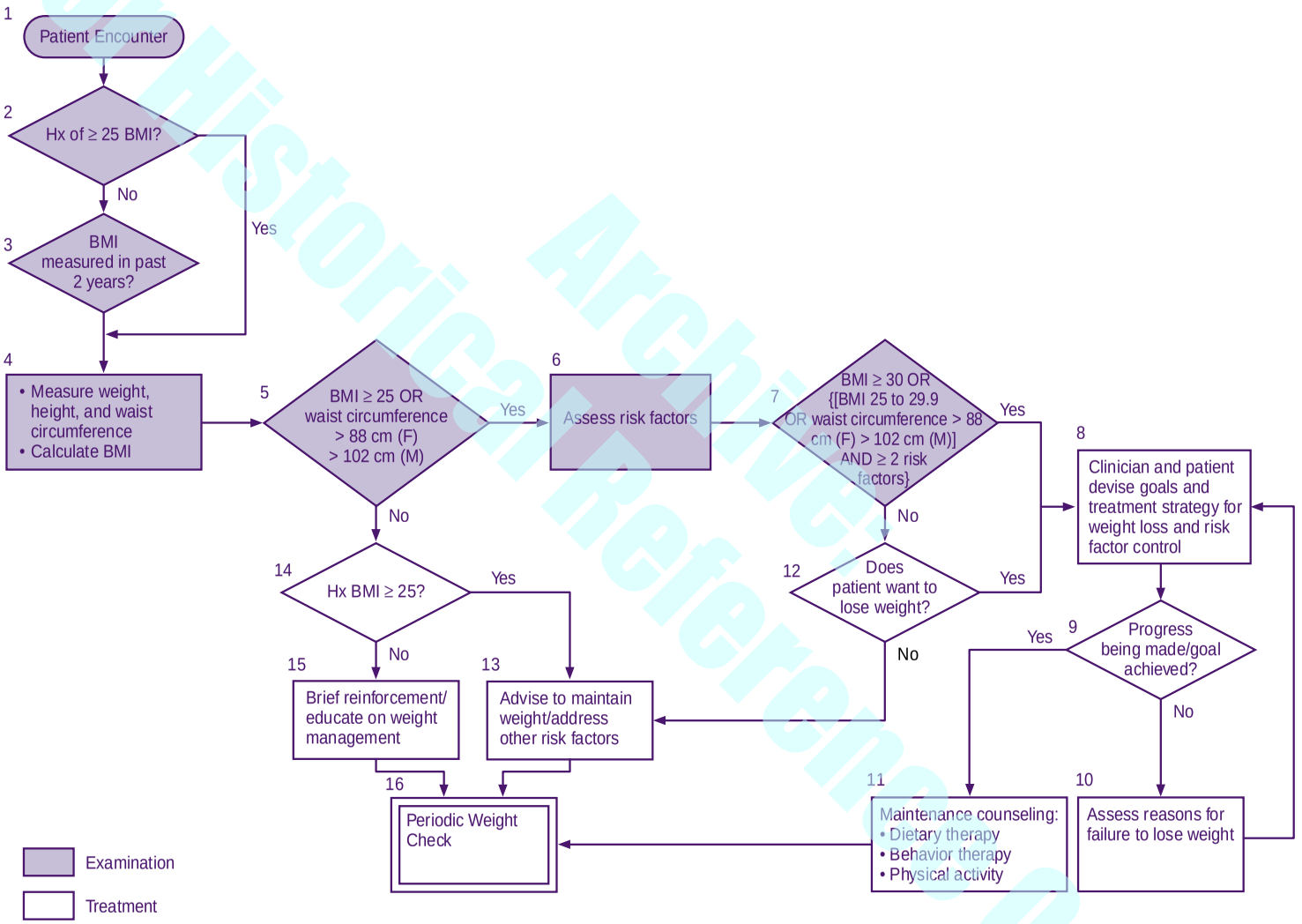
Treatment Algorithm*



* This algorithm applies only to the assessment for overweight and obesity and subsequent decisions based on that assessment. It does not include any initial overall assessment for cardiovascular risk factors or diseases that are indicated.

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based on that assessment. It does not include any initial overall assessment for cardiovascular risk factors or diseases that are indicated.

■ **Goals of Weight Loss and Management.**

The *initial goal* of weight loss therapy is to reduce body weight by approximately 10 percent from baseline. If this goal is achieved, further weight loss can be attempted, if indicated through further evaluation.

A *reasonable time line* for a 10 percent reduction in body weight is 6 months of therapy. For overweight patients with BMIs in the typical range of 27 to 35, a decrease of 300 to 500 kcal/day will result in weight losses of about ½ to 1 lb/week and a 10 percent loss in 6 months. For more severely obese patients with BMIs > 35, deficits of up to 500 to 1,000 kcal/day will lead to weight losses of about 1 to 2 lb/week and a 10 percent weight loss in 6 months. Weight loss at the rate of 1 to 2 lb/week (calorie deficit of 500 to 1,000 kcal/day) commonly occurs for up to 6 months. After 6 months, the rate of weight loss usually declines and weight plateaus because of a lesser energy expenditure at the lower weight.

Experience reveals that lost weight usually will be regained unless a weight maintenance program consisting of dietary therapy, physical activity, and behavior therapy is continued indefinitely.

After 6 months of weight loss treatment, efforts to maintain weight loss should be put in place. If more weight loss is needed, another attempt at weight reduction can be made. This will require further adjustment of the diet and physical activity prescriptions.

For patients unable to achieve significant weight reduction, prevention of further weight gain is an important goal; such patients may also need to participate in a weight management program.

■ **Strategies for Weight Loss and Weight Maintenance.**

Dietary Therapy: A diet that is individually planned and takes into account the patient's overweight status in order to help create a deficit of 500 to 1,000 kcal/day should be an integral part of any weight loss program. A patient may choose a diet of 1,000 to 1,200 kcal/day for women and 1,200 to 1,500 kcal/day for men. Depending on the patient's risk status, the low-calorie diet (LCD) recommended should be consistent with the NCEP's Step I or Step II Diet (see page 74 of the guidelines). Besides decreasing saturated fat, total fats should be 30 percent or less of total calories. Reducing the percentage of dietary fat alone will not produce weight loss unless total calories are also reduced. Isocaloric replacement of fat with carbohydrates will reduce the percentage of calories from fat but will not cause weight loss. Reducing dietary fat, along with reducing dietary carbohydrates, usually will be needed to produce the caloric deficit needed for an acceptable weight loss. When fat intake is reduced, priority should be given to reducing saturated fat to enhance lowering of LDL-cholesterol levels. Frequent contacts with the practitioner during dietary therapy help to promote weight loss and weight maintenance at a lower weight.

Physical Activity: An increase in physical activity is an important component of weight loss therapy, although it will not lead to substantially greater weight loss over 6 months. Most weight loss occurs because of decreased caloric intake. Sustained physical activity is most helpful in the prevention of weight regain. In addition, it has a benefit in reducing cardiovascular and diabetes risks beyond that produced by weight reduction alone. For most obese patients, exercise should be initiated slowly, and the intensity should be

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increased gradually. The exercise can be done all at one time or intermittently over the day. Initial activities may be walking or swimming at a slow pace. The patient can start by walking 30 minutes for 3 days a week and can build to 45 minutes of more intense walking at least 5 days a week. With this regimen, an additional expenditure of 100 to 200 calories per day can be achieved. All adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most, and preferably all, days of the week. This regimen can be adapted to other forms of physical activity, but walking is particularly attractive because of its safety and accessibility. Patients should be encouraged to increase "every day" activities such as taking the stairs instead of the elevator. With time, depending on progress and functional capacity, the patient may engage in more strenuous activities. Competitive sports, such as tennis and volleyball, can provide an enjoyable form of exercise for many, but care must be taken to avoid injury. Reducing sedentary time is another strategy to increase activity by undertaking frequent, less strenuous activities.

Behavior Therapy: Strategies, based on learning principles such as reinforcement, that provide tools for overcoming barriers to compliance with dietary therapy and/or increased physical activity are helpful in achieving weight loss and weight maintenance. Specific strategies include self-monitoring of both eating habits and physical activity, stress management, stimulus control, problem solving, contingency management, cognitive restructuring, and social support.

Combined Therapy: A combined intervention of behavior therapy, an LCD, and increased physical activity provides the most successful therapy for weight loss and weight maintenance. This type of intervention should be maintained for at least 6 months before considering pharmacotherapy.

Pharmacotherapy: In carefully selected patients, appropriate drugs can augment LCDs, physical activity, and behavior therapy in weight loss. Weight loss drugs that have been approved by the FDA for long-term use can be useful adjuncts to dietary therapy and physical activity for some patients with a BMI of ≥ 30 with no concomitant risk factors or diseases, and for patients with a BMI of ≥ 27 with concomitant risk factors or diseases. The risk factors and diseases considered important enough to warrant pharmacotherapy at a BMI of 27 to 29.9 are hypertension, dyslipidemia, CHD, type 2 diabetes, and sleep apnea. Continual assessment by the physician of drug therapy for efficacy and safety is necessary.

At the present time, sibutramine is available for long-term use. (Note: FDA approval of orlistat is pending a resolution of labeling issues and results of Phase III trials.) It enhances weight loss modestly and can help facilitate weight loss maintenance. Potential side effects with drugs, nonetheless, must be kept in mind. With sibutramine, increases in blood pressure and heart rate may occur. Sibutramine should not be used in patients with a history of hypertension, CHD, congestive heart failure, arrhythmias, or history of stroke. With orlistat, fat soluble vitamins may require replacement because of partial malabsorption. All patients should be carefully monitored for these side effects.

Weight Loss Surgery: Weight loss surgery is one option for weight reduction in a limited number of patients with clinically severe obesity, i.e., BMIs ≥ 40 or ≥ 35 with comorbid conditions. Weight loss surgery should be reserved for patients in whom efforts at medical therapy have failed and who are suffering from the complications of extreme obesity.

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Gastrointestinal surgery (gastric restriction [vertical gastric banding] or gastric bypass [Roux-en Y]) is an intervention weight loss option for motivated subjects with acceptable operative risks. An integrated program must be in place to provide guidance on diet, physical activity, and behavioral and social support both prior to and after the surgery.

- **Adapt Weight Loss Programs To Meet the Needs of Diverse Patients.** Standard treatment approaches for overweight and obesity must be tailored to the needs of various patients or patient groups. Large individual variation exists within any social or cultural group; furthermore, substantial overlap among subcultures occurs within the larger society. There is, therefore, no "cookbook" or standardized set of rules to optimize weight reduction with a given type of patient. However, to be more culturally sensitive and to incorporate patient characteristics in obesity treatment programs: consider and adapt the setting and staffing for the program; consider how the obesity treatment program integrates into other aspects of patient health care and self care; and expect and allow for program modifications based on patient responses and preferences.

  The issues of weight reduction after age 65 involve such questions as: does weight loss reduce risk factors in older adults; are there risks associated with obesity treatment that are unique to older adults; and does weight reduction prolong the lives of older adults? Although there is less certainty about the importance of treating overweight at older ages than at younger ages, a clinical decision to forgo obesity treatment in older adults should be guided by an evaluation of the potential benefit of weight reduction and the reduction of risk for future cardiovascular events.

In the obese patient who smokes, smoking cessation is a major goal of risk factor management. Many well-documented health benefits accompany smoking cessation, but a major obstacle to cessation has been the attendant weight gain observed in about 80 percent of quitters. This weight gain averages 4.5 to 7 lb, but in 13 percent of women and 10 percent of men, weight gain exceeds 28 lb. Weight gain that accompanies smoking cessation has been quite resistant to most dietary, behavioral, or physical activity interventions.

The weight gained with smoking cessation is less likely to produce negative health consequences than would continued smoking. For this reason, smoking cessation should be strongly advocated regardless of baseline weight. Prevention of weight gain through diet and physical activity should be stressed. For practical reasons, it may be prudent to avoid initiating smoking cessation and weight loss therapy simultaneously. If weight gain ensues after smoking cessation, it should be managed vigorously according to the guidelines outlined in this report. Although short-term weight gain is a common side effect of smoking cessation, this gain does not rule out the possibility of long-term weight control.

SUMMARY OF EVIDENCE-BASED RECOMMENDATIONS

A Advantages of Weight Loss

The recommendation to treat overweight and obesity is based not only on evidence that relates obesity to increased mortality but also on RCT evidence that weight loss reduces risk factors for disease. Thus, weight loss may not only help control diseases worsened by obesity, it may also help decrease the likelihood of developing these diseases. The panel reviewed RCT evidence to determine the effect of weight loss on blood pressure and hypertension, serum/plasma lipid concentrations, and fasting blood glucose and fasting insulin. Recommendations focusing on

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these conditions underscore the advantages of weight loss.

1. Blood Pressure

To evaluate the effect of weight loss on blood pressure and hypertension, 76 articles reporting RCTs were considered for inclusion in these guidelines. Of the 45 accepted articles, 35 were lifestyle trials and 10 were pharmacotherapy trials. There is strong and consistent evidence from these lifestyle trials in both overweight hypertensive and nonhypertensive patients that weight loss produced by lifestyle modifications reduces blood pressure levels. Limited evidence exists that decreases in abdominal fat will reduce blood pressure in overweight nonhypertensive individuals, although not independent of weight loss, and there is considerable evidence that increased aerobic activity to increase cardiorespiratory fitness reduces blood pressure (independent of weight loss). There is also suggestive evidence from randomized trials that weight loss produced by most weight loss medications, except for sibutramine, in combination with adjuvant lifestyle modifications will be accompanied by reductions in blood pressure. Based on a review of the evidence from the 45 RCT blood pressure articles, the panel makes the following recommendation:

Weight loss is recommended to lower elevated blood pressure in overweight and obese persons with high blood pressure. Evidence Category A.

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2. Serum/Plasma Lipids

Sixty-five RCT articles were evaluated for the effect of weight loss on serum/plasma concentrations of total cholesterol, LDL-cholesterol, very low-density lipoprotein (VLDL)-cholesterol, triglycerides, and HDL-cholesterol. Studies were conducted on individuals over a range of obesity and lipid levels. Of the 22 articles accepted for inclusion in these guidelines, 14 RCT articles examined lifestyle trials while the remaining 8 articles reviewed pharmacotherapy trials. There is strong evidence from the 14 lifestyle trials that weight loss produced by lifestyle modifications in overweight individuals is accompanied by reductions in serum triglycerides and by increases in HDL-cholesterol. Weight loss generally produces some reductions in serum total cholesterol and LDL-cholesterol. Limited evidence exists that a decrease in abdominal fat correlates with improvements in lipids, although the effect may not be independent of weight loss, and there is strong evidence that increased aerobic activity to increase cardiorespiratory fitness favorably affects blood lipids, particularly if accompanied by weight loss. There is suggestive evidence from the eight randomized pharmacotherapy trials that weight loss produced by weight loss medications and adjuvant lifestyle modifications, including caloric restriction and physical activity, does not result in consistent effects on blood lipids. The following recommendation is based on the review of the data in these 22 RCT articles:

Weight loss is recommended to lower elevated levels of total cholesterol, LDL-cholesterol, and triglycerides, and to raise low levels of HDL-cholesterol in overweight and obese persons with dyslipidemia. Evidence Category A.

---

3. Blood Glucose

To evaluate the effect of weight loss on fasting blood glucose and fasting insulin levels, 49 RCT articles were reviewed for inclusion in these guidelines. Of the 17 RCT articles accepted, 9 RCT articles examined lifestyle therapy trials and 8 RCT articles considered the effects of pharmacotherapy on weight loss and subsequent changes in blood glucose. There is strong evidence from the nine lifestyle therapy trials that

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weight loss produced by lifestyle modification reduces blood glucose levels in overweight and obese persons without diabetes, and weight loss reduces blood glucose levels and HbA_{1c} in some patients with type 2 diabetes. There is suggestive evidence that decreases in abdominal fat will improve glucose tolerance in overweight individuals with impaired glucose tolerance, although not independent of weight loss; and there is limited evidence that increased cardiorespiratory fitness improves glucose tolerance in overweight individuals with impaired glucose tolerance or diabetes, although not independent of weight loss. In addition, there is suggestive evidence from randomized trials that weight loss induced by weight loss medications does not appear to improve blood glucose levels any better than weight loss through lifestyle therapy in overweight persons both with and without type 2 diabetes. Based on a full review of the data in these 17 RCT articles, the panel makes the following recommendation:

Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes. Evidence Category A.

B Measurement of Degree of Overweight and Obesity

Patients should have their BMI and levels of abdominal fat measured not only for the initial assessment of the degree of overweight and obesity, but also as a guide to the efficacy of weight loss treatment. Although there are no RCTs that review measurements of overweight and obesity, the panel determined that this aspect of patient care warranted further consideration and that this guidance was deemed valuable. Therefore, the following four recommendations that are included in the Treatment Guidelines were based on nonrandomized studies as well as clinical experience.

1. BMI To Assess Overweight and Obesity

There are a number of accurate methods to assess body fat (e.g., total body water, total body potassium, bioelectrical impedance, and dual-energy X-ray absorptiometry), but no trial data exist to indicate that one measure of fatness is better than any other for following overweight and obese patients during treatment. Since measuring body fat by these techniques is often expensive and is not readily available, a more practical approach for the clinical setting is the measurement of BMI; epidemiological and observational studies have shown that BMI provides an acceptable approximation of total body fat for the majority of patients. Because there are no published studies that compare the effectiveness of different measures for evaluating changes in body fat during weight reduction, the panel bases its recommendation on expert judgment from clinical experience:

Practitioners should use the BMI to assess overweight and obesity. Body weight alone can be used to follow weight loss, and to determine efficacy of therapy. Evidence Category C.

---

2. BMI To Estimate Relative Risk

In epidemiological studies, BMI is the favored measure of excess weight to estimate relative risk of disease. BMI correlates both with morbidity and mortality; the relative risk for CVD risk factors and CVD incidence increases in a graded fashion with increasing BMI in all population groups. Moreover, calculating BMI is simple, rapid, and inexpensive, and can be applied generally to adults. The panel, therefore, makes this recommendation:

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The BMI should be used to classify overweight and obesity and to estimate relative risk of disease compared to normal weight. Evidence Category C.

3. Assessing Abdominal Fat

For the most effective technique for assessing abdominal fat content, the panel considered measures of waist circumference, waist-to-hip ratio (WHR), magnetic resonance imaging (MRI), and computed tomography. Evidence from epidemiological studies shows waist circumference to be a better marker of abdominal fat content than WHR, and that it is the most practical anthropometric measurement for assessing a patient's abdominal fat content before and during weight loss treatment. Computed tomography and MRI are both more accurate but impractical for routine clinical use. Based on evidence that waist circumference is a better marker than WHR—and taking into account that the MRI and computed tomography techniques are expensive and not readily available for clinical practice—the panel makes the following recommendation:

The waist circumference should be used to assess abdominal fat content. Evidence Category C.

4. Sex-Specific Measurements

Evidence from epidemiological studies indicates that a high waist circumference is associated with an increased risk for type 2 diabetes, dyslipidemia, hypertension, and CVD. Therefore, the panel judged that sex-specific cutoffs for waist circumference can be used to identify increased risk associated with abdominal fat in adults with a BMI in the range of 25 to 34.9. These cutpoints can be applied to all adult ethnic or racial groups. On the other hand, if a patient is very short, or has a BMI above the 25 to 34.9 range, waist cutpoints used for the general population may not be applicable. Based on the evidence from nonrandomized studies, the panel makes this recommendation:

For adult patients with a BMI of 25 to 34.9 kg/m^2, sex-specific waist circumference cutoffs should be used in conjunction with BMI to identify increased disease risks. Evidence Category C.

C Goals for Weight Loss

The general goals of weight loss and management are to reduce body weight, to maintain a lower body weight over the long term, and to prevent further weight gain. Evidence indicates that a moderate weight loss can be maintained over time if some form of therapy continues. It is better to maintain a moderate weight loss over a prolonged period than to regain from a marked weight loss.

1. Initial Goal of Weight Loss from Baseline

There is strong and consistent evidence from randomized trials that overweight and obese patients in well-designed programs can achieve a weight loss of as much as 10 percent of baseline weight. In the diet trials, an average of 8 percent of baseline weight was lost. Since this average includes persons who did not lose weight, an individualized goal of 10 percent is reasonable. The panel, therefore, recommends that:

The initial goal of weight loss therapy should be to reduce body weight by approximately 10 percent from baseline. With success, further weight loss can be attempted if indicated through further assessment. Evidence Category A.

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2. Amount of Weight Loss

Randomized trials suggest that weight loss at the rate of 1 to 2 lb/week (calorie deficit of 500 to 1,000 kcal/day) commonly occurs for up to 6 months.

Weight loss should be about 1 to 2 lb/week for a period of 6 months, with the subsequent strategy based on the amount of weight lost. Evidence Category B.

D How To Achieve Weight Loss

The panel reviewed relevant treatment strategies designed for weight loss that can also be used to foster long-term weight control and prevention of weight gain. The consequent recommendations emphasize the potential effectiveness of weight control using multiple interventions and strategies, including dietary therapy, physical activity, behavior therapy, pharmacotherapy, and surgery, as well as combinations of these strategies.

1. Dietary Therapy

The panel reviewed 86 RCT articles to determine the effectiveness of diets on weight loss (including LCDs, very low-calorie diets (VLCDs), vegetarian diets, American Heart Association dietary guidelines, the NCEP's Step I diet with caloric restriction, and other low-fat regimens with varying combinations of macronutrients). Of the 86 articles reviewed, 48 were accepted for inclusion in these guidelines. These RCTs indicate strong and consistent evidence that an average weight loss of 8 percent of initial body weight can be obtained over 3 to 12 months with an LCD and that this weight loss effects a decrease in abdominal fat; and, although lower-fat diets without targeted caloric reduction help promote weight loss by producing a reduced caloric intake, lower-fat diets with targeted caloric reduction promote greater weight loss than lower-fat diets alone. Further, VLCDs produce greater initial weight losses than LCDs (over the long term of >1 year, weight loss is not different than that of the LCDs). In addition, randomized trials suggest that no improvement in cardiorespiratory fitness as measured by VO_2 max appears to occur in obese adults who lose weight on LCDs alone without physical activity. The following recommendations are based on the evidence extracted from the 48 accepted articles:

LCDs are recommended for weight loss in overweight and obese persons. Evidence Category A. Reducing fat as part of an LCD is a practical way to reduce calories. Evidence Category A.

Reducing dietary fat alone without reducing calories is not sufficient for weight loss. However, reducing dietary fat, along with reducing dietary carbohydrates, can facilitate caloric reduction. Evidence Category A.

A diet that is individually planned to help create a deficit of 500 to 1,000 kcal/day should be an intregal part of any program aimed at achieving a weight loss of 1 to 2 lb/week. Evidence Category A.

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2. Physical Activity

Effects of Physical Activity on Weight Loss

Twenty-three RCT articles were reviewed to determine the effect of physical activity on weight loss, abdominal fat (measured by waist circumference), and changes in cardiorespiratory fitness (VO_2 max). Thirteen of these articles were accepted for inclusion in these guidelines. A review of these articles reveals strong evidence that physical activity alone, i.e., aerobic exercise, in obese adults results in modest weight loss and that physical activity in overweight and obese

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adults increases cardiorespiratory fitness, independent of weight loss. Randomized trials suggest that increased physical activity in overweight and obese adults reduces abdominal fat only modestly or not at all, and that regular physical activity independently reduces the risk for CVD. The panel's recommendation on physical activity is based on the evidence from these 13 articles:

Physical activity is recommended as part of a comprehensive weight loss therapy and weight control program because it: (1) modestly contributes to weight loss in overweight and obese adults (Evidence Category A), (2) may decrease abdominal fat (Evidence Category B), (3) increases cardiorespiratory fitness (Evidence Category A), and (4) may help with maintenance of weight loss (Evidence Category C).

Physical activity should be an integral part of weight loss therapy and weight maintenance. Initially, moderate levels of physical activity for 30 to 45 minutes, 3 to 5 days a week, should be encouraged. All adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most, and preferably all, days of the week. Evidence Category B.

Effects of Physical Activity and Diet on Weight Loss (Combined Therapy)

Twenty-three RCT articles were reviewed to determine the effects on body weight of a combination of a reduced-calorie diet with increased physical activity. Fifteen of these articles were accepted for inclusion in the guidelines. These articles contain strong evidence that the combination of a reduced-calorie diet and increased physical activity produces greater weight loss than diet alone or physical activity alone, and that the combination of diet and physical activity improves cardiorespiratory fitness as measured by VO_2 max in overweight and obese adults when compared to diet alone. The combined effect of a reduced calorie diet and increased-physical activity seemingly produced modestly greater reductions in abdominal fat than either diet alone or physical activity alone, although it has not been shown to be independent of weight loss. The panel's following recommendations are based on the evidence from these articles:

The combination of a reduced calorie diet and increased physical activity is recommended since it produces weight loss that may also result in decreases in abdominal fat and increases in cardiorespiratory fitness. Evidence Category A.

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3. Behavior Therapy

Thirty-six RCTs were reviewed to evaluate whether behavior therapy provides additional benefit beyond other weight loss approaches, as well as to compare various behavioral techniques. Of the 36 RCTs reviewed, 22 were accepted. These RCTs strongly indicate that behavioral strategies to reinforce changes in diet and physical activity in obese adults produce weight loss in the range of 10 percent over 4 months to 1 year. In addition, no one behavior therapy appeared superior to any other in its effect on weight loss; multimodal strategies appear to work best and those interventions with the greatest intensity appear to be associated with the greatest weight loss. Long-term follow-up of patients undergoing behavior therapy shows a return to baseline weight for the great majority of subjects in the absence of continued behavioral intervention. Randomized trials suggest that behavior therapy, when used in combi-

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nation with other weight loss approaches, provides additional benefits in assisting patients to lose weight short-term, i.e., 1 year (no additional benefits are found at 3 to 5 years). The panel found little evidence on the effect of behavior therapy on cardiorespiratory fitness. Evidence from these articles provided the basis for the following recommendation:

Behavior therapy is a useful adjunct when incorporated into treatment for weight loss and weight maintenance. Evidence Category B.

There is also suggestive evidence that patient motivation is a key component for success in a weight loss program. The panel, therefore, makes the following recommendation:

Practitioners need to assess the patient's motivation to enter weight loss therapy; assess the readiness of the patient to implement the plan and then take appropriate steps to motivate the patient for treatment. Evidence Category D.

---

4. Summary of Lifestyle Therapy

There is strong evidence that combined interventions of an LCD, increased physical activity, and behavior therapy provide the most successful therapy for weight loss and weight maintenance. The panel makes the following recommendation:

Weight loss and weight maintenance therapy should employ the combination of LCDs, increased physical activity, and behavior therapy. Evidence Category A.

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5. Pharmacotherapy

A review of 44 pharmacotherapy RCT articles provides strong evidence that pharmacological therapy (which has generally been studied along with lifestyle modification, including diet and physical activity) using dexfenfluramine, sibutramine, orlistat, or phentermine/fenfluramine results in weight loss in obese adults when used for 6 months to 1 year. Strong evidence also indicates that appropriate weight loss drugs can augment diet, physical activity, and behavior therapy in weight loss. Adverse side effects from the use of weight loss drugs have been observed in patients. As a result of the observed association of valvular heart disease in patients taking fenfluramine and dexfenfluramine alone or in combination, these drugs have been withdrawn from the market. Weight loss drugs approved by the FDA for long-term use may be useful as an adjunct to diet and physical activity for patients with a BMI of ≥ 30 with no concomitant obesity-related risk factors or diseases, as well as for patients with a BMI of ≥ 27 with concomitant risk factors or diseases; moreover, using weight loss drugs singly (not in combination) and starting with the lowest effective doses can decrease the likelihood of adverse effects. Based on this evidence, the panel makes the following recommendation:

Weight loss drugs approved by the FDA may be used as part of a comprehensive weight loss program, including dietary therapy and physical activity for patients with a BMI of ≥ 30 with no concomitant obesity-related risk factors or diseases, and for patients with a BMI of ≥ 27 with concomitant obesity-related risk factors or diseases. Weight loss drugs should never be used without concomitant lifestyle modifications. Continual assessment of drug therapy for efficacy and safety is necessary. If the drug is efficacious in helping the patient to lose and/or maintain weight loss

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and there are no serious adverse effects, it can be continued. If not, it should be discontinued. Evidence Category B.

6. Weight Loss Surgery

The panel reviewed 14 RCTs that examined the effect of surgical procedures on weight loss; 8 were deemed appropriate. All of the studies included individuals who had a BMI of 40 kg/m^2 or above, or a BMI of 35 to 40 kg/m^2 with comorbidity. These trials provide strong evidence that surgical interventions in adults with clinically severe obesity, i.e., BMIs ≥ 40 or ≥ 35 with comorbid conditions, result in substantial weight loss, and suggestive evidence that lifelong medical surveillance after surgery is necessary. Therefore, the panel makes the following recommendation:

Weight loss surgery is an option for carefully selected patients with clinically severe *obesity (BMI ≥ 40 or ≥ 35 with comorbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality. Evidence Category B.*

E Goals for Weight Loss Maintenance

Once the goals of weight loss have been successfully achieved, maintenance of a lower body weight becomes the challenge. Whereas studies have shown that weight loss is achievable, it is difficult to maintain over a long period of time (3 to 5 years). In fact, the majority of persons who lose weight, once dismissed from clinical therapy, frequently regain it—so the challenge to the patient and the practitioner is to maintain the weight loss. Successful weight reduction thus depends on continuing a maintenance program on a long-term basis. In the past, obtaining the goal of weight loss has been considered the end of weight loss therapy. Observation, monitoring, and encouragement of patients who have successfully lost weight should be continued long term. The panel's recommendations on weight loss maintenance are derived from RCT evidence as well as nonrandomized and observational studies.

1. Weight Maintenance Phase

RCTs from the Behavior Therapy section above suggest that lost weight usually will be regained unless a weight maintenance program consisting of dietary therapy, physical activity, and behavior therapy is continued indefinitely. Drug therapy in addition may be helpful during the weight maintenance phase. The panel also reviewed RCT evidence that considered the rate of weight loss and the role of weight maintenance. These RCTs suggest that after 6 months of weight loss treatment, efforts to maintain weight loss are important. Therefore, the panel recommends the following:

After successful weight loss, the likelihood of weight loss maintenance is enhanced by a program consisting of dietary therapy, physical activity, and behavior therapy which should be continued indefinitely. Drug therapy can also be used. However, drug safety and efficacy beyond 1 year of total treatment have not been established. Evidence Category B.

A weight maintenance program should be a priority after the initial 6 months of weight loss therapy. Evidence Category B.

Strong evidence indicates that better weight loss results are achieved with dietary therapy when the duration of the intervention is at least 6 months. Suggestive evidence also indicates that during dietary therapy, frequent contacts

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between professional counselors and patients promote weight loss and maintenance. Therefore, the panel recommends the following:

The literature suggests that weight loss and weight maintenance therapies that provide a greater frequency of contacts between the patient and the practitioner and are provided over the long term should be utilized whenever possible. This can lead to more successful weight loss and weight maintenance. Evidence Category C.

F Special Treatment Groups

The needs of special patient groups must be addressed when considering treatment options for overweight and obesity. The guidelines focus on three such groups including smokers, older adults, and diverse patient populations.

1. Smokers

Cigarette smoking is a major risk factor for cardiopulmonary disease. Because of its attendant high risk, smoking cessation is a major goal of risk-factor management. This aim is especially important in the overweight or obese patient, who usually carries excess risk from obesity-associated risk factors. Thus, smoking cessation in these patients becomes a high priority for risk reduction. Smoking and obesity together apparently compound cardiovascular risk, but fear of weight gain upon smoking cessation is an obstacle for many patients. Therefore, the panel recommends that:

All smokers, regardless of their weight status, should quit smoking. Evidence Category A. Prevention of weight gain should be encouraged and if weight gain does occur, it should be treated through dietary therapy, physical activity, and behavior therapy, maintaining the primary emphasis on the importance of abstinence from smoking. Evidence Category C.

2. Older Adults

The general nutritional safety of weight reduction at older ages is of concern because restrictions on overall food intake due to dieting could result in inadequate intake of protein or essential vitamins or minerals. In addition, involuntary weight loss indicative of occult disease might be mistaken for success in voluntary weight reduction. These concerns can be alleviated by providing proper nutritional counseling and regular body weight monitoring in older persons for whom weight reduction is prescribed. A review of several studies indicates that age alone should not preclude treatment for obesity in adult men and women. In fact, there is evidence from RCTs that weight reduction has similar effects in improving cardiovascular disease risk factors in older and younger adults. Therefore, in the panel's judgment:

A clinical decision to forego obesity treatment in older adults should be guided by an evaluation of the potential benefits of weight reduction for day-to-day functioning and reduction of the risk of future cardiovascular events, as well as the patient's motivation for weight reduction. Care must be taken to ensure that any weight reduction program minimizes the likelihood of adverse effects on bone health or other aspects of nutritional status. Evidence Category D.

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3. Diverse Patient Populations

Standard obesity treatment approaches should be tailored to the needs of various patients or patient groups. It is, however, difficult to determine from the literature how often this occurs, how specific programs and outcomes are influenced by tailoring, and whether it makes weight loss programs more effective. After reviewing two RCTs, four cross-sectional studies, and four intervention studies, as well as additional published literature on treatment approaches with diverse patient populations, the panel recommends the following:

The possibility that a standard approach to weight loss will work differently in diverse patient populations must be considered when setting expectations about treatment outcomes. Evidence Category B.

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Introduction

I

A Rationale for Guidelines Development

An estimated 97 million adults in the United States are overweight or obese, [1] a condition that substantially raises their risk of morbidity from hypertension, [2-6] type 2 diabetes, [7-10] stroke, [11-13] gallbladder disease, [14, 15] osteoarthritis, [16-18] sleep apnea and respiratory problems, [19-21] and endometrial, breast, prostate, and colon cancers. [22-24] As a major contributor to preventive death in the United States today, [25] overweight and obesity pose a major public health challenge. Not only is the prevalence of this serious medical condition soaring among adults (between 1960 and 1994, overweight increased from 30.5 to 32 percent among adults ages 20 to 74 and obesity increased from 12.8 percent to 22.5 percent), but it is also affecting ever greater numbers of American youth and exacting a particularly harsh toll from low income women and minorities. The Third National Health and Nutrition Examination Survey (NHANES III) estimated that 13.7 percent of children and 11.5 percent of adolescents are overweight, while a number of smaller, ethnic-specific studies suggest that overweight and obesity may afflict up to 30 to 40 percent of children and youth from minority populations. [26, 27]

The prevalence of overweight and obesity in adults in the United States increased markedly during the last decade. According to NHANES III data, 54.9 percent of U.S. adults aged 20 years and older are either overweight or obese; 32.6 percent are overweight, defined as having a body mass index (BMI)* of 25.0 to 29.9 kg/m^2; and 22.3 percent are obese with a BMI of ≥ 30 kg/m^2. [1] The panel acknowledges that overweight and obesity are not mutually exclusive; obese persons are also overweight. Since overweight and obesity lead to increased morbidity and mortality, these figures demonstrate the enormity of the public health problem, as well as the clinical problem, of overweight and obesity in this country.

In this report, overweight is defined as a BMI of 25.0 to 29.9 kg/m^2 and obesity as a BMI of ≥ 30 kg/m^2. The rationale behind these definitions is based on epidemiological data that show increases in mortality with BMIs above 25 kg/m^2. [28-32] The increase in mortality, however, tends to be modest until a BMI of 30 kg/m^2 is reached. [28, 31, 32] For persons with a BMI of ≥ 30 kg/m^2, mortality rates from all causes, and especially from cardiovascular disease, are generally increased by 50 to 100 percent above that of persons with BMIs in the range of 20 to 25 kg/m^2. [28, 31, 32]

Overweight and obesity result from a complex interaction between genes and the environment characterized by long-term energy imbalance due to a sedentary lifestyle, excessive caloric consumption, or both. [33] They develop in a sociocultural environment characterized by mechanization, sedentary lifestyle, and ready access to abundant food. Attempts to prevent overweight and obesity are difficult to both study and achieve. Indeed, few research efforts have investigated either individual or community-based prevention strategies. [34]

* The BMI is calculated as follows: BMI = weight (kg)/ height squared (m^2). Conversion: [weight (pounds)/height (inches) ^{2}] x 703 (1 lb = 0.45 kg) (1.in = 2.54 cm = 0.0254 m). A BMI of 25 is equivalent to 184 lb in a 6'0" person and to 155 lb in one5'6". A BMI of 30 is equivalent to 221 lb in a 6'0" person and to 186 lb in one 5'6". (The conversion of BMI according to weight for height is provided in Appendix V.)

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A substantial body of research, however, does exist on the health risks of overweight and obesity, and on methods for treatment. This report, which bases its recommendations primarily on published evidence, emphasizes the important role of primary care practitioners in evaluating all overweight and obese adults and promoting weight control through the use of multiple interventions and strategies tailored to particular patient needs. Although the recommendations and guidelines included in this report focus on the clinical assessment and treatment of overweight and obese patients, a second important goal is to encourage primary care practitioners to take an active role in preventing inappropriate weight gain among all their patients.

B Objectives of the Guidelines

- To identify, evaluate, and summarize published information about the assessment and treatment of overweight and obesity;
- To provide evidence-based guidelines for physicians, other health care practitioners, and health care organizations for the evaluation and treatment of overweight and obesity in adults; and
- To identify areas for future research.

C Guideline Development Methodology

The National Heart, Lung, and Blood Institute's (NHLBI) Obesity Education Initiative, in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases, convened the Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. These guidelines address the treatment of overweight and obesity only in adults, but it is the judgment of the panel that guidelines for treating obesity in children are equally important and should be drafted as soon as possible (see Appendix III for information on overweight and obesity in children). The panel's charge was to develop evidence-based clinical guidelines for primary care practitioners; however, the guidelines should also be useful for certain specialists. The decision to develop "evidence-based" guidelines was based on the increased attention being paid to clinical practice guidelines from methodologists, professional associations, third-party payers and policy makers, and the NHLBI's mission to analyze research results with the goal of providing information that may enable health care practitioners to enhance their ability to detect, treat, and prevent disease. [35] In keeping with this approach, the panel

- defined topics to be included in the guidelines;
- developed an evidence model depicting the strategy of inquiry for each area of scientific interest;
- established criteria for searching and abstracting the literature;
- constructed and reviewed evidence tables of individual studies and summary tables of studies falling within a specific category of evidence; and
- identified the level or strength of the evidence that served as the basis for the recommendations.

A complete description of the methodology used to develop the guidelines is included in the report as Appendix I.A.1.

The guidelines are based primarily on a systematic review of the published scientific literature in English found in MEDLINE from January 1980 through September 1997. This was done in the interest of time and economy. This information was supplemented by material provided by the panel and an ancestral search of appropriate references in eligible articles. The literature was searched and systematically reviewed by

- establishing *a priori* eligibility criteria for inclusion of studies;

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- reviewing titles and abstracts to select promising articles;
- reviewing these full articles; and
- compiling evidence tables summarizing those articles that met the inclusion criteria.

As a priority, the panel identified randomized controlled trials (RCTs) as the strongest level of evidence for the evaluation of treatment efficacy. Only RCTs lasting 4 months or more were considered. The only exceptions were a few 3-month trials in the diet and pharmacotherapy sections. With the assistance of the San Antonio Cochrane Center*, 394 publications of RCTs were reviewed for data abstraction. RCT evidence serves as the basis for the many recommendations contained in these guidelines related to treatment efficacy. Instances when the panel had to make recommendations where RCTs were insufficient or absent are clearly indicated in the text. These instances most often pertain to issues of obesity assessment, classification, and measurement where RCT evidence would not be appropriate to answer the question. These issues are best addressed by epidemiological/observational studies of large population groups. In those few cases where the literature could not credibly support a recommendation, panel members relied on clinical experience and knowledge.

The panel recognizes that by relying primarily on only published literature, a publication bias (a positive result is more likely to be published than is a negative result) may exist, so that treatment efficacy may be overstated. [36-39] However, no other reliable sources of information were available.

The targeted population for the guidelines is all overweight and obese adults (18 years of age and older) with a BMI ≥ 25, with particular emphasis on those with cardiovascular risk factors. While the guidelines are appropriate for patients with a BMI ≥ 40, their care is often complicated and may require surgery. These guidelines are not intended for pregnant women. Excluded from the analysis were adults with pharmacologically induced obesity and those with specific genetic syndromes associated with overweight and obesity.

The selection of weight loss interventions to be considered was determined by the literature review. Namely, the panel considered any topic for which articles meeting inclusion criteria were found, including diet, physical activity, behavior therapy, pharmacological therapy, surgery, and combinations of these modalities. No clinical interventions were excluded at the outset. However, the panel did not consider other interventions such as acupuncture or hypnosis, for which no randomized trial articles were available. Clinical interventions to prevent further weight gain in individuals already overweight were also considered relevant.

The panel also evaluated population factors and clinical situations that might potentially influence the physiological, medical, behavioral, or sociocultural context for obesity identification and treatment. Evidence on special populations and situations was provided from RCTs and non-RCTs when available, but in many cases such evidence was meager. Population factors and clinical situations selected for special consideration for obesity classification and treatment were age, gender, race/ethnicity, socioeconomic status, pregnancy, eating disorders, sleep apnea, extreme obesity (BMI ≥ 40), concurrent treatment of other major conditions (such as heart disease or diabetes), and treatment of obesity in conjunction with smoking cessation. When evidence on these special populations or clinical conditions was insufficient to meet standards for inclusion in the main text of the guidelines, relevant issues are identified for the user, and in some cases are cross-referenced to an appendix (see Appendix III) or discussed in sidebar text as a commentary.

* The San Antonio Cochrane Center is one of 12 centers around the world that comprise the Cochrane Collaboration. The Cochrane Collaboration is an international organization established in 1993 whose mission is to prepare, maintain, and disseminate systematic reviews and meta-analyses of health care interventions.

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The panel recognized the possibility of an advocacy "bias" due to the large number of panel members drawn from organizations with an advocacy role in the treatment of obesity. As a result, it was agreed to obtain formal external reviews of the document from 59 professional societies, consumer groups and goverment agencies representing a wide spectrum of expertise and concern about obesity.

The format for those sections of the report based on the RCT evidence begins with an evidence statement followed by the rationale for that statement. At the end of a series of related evidence statements, a recommendation is given.

Each evidence statement (other than those with no available evidence) and each recommendation is categorized by a level of evidence (A through D) as described below. Statements for which there is no available evidence are so indicated.

Category A: Evidence is from endpoints of well-designed RCTs (or trials that depart only minimally from randomization) that provide a consistent pattern of findings in the population for which the recommendation is made. Category A therefore requires substantial numbers of studies involving substantial numbers of participants.

Category B: Evidence is from endpoints of intervention studies that include only a limited number of RCTs, post-hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, and the trial results are somewhat inconsistent, or the trials were undertaken in a population that differs from the target population of the recommendation.

Category C: Evidence is from outcomes of uncontrolled or nonrandomized trials or from observation studies.

Category D: Expert judgment is based on the panel's synthesis of evidence from experimental research described in the literature and/or derived from the consensus of panel members based on clinical experience or knowledge that does not meet the above-listed criteria. This category is used only in cases where the provisions of some guidance was deemed valuable but an adequately compelling clinical literature addressing the subject of the recommendation was deemed insufficient to justify placement in one of the other categories (A through C).

In applying these guidelines, the reader should note some caveats:

- The emphasis of these guidelines was to identify effective interventions, not to rank-order them in terms of their efficacy or effectiveness. The panel chose not to emphasize comparisons among interventions because there were few studies that compared long-term outcomes. Also, since individual preferences and circumstances often dictate choice of therapy, the panel wished to present a menu of options rather than a ranked list of choices.
- When no evidence was available on the efficacy of a treatment, the panel usually rendered no opinion. An absence of studies should not be confused with an absence of effect. While clinicians may prefer to use proven therapies rather than untested ones, the lack of testing does not denote that the untested therapy does not work.
- The limitations of RCTs must be kept in mind. The RCT is the primary method for demonstrating efficacy. Often, participants enrolled in RCTs differ from the individuals in a primary care practice, and effectiveness in the community may differ from efficacy as measured in an RCT.
- The potential exists for misinterpretation of clinical trial results. Analysis of endpoints not specified at the outset, or post hoc or subgroup analysis, should be viewed as hypothesis-generating rather than hypothesis-testing.

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D Statement of Assumptions

The panel has made every attempt to base its recommendations on published evidence, with particular attention to RCTs. Data from RCTs provide the strongest evidence regarding the impact of an intervention. The RCT literature predominantly describes short-term outcomes (< 1 year), although there are a small number of published RCTs of intermediate and long-term treatment and maintenance of weight loss. The panel chose to examine RCTs lasting 4 months or longer as their first priority. However, there are some 3-month studies included in the diet and pharmacotherapy sections.

Evidence of beneficial effects of weight reduction on risk factors and on diseases with which obesity is associated, and evidence of the association of obesity and mortality, are also available in the non-RCT epidemiological literature. Therefore, although the treatment recommendations in these guidelines are derived primarily from RCT evidence, they also come in part from the considered judgment of the expert panel members who weighed the non-RCT epidemiological evidence.

In setting forth its recommendations, the panel assumes that, for most individuals, the benefits of weight loss on overall health outweigh the harmful effects, and that weight loss can be maintained in many individuals with resulting long-term health benefits. The recommendations apply to all segments of the adult population, although apparent differences in applicability have been considered and some guidance is provided with respect to certain sectors of the population such as the elderly and in clinical situations. This additional guidance is in the form of notations within the text and is sometimes supplemented by an appendix (Appendix III).

E Intended Users of These Guidelines

These guidelines were developed primarily for use by physicians and associated health professionals in clinical practice. They should also be useful to managed care organizations or other groups that define benefit plans for patients or handle health care resources. Users of these guidelines are encouraged to note text and appendix references to situations in which weight reduction treatment may be contraindicated or may involve special treatment techniques or safety considerations (e.g., in older adults or in certain sociocultural contexts).

These guidelines also provide a state-of-the-art review of the scientific basis of the relation between obesity and major disease endpoints and of the scientific rationale for the management of the overweight and obese patients. The systematic assessment of the literature contained in this document should be a valuable resource to health care policy makers and clinical investigators.

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2 Overweight and Obesity: Background

A Health and Economic Costs

In 1973, and again in 1977, the John E. Fogarty International Center at the National Institutes of Health (NIH), as part of its preventive medicine series, sponsored two conferences that dealt with obesity as a public health problem; controversy was apparent regarding the cause-and-effect relationship between obesity and ill health. [40, 41] In 1985, an NIH Consensus Development Conference was held on the health implications of obesity. This conference provided important national recognition that obesity is a serious health condition that leads to increased morbidity and mortality. The Consensus Development Conference concluded that both prevention and treatment of obesity were medical priorities in the United States [42]. In that conference, the terms 'overweight' and 'obesity' were defined as part of a continuum of increasing health risk.

In 1990, the Nation's health goals for the year 2000 were set forth with the release of Healthy People 2000 [43], in which a national goal to reduce the prevalence of overweight was articulated. In 1993, the Deputy Assistant Secretary for Health (J. Michael McGinnis) and the former Director of the Centers for Disease Control and Prevention (CDC) (William Foege) co-authored a journal article, "Actual Causes of Death in the U.S." It concluded that a combination of dietary factors and sedentary activity patterns accounts for at least 300,000 deaths each year, and, obesity was a key contributor. [25] In 1995, the Institute of Medicine issued a report that expressed concern about the growing prevalence of overweight and obesity in this country, and suggested ways to evaluate various weight loss and weight maintenance programs available to U.S. consumers. [44]

1. Prevalence and Time Trends

Nationally representative U.S. health examination surveys, in which weight and height were measured in samples of the population, date back to 1960. Beginning with the Second National Health and Nutrition Examination Survey (NHANES II) (1976-1980), the definition of overweight that has been used to compare these epidemiologic surveys has been a statistical one that corresponded to the 85th percentile of body mass index (BMI) for men and women aged 20 through 29 years in NHANES II with no particular relation to a specific increase in disease risk. [45] Adults in these surveys have been categorized as overweight with a BMI ≥ 27.8 kg/m^2 for men and ≥ 27.3 kg/m^2 for women. [45] The rationale for using persons aged 20 to 29 years as the reference population is supported largely by the observation that the increases in body weight after age 29 that commonly occur with aging are attributable primarily to fat accumulation. [46,47] However, the BMI levels used for the definition of overweight and obesity are somewhat arbitrary, since the relationship between body weight and disease risk is continuous with the exception of the extremely underweight: disease risk increases as weight increases.

Figure 1 depicts data from several NHANES surveys using the panel's definition of over-

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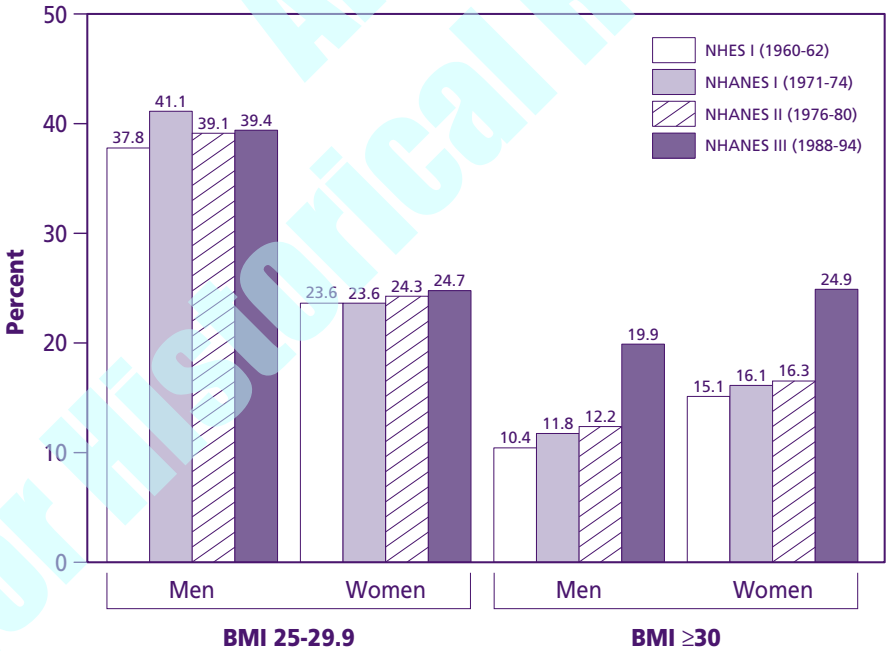
weight as a BMI of 25 to 29.9 kg/m^2 and of obesity as a BMI of ≥ 30 kg/m^2. From 1960 to 1994, the prevalence of overweight increased slightly from 37.8 to 39.4 percent in men and from 23.6 to 24.7 percent in women (National Center for Health Statistics/CDC) [48]. In men and women together, overweight increased from 30.5 to 32.0 percent. [48] During the same time period, however, the prevalence of obesity increased from 10.4 to 19.9 percent in men and from 15.1 to 24.9 percent in women. In men and women together, obesity increased from 12.8 to 22.5 percent. Most of the increase occurred in the past decade. In addition to adults, obesity in U.S. children increased markedly as well [49] (see Appendix III) and, if unchecked, portends an even greater increase in adult obesity in the future.

Table II-1 shows the combined prevalence of overweight and obesity, defined as a BMI of ≥ 25.0 kg/m^2, among persons aged 20 to 80 plus years, by age, race/ethnicity, and gender in the United States, 1960 to 1994. [48] The increase in overweight and obesity appears to have occurred among U.S. adults across all ages, genders, and racial/ethnic groups. The most recent NHANES III surveys, conducted from 1988-1994, reported that 59.4 percent of men and 50.7 percent of women in the United States are overweight or obese. The prevalence is much higher in non-Hispanic Black women (66.0 percent), in Mexican-American women (65.9 percent), and in Mexican-American men (63.9 percent).

Using the definition of obesity as a BMI of ≥ 30 kg/m^2, Table II-2 shows that in the United States, 19.5 percent of men and 25.0 percent of

Figure 1. Age-Adjusted Prevalence of Overweight (BMI 25-29.9) and Obesity (BMI ≥30)



Source: CDC/NCHS, United States, 1960-94 (ages 20-74 years)

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TABLE II-1:

Combined Prevalence of Overweight and Obesity (BMI≥25.0 kg/m²) Among Adults Age 20 to 80+ years, by Gender, Race/Ethnicity, and Age: United States, 1960-1994.[48]

Gender, race/ethnicity, age 20 years and older, age adjusted:	NHES I 1960-62 (age 20-74)	NHANES I 1971-74 (age 20-74)	NHANES II 1976-80 (age 20-74)	HHANES 1982-84 (age 20-74)	NHANES III 1988-94 (age ≥20)
Both Sexes	43.3	46.1	46.0		54.9
Men	48.2	52.9	51.4		59.4
Women	38.7	39.7	40.8		50.7
White men	48.8	53.7	52.3		61.0
White women	36.1	37.6	38.4		49.2
Black men	43.1	48.9	49.0		56.5
Black women	57.0	57.6	61.0		65.8
White, non-Hispanic men			52.0		60.6
White, non-Hispanic women			37.6		47.4
Black, non-Hispanic men			48.9		56.7
Black, non-Hispanic women			60.6		66.0
Mexican-American men				59.7	63.9
Mexican-American women				60.1	65.9
Age and gender-specific categories:					
Men					
20-29	39.9	38.6	37.0		43.1
30-39	49.6	58.1	52.6		58.1
40-49	53.6	63.6	60.3		65.5
50-59	54.1	58.4	60.8		73.0
60-69	52.9	55.6	57.4		70.3
70-79	36.0	52.7*	53.3*		63.1
80+	N/A**	N/A**	N/A**		50.6
Women					
20-29	17.0	23.2	25.0		33.1
30-39	32.8	35.0	36.8		47.0
40-49	42.3	44.6	44.4		52.7
50-59	55.0	52.2	52.8		64.4
60-69	63.1	56.2	56.5		64.0
70-79	57.4	55.9*	58.2*		57.9
80+	N/A**	N/A**	N/A**		50.1

* Prevalence for age 70 to 74 years ** Not available

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women are obese. [48] The prevalence of obesity is much higher in minority women, being 36.7 percent in non-Hispanic Black women and 33.3 percent in Mexican-American women.

2. Demographic Variations in Overweight and Obesity Prevalence

Although NHANES III data show that the prevalence of overweight and obesity is much higher in African-American and Mexican-American women than in white women or in men, these data provide ethnicity-specific estimates of overweight and obesity prevalence for only three racial-ethnic groups: non-Hispanic whites, non-Hispanic blacks, and Mexican-Americans. Examination survey data indicating a high overweight and obesity prevalence in other ethnic groups (e.g., for Puerto Ricans and Cuban-Americans) are available from the Hispanic HANES (HHANES) (1982-1984) [27] and for American Indians [26] and Pacific-Islander Americans, [50] from smaller population-specific studies (see Appendix III). The prevalence of overweight and obesity is generally higher for men and women in racial-ethnic minority populations than in U.S. whites, with the exception of Asian-Americans, for whom overweight and obesity prevalence is lower than in the general population. [51] In the 1982-1984 HHANES, the age-adjusted prevalence of a BMI of ≥ 27.3 in Puerto Rican women was 40 percent.[27] The Strong Heart Study reported the average prevalence of overweight using BMI ≥ 27.8 or ≥ 27.3 for men and women, respectively, in three groups of American Indians studied during 1988-1989 as follows: in Arizona, 67 percent of the men and 80 percent of the women; in Oklahoma, 67 percent of the men and 71 percent of the women; and in South Dakota and North Dakota, 54 percent of the men and 66 percent of the women. [52]

Women in the United States with low incomes or low education are more likely to be obese than those of higher socioeconomic status; the association of socioeconomic status with obesity is less consistent in men [53] (Appendix III). Obesity is less common after the age of 70 among both men and women, possibly due to a progressive decrease in BMI with increasing age past the fifth decade or to an excess in mortality associated with increasing BMI in the presence of increasing age. [1]

3. Economic Costs of Overweight and Obesity

Alarm about the increasing prevalence of overweight and obesity in the United States in recent years [54, 55] centers on the link between obesity and increased health risks, [42, 56] which translates into increased medical care and disability costs. [46,57] The total cost attributable to obesity amounted to $99.2 billion in 1995. Approximately $51.6 billion of these dollars were direct medical costs associated with diseases attributable to obesity. The direct costs also associated with obesity represent 5.7 percent of the national health expenditure within the United States. [58] The indirect costs attributable to obesity are $47.6 billion and are comparable to the economic costs of cigarette smoking. [58, 59] Indirect costs represent the value of lost output caused by morbidity and mortality, and may have a greater impact than direct costs at the personal and societal levels. [58]

Although a comprehensive cost analysis of obesity is beyond the scope of this panel, a systematic review of the literature identified studies estimating the current economic burden of obesity in several Western countries. [57, 60-63] Published estimates of the economic costs of obesity such as those noted above use the prevalence-based approach, assuming that obesity is causally related to a range of chronic illnesses. Estimating the economic benefits of weight loss requires details of long-term weight maintenance and the time course of risk reduction following weight loss, and ultimately must also consider the costs of treatment to reduce weight.

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TABLE II-2:

PREVALENCE OF OBESITY (BMI≥30.0 KG/M²) AMONG ADULTS AGE 20 TO 80+ YEARS, BY GENDER, RACE/ETHNICITY, AND AGE: UNITED STATES, 1960-1994.[48]

Gender, race/ethnicity, age 20 years and older, age adjusted:	NHES I 1960-62 (age 20-74)	NHANES I 1971-74 (age 20-74)	NHANES II 1976-80 (age 20-74)	HHANES 1982-84 (age 20-74)	NHANES III 1988-94 (age ≥20)
Both Sexes	12.8	14.1	14.4		22.3
Men	10.4	11.8	12.2		19.5
Women	15.1	16.1	16.3		25.0
White men	10.1	11.4	12.0		20.0
White women	13.7	14.7	14.9		23.5
Black men	13.9	15.9	15.2		20.6
Black women	25.0	28.6	30.2		36.5
White, non-Hispanic men			12.0		19.9
White, non-Hispanic women			14.8		22.7
Black, non-Hispanic men			15.0		20.7
Black, non-Hispanic women			30.0		36.7
Mexican-American men				15.4	20.6
Mexican-American women				25.4	33.3
Age and gender-specific categories:					
Men					
20-29	9.0	8.0	8.1		12.5
30-39	10.4	13.3	12.1		17.2
40-49	11.9	14.2	16.4		23.1
50-59	13.4	15.3	14.3		28.9
60-69	7.7	10.3*	13.5*		24.8
70-79	8.6	11.1**	13.6**		20.0
80+	N/A**	N/A	N/A		8.0
Women					
20-29	6.1	8.2	9.0		14.6
30-39	12.1	15.1	16.8		25.8
40-49	17.1	17.6	18.1		26.9
50-59	20.4	22.0	22.6		35.6
60-69	27.2	24.0*	22.0*		29.8
70-79	21.9	21.0	19.4**		25.0
80+	N/A**	N/A**	N/A		15.1

* Prevalence for age 70 to 74 years ** Not available

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B Prevention of Overweight and Obesity

Prevention of overweight and obesity is as important as treatment. Prevention includes primary prevention of overweight or obesity itself, secondary prevention or avoidance of weight regain following weight loss, and prevention of further weight increases in obese individuals unable to lose weight. [44, 64]

National and international observational data suggest that environmental and behavioral factors are likely to be important in the tendency of individuals within and between populations to be obese during childhood or to gain weight progressively with age during adulthood. [65] These factors are also influenced by the genetic makeup of individuals. There has been a paucity of intervention research to demonstrate how these factors can be manipulated to prevent obesity. [64] In two community studies, namely the Minnesota Heart Health Program and the Stanford Five City Study, multifaceted weight loss and weight control programs within the community were not associated with prevention of weight gain in longitudinally followed cohorts. [66] In another community study, the Pawtucket Heart Health Program, BMI levels did not change in the intervention cities while they increased in the comparison cities. [67] One obesity prevention study of American Indian children who are at high risk of becoming obese is under way. [68] Otherwise, the only long-term report suggesting an effective approach to obesity prevention is from follow-up of obese children in an experimental study in which they had been treated with or without a family-oriented treatment program. Long-term follow-up (10 years) of these children supported the importance of family involvement in reducing the progression of obesity. [69] One population-based randomized controlled pilot study of obesity prevention suggests that programs for weight gain prevention are feasible and effective in adults. [34] Another study in China has shown that the prevention of weight gain through diet, physical activity, and their combination can help prevent diabetes. [70]

It has been suggested that primary prevention of obesity should include environmentally based strategies that address major societal contributors to over-consumption of calories and inadequate physical activity such as food marketing practices, transportation patterns, and lack of opportunities for physical activity during the workday. [71,72] People at lower socioeconomic levels living in urban areas also lack access to physical activity sites. Such strategies will be essential for effective initial and long-term prevention of obesity for large numbers of individuals and for the community at large. Research is needed to clarify the role of societal policies, procedures, laws, and other factors that serve as disincentives to lifelong caloric balance. The importance of obesity prevention needs to be brought to the attention of health care payors and practitioners, employers, educators, and public officials as an important priority to be addressed in policies, programs, and direct services to individuals and families. The development and implementation of appropriate policies and programs will require outcomes research that identifies effective weight gain prevention approaches. These programs must be useful for multiple settings, including health care facilities, schools, worksites, community and religious institutions, and be applicable to a broad population. In the end, efforts should be made to make the general public more aware of the need to prevent overweight and obesity.

Efforts to understand the genetic, developmental, environmental, and behavioral underpinnings of obesity and to mount successful prevention strategies are particularly critical for populations in which overweight and obesity and related health problems such as diabetes are disproportionately prevalent; for example, women in lower socioeconomic groups and women and sometimes men in many racial/ethnic minority

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populations as described in Chapter 2.A.2 of this report. Public health approaches for preventing obesity, that is, approaches designed to reduce the difficulty for any given individual of adopting healthful eating and activity patterns, will particularly benefit the socially disadvantaged, who—compared to the more advantaged— may have less access to preventive health services and fewer feasible options for making changes in their daily routines and lifestyles. [73-75]

Primary care practitioners are an important element in preventing and managing obesity in the United States. Prevention of overweight and obesity in primary care settings is compatible with efforts to prevent their health consequences, through control of dyslipidemia, high blood pressure, and type 2 diabetes. Thus, both the quality and quantity of life may be enhanced through preventive strategies. As detailed elsewhere in this report, high blood pressure, high blood cholesterol, and type 2 diabetes should be aggressively treated in overweight patients and may be treated prior to and in conjunction with weight loss.

C Health Risks of Overweight and Obesity

1. Morbidity

Above a BMI of 20 kg/m^2 , morbidity for a number of health conditions increases as BMI increases. Higher morbidity in association with overweight and obesity has been observed for hypertension, [2-6, 76-80] type 2 diabetes, [7, 8, 10, 81, 82, 84-89] coronary heart disease (CHD), [11,42,86,88,90] stroke, [11-13] gallbladder disease, [14,15] osteoarthritis, [16-18, 91-95] sleep apnea and respiratory problems [21, 96-98] and some types of cancer (endometrial, breast, prostate, and colon). [107-115] Obesity is also associated with complications of pregnancy, menstrual irregularities, hirsutism, stress incontinence, and psychological disorders (depression). [112, 116-128]

The nature of obesity-related health risks is similar in all populations, although the specific level of risk associated with a given level of overweight or obesity may vary with race/ethnicity, and also with age, gender, and societal conditions. For example, the absolute risk of morbidity in chronic conditions such as CHD is highest in the aged population, while the relative risk of having CHD in obese versus nonobese individuals is highest in the middle adult years. [129-131] A high prevalence of diabetes mellitus in association with obesity is observed consistently across races/ethnicities, while the relative prevalence of hypertension and CHD in obese versus nonobese populations varies between groups.

The health risks of overweight and obesity are briefly described below:

1.a. Hypertension

Data from NHANES III show that the age-adjusted prevalence of high blood pressure increases progressively with higher levels of BMI in men and women (Figure 2). [2] High blood pressure is defined as mean systolic blood pressure ≥ 140 mm Hg, or mean diastolic blood pressure ≥ 90 mm Hg, or currently taking antihypertensive medication. The prevalence of high blood pressure in adults with BMI ≥ 30 is 38.4 percent for men and 32.2 percent for women, respectively, compared with 18.2 percent for men and 16.5 percent for women with BMI < 25, a relative risk of 2.1 and 1.9 for men and women, respectively. The direct and independent association between blood pressure and BMI or weight has been shown in numerous cross-sectional studies [3-5], including the large international study of salt (INTERSALT) carried out in more than 10,000 men and women. [6] INTERSALT reported that a 10 kg (22 lb) higher body weight is associated with 3.0 mm Hg higher systolic and 2.3 mm Hg higher diastolic blood pressure. [6] These differences in blood pressure translate into an estimated 12 percent increased risk for CHD and 24 percent

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increased risk for stroke. [132] Positive associations have also been shown in prospective studies. [76-80]

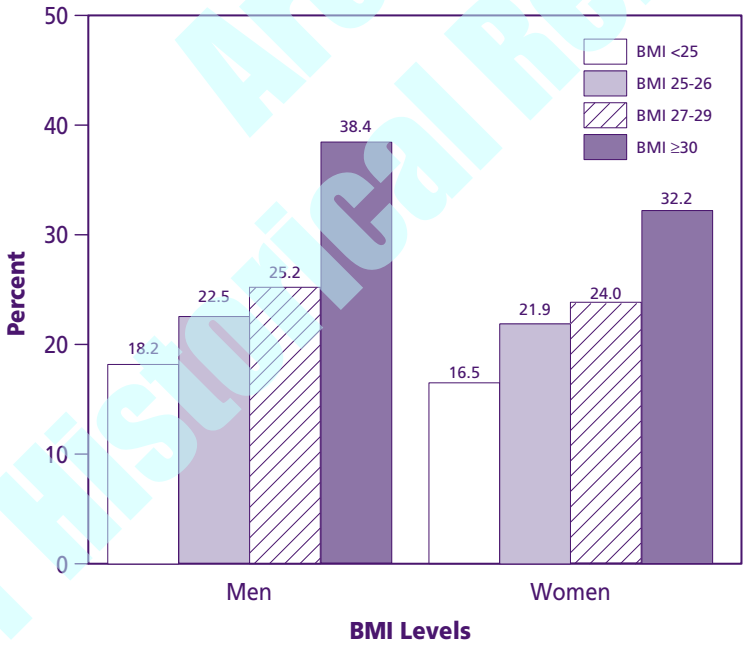
Obesity and hypertension are co-morbid risk factors for the development of cardiovascular disease. The pathophysiology underlying the development of hypertension associated with obesity includes sodium retention and associated increases in vascular resistance, blood volume, and cardiac output. These cardiovascular abnormalties associated with obesity are believed to be related to a combination of increased sodium retention, increased sympathetic nervous system activity, alterations of the renin-angiotensin system and insulin resistance. The precise mechanism whereby weight loss results in a decrease in blood pressure is unknown. However, it is known that weight loss is associated with a reduction in vascular resistance, total blood volume and cardiac output, an improvement in insulin resistance, a reduction in sympathetic nervous system activity, and suppression of the activity of the renin angiotensin aldosterone system. [764-769]

1.b. Dyslipidemia, manifested by:

High total cholesterol

The relationship of the age-adjusted prevalence of high total cholesterol, defined as ≥ 240 mg/dL (6.21 mmol/L), to BMI from NHANES III is shown in Figure 3. [2] At each BMI level, the prevalence of high blood cholesterol is greater in women than in men. In a smaller sample, higher body weight is associated with higher levels of total serum cholesterol in both men [133] and women [134] at levels of BMI > 25. Several large longitudinal studies also provide evidence that overweight, obesity and weight gain are associat-

Figure 2. NHANES III Age-Adjusted Prevalence of Hypertension* According to Body Mass Index



* Defined as mean systolic blood pressure ≥140 mm Hg, mean diastolic as ≥90 mm Hg, or currently taking antihypertensive medication.

Source: Brown C. et al. Body Mass Index and the Prevalence of Risk Factors for Cardiovascular Disease (submitted for publication).

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ed with increased cholesterol levels. [135-137] In women, the incidence of hypercholesterolemia also increases with increasing BMI. [138] In addition, the pattern of fat distribution appears to affect cholesterol levels independently of total weight. Total cholesterol levels are usually higher in persons with predominant abdominal obesity, defined as a waist-to-hip circumference ratio of ≥ 0.8 for women and ≥ 1.0 for men. [139]

High triglycerides

The strong association of triglyceride levels with BMI has been shown in both cross-sectional and longitudinal studies, for both sexes and all age groups. [133, 134, 140, 141] In three adult age groups, namely 20 to 44 years, 45 to 59 years, and 60 to 74 years, higher levels of BMI, ranging from 21 or less to more than 30, have been associated with increasing triglyceride levels; the difference in triglycerides ranged from 61 to 65 mg/dL (0.68 to 0.74 mmol/L) in women [134] and 62 to 118 mg/dL (0.70 to 1.33 mmol/L) in men. [133]

Low high-density lipoprotein cholesterol

The age-adjusted prevalence of low high-density lipoprotein (HDL)-cholesterol in relation to BMI levels, based on NHANES III data, is shown in Figure 4. [2] HDL-cholesterol levels at all ages and weights are lower in men than in women. Although low HDL-cholesterol in this study was defined as < 35 mg/dL (0.91 mmol/L) in men and < 45 mg/dL (1.16 mmol/L) in women [2], the panel accepts the definition of low HDL-cholesterol as < 35 mg/dL for men and women used by the National Cholesterol Education Program's *Second Report of the Expert Panel on the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* (Adult Treatment Panel II Report). [142] Cross-sectional studies have reported that HDL-cholesterol levels are lower in men and women with higher BMI. [143,144] Longitudinal studies have found that changes in BMI are associated with changes in HDL-cholesterol. A BMI change of 1 unit is associated with an HDL-cholesterol change of 1.1 mg/dL for young adult men and an HDL-cholesterol change of 0.69 mg/dL for young adult women. [145]

Normal to elevated low-density lipoprotein cholesterol

The link between total serum cholesterol and CHD is largely due to low-density lipoprotein (LDL). A high-risk LDL-cholesterol is defined as a serum concentration of ≥ 160 mg/dL. This lipoprotein is the predominant atherogenic lipoprotein and is therefore the primary target of cholesterol-lowering therapy. Cross-sectional data suggest that LDL-cholesterol levels are higher by 10 to 20 mg/dL in relation to a 10 unit difference in BMI, from levels of 20 to 30 kg/m^2. [133,134] According to extensive epidemiological data, a 10 mg/dL rise in LDL-cholesterol corresponds to approximately a 10 percent increase in CHD risk over a period of 5 to 10 years. [146]

Small, dense low-density lipoprotein particles

Few large-scale epidemiological data are available on small, dense LDL particles. [147-149] Clinical studies have shown that small, dense LDL particles are particularly atherogenic and tend to be present in greater proportion in hypertriglyceridemic patients with insulin resistance syndrome associated with abdominal obesity. [148-152]

1.c. Diabetes Mellitus

The increased risk of diabetes as weight increases has been shown by prospective studies in Norway [7], the United States [8], Sweden [9], and Israel. [10] More recently, the Nurses' Health Study, using data based on self-reported weights, found that the risk of developing type 2 diabetes increases as BMI increases from a BMI as low as 22. [81] Since women in particular tend to underreport weight, the actual BMI values associated with these risks are likely to be higher than the Nurses' Health Study data would suggest. An association between type 2 diabetes and increasing relative weight is also observed in popula-

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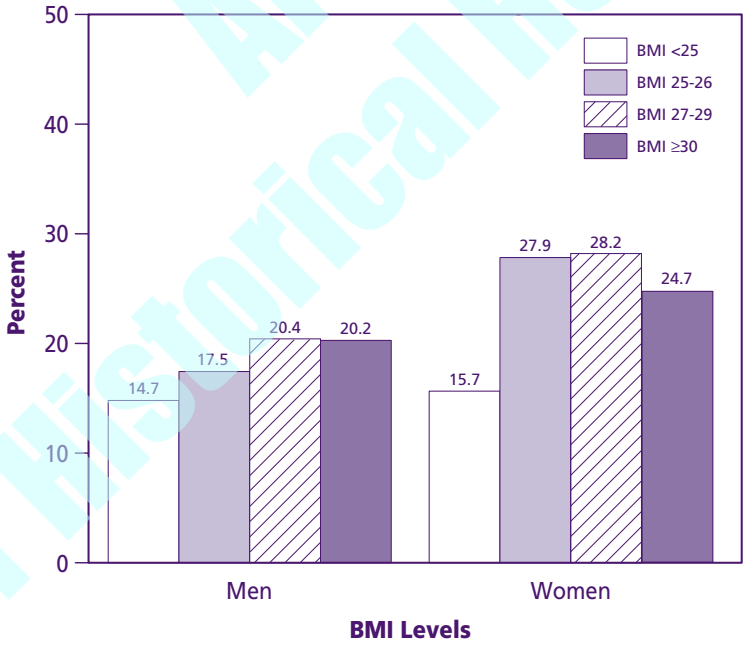
tions at high risk for obesity and diabetes, such as in American Indians. [153,154] In recent studies, the development of type 2 diabetes has been found to be associated with weight gain after age 18 in both men [82] and women. [81] The relative risk of diabetes increases by approximately 25 percent for each additional unit of BMI over 22 kg/m^2. [83] In addition, in a prospective study representative of the U.S. population, it was recently estimated that 27 percent of new cases of diabetes was attributable to weight gain in adulthood of 5 kg (11 lb) or more. [84] Both cross-sectional [85-87] and longitudinal studies [82,88,89] show that abdominal obesity is a major risk factor for type 2 diabetes. [82,87]

1.d. Coronary Heart Disease

Observational studies have shown that overweight, obesity, and excess abdominal fat are directly related to cardiovascular risk factors, including high levels of total cholesterol, LDL-cholesterol, triglycerides, blood pressure, fibrinogen and insulin, [86] and low levels of HDL-cholesterol. [42] Plasminogen activator inhibitor-1 causing impaired fibrinolytic activity is elevated in persons with abdominal obesity. [763] Overweight, obesity, and abdominal fat are also associated with increased morbidity and mortality from CHD. [11,42,155-161]

Recent studies have shown that the risks of nonfatal myocardial infarction and CHD death increase with increasing levels of BMI. Risks are lowest in men and women with BMIs of 22 or less and increase with even modest elevations of BMI. In the Nurses' Health Study, which controlled for age, smoking, parental history of CHD, menopausal status, and hormone use, rel-

Figure 3. NHANES III Age-Adjusted Prevalence of High Blood Cholesterol* According to Body Mass Index



*Defined as ≥240 mg/dL

Source: Brown C. et al. Body Mass Index and the Prevalence of Risk Factors for Cardiovascular Disease (submitted for publication).

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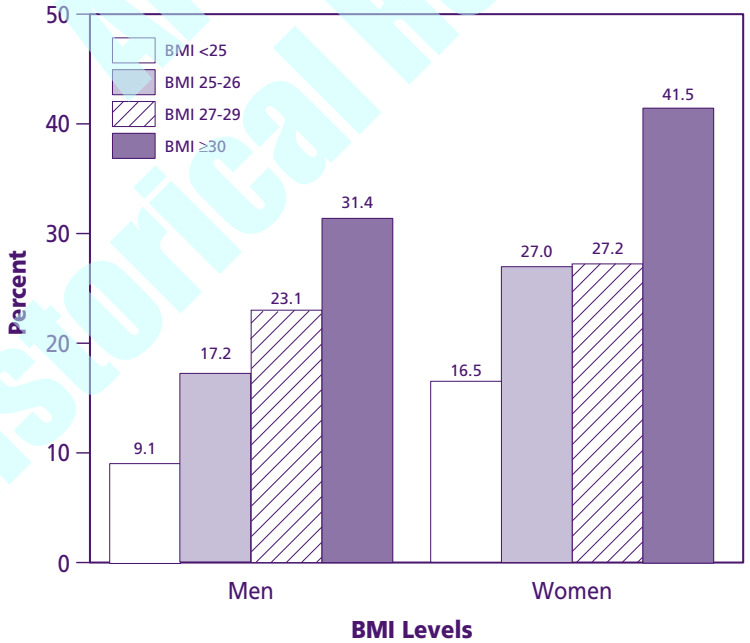
ative risks for CHD were twice as high at BMIs of 25 to 28.9, and more than three times as high at BMIs of 29 or greater, compared with BMIs of less than 21. [90] Weight gains of 5 to 8 kg (11 to 17.6 lb) increased CHD risk (nonfatal myocardial infarction and CHD death) by 25 percent, and weight gains of 20 kg (44 lb) or more increased risk more than 2.5 times in comparison with women whose weight was stable within a range of 5 kg (11 lb). [90] In British men, CHD incidence increased at BMIs above 22 and an increase of 1 BMI unit was associated with a 10 percent increase in the rate of coronary events. [162] Similar relationships between increasing BMI and CHD risk have been shown in Finnish, Swedish, Japanese, and U.S. populations. [90, 163, 164]

A relationship between obesity and CHD has not always been found. Two reasons may account for this: the first is an inappropriate controlling for cholesterol, blood pressure, diabetes, and other risk factors in statistical analysis; and the second is that there was not an adequate control for the confounding effect of cigarette smoking on weight. [88] People who smoke often have a lower body weight but more CHD.

1.e. Congestive Heart Failure

Overweight and obesity have been identified as important and independent risk factors for congestive heart failure (CHF) in a number of studies, including the Framingham Heart Study. [11, 165-169] CHF is a frequent complication of severe obesity and a major cause of death; duration of the obesity is a strong predictor of CHF. [170] Since

Figure 4. NHANES III Age-Adjusted Prevalence of Low HDL-Cholesterol* According to Body Mass Index



*Defined as <35 mg/dL in men and <45 mg/dL in women.

Source: Brown C. et al. Body Mass Index and the Prevalence of Risk Factors for Cardiovascular Disease (submitted for publication).

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hypertension and type 2 diabetes are positively associated with increasing weight, the coexistence of these conditions facilitates the development of CHF. [171] Data from the Bogalusa Heart Study demonstrate that excess weight may lead to acquisition of left ventricular mass beyond that expected from normal growth. [171] Obesity can result in alterations in cardiac structure and function even in the absence of systemic hypertension or underlying heart disease. Ventricular dilatation and eccentric hypertrophy may result from elevated total blood volume and high cardiac output. Diastolic dysfunction from eccentric hypertrophy and systolic dysfunction from excessive wall stress result in so-called "obesity cardiomyopathy". [172, 173] The sleep/apnea obesity hyperventilation syndrome occurs in 5 percent of severely obese individuals, and is potentially life-threatening. Extreme hypoxemia induced by obstructive sleep apnea syndrome may result in heart failure in the absence of cardiac dysfunction. [174]

1.f. Stroke

The relationship of cerebrovascular disease to obesity and overweight has not been as well studied as the relationship to CHD. A report from the Framingham Heart Study suggested that overweight might contribute to the risk of stroke, independent of the known association of hypertension and diabetes with stroke. [11] More recently published reports [12, 13] are based on larger samples and delineate the importance of stroke subtypes in assessing these relationships. They also attempt to capture all stroke events, whether fatal or nonfatal. These studies suggest distinct risk factors for ischemic stroke as compared to hemorrhagic stroke, and found overweight to be associated with the former, but not the latter. This may explain why studies that use only fatal stroke outcomes (and thus overrepresent hemorrhagic strokes) show only weak relationships between overweight and stroke. These recent prospective studies demonstrate that the risk of stroke shows a graded increase as BMI rises. For example, ischemic stroke risk is 75 percent higher in women with BMI > 27, and 137 percent higher in women with a BMI > 32, compared with women having a BMI < 21. [12]

1.g. Gallstones

The risk of gallstones increases with adult weight. Risk of either gallstones or cholecystectomy is as high as 20 per 1,000 women per year when BMI is above 40, compared with 3 per 1,000 among women with BMI < 24. [14] According to NHANES III data, the prevalence of gallstone disease among women increased from 9.4 percent in the first quartile of BMI to 25.5 percent in the fourth quartile of BMI. Among men, the prevalence of gallstone disease increased from 4.6 percent in the first quartile of BMI to 10.8 percent in the fourth quartile of BMI. [15]

1.h. Osteoarthritis

Individuals who are overweight or obese increase their risk for the development of osteoarthritis. [16-18,91,92] The association between increased weight and the risk for development of knee osteoarthritis is stronger in women than in men. [92] In a study of twin middle-aged women, it was estimated that for every kilogram increase of weight, the risk of developing osteoarthritis increases by 9 to 13 percent. The twins with knee osteoarthritis were generally 3 to 5 kg (6.6 to 11 lb) heavier than the co-twin with no disease. [16] An increase in weight is significantly associated with increased pain in weight-bearing joints. [175] There is no evidence that the development of osteoarthritis leads to the subsequent onset of obesity. [91] A decrease in BMI of 2 units or more during a 10-year period decreased the odds for developing knee osteoarthritis by more than 50 percent; weight gain was associated with a slight increase in risk. [93]

A randomized controlled trial of 6 months' duration examined the effect of weight loss on

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clinical improvement in patients with osteoarthritis. [176] Patients taking phentermine had an average weight loss of 12.6 percent after 6 months while the control group had an average weight loss of 9.2 percent. There was improvement in pain-free range of motion and a decrease in analgesic use in association with weight loss; patients with knee disease showed a stronger association than those with hip disease. Similarly, improvement of joint pain was observed in individuals who had undergone gastric stapling, resulting in an average weight loss of 45 kg (99 lb). [94, 95]

1.i. Sleep Apnea

Obesity, particularly upper body obesity, is a risk factor for sleep apnea and has been shown to be related to its severity. [19,20] The major pathophysiologic consequences of severe sleep apnea include arterial hypoxemia, recurrent arousals from sleep, increased sympathetic tone, pulmonary and systemic hypertension, and cardiac arrhythmias. [21] Most people with sleep apnea have a BMI > 30. [96,97] Large neck girth in both men and women who snore is highly predictive of sleep apnea. In general, men whose neck circumference is 17 inches or greater and women whose neck circumference is 16 inches or greater are at higher risk for sleep apnea. [98] Additional information on sleep apnea is included as Appendix IV.

1.j. Cancer

Colon Cancer

Many studies have found a positive relation between obesity and colon cancer in men but a weaker association in women. [8,22-24,99-106] More recent data from the Nurses' Health Study suggest that the relationship between obesity and colon cancer in women may be similar to that seen in men. Twice as many women with a BMI of > 29 kg/m^2 had distal colon cancer as women with a BMI < 21 kg/m^2. [107] In men, the relationship between obesity and total colon cancer was weaker than that for distal colon cancer. Other data from the Nurses' Health Study show a substantially stronger relationship between waist-to-hip ratio and the prevalence of colon polyps on sigmoidoscopy, than with BMI alone. [108] Even among leaner women, a high waist-to-hip ratio is also associated with significantly increased risk of colon polyps. [107]

Breast Cancer

Epidemiologic studies consistently show that obesity is directly related to mortality from breast cancer, predominantly in postmenopausal women, [8] but inversely related to the incidence of premenopausal breast cancer. [109-112] Ten or more years after menopause, the premenopausal "benefit" of obesity has dissipated. [113] Among postmenopausal women, peripheral fat is the primary source of estrogens, the major modifiable risk factor for postmenopausal breast cancer. This crossover in the relationship of obesity with breast cancer, pre- and postmenopausally, complicates prevention messages for this common female cancer. Recent data from the Nurses' Health Study, however, show that adult weight gain is positively related to risk of postmenopausal breast cancer. This relation is seen most clearly among women who do not use postmenopausal hormones. A gain of more than 20 lb from age 18 to midlife doubles a woman's risk of breast cancer. Even modest weight gains are positively related to risk of postmenopausal cancer. [114]

Endometrial Cancer

Obesity increases the risk of endometrial cancer. The risk is three times higher among obese women (BMI ≥ 30 kg/m^2) compared to normal-weight women. [115] However, the absolute risk of this condition is low when compared to breast cancer, heart disease, and diabetes. Adult weight gain is also related to increased risk. [115]

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Gallbladder Cancer

Obesity is related to the risk of gallbladder cancer, particularly among women. [177] Using a weight index of 100 as the average weight with a corresponding mortality ratio of 1.0 for the cohort, mortality ratios were 1.16 at a weight index of 120 to 129, 1.22 at 130 to 139, and 1.53 at ≥140.

1.k. Obesity and Women's Reproductive Health

Menstrual Function and Fertility

Obesity in premenopausal women is associated with menstrual irregularity and amenorrhea. [112,116] As part of the Nurses' Health Study, a case control study suggested that the greater the BMI at age 18 years, even at levels lower than those considered obese, the greater the risk of subsequent ovulatory infertility. [117] The most prominent condition associated with abdominal obesity is polycystic ovarian syndrome, [118] a combination of infertility, menstrual disturbances, hirsutism, abdominal hyperandrogenism, and anovulation. This syndrome is strongly associated with hyperinsulinemia and insulin resistance. [119]

Pregnancy

Pregnancy can result in excessive weight gain and retention. The 1988 National Maternal and Infant Survey observed that 41.6 percent of women reported retaining ≥ 9 lb of their gained weight during pregnancy, with 33.8 percent reporting ≥14 lb of retained weight gain. [120] The retained weight gain associated with pregnancy was corroborated by the study of Coronary Artery Risk Development in Young Adults (CARDIA). As a result of their first pregnancy, both black and white young women had a sustained weight gain of 2 to 3 kg (4.4 to 6.6 lb) of body weight. [121] Another study on a national cohort of women followed for 10 years reported that weight gain associated with childbearing ranged from 1.7 kg (3.7 lb) for those having one live birth during the study to 2.2 kg (4.9 lb) for those having three. [178] In addition, higher prepregnancy weights have been shown to increase the risk of late fetal deaths. [179]

Obesity during pregnancy is associated with increased morbidity for both the mother and the child. A tenfold increase in the prevalence of hypertension and a 10 percent incidence of gestational diabetes have been reported in obese pregnant women. [122] Obesity also is associated with difficulties in managing labor and delivery, leading to a higher rate of induction and primary Caesarean section. Risks associated with anesthesia are higher in obese women, as there is greater tendency toward hypoxemia and greater technical difficulty in administering local or general anesthesia. [123] Finally, obesity during pregnancy is associated with an increased risk of congenital malformations, particularly of neural tube defects. [123]

A certain amount of weight gain during pregnancy is desirable. The fetus itself, expanded blood volume, uterine enlargement, breast tissue growth, and other products of conception generate an estimated 13 to 17 lb of extra weight. Weight gain beyond this, however, is predominantly maternal adipose tissue. It is this fat tissue that, in large measure, accounts for the postpartum retention of weight gained during pregnancy. In turn, this retention reflects a postpartum energy balance that does not lead to catabolism of the gained adipose tissue. In part, this may reflect reduced energy expenditure through decreased physical activity, even while caring for young children, but it may also reflect retention of the pattern of increased caloric intake acquired during pregnancy. [180]

One difficulty in developing recommendations of optimal weight gain during pregnancy relates to the health of the infants. A balance must be achieved between high-birth-weight infants who may pose problems during delivery and who may face a higher rate of Caesarean sections and low-birth-weight infants who face a higher

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WEIGHT GAIN DURING PREGNANCY

BMI	Kilograms	Pounds
<19.8	12.5 to 18	28 to 40
19.8 to 26	11.5 to 16	25 to 35
>26 to 29	7 to 11.5	15 to 25
>29	≤6	≤13

infant mortality rate. [181] However, data from the Pregnancy Nutrition Surveillance System from the CDC showed that very overweight women would benefit from a reduced weight gain during pregnancy to help reduce the risk for high-birth-weight infants. [181]

The 1990 Institute of Medicine report made recommendations concerning maternal weight gain. [182] It recommended that each woman have her BMI measured and recorded at the time of entry into prenatal care. For women with a BMI of less than 20, the target weight gain should be 0.5 kg (1.1 lb) of weight gain per week during the second and third trimester. For a woman whose BMI is greater than 26, the weight gain target is 0.3 kg (0.7 lb) per week during the last two trimesters.

Women who are overweight or obese at the onset of pregnancy are advised to gain less total weight during the pregnancy (see box above). [182]

1.I. Psychosocial Aspects of Overweight and Obesity

A number of reviews have been published on the psychosocial aspects of obesity. [124-128,183] The specific topics that will be reviewed here include social stigmatization, psychopathology, binge eating, and body image perceptions.

Social stigmatization

In American and other Westernized societies there are powerful messages that people, especially women, should be thin, and that to be fat is a sign of poor self-control. [125, 126, 128, 184, 185] Negative attitudes about the obese have been reported in children and adults, [186-191] in health care professionals, [192-194] and in the overweight themselves. [195, 196]

People's negative attitudes toward the obese often translate into discrimination in employment opportunities, [197-199] college acceptance, [200] less financial aid from their parents in paying for college, [195, 201] job earnings, [202] rental availabilities, [203] and opportunities for marriage. [204]

Much of the research on the social stigma of obesity has suffered from methodological limitations. For example, a number of the early studies relied on line drawings rather than more lifelike representations of obese people and on checklists that forced one to make YES or NO choices. More importantly, there has been a lack of research that has looked at the impact of obesity in the context of other variables, such as physical attractiveness, the situational context, and the degree of obesity. [184,185] In addition, social stigma toward the obese has primarily been assessed among white individuals. There is some evidence that members of other racial and ethnic groups are less harsh in their evaluation of obese persons. One study assessed 213 Puerto Rican immigrants to the United States, and found a wide range of acceptable weights among them. [205] Crandall found that Mexican students were sig-

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nificantly less concerned about their own weight and were more accepting of other obese people than were U.S. students. [206] In addition, the degree of acceptance of obesity among people of lower education and income has not been well studied. Thus, these data are very incomplete with respect to racial and ethnic groups other than whites.

Psychopathology and Obesity

Research relating obesity to psychological disorders and emotional distress is based on community studies and clinical studies of patients seeking treatment. In general, community-based studies in the United States have not found significant differences in psychological status between the obese and nonobese. [126,183,207,208] However, several recent European studies in general populations do suggest a relationship between obesity and emotional problems. [209-211] Thus, it may be premature to state that there is no association between obesity and psychopathology or emotional distress in the general population. More focused, hypothesis-driven, and long-term studies are needed.[127, 212]

Overweight people seeking weight loss treatment may, in clinic settings, show emotional disturbances. [213-215] In a review of dieting and depression, there was a high incidence of emotional illness symptoms in outpatients treated for obesity. [213] However, several factors influenced these emotional responses, including childhood onset versus adult onset of obesity (those with childhood onset obesity appear more vulnerable). Another study that compared different eating disorder groups found that obese patients seeking treatment showed considerable psychopathology, most prominently mild to severe depression. [214] Sixty-two percent of the obese group seeking treatment showed clinically significant elevations on the depression subscale of the Minnesota Multiphasic Personality Inventory, and 37 percent of this same group showed a score of 20 or higher (indicating clinical depression) on the Beck Depression Inventory. Focusing on depression was considered an important component of the weight loss program. Another study compared obese people who had not sought treatment to an obese group that had sought treatment in a professional, hospital-based program, and to normal weight controls. [215] Again, obese individuals seeking treatment reported more psychopathology and binge eating compared to the other groups. Both obese groups reported more symptoms of distress than did normal weight controls. The authors suggest that the obese population is not a homogenous group, and thus, may not respond in the same way to standardized treatment programs. In particular, obese individuals seeking treatment in clinic settings are more likely than obese individuals not seeking treatment and normal controls to report more psychopathology and binge eating.

Binge Eating Disorder

Binge eating disorder (BED) is characterized by eating larger amounts of food than most people would eat in a discrete time period (e.g., 2 hours) with a sense of lack of control during these episodes.[762] It is estimated to occur in 20 to 50 percent of individuals who seek specialized obesity treatment. [216-218] In community-based samples, the prevalence is estimated to be approximately 2 percent. [219] Comparisons have been made between BED and bulimia nervosa (BN), an eating disorder characterized by recurrent and persistent binge eating, accompanied by the regular use of behaviors such as vomiting, fasting, or using laxatives. Studies comparing normal weight individuals who have BN with obese BED individuals have found that obese binge eaters are less likely to demonstrate dietary restraint and show few if any adverse reactions to moderate or severe dieting. Most obese binge eaters do not engage in inappropriate compensatory behaviors such as purging. [220] Compared with BN, the demographic distribution of BED

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is broader with respect to age, gender, and race [218, 219, 221-225] while data suggest that BED is as common in African-American women as in white women. [226] The difference between BED and BN is dramatic regarding gender. Very few men have BN, [227] whereas the distribution is close to equal in BED. [225, 228, 229]

Compared to obese nonbingers, obese individuals with BED tend to be heavier, [230] report greater psychological distress, and are more likely to have experienced a psychiatric illness (especially affective disorders). [225,231-236] They also report an earlier onset of obesity and a greater percentage of their lifetime on a diet. [237, 238] Some studies have shown histories of greater weight fluctuation or weight cycling in obese binge eaters compared with nonbingers, [219, 237, 238] but others have not. [239] These individuals are also more likely than nonbinging obese people to drop out of behavioral weight loss programs, [233] and to regain weight more quickly. [220,233,240]

Critics of behavioral treatment of obesity have argued that caloric restriction may cause or contribute to the episodes of binge eating and BN. [241] Three studies have tested this hypothesis. [218, 242,243] Neither moderate nor severe caloric restriction exacerbated binge eating. All three studies showed that weight control treatment featuring caloric restriction significantly reduced the frequency of binge eating in these patients.

Body Image

Body image is defined as the perception of one's own body size and appearance and the emotional response to this perception. [183,244] Inaccurate perception of body size or proportion and negative emotional reactions to size perceptions contribute to poor body image. Obese individuals, especially women, tend to overestimate their body size. [245-249]

People at greater risk for a poor body image are binge eaters, women, those who were obese during adolescence or with early onset of obesity, and those with emotional disturbances. [127, 235, 244, 250-253] It is no surprise, then, that in some groups of obese persons, these individuals are more dissatisfied and preoccupied with their physical appearance, and avoid more social situations due to their appearance. [254, 255] Body image dissatisfaction and the desire to improve physical appearance often drives individuals to seek weight loss. However, obese persons seeking weight reduction must come to terms with real limits in their biological and behavioral capacities to lose weight. Otherwise, weight loss attempts may only intensify the sense of failure and struggle that is already present among many obese individuals. For this reason, psychosocial interventions which incorporate strategies to improve body image may be helpful for those who want to lose weight and are very concerned about their physical appearance. A review of body image interventions in obese persons can be found in Rosen (1996). [256]

Body image perceptions of individuals in various ethnic and racial groups may be different, on average, from those of the mainstream culture. There may be a similar range of attitudes but on a different scale; for example, it may take a much greater degree of overweight to elicit negative reactions. [257] Differences in body image and weight-related concerns between black and white girls and women have been observed. [257] In general, black girls and women report: less social pressure to be slim, [258-260] fewer incidences of weight-related discrimination, [261] less weight and body dissatisfaction, and greater acceptance of overweight than their white counterparts. [259,262-266] College-age black women report less concern and fear about fatness, less drive to be thin, and less concern about dieting than do college-age white women. [267] In addition, black women may ascribe some positive qualities to being large, such as having stamina, strength, and solidity, and are less likely to link body size to health

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than white women. Black elementary school and high school girls were more likely to be trying to gain weight [268, 269] and less likely to be trying to lose weight as compared to white girls. [269] Because of the above, it is possible that weight control initiatives may elicit different reactions from black and white women. Less is known about the relationship between obesity and body image disturbance in other racial and ethnic groups. [270]

2. Overweight/Obesity and Morbidity in Minority Populations

The data on overweight and obesity in minority populations include men and women across a wide age range and geographic area. Relevant studies increasingly consist of well-designed, population-based surveys and longitudinal studies. These studies have standardized, objective measurements of overweight and obesity and risk factors or disease outcomes. There is now a wealth of evidence to demonstrate that overweight and obesity incidence (both generalized and abdominal) predisposes to chronic diseases in racial/ethnic minority populations as it does in whites, though the absolute risk may differ. [51-52, 271-284] Indications for treatment of overweight and obesity in minority populations are, therefore, the same as those for non-Hispanic whites. Apparent differences in the strength of association between obesity and disease in various populations are not necessarily relevant to individuals in clinical settings, and obesity should be treated in any situation in which excess weight is associated with an observable or probable risk of morbidity. In addition, from a public health perspective, the need for obesity prevention and treatment is particularly pressing in racial/ethnic minority populations because of the high proportion of overweight and obese persons in many such populations.

3. Obesity and Mortality

As stated in the introduction to the guidelines, in the majority of epidemiologic studies, mortality begins to increase with BMIs above 25 kg/m^2. [28-32] The increase in mortality generally tends to be modest until a BMI of 30 kg/m^2 is reached. [28, 29, 31, 32] For persons with a BMI of 30 kg/m^2 or above, mortality rates from all causes, and especially from cardiovascular disease, are generally increased by 50 to 100 percent above that of persons with BMIs in the range of 20 to 25 kg/m^2. [28,31,32] Three aspects of the association between obesity and mortality remain unresolved:

3.a. Association of Body Mass Index With Mortality

Many of the observational epidemiologic studies of BMI and mortality have reported a 'U-' or 'J-shaped' relationship between BMI and mortality. [28] Mortality rates are elevated in persons with low BMI (usually below 20) as well as in persons with high BMI. [28, 31, 32] In some studies, adjustment for factors that potentially confound the relationship between BMI and mortality, such as smoking status and pre-existing illness, tends to reduce the upturn in mortality rate at low BMI,[31] but in a meta-analysis the higher mortality at low BMIs was not eliminated after adjustment for confounding factors. [32] It is unclear whether the elevated mortality observed at low BMI is due to an artifact of incomplete control for confounding factors, [285] inadequate body fat and/or inadequate body protein stores that result from unintentional weight loss, [286] or individual genetic factors. Currently, there is no evidence that intentional weight gain in persons with low BMIs will lead to a reduction in mortality.

3.b. Association of Body Mass Index With Mortality in Older Adults

Many of the observational epidemiologic studies suggest that the relationship between BMI and mortality weakens with increasing age, especially among persons aged 75 and above. [287-290] Several

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factors have been proposed to explain this observation. Older adults are more likely than younger adults to have diseases that both increase mortality and cause weight loss leading to lower body weight. [291-293] In addition, as people age, they tend to have larger waist circumferences that increase their risk of mortality even at lower BMIs. [294] Also, weight in middle age is positively related to risk of mortality in old age.[292] The impact of smoking on body weight and mortality is likely to be much stronger in older adults because of the cumulative health effects of smoking. [295]

BMI, which is an indirect estimate of adiposity, may underestimate adiposity in older adults whose BMI is similar to younger adults. [296] It is also possible that persons most sensitive to the adverse health effects of obesity are more likely to have died before reaching older ages, resulting in older cohorts that are more "resistant" to the health effects of obesity. Recently, a 20-year prospective study of a nationally representative sample of U.S. adults aged 55 to 74 years suggested that lowest mortality occurs in the BMI range of 25 to 30. [297 298] After adjusting for smoking status and pre-existing illness, lowest mortality occurred at a BMI of 24.5 in white men, 26.5 in white women, 27.0 in black men, and 29.8 in black women (see commentary on older adults on pages 90-91).

3.c. Association of Body Mass Index With Mortality in Ethnic Minorities

The levels of BMI associated with increased mortality are based on epidemiological studies of primarily white populations. The interest in confirming the association between BMI and mortality in other racial/ethnic groups stems partly from observations that lower-than-average total mortality has been observed among some populations with a high BMI level, [299] and partly from observations that within certain populations there appears to be no effect of obesity at all or at the BMI levels that are associated with higher mortality in whites.

African-Americans:
Three small cohort studies of narrowly defined populations of African-Americans failed to show the expected association of BMI and mortality based on data from white populations. [300-303] Although the shape of the association of BMI and mortality in two large, representative U.S. data sets (the National Health and Nutrition Examination Follow-up Study and the National Health Interview Survey) is similar for black and white males and females, [304] the BMI-related increase in risk begins at a 1 to 3 kg/m^2 higher BMI level for blacks than for whites. For example, in the National Health and Nutrition Examination Follow-up Survey, the estimated BMI associated with minimum mortality was 27.1 for black men and 26.8 for black women, compared with 24.8 and 24.3, respectively, for white men and women. On the basis of these data, the use of the cutpoint of BMI ≥ 30 kg/m^2 for defining obesity is clearly applicable to African-Americans as well as to whites.

Other Ethnic Minority Populations:
Limited data relating obesity to mortality in American Indians were identified, but no data were found relating obesity to mortality in Hispanic-Americans, Asian-Americans, or Pacific Islanders. [305] The lowest mortality rate among Pima men is observed at a BMI range of 35 to 40 kg/m^2 for men, and no relationship between BMI and mortality is observed among Pima women. [306, 307] Based on mortality data alone, it would be hard to justify using the same standard for defining obesity in populations, such as American Indians, among whom the mean BMI is much higher than in the general U.S. population. However, diabetes-related morbidity among obese American Indians is extremely high, [154] and the overall age-specific mortality among American Indians is generally higher

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than in the U.S. general population. [306,307] Thus, obesity in American Indians is associated with a compromised overall survival of the population.

Although the data on mortality are still fragmentary for many minority populations, there are no studies that would support the exclusion of any racial/ethnic group from the current definitions of obesity. Secular trends in many populations in the United States and throughout the world have demonstrated that longstanding overweight and obesity eventually leads to the emergence of chronic diseases. Therefore, prevalent overweight and obesity cannot be ignored even where the associated health problems have not reached the level that would be expected on the basis of data for white populations.

D Weight Loss and Mortality

A number of studies of "generic weight loss" (cause of weight loss unknown), "weight cycling" (cycles of weight loss followed by weight regain), and mortality have been published. [308-311] In most, [308,309,311] but not all, [310] of these studies, generic weight loss and weight cycling are associated with increases in mortality. None of these studies, however, differentiated between intentional and unintentional weight loss. [311] With the exception of the studies below, very little is currently known about factors related to intentional and unintentional weight loss in the general population or about the relationship between weight loss intention and mortality. [312]

Two studies of factors related to weight loss intention have been carried out in the general population: French and colleagues assessed correlates of intentional and unintentional weight loss of > 20 lb in the Iowa Women's Health Study, a cohort study of approximately 29,000 women with a mean age of about 65 years; [313-315] and Meltzer and Everhart analyzed data on 1-year self-reported weight change from approximately 9,000 participants in the nationally representative U.S. National Health Interview Survey, aged 45 years and above. [316] The results of these two studies suggest the following:

- In cross-sectional studies of weight loss recall, heavier persons are more likely to report intentional weight loss than unintentional weight loss, while the reverse is true for leaner persons;
- Intentional and unintentional weight losses occur with similar frequency in the U.S. population and contribute similarly to long-term weight fluctuation;
- The frequency of intentional weight loss is lower at older ages, while the frequency of unintentional weight loss is higher at older ages; and
- Unintentional weight loss occurs more often in persons who report that their health status is poor, who use medications for chronic health conditions, and who smoke. [312]

To date, only three studies have examined the relationship between intentional weight loss and mortality. Singh and colleagues [317] published results from a 1-year randomized controlled trial of a "cardioprotective diet" in East Indian patients hospitalized with recent myocardial infarction (mean age 50 years, mean BMI about 24 kg/m^2). Although this study was not designed to specifically test the efficacy of intentional weight loss on lower mortality, the authors found that those who lost at least 0.5 kg (1.1 lb) had a 50 percent lower incidence of cardiac events and a 54 percent lower risk of overall mortality compared with counterparts who lost < 0.5 kg (1.1 lb). [317]

Williamson and colleagues [318] published a 12-year prospective observational study of weight loss and mortality that directly assessed weight loss intention. They analyzed data from 43,457 overweight (BMI > 27), never-smoking, white women ages 40 to 64 years. Mortality ratios were compared for women who intentionally

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lost weight with those for women who had no change in weight. In women with obesity-related comorbidities, intentional weight loss of any amount was associated with a statistically significant 20 percent reduction in all-cause mortality, primarily due to a significant 40 to 50 percent reduction in mortality from obesity-related cancers; diabetes-related mortality was also significantly reduced by 30 to 40 percent in those who intentionally lost weight. In women with no comorbidities, intentional weight loss was generally unrelated to mortality; however, after subdividing intentional weight loss by time interval, it was found that a loss of at least 20 lb that occurred within the previous year was associated with small to modest increases in mortality. The authors concluded that the association between intentional weight loss and longevity in middle-age overweight women depends on health status. In addition, preliminary evidence suggests that intentional weight loss in middle-age overweight men may be associated with a similar reduction of diabetes-related mortality as was observed in the overweight women. [319]

The ongoing Swedish Obesity Study is a controlled trial of surgically induced weight loss and subsequent morbidity and mortality over a 10-year follow-up period (1,006 participants aged 37 to 57 years; initial BMI of 34 in men and 38 in women [320, 321]). Although the study is not randomized (participants self-select for surgery), the controls (who receive a behavioral weight loss program) are computer-matched to surgical participants on a large number of potential confounders including weight. [320] In a preliminary abstract, [322] the study reported the 2-year incidence rates shown in Table II-3.

These results for disease and risk factor incidences suggest that 10-year mortality will ultimately be lower in the surgical intervention group. Definitive mortality results have not been reported to date.

E Environment

The environment is a major determinant of overweight and obesity. Environmental influences on overweight and obesity are primarily related to food intake and physical activity behaviors [71]. In countries like the United States, there is an overall abundance of palatable, calorie-dense food. In addition, aggressive and sophisticated food marketing in the mass media, supermarkets, and restaurants, and the large portions of food served outside the home, promote high calorie consumption. Many of our sociocultural traditions promote overeating and the preferential consumption of high calorie foods. For many people, even when caloric intake is

TABLE II-3:

Two-Year Incidence Rates

	Control	Surgery
Diabetes	16 percent	0.5 percent
Hypertriglyceridemia	23 percent	6.0 percent
Low High-Density Lipoprotein Levels	16 percent	5.0 percent

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not above the recommended level, the number of calories expended in physical activity is insufficient to offset consumption. Mechanization limits the necessity of physical activity required to function in society. Many people are entrenched in sedentary daily routines consisting of sitting at work, sitting in traffic, and sitting in front of a television or a computer monitor for most of their waking hours.

In this obesity-promoting environment, individual attitudes and behaviors are critical in weight management. Many individuals may need extended treatment in clinical or community settings to enable them to cope with the complexities of long-term weight management, especially if there is a history of unsuccessful attempts at self-treatment. [44] When the typical daily routine is so strongly biased towards promoting and perpetuating overweight and obesity, very high levels of knowledge, motivation, personal behavioral management skill, and lifestyle flexibility are required for an overweight or obesity-prone individual to avoid becoming overweight, or progressing to moderate or severe obesity.

Although there are undoubtedly some inter- and intrapopulation variations in the genetic predisposition to become overweight or obese, several lines of evidence suggest that genetic factors alone cannot explain the demographic and ethnic variations in overweight and obesity prevalence. For example, there is a difference in obesity prevalence among low- and high-income white women in industrialized societies. [323,324] Other studies of populations, including migration studies, have shown an increase in average body weight in those who move from a traditional to a Westernized environment. [325-328] Culturally determined attitudes about food, physical activity, and factors that vary with income, education, and occupation may increase the level of difficulty in weight management. Body image concerns and other motivations for avoiding obesity or controlling weight within given limits also vary with ethnic background, age, socioeconomic status, and gender. Thus, the competence of practitioners in working with diverse sociocultural perspectives can be a critical factor in the success of obesity treatment. [257] For a discussion of cultural issues in obesity treatment and related references, see Appendix III.

F Genetic Influence in the Development of Overweight and Obesity

Obesity is a complex multifactorial chronic disease developing from interactive influences of numerous factors—social, behavioral, physiological, metabolic, cellular, and molecular. Genetic influences are difficult to elucidate and identification of the genes is not easily achieved in familial or pedigree studies. Furthermore, whatever the influence the genotype has on the etiology of obesity, it is generally attenuated or exacerbated by nongenetic factors.

A large number of twin, adoption, and family studies have explored the level of heritability of obesity; that is, the fraction of the population variation in a trait (e.g., BMI) that can be explained by genetic transmission. Recent studies of individuals with a wide range of BMIs, together with information obtained on their parents, siblings, and spouses, suggest that about 25 to 40 percent of the individual differences in body mass or body fat may depend on genetic factors. [329-331] However, studies with identical twins reared apart suggest that the genetic contribution to BMI may be higher, i.e., about 70 percent. [332] There are several other studies of monozygotic twins reared apart that yielded remarkably consistent results. [333] Some of the reasons behind the different results obtained from twin versus family studies have been reported. [334-336] The relative risk of obesity for first-degree relatives of overweight, moderately obese, or severely obese persons in comparison to the population prevalence of the condition

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reaches about 2 for overweight, 3 to 4 for moderate obesity, and 5 and more for more severe obesity. [337,338]

Support for a role of specific genes in human obesity or body fat content has been obtained from studies of Mendelian disorders with obesity as one of the clinical features, single-gene rodent models, quantitative trait loci from crossbreeding experiments, association studies, and linkage studies. From the research currently available, several genes seem to have the capacity to cause obesity or to increase the likelihood of becoming obese. [339] The rodent obesity gene for leptin, a natural appetite-suppressant hormone, has been cloned [340] as has been its receptor. [341] In addition, other single gene mutants have been cloned. [341, 342] However, their relationship to human disease has not been established, except for one study describing two subjects with a leptin mutation. [342] This suggests that for most cases of human obesity, susceptibility genotypes may result from variations of several genes.

Severely or morbidly obese persons are, on the average, about 10 to 12 BMI units heavier than their parents and siblings. Several studies have reported that a single major gene for high body mass was transmitted from the parents to their children. The trend implies that a major recessive gene, accounting for about 20 to 25 percent of the variance, is influenced by age and has a frequency of about 0.2 to 0.3. [343] However, no gene(s) has (have) yet been identified. Evidence from several studies has shown that some persons are more susceptible to either weight gain or weight loss than others. [344,345] It is important for the practitioner to recognize that the phenomenon of weight gain cannot always be attributed to lack of adherence to prescribed treatment regimens.

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Examination of Randomized Controlled Trial Evidence

3

A Why treat overweight and obesity?

The recommendation to treat overweight and obesity is based not only on the previously presented evidence that shows overweight is associated with increased morbidity and mortality, but also on randomized controlled trial (RCT) evidence that weight loss reduces risk factors for disease. Thus, weight loss may help control diseases worsened by overweight and obesity and may also decrease the likelihood of developing these diseases. The evidence meeting the panel's inclusion criteria is presented in the following section in the form of evidence statements with a corresponding rationale for each statement. The details of the studies reviewed but not discussed here are provided in Appendix II.

Many of the RCTs examined by the panel included the use of pharmacotherapy for weight loss. When the panel began its deliberations in 1995, two weight loss drugs, fenfluramine and dexfenfluramine, were being used widely for long-term weight loss, i.e., 14 million prescriptions were given out over 1½ years. However, as of September 1997, the Food and Drug Administration (FDA) requested the voluntary withdrawal of these drugs from the market due to a reported association between valvular heart disease and the use of dexfenfluramine and fenfluramine alone or combined with phentermine. [761] In November 1997, the FDA approved the drug sibutramine hydrochloride monohydrate for the management of obesity, including weight loss and maintenance of weight loss when used in conjunction with a reduced-calorie diet. Thus, at the present time only one weight loss drug is available for long-term weight loss. (Note: FDA approval for orlistat is pending a resolution of labeling issues and results of Phase III trials.) However, due to rapidly evolving information regarding the use of pharmacotherapy for weight loss, the panel decided to present (below) their critique of those pharmacotherapy trials meeting their criteria for consideration.

1. Blood Pressure

To evaluate the effect of weight loss on blood pressure and hypertension, 76 articles reporting the results of RCTs were potentially eligible for inclusion. Sixty articles included lifestyle trials that studied diet and/or physical activity, and 16 articles were of pharmacotherapy trials. Dietary interventions included low-calorie diets and diets that promoted macronutrient composition changes, such as amount and type of dietary fat. Physical activity, when included, was used to help promote increased energy expenditure. These trials did not always control for other dietary factors that lower blood pressure, such as dietary salt, and the degree to which those taking the blood pressure measurements were blinded to the patient's change in weight.

Of the 35 lifestyle RCT articles deemed acceptable, 16 included hypertensive patients, [346-361] and 19 were conducted in individuals with normal or high-normal blood pressure. [362-380]

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1.a.(1). Lifestyle Trials in Hypertensive Patients

Evidence Statement: *Weight loss produced by lifestyle modifications reduces blood pressure in overweight hypertensive patients. Evidence Category A.*

Rationale: A 1987 meta-analysis [381] covering five of the acceptable studies [351, 352, 356-358] in hypertensive patients concluded that weight loss accomplished by dietary interventions significantly lowered blood pressure. In hypertensive patients, 10 kg (22 lb) of weight loss was associated with an average reduction of 7 mm Hg systolic and 3 mm Hg diastolic blood pressure compared with controls. [381]

Since publication of this meta-analysis in 1987, almost all relevant studies have reported that weight loss reduces blood pressure or the need for medication in hypertensive patients: [346- 348, 350, 352-361]

- The Trial of Antihypertensive Interventions and Management (TAIM), conducted in hypertensive individuals not taking medication for 6 months, reported that, compared with controls, a mean net weight reduction of 4.7 kg (10.4 lb) reduced systolic and diastolic blood pressure by 2.8 mm Hg and 2.5 mm Hg, respectively; [355] the effects on blood pressure were equivalent to drug therapy among those participants who lost 4.5 kg (9.9 lb) or more. [360]
- One study in older (age 60 to 80 years) hypertensive adults whose blood pressure medication was withdrawn (Trial of Nonpharmacologic Interventions in the Elderly, TONE) showed that after 2 years, mean net weight loss of nearly 4 kg (9 lb) resulted in more participants free of trial endpoints (occurrence of high blood pressure, resumption of blood pressure medication, or occurrence of a cardiovascular-clinical complication [39.2 percent versus 26.2 percent]). [382] Furthermore, blood pressure control was similar for men and women and for African-Americans and whites. [353]
- In other studies of primarily middle-aged hypertensive adults, compared with controls, weight loss significantly reduced a return to hypertension medication at 1 year [354] and at 4 to 5 years. [348, 359]
- The Multiple Risk Factor Intervention Trial, which recruited 12,866 high-risk men, 30 percent of whom had hypertension, delivered an integrated intervention addressing several lifestyle behaviors and included weight loss as an important component. Significant reductions in systolic and diastolic blood pressure were found over 6 years compared with the usual care group and were directly related to weight loss: 1 kg (2.2 lb) of weight loss was associated with a reduction of 0.4 mm Hg systolic and 0.3 mm Hg diastolic blood pressure in men not taking antihypertensive medications. The effect was slightly lower for men taking antihypertensive medications.
- Only one RCT conducted in hypertensive patients reported no significant change in blood pressure despite weight loss of 3.3 kg (7.3 lb). [351]
- Another study conducted in hypertensive individuals suggested that weight loss reduced blood pressure only when sodium intake was also reduced. [349] This finding was not consistent with a prior study of hypertensive patients [358] and has not been corroborated in subsequent larger trials conducted in nonhypertensive individuals. [378, 379]

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1.a.(2). Lifestyle Trials in Nonhypertensive Individuals

Evidence Statement: *Weight loss produced by lifestyle modifications reduces blood pressure in overweight nonhypertensive individuals. Evidence Category A.*

Rationale: A semiquantitative review [383] covering four of the acceptable studies [363, 366, 372, 374] in nonhypertensive individuals concluded that weight loss through dietary interventions significantly lowered blood pressure. In nonhypertensives, excluding one outlier trial that showed very large reductions in blood pressure, [372] 1 kg (2.2 lb) of weight loss was associated with a reduction of 0.45 mm Hg in both systolic and diastolic blood pressure. Since this review, published in 1991, almost all relevant studies have reported that weight loss reduces blood pressure in nonhypertensive individuals. [364, 365, 367-371, 373, 375-380, 384]

The Trials of Hypertension Prevention Phase 1 (TOHP I) and Phase 2 (TOHP II) are among the larger, well-designed randomized trials, having follow-up rates exceeding 90 percent. They followed the participants for 18 months [378] and 3 to 4 years. [379] The sample size of the weight loss intervention arms ranged from approximately 300 (TOHP I) to 600 (TOHP II). The populations were diverse, consisting of 30 to 35 percent women and 15 to 18 percent African-Americans, and were recruited from 10 centers in TOHP I and 9 centers in TOHP II. Results from both TOHP I and TOHP II demonstrated that weight loss reduced blood pressure and the incidence of hypertension. Compared with controls, in both trials 10 kg (22 lb) of weight loss was associated with a reduction of 7 mm Hg systolic and 5 to 6 mm Hg diastolic blood pressure at 18 months. At 36 months, systolic and diastolic blood pressure was reduced by 6 and 4 mm Hg, respectively, for every 10 kg of weight loss.[379] In addition, weight loss reduced the incidence of hypertension at 18 months by 20 to 50 percent [378, 379] and at 3 years by 19 percent. [379] Secondary analyses from TOHP I [376] and analyses under way from TOHP II [385] demonstrated that the greater the weight loss the greater the blood pressure reduction, and as long as weight loss was maintained, blood pressure remained reduced. One study that focused on older African-American diabetics showed that weight loss of 2.4 kg (5.3 lb) at 6 months resulted in a reduction of 3.9 and 4.0 mm Hg systolic and diastolic blood pressure. [362] Only one study in nonhypertensive individuals [368] showed inconsistent results, where weight reduction decreased systolic (significant) and diastolic (nonsignificant) blood pressure at 12 months in women but not in men. Another study [377] showed short-term (3 months) blood pressure reduction but no longer-term (9 months) blood pressure reduction despite maintenance of weight loss of 9 kg (19.8 lb). [384]

1.b.Pharmacotherapy Trials

Evidence Statement: *Weight loss produced by most weight loss medications (except for sibutramine) and adjuvant lifestyle modifications is accompanied by reductions in blood pressure. Evidence Category B.*

To determine the effects of pharmacological therapy on weight loss and subsequent changes in blood pressure levels, 10 RCT articles were examined. [386-395] Weight loss studies using pharmacotherapy were conducted predominantly in white women and assumed that dietary changes were uniform in the active drug and placebo groups. All of these studies had a placebo-control group for which dietary recommendations for weight loss were provided; weight loss also occurred in the placebo group. No studies exam-

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ined whether weight loss using pharmacotherapy results in blood pressure reductions similar to weight loss produced by diet therapy, nor were the results compared with a pure control group with no weight loss. In addition, none of the studies that examined the effect of pharmacotherapy on blood pressure controlled for weight loss. In general, the use of phentermine, fenfluramine, and dexfenfluramine resulted in similar or better weight loss than that seen in the control or placebo group, and reductions in systolic and diastolic blood pressure were concomitantly similar to or better than those observed in the diet plus placebo group. [386, 390-393, 395] However, one study on dexfenfluramine [394] showed increased blood pressure compared to controls, even though weight loss was greater with dexfenfluramine than with placebo. Another study showed blood pressure lowering consistent with weight reduction produced by dexfenfluramine in women with upper-body obesity, but not in women with lower-body obesity. [387] In a combined summary of data on orlistat presented at the FDA Endocrinologic and Metabolic Drugs Advisory Committee Meeting (held in Bethesda, Maryland, in May 1997), only a small decrease in systolic (approximately 2 mm Hg) and diastolic (approximately 1 mm Hg) blood pressure was observed compared to the placebo. [388] In a study of sibutramine, a net weight loss at 3 months of approximately 2 kg (4.4 lb) did not result in lower blood pressure compared with placebo controls. [389] Eleven double-blind placebo-controlled trials lasting from 12 to 52 weeks showed that sibutramine is associated with mean increases in systolic blood pressure of 1 to 3 mm Hg, in diastolic pressure of 1 to 2 mm Hg, and mean increases in pulse rate of 3 to 5 beats per minute relative to placebo. In hypertensive obese patients, the mean change in blood pressure was the same in the sibutramine group and the placebo group; both dropped. Systolic pressure decreased 5.4 mm Hg in the sibutramine group and 5.8 mm Hg in the placebo group, while the diastolic drop was 5.9 mm Hg and 3.7 mm Hg, respectively. At the FDA recommended doses, 45 percent of patients had an increase, 35 percent had a decrease, and 20 percent had no change in blood pressure. [389]

1.c. Abdominal Fat

Evidence Statement: *Limited evidence suggests that decreases in abdominal fat reduce blood pressure in overweight nonhypertensive individuals, although this has not been shown to be independent of weight loss. Evidence Category C.*

Rationale: Five RCTs [365,369,373, 375,377] testing the effects of weight loss on blood pressure also measured abdominal fat by waist circumference or by dual-energy X-ray absorptiometry. In all five studies, waist circumference was reduced along with weight, and blood pressure was decreased. These studies were not designed to test whether reduction in abdominal fat reduces blood pressure independent of weight loss.

1.d. Fitness

Evidence Statement: *Increased aerobic activity to increase cardiorespiratory fitness reduces blood pressure independent of weight loss. Evidence Category A.*

Rationale: Seven RCTs testing the effects of weight loss on blood pressure in overweight and obese individuals also had measures of cardiorespiratory fitness, as measured by maximal oxygen uptake [346, 363, 369, 375, 377, 380]; or submaximal heart rate tests. [365] Weight loss was accompanied by increased fitness, primarily if the intervention included increased physical activity or physical activity combined with diet. [346, 363, 375, 377, 380] These

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studies were not designed to test whether increased cardiorespiratory fitness reduces blood pressure independent of weight loss in overweight and obese adults. By contrast, in 3 meta-analyses of 68 controlled studies of physical activity conducted in normotensive and hypertensive individuals, obesity was not an outcome measure nor was it included in the eligibility criteria. These meta-analyses showed that aerobic exercise to increase cardiorespiratory fitness significantly reduces blood pressure independent of or in the absence of weight loss. [396-398]

RECOMMENDATION: *Weight loss is recommended to lower elevated blood pressure in overweight and obese persons with high blood pressure. Evidence Category A.*

2. Serum/Plasma Lipids and Lipoproteins

Sixty-five RCT articles were evaluated for the effect of weight loss on serum/plasma concentrations of total cholesterol, low-density lipoprotein (LDL)-cholesterol, very low-density lipoprotein cholesterol, triglycerides, and high-density lipoprotein (HDL)-cholesterol. Studies were conducted on individuals over a range of overweight and lipid levels. Weight loss in 52 of these trials was induced by various lifestyle modifications, including diet modification (reducing calories, or saturated fat and cholesterol, or both) and increased physical activity.

2.a. Lifestyle Trials

Evidence Statement: *Weight loss produced by lifestyle modifications reduces serum triglycerides and increases HDL-cholesterol, and generally produces some reductions in serum total cholesterol, and LDL-cholesterol. Evidence Category A.*

Rationale: Fourteen RCT articles that studied the effects of diet and/or physical activity on lipids were reviewed. [365, 368, 370, 373, 380, 384, 399-406]
Table III-1 summarizes RCTs in which diet alone was used to produce weight loss. Entries under percentage change were calculated as follows: the percentage change (value at the end of study minus the value at baseline, divided by the value at baseline) was determined for the intervention group and the control group; the percentage change for the control group was then subtracted from the percentage change for the intervention group, giving the numerical value presented. When a run-in period was used, the "baseline" subtracted was the value at the end of the run-in, which was when the intervention began.

Reductions in body weight varied from 5 to 13 percent compared to the control group. The following changes in plasma lipids and lipoproteins were observed: total cholesterol, 0 to -18 percent; triglycerides, -2 to -44 percent; LDL-cholesterol, -3 to -22 percent; and HDL-cholesterol, -7 to +27 percent. Most of the trials were of sufficient duration to ensure that these changes were not the result of acute caloric deficit.

Table III-2 summarizes RCTs in which diet plus physical activity or physical activity alone was used to produce weight loss. Entries under percentage change were calculated as for Table III-1. Similar changes were observed as for diet alone, although there was perhaps a more consistent trend for all the lipid parameters with the combination of diet and physical activity and with physical activity alone.

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TABLE III-1:

Weight Reduction by Diet Alone

Study	N, Sex, and Duration	Weight Loss	Percentage Change TC	TG	LDL-C	HDL-C
Dengel [399]	28M experimental 14M control 9 months	-12	-9	-36	-9	-3
Hellenius[365]	40M experimental 39M control 6 months	BMI -2	-1	-2	-3	+2
Jalkanen[400]	24 experimental (wt) 22 experimental (lipid) 25 control (wt) 22 control (lipid) 12 months	-5	-7	-28	—	+8
Karvetti[368]	71F experimental 76F control 12 months	-6	-2	—	—	+12
	22M experimental 20M control 12 months	-11	0	—	—	+27
Marniemi[402]	37 (27F/10M) mixed diet 42 (32F/10M) control 12 months	-13	-4	-41	—	+18
	31 (23F/8M) lactovegetarian 42 (32F/10M) control 12 months	-11	-4	-21	—	+10
Puddey[370]	22M experimental 20M control 18 weeks	-8	-7	-27	—	+9
Simkin-Silverman[373]	253F experimental 267F control 6 months	-7	-8	-11	-9	+4
Svendsen[384]	50F experimental 20F control 12 weeks	-13	-18	-44	-22	+3
Wood[380]	40M experimental 40M control 12 months	-7	-5	-21	-5	+6
	31F experimental 39F control 12 months	-7	-7	-5	-8	-7
Wood[406]	42M experimental 42M control 12 months	-8	-2	-22	-3	+13

TC= Total Cholesterol
TG= Triglycerides
BMI= Body Mass Index
LDL-C= Low-Density Lipoprotein Cholesterol
HDL-C= High-Density Lipoprotein Cholesterol

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TABLE III-2:

Weight Reduction by Diet Plus Physical Activity or Physical Activity Alone

Study	N, Sex, and Duration	Weight Loss	Percentage Change TC	TG	LDL-C	HDL-C
Hellenius[365]	Diet+physical activity 39M experimental 39M control 6 month	BMI -4	-5	-12	-4	-1
	Physical activity only 39M experimental 39M control 6 months	BMI -2	0	-11	0	+2
King[401]	Physical activity only 40M high intensity group 41M control 12 months	BMI -1	—	-6	+2	-1
	Physical activity only 42M high intensity home 41M control 12 months	BMI -1	—	0	-1	+1
	Physical activity only 45M low intensity 41M control 12 months	BMI -4	—	-14	0	+3
	Physical activity only 34F high intensity group 34F control 12 months	BMI +2	—	+1	-4	+1
	Physical activity only 35F high intensity home 34F control 12 months	BMI 0	—	-2	+3	0
	Physical activity only 29F low intensity 34F control 12 months	BMI -2	—	+4	+3	0

TC= Total Cholesterol
TG= Triglycerides
BMI= Body Mass Index
LDL-C= Low-Density Lipoprotein Cholesterol
HDL-C= High-Density Lipoprotein Cholesterol

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Weight Reduction by Diet Plus Physical Activity or Physical Activity Alone (continued)

Study	N, Sex, and Duration	Weight Loss	Percentage Change TC	TG	LDL-C	HDL-C
Nilsson[403]	Diet+physical activity 30 (24M/6F) experimental 29 (22M/7F) control 12 months	BMI -2	-3	-4	-3	-1
Ronnemaa[404]	Physical activity only 13 (8M/5F) experimental 12 (7M/5F) control 4 months	-3	-6	-3	-5	+2
Schuler[405]	Diet+physical activity 56M experimental 57M control 12 months	-5	-10	-7	-10	+3
Svendsen[384]	Diet+physical activity 48F experimental 20F control 12 weeks	-14	-17	-35	-26	0
Wood[380]	Diet+physical activity 39M experimental 40M control 12 months	-11	-4	-46	-2	+17
	Diet+physical activity 42F experimental 39F control 12 months	-9	-5	-18	-8	+5

TC= Total Cholesterol
TG= Triglycerides
BMI= Body Mass Index
LDL-C= Low-Density Lipoprotein Cholesterol
HDL-C= High-Density Lipoprotein Cholesterol

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2.b. Pharmacotherapy Trials

Evidence Statement: *Weight loss produced by weight loss medications and adjuvant lifestyle modifications produces no consistent change in blood lipids. Evidence Category B.*

Rationale: The effects of pharmacological therapy on weight loss and subsequent changes in total serum cholesterol levels were evaluated by examining eight RCTs [386, 390-393, 395, 407,408] (Table III-3). The four trials of dexfenfluramine showed no consistent effects on total cholesterol; three trials showed decreases in triglycerides ranging from 14 to 40 percent and two trials showed increases in HDL-cholesterol of 8 percent in women to 27 percent in men. One trial of phentermine plus fenfluramine showed a 24 percent decrease in triglycerides and a slight change in HDL-cholesterol. [395] The trial of orlistat showed a decrease in total cholesterol and an increase in triglycerides, while the trial of fluoxetine showed the opposite. [407, 408] Other RCTs using orlistat have shown a modest improvement in lipids with weight loss. [388]

In a combined summary of data presented at the FDA Endocrinologic and Metabolic Drugs Advisory Committee Meeting (held in Bethesda, Maryland, in September 1996), use of sibutramine, which resulted in a greater net weight loss of 2.4 kg (5.3 lb) at 4 months, also resulted in modestly lower levels of total cholesterol, LDL-cholesterol, and triglycerides, along with slightly higher HDL-cholesterol levels, compared to placebos. [389]

2.c. Abdominal Fat

Evidence Statement: *Limited evidence suggests that decreases in abdominal fat correlate with improvements in the lipid profile of overweight individuals, although these improvements have not been shown to be independent of weight loss. Evidence Category C.*

Rationale: Four RCTs testing the effects of weight loss on blood lipids also included measures of abdominal fat, as measured by waist circumference. [365,373,375, 399] In each study, waist circumference was reduced along with weight, and blood lipids were improved. These studies were not designed to test whether reductions in abdominal fat reduce blood lipids independent of weight loss. However, evidence exists from epidemiologic observational studies that abdominal fat is related to an adverse lipid profile, including higher levels of total cholesterol, LDL-cholesterol, and triglycerides, and lower levels of HDL-cholesterol. [409,410]

2.d. Fitness

Evidence Statement: *Increased aerobic activity to increase cardiorespiratory fitness favorably affects blood lipids, particularly if accompanied by weight loss. Evidence Category A.*

Rationale: Nine RCTs testing the effects of weight loss on lipoproteins measured cardiorespiratory fitness, as measured by maximal oxygen uptake. [369, 375, 380, 384, 399, 401, 404-406] Weight loss was accompanied by increased fitness if the intervention included increased physical activity or physical activity combined with diet. [375, 380, 401, 404-406] These studies were not designed to test whether increased cardiorespiratory fitness reduces blood lipids independent of weight loss in overweight and obese adults. However, considerable evidence exists that aerobic exercise decreases triglycerides and total cholesterol and may increase HDL-cholesterol in men and women, particularly if accompanied by weight loss. [411]

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TABLE III-3:

WEIGHT REDUCTION BY DRUG THERAPY

Study	N, Sex, and Duration	Weight Loss	Percentage Change TC	TG	LDL-C	HDL-C
Bremer[386]	Dexfenfluramine 12 (8M/4F) experimental 14 (8M/6F) control 12 weeks	-6	-14	-40	-9	+15
Mathus-Vliegen[391]	Dexfenfluramine 17 experimental 18 control 12 months	-4	+7	-14	—	—
O'Connor[392]	Dexfenfluramine 27 (6M/21F) experimental 24 (14M/10F) control 6 months	-6	+5	-26	—	+27M +8F
Pfohl[393]	Dexfenfluramine 19 experimental 15 control 12 months	-2	-3	+26	—	—
Weintraub[395]	Fen/Phen 53 Fen/Phen 51 placebo 34 weeks	-13	-6	-24	-2	-1
Drent[407]	Orlistat 20 (3M/17F) Orlistat 19 (3M/16F) placebo 12 weeks	-2	-2	+8	—	—
O'Kane[408]	Fluoxetine 7 Fluoxetine 9 placebo	-6	+9	-25	—	—

TC= Total Cholesterol
LDL-C= Low-Density Lipoprotein Cholesterol
HDL-C= High-Density Lipoprotein Cholesterol
TG= Triglycerides
BMI= Body Mass Index

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RECOMMENDATION: *Weight loss is recommended to lower elevated levels of total cholesterol, LDL-cholesterol and triglycerides and to raise low levels of HDL-cholesterol in overweight and obese persons with dyslipidemia. Evidence Category A.*

3. Impaired Glucose Tolerance and Diabetes

Forty-nine articles of RCTs were reviewed to evaluate the effect of weight loss on fasting blood glucose and fasting insulin. Studies were conducted in individuals with normal blood glucose levels (fasting plasma glucose < 115 mg/dL [< 6.4 mmol/L]), in individuals with impaired glucose tolerance (fasting plasma glucose of < 140 mg/dL [7.8 mmol/L] or 2 hours postprandial plasma glucose of ≥ 140 to < 200 mg/dL [7.8-11.1 mmol/L]), or in individuals with diabetes (fasting plasma glucose of > 140 mg/dL or 2 hours postprandial plasma blood glucose ≥ 200 mg/dL).*

The methods of weight loss included diet, physical activity, or both; behavior therapy; and pharmacotherapy. The dietary interventions included low calorie and very low calorie, and those that promoted changes in diet composition, such as amount and type of dietary fat. Physical activity varied from controlled individualized exercise programs to informal group sessions coupled with behavior therapy and dietary changes. The degree of blinding of outcome measures was not always well described, nor was there a systematic consideration of concurrent effects of changes in medication or adherence to medication among diabetic patients enrolled in these weight reduction studies.

Of the 17 RCT articles considered acceptable, 10 included normoglycemic individuals, [367, 373, 386, 387, 390-393, 403, 412] 2 included patients with impaired glucose tolerance, [70, 369] and 5 included patients with type 2 diabetes. [362, 404, 408, 413, 414]

3.a.Lifestyle Trials

Evidence Statement: *Weight loss produced by lifestyle modifications, reduces blood glucose levels in overweight and obese persons without type 2 diabetes, and reduces blood glucose levels and HbA_{1c} in some patients with type 2 diabetes. Evidence Category A.*

Rationale: Nine RCTs examined lifestyle therapy. [70, 362, 367, 369, 373, 403, 404, 412, 413] Five RCTs among normoglycemic overweight individuals examined the effects of behavior therapy or lifestyle change on weight loss. Changes in fasting glucose or fasting insulin are used as secondary outcome measures. Improvements in the levels of fasting insulin with weight loss ranged from 18 to 30 percent. While weight loss was maintained, improvements were observed for fasting glucose, fasting insulin, and glucose and insulin levels during oral glucose tolerance testing compared to controls. [367, 373, 403, 412]

Three RCTs of lifestyle modifications were conducted among overweight diabetic patients. [362,404,413] One RCT of diet and physical activity in African-Americans aged 55 to 79 years with type 2 diabetes showed a 2.4 kg (5.3 lb) weight loss at 6 months compared to the usual-care control group. The intervention group also decreased HbA_{1c} by 2.4 percentage units at 6 months. [362] In another study, weight loss of 5 kg (11 lb) through diet resulted in a reduction of HbA_{1c} by 2 percentage units at 6 months compared with the controls. [413] At 1 year, the difference in weight loss between the two groups was reduced, and diabetic control was similar in each group. In the third study, weight loss, through physical activity in 25 type 2 diabetes patients randomly

* The reviewed articles used the "old" definitions of the American Diabetes Association (ADA) for impaired glucose tolerance and diabetes. As of November 1997, the new ADA definitions define "impaired fasting glucose" as those individuals having a fasting plasma glucose of 110 to 125 mg/dL, and "diabetes" as those individuals having a fasting plasma glucose of ≥ 126 mg/dL or 2 hours postprandial plasma glucose of ≥ 200 mg/dL.

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assigned to physical activity (13 patients) or control (12 patients) groups, was associated with improved HbA_{1c}. [404]

One RCT of 530 individuals in China with impaired glucose tolerance compared the effects of diet, physical activity, and diet plus physical activity on the incidence of diabetes. The data were analyzed for the group as a whole and for the lean and overweight groups separately. The overweight individuals in the diet and diet plus physical activity groups lowered their BMIs, while the lean individuals did not. After 6 years, the cumulative incidence rates of diabetes were significantly lower in all three intervention groups than they were in the controls (43.8 percent in the diet group, 41.1 percent in the physical activity group, 46 percent in the diet plus physical activity group, and 67.7 percent in the controls). This was true also if only the overweight persons were included in the analysis. [70]

3.b. Pharmacotherapy Trials

Evidence Statement: *Weight loss produced by weight loss medications has not been shown to be any better than weight loss through lifestyle modification for improving blood glucose levels in overweight or obese persons both with and without type 2 diabetes. Evidence Category B.*

Rationale: Eight RCT articles considered the effects of pharmacotherapy on weight loss and subsequent changes in blood glucose. [386, 387, 390-393 408, 414]

Six trials in nondiabetic individuals reported weight loss with anorexiant drugs. [386, 387 390-393] One study of 75 subjects with refractory obesity showed that those taking dexfenfluramine had a significantly better improvement in their blood glucose levels as compared to placebo controls. [390] Another trial showed that after 6 months on dexfenfluramine, fasting serum insulin levels fell from 105 at baseline to 89 at 6 months, but glucose levels did not decrease. [392] This study was difficult to interpret. Four other RCTs of dexfenfluramine failed to show any significant differences between the active drug and placebo groups for glucose or insulin, despite significant differences in weight reduction. [386, 387, 391, 393]

Among diabetic patients, there were two trials of anorexiant drugs. One trial of dexfenfluramine compared with standard clinic practice showed significantly greater weight loss at 3 months but not at 6 or 12 months. [414] Weight loss at 3 months was 3.4 kg (7.5 lb) in the dexfenfluramine group and 1.59 kg (3.5 lb) in the clinic group. At 6 months, the weight loss was 3.13 kg (6.9 lb) in the dexfenfluramine group and 1.70 kg (3.7 lb) in the clinic group. By 1 year, both groups had regained some weight. Despite more than a 1 kg (2.2 lb) difference of weight between the dexfenfluramine group and the control group, there were no significant differences between groups in changes from baseline for HbA_{1c} at any of the follow-up times (3, 6, or 12 months). In the trial of fluoxetine, those patients on 60 mg of fluoxetine daily compared with the placebo group had significant weight loss at 6 months, a finding that was associated with improvements in glucose and HbA_{1c}. At 12 months, these differences were no longer significant. [408] The RCTs of orlistat showed a drop in both fasting glucose and HBA_{1c} in diabetic patients on a combination therapy of lifestyle change and orlistat for weight loss. [388]

3.c. Abdominal Fat

Evidence Statement: *Decreases in abdominal fat improve glucose tolerance in overweight individuals with impaired glucose tolerance, although this has not been shown to be independent of weight loss. Evidence Category C.*

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Rationale: Two RCTs testing the effects of weight loss on changes in glucose tolerance and insulin also had measures of abdominal fat, as measured by waist circumference. [369,373] In each study, waist circumference was reduced along with weight loss and glucose tolerance improved. Neither study was designed to test whether reductions in waist circumference improved glucose tolerance or diabetic control independent of weight loss.

Evidence exists from observational studies that abdominal fat is related to impaired glucose tolerance or type 2 diabetes independent of BMI. For instance, a few studies have found a significant relationship between abdominal fat loss and improvement in glucose tolerance and insulin action. [415-418]

3.d. Fitness

Evidence Statement: *Increased cardiorespiratory fitness improves glucose tolerance in overweight individuals, but no evidence shows this relationship to be independent of weight loss. Evidence Category C.*

Rationale: Two RCTs that examined the effects of weight loss on glucose tolerance in older men [369] and in persons with diabetes [404] also had measures of VO_2 max (oxygen consumption) as a measure of fitness. In both studies, physical activity resulted in a net weight loss of approximately 2.3 to 2.5 kg (2 to 3 percent) and increased VO_2 max by 9 to 18 percent. In one study [419] most measures of glucose tolerance improved, whereas in the other study [369] only 2-hour insulin improved. Neither study was designed to test whether increased fitness improves glucose tolerance independent of weight loss.

RECOMMENDATION: *Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes. Evidence Category A.*

4. Decreases in Abdominal Fat With Weight Loss

Evidence Statement: *Weight loss is associated with decreases in abdominal fat, as measured by waist circumference. Evidence Category A.*

Rationale: Six acceptable RCTs on weight loss that measured waist circumferences all show that weight loss is associated with reductions in waist circumference. [365, 369, 373, 375, 384, 399] Waist circumference is commonly used as a surrogate measure for abdominal visceral fat. [420, 421] Although no RCTs examined changes in visceral fat per se, one observational study [422] showed significant decreases in visceral fat with a mean weight loss of 12.9 kg (28.4 lb).

In addition, many observational and non-RCT interventional studies have reported that weight loss caused by a variety of treatments reduces abdominal visceral fat levels. [417, 423-428] Fat located in the abdominal region is associated with greater health risks than that in peripheral regions, e.g., the gluteal-femoral area. [155-159, 429, 430] Many studies used the waist-to-hip ratio as the measure of abdominal fat; however, the panel considered waist circumference to be a better marker of abdominal fat content than the waist-to-hip ratio. For more information on abdominal fat, see Section 4.B.

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B What Treatments are Effective?

A variety of modalities may be used to treat overweight and obesity. To assess their effectiveness on weight loss, loss of abdominal fat, and cardiorespiratory fitness, evidence from RCTs was examined. These trials considered dietary therapy, physical activity, combined therapy, behavior therapy, pharmacotherapy, and surgery. The details of the studies reviewed and subsequently not included are provided in Appendix II.

1. Dietary Therapy

Eighty-six RCT articles evaluated the effectiveness of many different diets on weight loss: low-calorie diets (LCDs), very low-calorie diets (VLCDs), vegetarian, American Heart Association guidelines and the National Cholesterol Education Program's Step I diet with caloric restriction, and other low-fat regimens with varying combinations of macronutrients. The trials that included participants who were not overweight were rejected. Some trials were done in patient populations with diabetes, hypertension, or hyperlipidemia. Many of the trials do not mention whether concomitant physical activity programs were promoted, and many do not give information about the behavioral approaches that were used to deliver the diet or physical activity intervention. Approximately 60 percent of the trials are equal to or greater than 6 months in duration.

1.a Low-Calorie Diets

Evidence Statement: *LCDs can reduce total body weight by an average of 8 percent over 3 to 12 months. Evidence Category A.*

Rationale: Thirty-four RCT articles examined the impact on weight loss of an LCD consisting of approximately 1,000 to 1,200 kilocalories/day. Many of these LCDs also promoted low fat intake as a practical way to reduce calories. Twenty-five RCT articles covered interventions lasting 6 or more months. [346-348, 350, 354, 355, 359, 363-366, 368, 369, 373, 375, 378-380, 399, 400, 406, 413, 431-433]

Another nine RCTs lasted 12 to 21 weeks. [349, 351, 356, 370, 371, 377, 384, 434, 435]

All of the studies, regardless of the length of the intervention, showed that LCDs result in weight loss. From the 25 RCT articles with a duration of ≥ 6 months, compared to controls, LCDs brought about a mean weight loss of approximately 8 percent of body weight over a period of 6 months and up to 1 year. The nine studies with an intervention lasting from 3 months up to 6 months also averaged approximately 8 percent weight loss compared to controls. Four studies that included a long-term weight loss and maintenance intervention lasting 3 to 4.5 years reported an average weight loss of 4 percent over the long term. [348, 359, 366, 379]

Evidence Statement: *LCDs resulting in weight loss effect a decrease in abdominal fat. Evidence Category A.*

Four RCTs testing the effects of LCDs alone on weight loss also had measures of abdominal fat, as measured by waist circumference. [365, 369, 375, 399] The studies showed consistently that waist circumference decreases along with weight loss produced by LCDs. After 6 to 12 months, LCDs resulted in a mean weight loss of as little as 0.3 BMI unit to as much as 11 kg (24.3 lb) body weight, and a concomitant reduction in waist circumference of 1.5 to 9.5 cm compared to controls.

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Evidence Statement: *No improvement in cardiorespiratory fitness as measured by VO_2 max appears to occur in overweight or obese adults who lose weight on LCDs without increasing physical activity. Evidence Category B.*

Rationale: Ten RCTs examined whether weight loss through diet alone without increased physical activity had an effect on cardiorespiratory fitness as measured by VO_2 max when compared to controls with no weight loss. Four RCTs reported no improvement in VO_2 max, [363,375,399,435] while six RCTs reported an improvement. [346, 369, 380, 384, 406, 432] In three of the six studies, improvement in those on the LCD was shown because the control group had a large decrease in VO_2 max. [346,406,432] In all six studies that showed improvement, VO_2 max was expressed as ml/kg/min rather than liters/min. Because the ratio of ml O_2/kg/min increases with weight loss alone and not necessarily from an improvement in oxygen uptake, results from studies reporting VO_2 max in terms of ml O_2/kg/min are equivocal. The three studies that reported VO_2 max as liters/min consistently showed no improvement from diet alone. [375,399,435]

1.b. Very Low-Calorie Diets

Evidence Statement: *VLCDs produce greater initial weight loss than LCDs. However, the long-term (> 1 year) weight loss is not different from that of the LCD. Evidence Category A.*

Four RCTs compared VLCDs to LCDs. [436-439] The VLCDs provided about 400 to 500 kcal/day, whereas the LCDs provided approximately 1,000 to 1,500 kcal/day. During the active phase, VLCDs were given exclusively for 12 to 16 weeks and then were followed by LCDs for a total duration ranging from 24 weeks to 5 years. The participants in these trials were primarily women who were extremely obese.

VLCDs either alone or, usually, combined with behavioral therapy, promoted weight loss of approximately 13 to 23 kg (28.7 to 50.7 lb) during the active phase of the VLCD intervention, compared to 9 to 13 kg (19.8 to 28.7 lb) with LCDs. In three of the four studies, VLCDs resulted in 4 to 12 kg (8.8 to 26.5 lb) greater weight loss than the LCDs at the end of the active phase. [436-438] Over the medium term of 6 to 12 months, weight loss on the VLCDs ranged from 1.1 kg (2.4 lb) to as much as 10.4 kg (22.9 lb) greater than weight loss on LCDs. One study did not show a particular advantage of VLCD over LCD either during the active phase or at 24 weeks. [439] After 1 year, there was no long-term advantage of VLCDs over LCDs. [436, 437]

1.c. Lower-Fat Diets

Evidence Statement: *Although lower-fat diets without targeted caloric reduction help promote weight loss by producing a reduced caloric intake, lower-fat diets coupled with total caloric reduction produce greater weight loss than lower-fat diets alone. Evidence Category A. Lower-fat diets produce weight loss primarily by decreasing caloric intake. Evidence Category B.*

Rationale: Nine RCTs testing the effects of diet on weight loss promoted diets that varied in fat and caloric content. [317, 364, 369, 434, 440-444] Lower-fat diets varied from 20 to 30 percent of calories from fat, and calories ranged from 1,200 to 2,300 calories.

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Three RCTs, all 6 months or greater in duration, promoted lower-fat diets with ad libitum caloric intake. Two of the three RCTs reported that lower-fat diets with ad libitum energy intake resulted in a reduction in caloric intake of 85 kcal and 300 kcal, [317, 444] and all three RCTs produced greater weight loss by 1 to 3.9 kg (2.2 to 8.6 lb), compared to a higher-fat diet. [317, 441, 444] The third RCT had a large disparity in baseline caloric intake between the two diet groups, making the reported caloric intakes at the end of the study difficult to compare. [441]

Three RCTs compared lower-fat diets with targeted caloric reduction to lower-fat diets alone, and all three found that weight loss is greater in the lower-fat diet with caloric reduction than with the lower-fat diet alone. [369, 434, 442]

When similar caloric levels occur between lower-fat and higher-fat diets, similar amounts of weight loss were reported in two studies, [364, 443] whereas one study showed 1.8 kg (4 lb) greater weight loss on the lower-fat compared with the higher-fat diet, despite similar reported calorie levels. [440]

Taken together, these studies show that lower-fat diets ranging from 20 to 30 percent of calories can contribute to lower caloric intake even when caloric reduction is not the focus of the intervention, [317, 444] but when LCDs are targeted with lower-fat diets, better weight loss is achieved. [369, 434, 442] However, there is little evidence that lower-fat diets (per se) cause weight loss independent of caloric reduction.

RECOMMENDATION: *LCDs are recommended for weight loss in overweight and obese persons. Evidence Category A. Reducing fat as part of an LCD is a practical way to reduce calories. Evidence Category A.*

2. Physical Activity

Twenty-four RCT articles were reviewed for the effect of physical activity on weight loss, abdominal fat (measured by waist circumference), and changes in cardiorespiratory fitness (VO_2 max). Thirteen articles were deemed acceptable. [346, 363, 365, 369, 375, 401, 404, 406, 432, 434, 445-447] Only one of these RCTs compared different intensities and format with a control group, although the goal was to increase physical activity and not specifically to produce weight loss. [401] Results from this trial were subsequently reported after 2 years, but these no longer included the control group. [447] One additional study did not have a no-treatment control group, but compared three active treatment groups with each other: diet only, exercise only, and combination exercise plus diet. [448]

Most RCTs described the type of physical activity as cardiovascular endurance activities in the form of aerobic exercise such as aerobic dancing, brisk walking, jogging, running, riding a stationary bicycle, swimming, and skiing, preceded and followed by a short session of warmup and cool down exercises. Some physical activity programs also included unspecified dynamic calisthenic exercises. [363, 369, 406, 446]

The intensity of the physical activity was adapted to each individual and varied from 60 to 85 percent of the individual's estimated maximum heart rate, or was adjusted to correspond to approximately 70 percent of maximum aerobic capacity (VO_2 max). The measure of physical fitness included VO_2 max. The frequency of physical activity varied from three to seven sessions a week and the length of the physical activity session ranged from 30 to 60 minutes. Some physical activity programs were supervised, and some were home-based. Adherence to the prescribed physical activity program was recorded and reported in some studies and not mentioned in others. Most studies did not estimate the caloric expenditure from the physical activity or report calorie intake. The duration of the intervention

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varied from 16 weeks to 1 year; six articles reported on trials that lasted at least 1 year. [346, 363, 375, 401, 406, 432]

Evidence Statement: *Physical activity, i.e., aerobic exercise, in overweight and obese adults results in modest weight loss independent of the effect of caloric reduction through diet. Evidence Category A.*

Rationale: Twelve RCT articles examined the effects of physical activity, consisting primarily of aerobic exercise, on weight loss compared to controls. [346, 363, 365, 369, 375, 401, 404, 406, 432, 434, 445, 446] Ten of the 12 RCT articles reported a mean weight loss of 2.4 kg (5.3 lb) (or 2.4 percent of weight) [363, 369, 375, 406, 419, 432, 434] or a mean reduction in BMI of 0.7 kg/m^2 (2.7 percent reduction) [346, 365, 401] in the exercise group compared to the control group. In three of these ten studies, the weight loss was < 2 percent of body weight (< 2 kg) (4.4 lb). [369, 375, 434] In contrast, two RCTs showed no benefit on weight from exercise, reporting weight gain in the exercise group compared to the control group. [445, 446] In one of these studies, the control group received only diet advice but nevertheless lost 9 kg (19.8 lb), whereas the exercise group lost only 7 kg (15.4 lb). [445] In the second study, there was a total of only 10 participants, all having noninsulin-dependent diabetes mellitus, and the control group lost 3 kg (6.6 lb) whereas the exercise group lost only 2 kg (4.4 lb). [446] A meta-analysis of 28 publications of the effect on weight loss of exercise compared to diet or control groups showed that aerobic exercise alone produces a modest weight loss of 3 kg (6.6 lb) in men and 1.4 kg (3.1 lb) in women compared to controls. [449]

Ten articles reported on RCTs that had a diet-only group in addition to an exercise-only group. [346, 363, 365, 369, 375, 406, 432, 434, 445, 448] In every case except one, [365] the exercise-only group did not experience as much weight loss as the diet-only group. The diet-only group produced approximately 3 percent, or 3 kg (6.6 lb), greater weight loss than the exercise-only group.

No single study examined the length of the intervention in relation to the weight loss outcome. Only one study compared the effect on maximum oxygen uptake of different intensities and formats of physical activity over a 1-year follow-up [401] and 2-year follow-up period. [447] Better adherence over 1 year was found if the exercise was performed at home rather than in a group setting, regardless of the intensity level. Subsequently, the different exercise groups were compared with each other over the longer term (2 years), and better long-term adherence was found in the higher intensity home-based exercise group compared to the lower intensity home-based or higher intensity group-based exercise groups. [447]

The question of whether physical activity enhances long-term maintenance of weight loss has not been formally examined in RCTs. Examination of long-term weight loss maintenance produced by physical activity interventions compared with diet-only interventions cannot easily be compared between RCTs because of numerous differences between studies with respect to design, sample size, intervention content and delivery, and characteristics of the study population samples. However, a number of analyses of observational and post hoc analyses of intervention studies have examined whether physical activity has a beneficial effect on weight. Cross-sectional studies have generally shown that physical activity is inversely related to body weight [450-454] and rate of weight gain with age. [455] Longitudinal studies with 2 to 10 years of follow-up results have observed that physical activity is related to less weight gain over time [456-459], less weight gain after smoking cessation in women, [460] and weight loss over 2 years. [461] In

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addition, post hoc analyses of several weight loss intervention studies reported that physical activity was a predictor of successful weight loss. [454, 462, 463]

The results of these RCTs showed that physical activity produces only modest weight loss and observational analyses from other studies suggest that physical activity may play a role in long-term weight control and/or maintenance of weight loss.

Evidence Statement: *Physical activity in overweight and obese adults modestly reduces abdominal fat. Evidence Category B.*

Rationale: Only three RCTs testing the effect of physical activity on weight loss also had measures of abdominal fat as assessed by waist circumference. [365, 369, 375] One study demonstrated that physical activity reduced waist circumference compared with the control group, [365] and another study showed a small effect on waist circumference (0.9 cm) in men but not women. [375] One study in men showed a small increase in waist circumference. [369] Weight loss was modest in all of these studies. These studies were not designed to test the effects of physical activity on abdominal fat independent of weight loss.

However, several large studies in Europe, [464] Canada, [453] and the United States [465-468] reported that physical activity has a favorable effect on body fat distribution. These studies showed an inverse association between energy expenditure through physical activity and several indicators of abdominal obesity, such as waist circumference and waist-to-hip and waist-to-thigh circumference ratios.

Evidence Statement: *Physical activity in overweight and obese adults increases cardiorespiratory fitness independent of weight loss. Evidence Category A.*

Rationale: Eleven RCT articles testing the effect of physical activity alone on weight loss in men and women also included measures of cardiorespiratory fitness, as measured by maximal oxygen uptake (VO_2 max). [346, 363, 369, 375, 401, 404, 406, 432, 434, 445, 446] All 11 showed that physical activity increased maximum oxygen uptake in men and women in the exercise groups by an average of 14 percent (ml/kg body weight) to 18 percent (L/min). Even in studies with modest weight loss (< 2 percent), physical activity increased VO_2 max by an average of 12 percent (L/min) to 16 percent (ml/kg). [369, 375, 434]

One study that compared different formats and intensities of physical activity on VO_2 max reported that improvement in VO_2 max was related to adherence to the physical activity regime. In that study, the lower-intensity program was equally effective on VO_2 max as a higher-intensity program, largely as a result of different levels of adherence. [401]

The results of the RCTs strongly demonstrate that physical activity increases cardiorespiratory fitness in overweight and obese individuals.

RECOMMENDATION: *Physical activity is recommended as part of a comprehensive weight loss therapy and weight maintenance program because it: (1) modestly contributes to weight loss in overweight and obese adults (Evidence Category A), (2) may decrease abdominal fat (Evidence Category B), (3) increases cardiorespiratory fitness (Evidence Category A), and (4) may help with maintenance of weight loss (Evidence Category C).*

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3. Combined Therapy (Diet and Physical Activity)

Twenty-three RCT articles investigated the effects on body weight of a combination of a reduced calorie diet with increased physical activity. The control groups used diet alone or physical activity alone.

Of the 15 studies deemed acceptable, each of them compared the combined intervention with diet alone, [346, 365, 375, 377, 380, 384, 434, 435, 445, 448, 469-473] and 6 of them also compared the combined intervention to physical activity alone. [346, 365, 375, 434, 448, 474] The studies varied in terms of the length of the active intervention period as well as the length of the follow-up. Many of the programs lasted for more than 6 months, and five studies had intervention or follow-up data for at least 1 year. [346, 375, 380, 445, 473] Two studies included patients with type 2 diabetes. [470, 473] Participants in the diet and physical activity group most often participated in supervised group-based physical activity consisting of 30- to 60-minute sessions 3 times a week, and they were encouraged to maintain a maximum heart rate between 60 and 80 percent. There were three diet components: general dietary advice, caloric reduction of 500 to 1,000 kcal per day, or a diet containing 1,200 kcal per day.

Evidence Statement: *The combination of a reduced calorie diet and increased physical activity produces greater weight loss than diet alone or physical activity alone. Evidence Category A.*

Rationale: Of the 15 RCT articles, 12 observed that the combined diet and physical activity group had a mean greater weight loss of 1.9 kg (4.2 lb) and a mean greater BMI reduction of 0.4 (range of 0.3 to 0.5) than the diet-alone group. [346, 365, 375, 377, 380, 384, 434, 435, 448, 469, 470, 473]

One study compared different forms of physical activity in combination with diet and found that, compared to diet alone, the greatest weight loss occurred when the combination intervention included both aerobic and resistance training: 0.9 kg (2 lb) greater weight loss than aerobic exercise plus diet. [435] Another study reported that participants receiving resistance training in combination with diet had 2.2 and 5.0 kg (4.9 and 11 lb) greater weight loss than the diet-alone group after 24 and 48 weeks, respectively. [469]

Five of the six studies that compared combined intervention with physical activity alone observed that the combined intervention group had a 5.3 kg (11.7 lb) (range of 3.6 to 6.2 kg) (7.9 to 13.7 lb) greater weight loss and 0.9 change in BMI unit than the physical activity-alone group. [346, 365, 375, 434, 448] This greater weight loss was significant in three studies. [365, 375, 448]

Three RCTs compared the longer-term versus the shorter-term effects of the combination of physical activity and diet versus diet alone. [384, 469, 473] All three studies found that the combination resulted in approximately 1.5 to 3 kg (3.3 to 6.6 lb) greater weight loss than diet alone over the longer term of 9 months to 2 years.

Evidence Statement: *The combination of a reduced calorie diet and increased physical activity produces greater reductions in abdominal fat than either diet alone or physical activity alone, although it has not been shown to be independent of weight loss. Evidence Category B.*

Rationale: Three RCTs [365, 375, 471] that examined the combined effect of diet and physical activity on weight loss also had measures of abdominal fat, as measured by waist circumference. Two of the three RCTs showed that the combination intervention resulted in greater reduction in waist cir-

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cumference than diet alone in men [365, 375] and (only one) in women. [375] In the other RCT, no differences in reduced waist circumference were observed. [471] Of the three RCTs comparing combination therapy to physical activity alone, one study reported a greater waist reduction of 2.7 to 3.8 cm in women and men, respectively, [375] and by less than 1 cm in another study. [365] The effects of combination therapy on abdominal fat in these studies are not separable from the effects on weight loss.

Evidence Statement: *A combination of a reduced calorie diet and increased physical activity improves cardiorespiratory fitness as measured by VO_2 max when compared to diet alone. Evidence Category A.*

Rationale: Nine RCTs examined the effect of a combination of diet and physical activity on fitness compared to diet alone. [346, 375, 377, 380, 434, 435, 445, 448, 475] In most studies, the physical activity was in the range of 60 to 80 percent VO_2 max. All nine RCTs showed that a combination of diet and physical activity improved cardiorespiratory fitness, as measured by VO_2 max, more than diet alone, whether reported relative to body mass in ml O_2/kg/min or in absolute values by ml O_2/min. [346, 375, 377, 380, 434, 435, 445, 448, 475] Studies of longer duration tended to show the greatest improvement. This improvement was significant in six of the studies. [346, 375, 377, 380, 434, 448]

RECOMMENDATION: *The combination of a reduced calorie diet and increased physical activity is recommended, since it produces weight loss, decreases abdominal fat, and increases cardiorespiratory fitness. Evidence Category A.*

4. Behavior Therapy

Behavior therapy constitutes those strategies, based on learning principles such as reinforcement, that provide tools for overcoming barriers to compliance with dietary therapy and/or increased physical activity. Two questions are important in assessing the effect of behavior therapy in the treatment of overweight and obesity. First, does behavior therapy provide additional benefits above and beyond the other weight loss approaches—diet, physical activity, or drug therapy? Second, are there behavioral strategies that are more effective than others?

4.a. Additional Benefits Beyond Other Weight Loss Approaches

Thirty-six RCT articles were examined to evaluate whether behavior therapy provides additional benefits beyond other weight loss approaches. The acceptable RCTs compared behavior therapy plus another weight loss strategy to that weight loss strategy without behavior therapy.

Evidence Statement: *Behavior therapy, when used in combination with other weight loss approaches, provides additional benefits in assisting patients to lose weight short term (1 year). Evidence Category B. No additional benefits are found at 3 to 5 years in the absence of continued intervention. Evidence Category B.*

Rationale: Four RCTs addressed the question of whether behavior therapy, in order to reinforce a healthy diet, provides additional benefits above and beyond other weight loss approaches. Three studies compared behavior therapy plus dietary intervention to a dietary intervention alone. [436, 476, 477] No studies were found that examined the added benefit of behavior therapy when combined with either physical activity or diet and physical activity. One study was found that compared behavior therapy to drug therapy. [478]

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One study compared 36 obese women in one of three groups of 12 participating in a 16-week intervention: (1) individual counseling; (2) group counseling; and (3) group counseling plus behavior therapy. All groups lost weight at the end of treatment, and there were no significant differences among the groups. By the 1-year follow-up, participants in groups 1 and 3 were equally successful in maintaining weight loss, while most participants in group 2 regained most of their weight. [476]

Other studies examined the effect of VLCD alone and in combination with behavior therapy. [436, 477] Subjects were randomly assigned to either: (1) VLCD alone; (2) behavior therapy plus LCD (1,000 to 1,200 kcal), denoted as the behavior therapy-alone group; or (3) VLCD plus behavior therapy (combined treatment). They were assessed at the end of treatment and at 1- and 5-year follow-ups. At the end of treatment, and at the 1-year follow-up, weight loss was significantly greater for the combination group as compared to the other two groups. About one-third of those receiving behavior therapy (either in combination with an LCD or VLCD) were able to maintain their full end-of-treatment weight loss at 1 year, compared to only 5 percent of those in the diet-alone group. By the 5-year follow-up, the mean weight loss was not significantly different across groups.

Thus, although the weight loss results of behavioral treatment in combination with either an LCD or VLCD were quite good at the end of treatment and at the 1-year follow-up, they were not maintained by 5 years. These results may well have been due to the infrequent practice of the behavioral strategies by the subjects. Wadden and colleagues recommended that patients participate in a 6- to 12-month weight maintenance program after weight loss (which subjects did not do in the study described above), and that if they experience a gain of ≥5 kg (11 lb) which they cannot reverse on their own, that they should reenter a weight loss therapy program.

One study assessed the short- and long-term weight loss of behavior therapy, fenfluramine, or a combination of the two in 120 obese women. [478] Patients in the drug group and those in the combined drug plus behavior therapy group lost significantly more weight than did the group that received behavior therapy only and the control group; the drug-only group and combination group did not differ from each other at the end of the 6-month treatment. However, at the 1-year follow-up, significantly less weight was regained by the patients in the behavior-therapy-only group compared to the combined treatment group and the pharmacotherapy group, resulting in significantly better overall net weight loss. Results of this study suggest that the various interventions had different effects at the end of treatment and at follow-up.

To summarize, three of the four studies demonstrated that behavior therapy, when used in conjunction with other weight loss approaches, was more effective in reducing weight or delaying weight regain, either at the end of treatment or at the 1-year follow-up or both. [476-478] Behavior therapy was not better in its effect on weight loss at the 5-year follow-up.

No RCTs examined the additional effect of behavior therapy combined with diet and physical activity on cardiorespiratory fitness or abdominal fat.

4.b. Comparison of Behavior Therapy Strategies

Another way to examine the efficacy of behavior therapy in the treatment of overweight and obesity is to evaluate studies that compare various behavioral techniques with one another. Of 31 RCTs that compared one or more behavioral interventions, 19 were deemed acceptable.

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Evidence Statement: *No one behavior therapy appeared superior to any other in its effect on weight loss; rather, multimodal strategies appeared to work best and those interventions with the greatest intensity appeared to be associated with the greatest weight loss. Evidence Category A.*

Of the 19 RCTs, 17 produced weight loss. [367, 476, 479-493] Behavioral strategies to reinforce changes in diet and physical activity in obese adults produce weight loss in the range of 10 percent of baseline over 4 months to 1 year. The greatest amount of weight loss was usually observed in less than 12 months of the intervention; however, weight loss was observed for up to 2½ years in some studies. Multimodal strategies worked best, and the intensity (number of contacts and duration) and degree (albeit difficult to discern in some of these studies) of a particular reinforcement were most related to weight loss. Although initial therapy proved successful, it also appeared that when behavioral therapy ceased, weight was regained on average, but not all subjects relapsed back to baseline levels. Ten of the 19 studies were based on at least 1-year results. [367, 476, 479, 480, 484, 486-488, 492, 493]

Fourteen trials compared different behavior therapy strategies. Two trials compared cognitive behavior therapy techniques, specifically cognitive rehearsal, social pressure, and cue avoidance (see Glossary) with other behavior therapies. [479, 480] With regard to weight loss, cognitive rehearsal was no more effective than the group support or "social pressure" condition and was less effective than cue avoidance. [480] Another study indicated no clear benefits for cognitive rehearsal above and beyond other behavioral strategies. [479] One [483] of two studies that assessed the effect of monetary incentives reported greater weight loss. [367, 483]

The effect of extending treatment in various ways was evaluated in several studies. [486, 487, 489, 494] One study evaluated 20 weeks versus 40 weeks of standard behavior therapy and found greater weight loss with the extended therapy that was maintained at 72 weeks. [486] Another study evaluated behavior therapy and the effect of a post-treatment therapist on weight loss. [487] The study evaluated the effect of extended treatment using therapist contact in general, therapist contact emphasizing social influence, and extended treatment emphasizing physical activity. The emphasis of physical activity plus social influence produced greater weight loss than not having contact emphasizing these components. Extended contact with a therapist produced about 10 kg (22 lb) greater weight loss than no extended contact, even over the long term. At 18 months, all strategies that combined behavior therapy with a post-treatment maintenance program yielded a significantly greater long-term weight loss than behavior therapy alone.

Another study examined the effect of extending cognitive behavior therapy for 3 months in addition to the initial 3 months of therapy for obese patients with binge eating disorder, and found that extended cognitive behavior therapy improved binge eating behavior, although not weight. [494] A pilot study of women with type 2 diabetes compared a 16-week group-behavioral weight loss program to the same group, but with three individualized motivational interviewing sessions added. Both groups demonstrated significant weight loss with the motivational group losing 5.5 kg (12.1 lb) on average and the standard behavioral group losing 4.5 kg (9.9 lb); there were no differences between the two. However, those in the motivational interviewing group demonstrated better attendance at meetings (attending on average 13.3 meetings versus 8.9 meetings), had significantly better glucose control, and recorded blood glucose and food diaries more frequently [489] than did members of the standard behavioral group.

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A study that involved self-instruction plus incentives versus group instruction plus incentives demonstrated no effect of the group treatment on weight loss. [481] Weight loss was positively associated with attendance; however, mandatory attendance did not seem to increase program effectiveness and seemed to discourage attendance among men. The program was equally effective when implemented through either self-help materials or by professionals. Another study compared stimulus-narrowing during the reintroduction of food (achieved by providing prepackaged food) for those on VLCDs to providing regular food during the reintroduction. [495] They also compared reintroduction of foods based on progress in losing weight or maintaining weight loss versus a time-dependent basis. Neither strategy was helpful in maximizing weight loss or weight maintenance.

Two trials evaluated the impact of spousal involvement versus no spousal involvement in behavior therapy. [488, 492] One study found no overall differences in weight loss between those treated with spouses and those treated without spouses; however, women lost more weight when treated with a spouse, and men did better when treated alone ($P < .01$ at end of treatment; $P < .06$ at 1 year). [492] Another study found a positive effect of spousal involvement on weight loss soon after treatment was completed; however, this effect had largely dissipated by the 3-year follow-up. [488]

In summary, a variety of behavioral therapy strategies promote weight loss, with no one particular behavioral strategy having the greatest efficacy. Multimodal strategies with greater intensity appear to be most effective.

Evidence Statement: *Long-term follow-up of patients undergoing behavior therapy shows a return to baseline weight in the great majority of subjects in the absence of continued behavioral intervention. Evidence Category B.*

Rationale: Studies have shown that while weight loss is achieved, it is very difficult to maintain over a long period of time (1 to 5 years) in the absence of continued intervention. [436, 477, 486, 491] This emphasizes the great importance of continuing a maintenance program on a long-term basis.

Evidence Statement: *Little evidence exists on the effect of behavior therapy in combination with diet and physical activity on cardiorespiratory fitness.*

Rationale: One RCT examined the impact of different levels of behavior therapy in combination with diet and aerobic exercise on cardiorespiratory fitness. [484] Subjects were randomly assigned to one of three groups which varied in their degree of training in, and detailed application of, behavioral change principles (described as the basic, extended, and maximal behavioral therapy groups). All groups incorporated frequent intensive therapist contact, self-monitoring of behavior, regular objective assessment, and feedback of change in status. The three groups differed in the degree of emphasis given to behavioral self-management training, amount of detail provided on individual risk factors and overall coronary heart disease risk, and establishment of realistic short-term goals for coronary risk factor change. In terms of cardiorespiratory fitness, the group receiving the extended behavioral therapy and the group receiving the maximal behavior therapy showed improvements in VO_2 max of 2.90 and 3.40 mL/kg/min, respectively, when compared with controls who

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received the basic behavior therapy. However, it is unlikely that behavior therapy caused these improvements independent of weight loss.

No RCT evidence exists on the effect of behavior therapy combined with diet and physical activity on changes in abdominal fat as measured by waist circumference.

RECOMMENDATION: *Behavior therapy is a useful adjunct when incorporated into treatment for weight loss and weight maintenance. Evidence Category B.*

Commentary: Do the same treatment approaches for overweight and obesity fit diverse patient populations?

Whether or not the same weight reduction program will accomplish equivalent weight change in ethnically diverse population groups can be questioned on theoretical grounds. Weight reduction programs address motivations and behaviors strongly influenced by sociocultural factors that vary with ethnicity. [257, 496, 497] *Sociocultural factors may also influence the relative efficacy of behavioral programs in young, middle, and older adulthood; men or women; or any other patient groups where the motivations and lifestyle factors targeted may vary from those commonly assumed to be in operation. Innate or acquired physiological factors that affect energy metabolism may also influence the relative efficacy of behavioral weight reduction programs. For example, some cross-sectional comparisons have suggested that the relative weight loss achieved for a given degree of calorie restriction will be lower in African-Americans than whites because of a lower resting metabolic rate in African-Americans.* [498-501] *Another study suggests metabolic influences on weight loss in premenopausal versus postmenopausal women.* [502]

The diversity of populations in obesity treatment studies is limited, and there is not a coherent body of studies evaluating systematic differences in the outcomes of overweight and obesity treatment by age, socioeconomic status, or other participant characteristics that might be expected to influence outcome. However, the possibility of differences in the effectiveness of behavioral weight reduction approaches between African-Americans and whites has been suggested by reports from several intervention studies. [360, 503-505] *In some of these trials, weight reduction was the only intervention; in other instances it was combined with sodium reduction or other dietary or lifestyle changes. Taken together, these studies suggest that, on average, within the same program, weight losses of African-Americans are less than those of their white counterparts, particularly among women. A formal analysis of this issue in two RCTs—the Hypertension Prevention Trial and Phase 1 of the Trials of Hypertension Prevention—suggested that the weight gain in control participants was also higher among African-Americans than whites, but, in women, the net weight loss (i.e., active intervention minus control) was still less in African-Americans. There is ample evidence to support explanations of this differential weight loss on the basis of cultural or behavioral factors related to program adherence.* [257] *However, data to evaluate the alternative or additional contribution of metabolic factors to this differential are lacking. To date, no published studies permit separation of metabolic and behavioral influences on the observed ethnic differences in weight loss. (Also see commentary on pages 89 to 91 under treatment guidelines.)*

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RECOMMENDATION: *The possibility that a standard approach to weight loss will work differently in diverse patient populations must be considered when setting expectations about treatment outcomes. Evidence Category B.*

5. Pharmacotherapy

Since 1995, the use of the prescription drugs fenfluramine or dexfenfluramine for weight loss had increased greatly to 14 million prescriptions in 1½ years. The increased interest in drug treatment of obesity derives from the poor long-term results often obtained with behavior therapy, including diet and physical activity, as noted earlier in this report. The rationale for the addition of drugs to these regimens is that a more successful weight loss and maintenance may ensue. However, as of September 1997, the FDA requested the voluntary withdrawal of fenfluramine and dexfenfluramine from the market, due to a reported association between valvular heart disease with the drugs dexfenfluramine and fenfluramine, alone or combined with phentermine. [761] In November 1997, the FDA provided clearance for marketing the drug sibutramine hydrochloride monohydrate for the management of obesity, including weight loss and maintenance of weight loss when used in conjunction with a reduced-calorie diet. Due to the rapidly evolving information regarding the use of pharmacotherapy for weight loss, the panel decided to present their critique of those pharmacotherapy trials meeting their criteria for consideration.

Forty RCT articles evaluated the effect of pharmacotherapy on weight loss. In most studies, advice or behavioral therapy promoting reduced energy intake and increased physical activity was included in all treatment arms, including the placebo group.

Drugs that have been evaluated alone or in combination for at least 1 year by RCTs are phentermine, d,l-fenfluramine, dexfenfluramine, sibutramine, and orlistat. Two reports addressing dexfenfluramine [390, 506] represent a subset of a larger multicenter trial, the International Dexfenfluramine Study (INDEX trial). [507] Of the nine trials with dexfenfluramine, four had interventions of approximately 1 year, three of approximately 6 months, and two of 3 months. Most of the trials included a majority of white women, and some included persons with diabetes. Most of the trials have weight regain data. One RCT [508] evaluated the effect of dexfenfluramine versus placebo on patients who had been on an 8-week VLCD for an additional 24 weeks. One RCT [509] evaluated the effect of phentermine versus placebo on patients with osteoarthritis. One RCT [510] evaluated the effect of various doses of sibutramine on weight loss over a 24-week period. Two RCTs of 12 and 8 weeks in duration studied phenylpropanolamine versus placebo. [511, 512] One used phenylpropanolamine with diet, [512] and the other with diet, exercise, and behavior therapy. [511] Phenylpropanolamine is available as an over-the-counter drug. The average weight loss after 8 weeks of treatment was 2.59 kg (5.7 lb) for the drug versus 1.07 kg (2.4 lb) for the placebo, a difference of 1.5 kg (3.3 lb). [511] Short-term, but not long-term (over 1 year), effectiveness has been documented.

Evidence Statement: *Pharmacotherapy, which has generally been studied along with lifestyle modification including diet and physical activity, using dexfenfluramine, sibutramine, orlistat, or phentermine/fenfluramine, results in weight loss in obese adults when used for 6 months to 1 year. Evidence Category B.*

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Rationale: Data reporting the results of 52 weeks of drug treatment are available only for dexfenfluramine, orlistat, phentermine, d,l-fenfluramine, and sibutramine. The effect on weight loss from these drugs after 1 year is modest: 2.6 kg (5.7 lb) difference on average between dexfenfluramine and placebo (9.8 kg [21.6 lb] versus 7.2 kg [15.9 lb], baseline weights of 98.0 kg [216 lb] and 96.6 kg [213 lb]). [507] For sibutramine, a difference of 2.8 kg (6.2 lb) was seen at 1 year (4.4 kg [9.7 lb] versus 1.6 kg [3.5 lb]). [513] In another study of sibutramine, the difference was a net loss of 5.5 kg (12.1 lb) at 24 weeks with a 20 mg dose. [510] In all of the weight loss studies that were up to 1 year in duration, the majority of the weight loss occurred in the first 6 months with a plateauing or actual increase in weight in the following 6 months. [388, 389, 507, 514] For orlistat, a difference of 2.2 kg (4.9 lb) (4.3 kg [9.5 lb] versus 2.1 kg [4.6 lb]) was found in a 16-week study. [407] After a 210-week study on phentermine and d,l-fenfluramine, participants averaged a weight loss of 1.4 kg (3.1 lb) from baseline weight at week 210. [395, 514]

There are no known pharmacologic agents whose specific effect is to reduce abdominal fat or to improve cardiorespiratory fitness. Any improvements in abdominal fat or fitness would be secondary to weight loss or other interventions.

Sibutramine is approved for long-term use. (Note: FDA approval of orlistat is pending a resolution of labeling issues and results of Phase III trials.) Such drugs can then be used as an adjunct to modifications in behavior, including diet and physical activity. Drugs should be discontinued if significant weight loss is not achieved, i.e., a loss of < 4 pounds in the first 4 weeks, or if serious adverse effects occur.

RECOMMENDATION: *Weight loss drugs may only be used as part of a comprehensive weight loss program including diet and physical activity for patients with a BMI of ≥30 with no concomitant obesity-related risk factors or diseases, or for patients with a BMI of ≥27 with concomitant obesity-related risk factors or diseases. Evidence Category B.*

6. Surgery

Fourteen RCTs compared the weight-reducing effect of different surgical interventions. They did not compare surgery versus no intervention. Because of the nature of the intervention, there is a reluctance to do such a randomized trial.

Evidence Statement: *Surgical interventions in adults with a BMI ≥ 40 or a BMI ≥ 35 with comorbid conditions result in substantial weight loss. Evidence Category B.*

Rationale: Of the 14 RCTs that examined the effect of surgical procedures on weight loss, 8 were deemed appropriate. All the studies included individuals who had a BMI of 40 kg/m^2 or above, or a BMI of 35 to 40 kg/m^2 with comorbidity; most of the study participants were women. Weight loss due to surgical intervention such as the gastric bypass ranged from 50 kg (110 lb) to as much as 100 kg (220 lb) over a period of 6 months to 1 year. Gastroplasty with diet had a favorable net outcome on weight loss after 2 years compared to diet alone. [515] Vertical-banded gastroplasty was more effective than horizontal-banded gastroplasty. [516] Gastric resection with a modest biliopancreatic diversion without intestinal exclusion resulted in significantly greater weight loss than conventional Roux-en Y

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gastric bypass; this long-limb modification of Roux-en Y gastric bypass was shown to be safe and effective in patients who were 200 lb or more overweight and did not cause additional metabolic sequelae or diarrhea. [517]

The Swedish Obesity Study (SOS), [518] a non-RCT, found that gastric bypass produced greater weight loss than gastroplasty, 42.3 kg (93.3 lb) versus 29.9 kg (67 lb), at 1 year. The gastric bypass was deemed superior to gastroplasty or gastric partitioning in other RCTs as well. [518-522] The SOS also evaluated the correlation between stoma size and weight loss in patients assigned to gastric bypass or gastroplasty, and found no significant correlation in the gastric bypass group.

Comorbidity factors associated with weight loss showed improvement after surgery. One study showed that medical illnesses either improved (47 percent) or resolved (43 percent) in all but four patients (9 percent), and these four had unsatisfactory weight loss. [517] The Adelaide Study showed that 60 percent of the patients who initially had obesity-related comorbidity were free of medication for these comorbidities 3 years after surgery. [519]

Extremely obese persons often do not benefit from the more conservative treatments for weight loss and weight maintenance. Obesity severely impairs quality of life, and these individuals are at higher risk for premature death. [523] The National Institutes of Health Consensus Development Conference consensus statement, "Gastrointestinal Surgery for Severe Obesity, [523] " concluded that the benefits outweigh the risks and that this more aggressive approach is reasonable in individuals who strongly desire substantial weight loss and have life-threatening comorbid conditions.

The effects of surgery on abdominal fat or cardiorespiratory fitness independent of weight loss are unknown. One small study demonstrated that surgery (adjustable silicone gastric banding) reduced abdominal visceral fat. No analyses were performed to examine whether visceral fat reduction was independent of weight loss. [524] There are no data on the effects of surgery on changes in cardiorespiratory fitness.

RECOMMENDATION: *Surgical intervention is an option for carefully selected patients with clinically severe obesity (a BMI ≥40 or ≥35 with comorbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity and mortality. Evidence Category B.*

7. Other Interventions for Overweight and Obesity Treatment

Other types of interventions considered for overweight and obesity treatment included acupuncture, herbal remedies, supplements, and hypnosis. However, these treatments did not fulfill the *a priori* inclusion criteria, and for that reason were not included in this review.

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4 Treatment Guidelines

A Overview

The presence of overweight and obesity in a patient is of medical concern because it increases the risk for several diseases, particularly cardiovascular diseases (CVDs) and diabetes mellitus (see Chapter 2.C.) and it increases all-cause mortality. Treatment of the overweight and obese patient is a two-step process: assessment and management. Assessment requires determination of the degree of obesity and absolute risk status. Management includes both weight control or reducing excess body weight and maintaining that weight loss as well as instituting other measures to control associated risk factors. The aim of this guideline is to provide useful advice on how to achieve weight reduction and maintenance of a lower body weight. Obesity is a chronic disease, and both the patient and the practitioner need to understand that successful treatment requires a life-long effort.

B Assessment and Classification of Overweight and Obesity

1. Assessment of Overweight and Obesity

- *Determination of total body fat.* Overweight is defined as a body mass index (BMI) of 25 to 29.9 kg/m^2. Obesity is defined as an excess of total body fat that is documented by a BMI of ≥30 kg/m^2. Several methods are available for determining or calculating total body fat: total body water, total body potassium, bioelectrical impedance, and dual-energy X-ray absorptiometry.

Evidence Statement: *Measures of body fat give reasonably equivalent values for following overweight or obese patients during treatment. Evidence Category D.*

Rationale: Even though accurate methods to assess body fat exist, measuring body fat content by these techniques is often expensive and is not readily available clinically. Although bioelectrical impedance devices are becoming more readily available, they lose accuracy in severely obese persons and are of limited usefulness for tracking changes in total body fat in persons losing weight. Thus, bioelectrical impedance offers no significant advantage over BMI in the clinical management of patients. No trial data exist to indicate that one measure of fatness is better than any other for following overweight and obese patients during treatment. No studies have been published to compare the effectiveness of different measures for evaluating changes in body fat during weight reduction. BMI provides a more accurate measure of total body fat than relying on weight alone. It has an advantage over percent above ideal weight (e.g., based on the Metropolitan Life Insurance Tables). Ideal body weight tables were developed primarily from white, higher socioeconomic status populations and have not been documented to accurately reflect body fat content in the public at large. In addition, separate tables are required for men and women. The weight tables also are based on

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mortality outcomes and do not necessarily predict morbidity. BMI is recommended as a practical approach for the clinical setting. BMI provides an acceptable approximation for assessment of total body fat for the majority of patients. [525-527] However, simply measuring body weight is a practical approach to follow weight changes.

RECOMMENDATION: *Practitioners should use the BMI to assess overweight and obesity. Body weight alone can be used to follow weight loss and to determine efficacy of therapy. Evidence Category C.*

Rationale: The panel concentrated on tools available in the office, i.e., weight, height and the BMI. BMI is a practical indicator of the severity of obesity, and it can be calculated from existing tables. BMI is a direct calculation based on height and weight, regardless of gender. The limitations of BMI as a measure of total body fat, nonetheless, must be recognized. For example, BMI overestimates body fat in persons who are very muscular and can underestimate body fat in persons who have lost muscle mass (e.g., the elderly).

The BMI is calculated as follows:

BMI = weight (kg)/height squared (m^2)

To estimate BMI from pounds and inches use:

[weight (pounds)/ height (inches)^2] x 703 [528]

(1 lb = 0.4536 kg)
(1 in = 2.54 cm = 0.0254 m)

A simple BMI chart is provided in Appendix V. A patient should be weighed with shoes off and clad only in a light robe or undergarments.

- *Determination of degree of abdominal obesity.* The presence of excess fat in the abdomen, out of proportion to total body fat, is an independent predictor of risk factors and morbidity. Relatively accurate measures of total abdominal fat can be made by magnetic resonance imaging [529] or computed tomography. [500, 530] These methods, however, are expensive and not readily available for clinical practice. Research with these techniques, nonetheless, has shown that the waist circumference correlates with the amount of fat in the abdomen, and thus is an indicator of the severity of abdominal obesity. In this document the term "waist" circumference is used instead of "abdominal" circumference because it more accurately describes the anatomical site of measurement.

Evidence Statement: *Waist circumference is the most practical anthropometric measurement for assessing a patient's abdominal fat content before and during weight loss treatment. Computed tomography and magnetic resonance imaging are both more accurate but are impractical for routine clinical use. Evidence Category C.*

Rationale: Fat located in the abdominal region is associated with greater health risks than that in peripheral regions, e.g., the gluteal-femoral area. [155-159, 429, 430] Abdominal fat is described as having three compartments: visceral, retroperitoneal, and subcutaneous. [529, 531, 532] Several studies suggest that the visceral fat component of abdominal fat is the most strongly correlated with risk factors; [160, 161, 533, 534] other studies, however, indicate that the subcutaneous component is the most highly correlated with insulin resistance. [529, 535, 536] Therefore, the relative contributions of different components of abdominal fat to overall risk remain to be determined with certainty. Nonetheless, the presence of increased total abdominal fat appears to be an independent risk

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predictor when the BMI is not markedly increased. [537] Therefore, waist or abdominal circumference, as well as BMI, should be measured not only for the initial assessment of obesity, but also as a guide to the efficacy of weight loss treatment.

The waist-to-hip ratio (WHR) also has been used in a number of epidemiologic studies to show increased risk for diabetes, coronary artery disease, and hypertension. [500] However, waist circumference has been found to be a better marker of abdominal fat content than is WHR. [85] Whether WHR imparts any independent information about disease risk beyond waist circumference is uncertain, but between the two, the waist circumference appears to carry greater prognostic significance. Therefore, in clinical practice, abdominal fat content should be assessed and followed by measuring waist circumference.

RECOMMENDATION: *The waist circumference should be used to assess abdominal fat content. Evidence Category C.*

2. Classification of Overweight and Obesity

- *According to BMI.* The primary classification of obesity is based on the measurement of BMI. This classification is designed to relate BMI to risk of disease. It should be noted that the relation between BMI and disease risk varies among individuals and among different populations. Therefore, the classification must be viewed as a broad generalization. Individuals who are very muscular may have a BMI placing them in an overweight category when they are not overly fat. Also, very short persons (under 5 feet) may have high BMIs that may not reflect overweight or fatness. In addition, susceptibility to risk factors at a given weight varies among individuals. Some individuals may have multiple risk factors

Instructions for Measuring Waist Circumference, According to NHANES III Protocol

To define the level at which waist circumference is measured, a bony landmark is first located and marked. The subject stands and the examiner, positioned at the right of the subject, palpates the upper hip bone to locate the right iliac crest. Just above the uppermost lateral border of the right iliac crest, a horizontal mark is drawn, then crossed with a vertical mark on the midaxillary line. The measuring tape is placed in a horizontal plane around the abdomen at the level of this marked point on the right side of the trunk. The plane of the tape is parallel to the floor and the tape is snug, but does not compress the skin. The measurement is made at a normal minimal respiration (see Figure 5).

REF: U.S. Department of Health and Human Services, PHS. NHANES III Anthropometric Procedures Video. U.S. Government Printing Office Stock Number 017-022-01335-5. Washington, D.C.: U.S. GPO, Public Health Service; 1996. [538]

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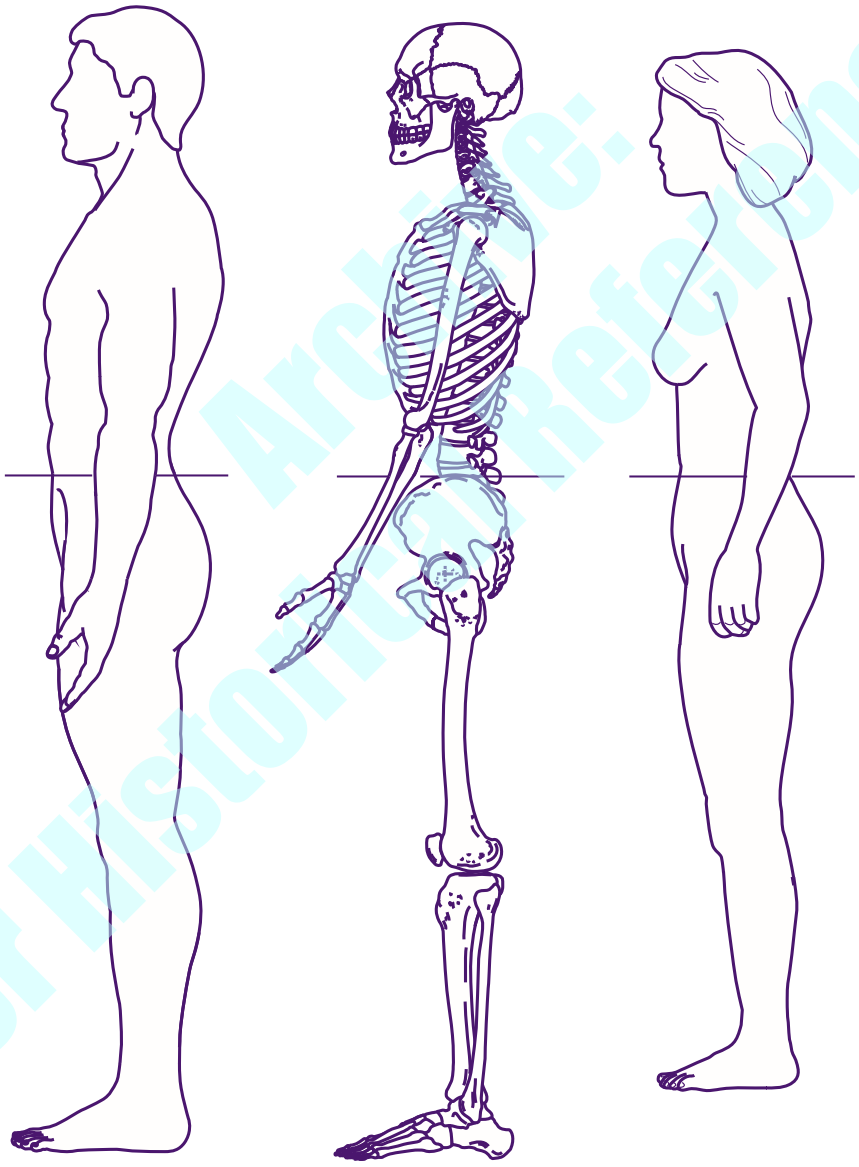
with mild obesity, whereas others may have fewer risk factors with more severe obesity. It should also be noted that the risk levels shown for each increment in risk are relative risks; that is, relative to risk at normal weight. They should not be equated with absolute risk which is determined by a summation of risk factors. No randomized controlled trial studies exist that support a specific system for classification that establishes the degree of disease risk for patients during weight loss or weight maintenance. The classification is based on observational and prospective epidemiological studies.

Figure 5. Measuring tape position for waist (abdominal) circumference



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RECOMMENDATION: *The BMI * should be used to classify overweight and obesity and to estimate relative risk for disease compared to normal weight. Evidence Category C.*

Rationale: Overweight and obesity are classified by BMI (see Table IV-1).

Calculating BMI is simple, rapid, and inexpensive. The classification can be applied generally to adults. See Appendix III for comments about obesity and its classification in children. The basis for this BMI classification scheme stems from observational and epidemiologic studies which relate BMI to risk of morbidity and mortality. [11, 81-83, 131, 155, 278, 539-541] For example, relative risk for CVD increases in a graded fashion with increasing BMI in all population groups, although absolute risk in obese versus nonobese persons depends on the summed contribution of all risk factors.

Evidence Statement: *The same BMI cutpoints (see Table IV-1) can be used to classify the level of overweight and obesity for adult men and adult nonpregnant women, and generally for all racial/ethnic groups. Evidence Category C.*

Rationale: Clinical judgment must be used in interpreting BMI in situations in which it may not be an accurate indicator of total body fat. Examples are the presence of edema, high muscularity, muscle wasting, or for very short people. The relationship between BMI and body fat content varies somewhat with age, sex, and possibly ethnicity because of differences in factors such as composition of lean tissue, sitting height, and hydration state. [526, 542] For example, older persons often have lost muscle mass and have more fat for a given BMI than younger persons, women may have more fat for a given BMI than men, and persons with clinical edema

TABLE IV-1:

CLASSIFICATION OF OVERWEIGHT AND OBESITY BY BMI*

	Obesity Class	BMI (kg/m²)
Underweight		< 18.5
Normal		18.5 – 24.9
Overweight		25.0 – 29.9
Obesity	I	30.0 – 34.9
	II	35.0 – 39.9
Extreme Obesity	III	≥ 40

Source (adapted from): Preventing and Managing the Global Epidemic of Obesity. Report of the World Health Organization Consultation of Obesity. WHO, Geneva, June 1997.[65]

* Pregnant women who, on the basis of their prepregnant weight, would be classified as obese may encounter certain obstetrical risks. However, the inappropriateness of weight reduction during pregnancy is well recognized. [44] Hence, this guideline specifically excludes pregnant women.

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may have less fat for a given BMI than persons without edema. Nevertheless, these differences generally do not markedly influence the validity of BMI cutpoints either for classifying individuals into broad categories of overweight and obesity or for monitoring weight status of individuals in clinical settings. [526]

- *According to waist circumference.* Although waist circumference and BMI are interrelated, waist circumference provides an independent prediction of risk over and above that of BMI. Waist circumference measurement is particularly useful in patients who are categorized as normal or overweight on the BMI scale. At BMIs ≥ 35, waist circumference has little added predictive power of disease risk beyond that of BMI. It is therefore not necessary to measure waist circumference in individuals with BMIs ≥ 35.

Evidence Statement: *Sex-specific cutoffs for waist circumference can be used to identify increased risk associated with abdominal fat in adults with a BMI in the range of 25 to 34.9 kg/m². An increase in waist circumference may also be associated with increased risk in persons of normal weight. Evidence Category C.*

Waist circumference cutpoints can generally be applied to all adult ethnic or racial groups. On the other hand, if a patient is very short (under 5 feet) or has a BMI above the 25 to 34.9 kg/m² range, waist cutpoints used for the general population may not be applicable. Evidence Category D.

Rationale: A high waist circumference is associated with an increased risk for type 2 diabetes, dyslipidemia, hypertension, and CVD in patients with a BMI in a range between 25 and 34.9 kg/m.[2 82] Monitoring changes in waist circumference over time may be helpful, in addition to measuring BMI, since it can provide an estimate of increased abdominal fat even in the absence of a change in BMI. Furthermore, in obese patients with metabolic complications, changes in waist circumference are useful predictors of changes in CVD risk factors. [537] The waist circumference at which there is an increased relative risk is defined as follows:

HIGH RISK

Men > 102 cm (> 40 in)

Women > 88 cm (> 35 in)

To evaluate health risks, it is not necessary to measure waist circumference in patients with a BMI ≥ 35 kg/m²; the measurement usually will be greater than the cutpoints given above, and waist measurements lose their predictive power at very high BMIs.

There are ethnic and age-related differences in body fat distribution that modify the predictive validity of waist circumference as a surrogate for abdominal fat. [526] These variations may partly explain differences between ethnic or age groups in the power of waist circumference or WHR to predict disease risks. [429, 543]

In some populations, waist circumference is a better indicator of relative disease risk than is BMI; examples include Asian-Americans or persons of Asian descent living elsewhere. [51, 273, 544] Waist circumference also assumes greater value for estimating risk for obesity-related disease at older ages. Table IV-2 incorporates both BMI and waist circumference in the classification of overweight and obesity, and provides an indication of disease risk.

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RECOMMENDATION: *For adult patients with a BMI of 25 to 34.9 kg/m², sex-specific waist circumference cutoffs should be used in conjunction with BMI to identify increased disease risk. Evidence Category C.*

C Assessment of Risk Status

The patient's risk status should be assessed by determining the degree of overweight or obesity based on BMI, the presence of abdominal obesity based on waist circumference, and the presence of concomitant CVD risk factors or comorbidities. Some obesity-associated diseases and risk factors place patients in a very high risk category for subsequent mortality. These diseases will require aggressive modification of risk factors in addition to their own clinical management. Other obesity-associated diseases are less lethal, but still require appropriate clinical therapy. Obesity also has an aggravating influence on several cardiovascular risk factors. Identifying these risk factors is required as a guide to the intensity of clinical intervention.

1. Determination of relative risk status based on overweight and obesity parameters.
Table IV-2 defines relative risk categories according to BMI and waist circumference. It is important to note that these categories denote *relative* risk, not *absolute* risk. They relate to the need to institute weight loss therapy, and do not directly define the required intensity of risk factor modification. The latter is determined by estimation

TABLE IV-2:

Classification of Overweight and Obesity by BMI, Waist Circumference and Associated Disease Risk*

			Disease Risk* Relative to Normal Weight and Waist Circumference	
	BMI (kg/m²)	Obesity Class	Men ≤102 cm (≤40 in) Women ≤88 cm (≤35 in)	>102 cm (>40 in) >88 cm (>35 in)
Underweight	<18.5		—	—
Normal+	18.5 – 24.9		—	—
Overweight	25.0 – 29.9		Increased	High
Obesity	30.0 – 34.9	I	High	Very High
	35.0 – 39.9	II	Very High	Very High
Extreme Obesity	≥40	III	Extremely High	Extremely High

* Disease risk for type 2 diabetes, hypertension, and CVD.
\+ Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

Source (adapted from): Preventing and Managing the Global Epidemic of Obesity. Report of the World Health Organization Consultation of Obesity. WHO, Geneva, June 1997.[65]

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of absolute risk based on the presence of associated disease or risk factors.

2. Identification of patients at very high absolute risk.
The following disease conditions or target organ damage in hypertensive patients denote the presence of very high absolute risk that triggers the need for intense risk factor modification as well as disease management. For example, the presence of very high absolute risk indicates the need for aggressive cholesterol-lowering therapy. [142]

2.a. Established coronary heart disease (CHD)

2.a.1. History of myocardial infarction

2.a.2. History of angina pectoris (stable or unstable)

2.a.3. History of coronary artery surgery

2.a.4. History of coronary artery procedures (angioplasty)

2.b. Presence of other atherosclerotic diseases

2.b.1. Peripheral arterial disease

2.b.2. Abdominal aortic aneurysm

2.b.3. Symptomatic carotid artery disease

2.c. Type 2 diabetes

2.d. Sleep apnea (For more information, see Appendix IV.)

3. Identification of other obesity-associated diseases.
Obese patients are at increased risk for several conditions that require detection and appropriate management, but that generally do not lead to widespread or life-threatening consequences. These include:

3.a. Gynecological abnormalities

3.b. Osteoarthritis

3.c. Gallstones and their complications

3.d. Stress incontinence

Management options of risk factors for preventing CVD, diabetes mellitus, and other chronic diseases are described in detail in other reports. For details on the management of serum cholesterol and other lipoprotein disorders, refer to the National Cholesterol Education Program's Second Report of the Expert Panel on the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II/ATP II) *(1993).* [142] *For the treatment of hypertension, the National High Blood Pressure Education Program recently issued the* Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI) *(1997).* [545] *For the most recent recommendations about type 2 diabetes from the American Diabetes Association, see the ADA Clinical Practice Recommendations (1998).* [546] *Finally, smoking cessation is strongly recommended in obese smokers, with particular attention to methods that diminish the weight gain associated with cessation (see pages 91-92). For strategies and recommendations for supporting and delivering effective smoking cessation intervention, see the Agency for Health Care Policy and Research's* Clinical Practice Guidelines on Smoking Cessation. [547]

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Although obese patients are at increased risk for gallstones, this risk increases even more during periods of rapid weight reduction.

4. Identification of cardiovascular risk factors that impart a high absolute risk.
Patients can be classified as being at high absolute risk for obesity-related disorders if they have three or more of the multiple risk factors listed below. The presence of high absolute risk increases the intensity of cholesterol-lowering therapy [142] and blood pressure management. [545]

4.a. Cigarette smoking

4.b. Hypertension—A patient is classified as having hypertension if systolic blood pressure is ≥ 140 mm Hg or diastolic blood pressure is ≥ 90 mm Hg, or if the patient is taking antihypertensive agents.

4.c. High-risk low-density lipoprotein cholesterol—A high-risk LDL-cholesterol is defined as a serum concentration of ≥160 mg/dL. A borderline high-risk LDL-cholesterol (130 to 159 mg/dL) together with two or more other risk factors also confers high risk.

4.d. Low high-density lipoprotein cholesterol—A low HDL-cholesterol is defined as a serum concentration of < 35 mg/dL.

4.e. Impaired fasting glucose (IFG)—The presence of clinical type 2 diabetes (fasting plasma glucose of ≥ 126 mg/dL or 2 hours postprandial plasma glucose of ≥ 200 mg/dL) is a major risk factor for CVD, and its presence alone places a patient in the category of very high absolute risk (see above). IFG (fasting plasma glucose 110 to 125 mg/dL) is considered by many authorities to be an independent risk factor for cardiovascular (macrovascular) disease, justifying its inclusion among risk factors contributing to high absolute risk. Although including IFG as a separate risk factor for CVD departs from the ATP II and JNC VI reports, its inclusion in this list may be appropriate. IFG is well established as a risk factor for type 2 diabetes.

4.f. Family history of premature CHD—A positive family history of premature CHD is defined as definite myocardial infarction or sudden death at or before 55 years of age in the father or other male first-degree relative, or at or before 65 years of age in the mother or other female first-degree relative.

4.g. Age

4.g.1. Male ≥ 45 years

4.g.2. Female ≥ 55 years (or postmenopausal)

Methods for estimating absolute risk status for developing CVD based on these risk factors are described in detail in the ATP II and JNC VI reports. The intensity of intervention for high blood cholesterol or hypertension is adjusted depending on the absolute risk estimated by these factors. Approaches to therapy for cholesterol disorders and hypertension are described in the ATP II and JNC VI, respectively.

5. Other risk factors deserve special consideration for their relation to obesity. When these factors are present, patients can be considered to have incremental absolute risk above that estimated from the preceding risk factors. Quantitative risk contributions are not available for these risk factors, but their presence heightens the need for weight reduction in obese persons.

5.a. Physical inactivity—A lack of physical activity imparts an increased risk for both CVD and type 2 diabetes. Physical inactivity enhances the severity of other risk factors, but it also has been shown to be an "independent" risk factor for all-cause mortality or CVD mortality. [411, 548]
Although physical inactivity is not listed as a risk factor that modifies the intensity of therapy required for elevated cholesterol or blood pressure, increased physical activity is indicated for management of these conditions (see the ATP II and JNC VI). Increased physical activity is espe-

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cially needed in obese patients because it promotes weight reduction and favorably modifies obesity-associated risk factors. Conversely, the presence of physical inactivity in an obese person warrants intensified efforts to remove excess body weight, because physical inactivity and obesity both heighten disease risks.

5.b. High triglycerides—Obesity is commonly accompanied by elevated serum triglycerides. The relationship between high triglycerides and CHD is complex. Triglyceride-rich lipoproteins may be directly atherogenic. In addition, elevated serum triglycerides are the most common manifestation of the atherogenic lipoprotein phenotype (high triglycerides, small LDL particles, and low HDL-cholesterol levels). [142, 549] Moreover, in the presence of obesity, high serum triglycerides are commonly associated with a clustering of metabolic risk factors known as the metabolic syndrome (atherogenic lipoprotein phenotype, hypertension, insulin resistance and glucose intolerance, and prothrombotic states). Thus, in obese patients, elevated serum triglycerides are a marker for increased cardiovascular risk. According to current guidelines (ATP II and JNC VI), the presence of high triglycerides does not modify the intensity of cholesterol or blood pressure-lowering therapy. Their presence in obese patients, however, calls for an intensified effort to achieve weight reduction and increase physical activity. Both will reduce the various risk factors characteristic of the metabolic syndrome, and thus should reduce overall cardiovascular risk as well as decrease the risk for type 2 diabetes.

According to the ATP II guidelines, [142] triglyceride levels are classified as follows:

Category	Serum Triglyceride Levels
Normal triglycerides	Less than 200 mg/dL
Borderline-high triglycerides	200 to 400 mg/dL
High triglycerides	400 to 1,000 mg/dL
Very high triglycerides	Greater than 1,000 mg/dL

Patients with very high triglycerides are at increased risk for acute pancreatitis and must undergo immediate triglyceride-lowering therapy.

D Evaluation and Treatment Strategy

When physicians encounter patients in the clinical setting, the opportunity exists for identifying overweight and obesity and accompanying risk factors and for initiating treatment for both the weight and the risk factors, as well as chronic diseases such as CVD and type 2 diabetes. When assessing a patient for treatment of overweight and obesity, consider the patient's weight, waist circumference, and the presence of risk factors. The strategy for the evaluation and treatment of overweight patients is presented in Figure 6 (Treatment Algorithm). This algorithm applies only to the assessment for overweight and obesity and subsequent decisions based on that assessment. It does not reflect any initial overall testing for other conditions and diseases that the physician may wish to do. Approaches to therapy for cholesterol disorders and hypertension are described in ATP II and JNC VI, respectively. In overweight patients, control of cardiovascular risk factors deserves equal emphasis as weight loss therapy. Reductions of risk factors will reduce the risk for cardiovascular disease whether or not efforts at weight loss are successful. The panel recognizes that the assessment for overweight and obesity may take place as part of an overall health assessment; however, for clarity, the algorithm focuses only on the evaluation and treatment of overweight and obesity.

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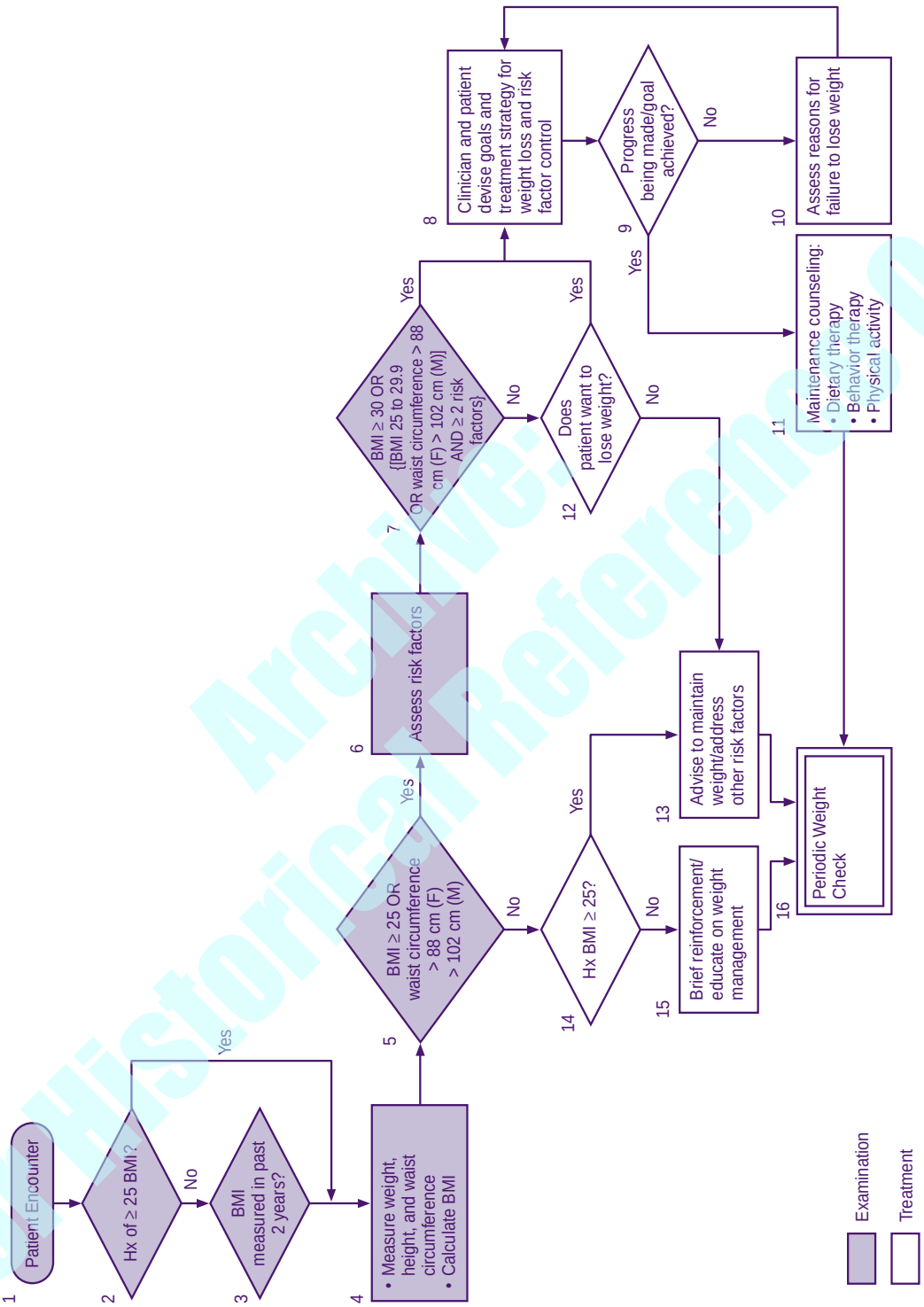
Figure 6. Treatment Algorithm*



* This algorithm applies only to the assessment for overweight and obesity and subsequent decisions based on that assessment. It does not include any initial overall assessment for cardiovascular risk factors or diseases that are indicated.

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Each step (designated by a box) in this process is reviewed in this section and expanded upon in subsequent sections.

Box 1: "Patient Encounter"

A patient encounter is defined as any interaction between a health care practitioner (generally a physician, nurse practitioner or physician's assistant) that provides the opportunity to assess a patient's weight status and provide advice, counseling, or treatment.

Box 2: "History of Overweight or Recorded BMI ≥ 25"

The practitioner must seek to determine whether the patient has ever been overweight. While a technical definition is provided, a simple question such as "Have you ever been overweight?" will accomplish the same goal. Questions directed towards weight history, dietary habits, physical activities, and medications may provide useful information about the origins of obesity in particular patients.

Box 3: "BMI Measured in Past 2 Years"

For those who have not been overweight, a 2-year interval is appropriate for the reassessment of BMI. While this time span is not evidence-based, it is believed to be a reasonable compromise between the need to identify weight gain at an early stage and the need to limit the time, effort, and cost of repeated measurements.

Box 4: "Measure Weight, Height, Waist Circumference; Calculate BMI"

Weight must be measured so that the BMI can be calculated. Most charts are based on weights obtained with the patient wearing undergarments and no shoes. BMI can be manually calculated (kg/[height in meters]^2), but is more easily obtained from a nomogram (see Appendix V). Waist circumference is important because evidence suggests that abdominal fat is a particularly strong determinant of cardiovascular risk in those with a BMI of 25 to 34.9 kg/m^2. Increased waist circumference can also be a marker of increased risk even in persons of normal weight. The technique for measuring waist circumference is described on page 58. A nutrition assessment will also help to assess the diet and physical activity habits of overweight patients.

Box 5: "BMI ≥ 25, OR Waist Circumference > 88 cm(F) or > 102 cm(M)"

These cutpoints divide overweight from normal weight and are consistent with other national and international guidelines. The relation between weight and mortality is J-shaped, and evidence suggests that the right side of the "J" begins to rise at a BMI of 25. Waist circumference is incorporated as an "or" factor because some patients with BMI lower than 25 will have disproportionate abdominal fat, and this increases their cardiovascular risk despite their low BMI (see page 61). These abdominal circumference values are not necessary for patients with a BMI ≥ 35 kg/m^2.

Box 6: "Assess Risk Factors"

Risk assessment for CVD and diabetes in a person with evident obesity will include special considerations for the history, physical examination, and laboratory examination. Of greatest urgency is the need to detect existing CVD or end-organ damage. Since the major risk of obesity is indirect (obesity elicits or aggravates hypertension, dyslipidemias, and diabetes, which cause cardiovascular complications), the management of obesity should be implemented in the context of these other risk factors. While there is no direct evidence demonstrating that addressing risk factors increases weight loss, treating the risk factors through weight loss is a recommended strategy. The risk factors that should be considered are provided on pages 63-65. With regard to age, please see commentary on pages 90-91.

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Box 7: "BMI ≥ 30, OR ([BMI 25 to 29.9 OR Waist Circumference > 88 cm(F) or > 102 cm(M)] AND ≥ 2 risk factors)"

The panel recommends that all patients meeting these criteria attempt to lose weight. However, it is important to ask the patient whether or not they want to lose weight. Those with BMIs between 25 and 29.9 kg/m^2 who have one or no risk factors should work on maintaining their current weight rather than embark on a weight reduction program. The panel recognizes that the decision to lose weight must be made in the context of other risk factors (e.g., quitting smoking is more important than losing weight) and patient preferences.

Box 8: "Clinician and Patient Devise Goals"

The decision to lose weight must be made jointly between the clinician and patient. Patient involvement and investment is crucial to success. The patient may choose not to lose weight but rather to prevent further weight gain as a goal. The panel recommends as an initial goal the loss of 10 percent of baseline weight, to be lost at a rate of 1 to 2 lb/week, establishing an energy deficit of 500 to 1,000 kcal/day. (See pages 71-72.) For individuals who are overweight, a deficit or 300 to 500 kcal/day may be more appropriate, providing a weight loss of about 1/2 lb/week. Also, there is evidence that an average of 8 percent of weight can be lost in a 6-month period. Since the observed average 8 percent weight loss includes people who do not lose weight, an individual goal of 10 percent is reasonable. After 6 months, most patients will equilibrate (caloric intake balancing energy expenditure) and will require adjustment of energy balance if they are to lose more weight. (See pages 72-73.)

The three major components of weight loss therapy are dietary therapy, increased physical activity, and behavior therapy. (See pages 73-82.) Lifestyle therapy should be tried for at least six months before considering pharmacotherapy. In addition, pharmacotherapy should be considered as an adjunct to lifestyle therapy in patients with a BMI ≥ 30 with no concomitant obesity-related risk factors or diseases, or for patients with a BMI ≥ 27 with concomitant obesity-related risk factors or diseases. The risk factors or diseases considered important enough to warrant pharmacotherapy at a BMI of 27 to 29.9 are hypertension, dyslipidemia, CHD, type 2 diabetes, and sleep apnea. However, sibutramine, the only FDA approved drug for long-term use, should not be used in patients with a history of hypertension, CHD, congestive heart failure, arrhythmias, or history of stroke. Certain patients may be candidates for weight loss surgery. Each component of weight loss therapy can be introduced briefly. The selection of weight loss methods should be made in the context of patient preferences, analysis of past failed attempts, and consideration of the available resources.

Box 9: "Progress Being Made/Goal Achieved"

During the acute weight loss period and at 6-month and 1-year follow-up visits, the patients should be weighed, BMI calculated, and progress assessed. If at any time it appears that the program is failing, a reassessment should take place to determine the reasons (see Box 10). If pharmacotherapy is being used, appropriate monitoring for side effects is recommended (See page 86). If a patient can achieve the recommended 10 percent reduction in body weight in 6 months to 1 year, this change in weight can be considered good progress. The patient can then enter the phase of weight maintenance and long-term monitoring. It is important for the practitioner to recognize that some persons are more apt to lose or gain weight on a given regimen and that this phenomenon cannot always be attributed to degree of compliance. However, if significant obesity remains and absolute risk

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from obesity-associated risk factors remains high, at some point an effort should be made to reinstitute weight loss therapy to achieve further weight reduction. Once a limit of weight loss has been obtained, the practitioner is responsible for long-term monitoring of risk factors and for encouraging the patient to maintain a reduced weight level.

Box 10: "Assess Reasons for Failure to Lose Weight"

If a patient fails to achieve the recommended 10 percent reduction in body weight in 6 months or 1 year, a reevaluation is required. A critical question is whether the level of motivation is high enough to continue clinical therapy. If motivation is high, revise the goals and strategies (see Box 8). If motivation is not high, clinical therapy should be discontinued, but the patient should be encouraged to embark on efforts to lose weight or to at least avoid further weight gain. Even if weight loss therapy is stopped, risk factor management must be continued.

Failure to achieve weight loss should prompt the practitioner to investigate energy intake (dietary recall including alcohol intake, daily intake logs), energy expenditure (physical activity diary), attendance at behavior therapy group meetings, recent negative life events, family and societal pressures, or evidence of detrimental psychiatric problems (depression, binge eating disorder). If attempts to lose weight have failed, and the BMI is ≥ 40, surgical therapy should be considered.

Box 11: "Maintenance Counseling"

Evidence suggests that over 80 percent of persons who lose weight will gradually regain it (see page 72). Patients who continue on weight maintenance programs have a greater chance of keeping weight off. Maintenance consists of continued contact with the health care practitioner for continued education, support, and medical monitoring (see page 72 and 75).

Box 12: "Does the Patient Want to Lose Weight?"

All patients who are overweight (BMI 25 to 29.9), or do not have a high waist circumference, and have few (0 to 1) cardiovascular risk factors and do not want to lose weight, should be counseled regarding the need to keep their weight at or below its present level. Patients who wish to lose weight should be guided per Boxes 8 and 9. The justification for offering these overweight patients the option of maintaining (rather than losing) weight is that their health risk, while higher than that of persons with a BMI < 25, is only moderately increased (page 62).

Box 13: "Advise to Maintain Weight/Address Other Risk Factors"

Those who have a history of overweight and are now at appropriate weight, and those who are overweight and not obese but wish to focus on maintenance of their current weight, should be provided with counseling and advice so that their weight does not increase. An increase in weight increases their health risk and should be prevented. The physician should actively promote prevention strategies including enhanced attention by the patient to diet, physical activity, and behavior therapy. For addressing other risk factors, see Box 6, because even if weight loss cannot be addressed, other risk factors should be covered.

Box 14: "History of BMI ≥ 25"

This box differentiates those who are not overweight now and never have been from those with a history of overweight; see Box 2.

Box 15: "Brief Reinforcement"

Those who are not overweight and never have been should be advised of the importance of staying in this category.

Box 16: "Periodic Weight, BMI, and Waist Circumference Check"

Patients should receive periodic monitoring of their weight, BMI, and waist circumference.

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Patients who are not overweight or have no history of overweight should be screened for weight gain every 2 years. This time span is a reasonable compromise between the need to identify weight gain at an early stage and the need to limit the time, effort, and the cost of repeated measurements.

E Exclusion from Weight Loss Therapy

Patients in whom weight loss therapy is not appropriate include most pregnant or lactating women, those with serious psychiatric illness, and patients who have a variety of serious illnesses in whom caloric restriction might exacerbate the illness.

F Patient Motivation

Assessment of patient motivation is a prerequisite for weight loss therapy. Weight reduction in the clinical setting represents a major investment of time and effort on the part of the health care team and expense to the patient. For these reasons, motivation for weight loss should be relatively high before initiating clinical therapy. At the same time, it is the duty of the primary care practitioner to heighten a patient's motivation for weight loss when such is perceived to be of significant benefit for risk reduction. This can be done by enumerating the dangers associated with persistent obesity and by describing the strategy for clinically assisted weight reduction. For patients who are not motivated (or able) to enter clinical weight loss therapy, appropriate management of risk factors (e.g., high serum cholesterol, hypertension, smoking, and type 2 diabetes) is still necessary. Sustained weight reduction may facilitate control of cardiovascular risk factors and delay the onset of type 2 diabetes.

Evidence Statement: *Patient motivation is a key component for success in a weight loss program. Evidence Category D.*

Rationale: Assessment of the patient's motivation for treatment by the practitioner is important in the decision to initiate a weight loss program. The following factors must be evaluated:

- Reasons and motivation for weight loss—What is the extent of the patient's seriousness and readiness to undergo a sustained period of weight loss at this time? What is the patient's current attitude about making a lifelong commitment to behavior change?
- Previous history of successful and unsuccessful weight loss attempts—What factors were responsible for previous failures and successes at weight loss or maintenance of normal body weight?
- Family, friends, and work-site support—What is the social framework in which the patient will attempt to lose weight, and who are the possible helpers and antagonists to such an attempt?
- The patient's understanding of overweight and obesity and how it contributes to obesity-associated diseases—Does the patient have an appreciation of the dangers of obesity, and are these dangers of significant concern to the patient?
- Attitude toward physical activity—Is the patient motivated to enter a program of increased physical activity to assist in weight reduction?
- Time availability—Is the patient willing to commit the time required to interact with health professionals in long-term weight loss therapy?
- Barriers—What are the obstacles that will interfere with the patient's ability to implement the suggestions for change?
- Financial considerations—Is the patient willing to pay for obesity therapy? This may include having to pay for travel to the med-

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ical facility, time lost from work, and paying for professional counseling that is not covered by insurance.

One of the most important aspects of the initial evaluation is to prepare patients for treatment. Reviewing patients' past attempts at weight loss and explaining how the new treatment plan will be different can encourage patients and provide hope for successful weight loss. It is helpful to discuss the proposed course of treatment and describe necessary behaviors, such as keeping diaries of food intake and physical activity.

Finally, given the social stigmatization that obese patients often feel, even from health care professionals, the initial evaluation is an opportunity to show the patient respect, concern, and hope.[550] A patient who has shared feelings about being overweight and previous attempts to lose weight with a sympathetic listener may be more willing to consider new ideas and information. A partnership in which the patient feels supported and understood can help to sustain the necessary motivation for the difficult task of weight loss and maintenance. [551,552]

RECOMMENDATION: *Practitioners need to assess the patient's motivation to enter weight loss therapy; assess the readiness of the patient to implement the plan; and then take appropriate steps to motivate the patient for treatment. Evidence Category D.*

G Goals of Weight Loss and Management

The general goals of weight loss and management are: (1) to reduce body weight; and (2) to maintain a lower body weight over the long term; or (3) at a minimum, to prevent further weight gain. Specific targets for each of these goals can be considered.

1. Weight Loss

1.a. Target levels for weight loss—The initial target goal of weight loss therapy for overweight patients is to decrease body weight by about 10 percent. If this target can be achieved, consideration can be given to the next step of further weight loss.

Evidence Statement: *Overweight and obese patients in well-designed programs can achieve a weight loss of as much as 10 percent of baseline weight, a weight loss that can be maintained for a sustained period of time (1 year or longer). Evidence Category A.*

Rationale: The rationale for this initial goal is that even moderate weight loss, i.e., 10 percent of initial body weight, can significantly decrease the severity of obesity-associated risk factors. It can also set the stage for further weight loss, if indicated. Available evidence indicates that an average weight loss of 8 percent can be achieved in 6 months; however, since the observed average 8 percent includes people who do not lose weight, an individual goal of 10 percent is reasonable. This degree of weight loss can be achieved and is realistic, and moderate weight loss can be maintained over time. It is better to maintain a moderate weight loss over a prolonged period than to regain from a marked weight loss. The latter is counterproductive in terms of time, costs, and self-esteem. Patients generally will wish to lose more weight than 10 percent, and will need to be counseled and persuaded of the appropriateness of this initial goal. [553, 554] Further weight loss can be considered after this initial goal is achieved and maintained for 6 months.

RECOMMENDATION: *The initial goal of weight loss therapy should be to reduce body weight by approximately 10 percent*

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from baseline. With success, further weight loss can be attempted, if indicated through further assessment. Evidence Category A.

1.b. Rate of weight loss—A reasonable time line for weight loss is to achieve a 10 percent reduction in body weight over 6 months of therapy. For overweight patients with BMIs in the typical range of 27 to 35, a decrease of 300 to 500 kcal/day will result in weight losses of about ½ to 1 lb/week and a 10 percent weight loss in 6 months. For more severely obese patients with BMIs ≥ 35, deficits of up to 500 to 1,000 kcal/day will lead to weight losses of about 1 to 2 lb/week and a 10 percent weight loss in 6 months.

Evidence Statement: *Weight loss at the rate of 1 to 2 lb/week (calorie deficit of 500 to 1,000 kcal/day) commonly occurs for up to 6 months, at which point weight loss begins to plateau unless a more restrictive regimen is implemented. Evidence Category B.*

Rationale: To achieve significant weight loss, an energy deficit must be created and maintained. Weight can be lost at a rate of 1 to 2 lb/week with a calorie deficit of 500 to 1,000 kcal/day. After 6 months, this caloric deficit theoretically should result in a loss of 26 to 52 lb. However, the average amount of weight lost actually observed over this time period usually is in the range of 20 to 25 lb. A greater rate of weight loss does not yield a better result at the end of 1 year. [437] It is difficult for most patients to continue to lose weight after a period of 6 months due to changes in resting metabolic rates and difficulty in adhering to treatment strategies, although some can do so. To continue to lose weight, diet and physical activity goals need to be revised to create an energy deficit at the lower weight, since energy requirements decrease as weight is decreased. To achieve additional weight loss, the patient must further decrease calories and/or increase physical activity. Many studies show that rapid weight reduction almost always is followed by regaining of weight. Moreover, with rapid weight reduction, there is an increased risk for gallstones and, possibly, electrolyte abnormalities.

RECOMMENDATION: *Weight loss should be about 1 to 2 lb/week for a period of 6 months with the subsequent strategy based on the amount of weight lost. Evidence Category B.*

2. Weight Maintenance at Lower Weight

Once the goals of weight loss have been successfully achieved, maintenance of a lower body weight becomes a major challenge. In the past, obtaining the goal of weight loss has been considered the end of weight loss therapy. Unfortunately, once patients are dismissed from clinical therapy, they frequently regain the lost weight. This report recommends that observation, monitoring, and encouragement of patients who have successfully lost weight be continued on a long-term basis.

Evidence Statement: *After 6 months of weight loss treatment, efforts to maintain weight loss through diet, physical activity, and behavior therapy are important. Evidence Category B.*

Rationale: After 6 months of weight loss, the rate of weight loss usually declines and plateaus. [395, 507, 555] The primary care practitioner and patient should recognize that at this point, weight

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maintenance, the second phase of the weight loss effort, should take priority. Successful weight maintenance is defined as a weight regain of < 3 kg (6.6 lb) in 2 years and a sustained reduction in waist circumference of at least 4 cm. If a patient wishes to lose more weight after a period of weight maintenance, the procedure for weight loss outlined above can be repeated.

RECOMMENDATION: *A weight maintenance program should be a priority after the initial 6 months of weight loss therapy. Evidence Category B.*

Evidence Statement: *Lost weight usually will be regained unless a weight maintenance program consisting of dietary therapy, physical activity, and behavior therapy is continued indefinitely. Drug therapy can also be used; however, drug safety and efficacy beyond 1 year of total treatment have not been established. Evidence Category B.*

Rationale: After a patient has achieved the goals of weight loss, the combined modalities of therapy (dietary therapy, physical activity, and behavior therapy) must be continued indefinitely; otherwise, excess weight likely will be regained. Numerous strategies are available for motivating the patient; all of these require that the practitioner continue to communicate frequently with the patient. Long-term monitoring and encouragement can be accomplished in several ways: by regular clinic visits, at group meetings, or via telephone or E-mail. The longer the weight maintenance phase can be sustained, the better the prospects for long-term success in weight reduction. Drug therapy may also be helpful during the weight maintenance phase.

RECOMMENDATION: *After successful weight loss, the likelihood of weight loss maintenance is enhanced by a program consisting of dietary therapy, physical activity, and behavior therapy, which should be continued indefinitely. Drug therapy can also be used. However, drug safety and efficacy beyond 1 year of total treatment have not been established. Evidence Category B.*

3. Prevention of Further Weight Gain

Some patients may not be able to achieve significant weight reduction. In such patients, an important goal is to prevent further weight gain that would exacerbate disease risk. Thus, prevention of further weight gain may justify entering a patient into weight loss therapy. Prevention of further weight gain can be considered a partial therapeutic success for many patients. Moreover, if further weight gain can be prevented, this achievement may be an important first step toward beginning the weight loss process. Primary care practitioners ought to recognize the importance of this goal for those patients who are not able to immediately lose weight. The need to prevent weight gain may warrant maintaining patients in a weight management program for an extended period.

H Strategies for Weight Loss and Weight Maintenance

1. Dietary Therapy

In the majority of overweight and obese patients, adjustment of the diet to reduce caloric intake will be required. Dietary therapy consists, in large part, of instructing patients on how to modify their diets to achieve a decrease in caloric intake. A key element of the current recommendation is the use of a moderate reduction in caloric intake to achieve a slow but progressive weight loss. Ideally, caloric intake should be

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reduced only to the level required to maintain weight at the desired level. If this level of caloric intake is achieved, excess weight will gradually disappear. In practice, somewhat greater caloric deficits are used in the period of active weight loss, but diets with very low calories are to be avoided. Finally the composition of the diet should be modified to minimize other cardiovascular risk factors. [142]

The centerpiece of dietary therapy for weight loss in overweight patients is a low-calorie diet (LCD) (800 to 1,500 kcal/day). This diet is to be distinguished from a very low-calorie diet (VLCD) (250 to 800 kcal/day), which has been unsuccessful in achieving weight loss over the long term. The LCD recommended in this report also contains nutrient compositions that will decrease other risk factors, notably, high serum cholesterol and hypertension.

Evidence Statement: *LCDs can reduce total body weight by an average of 8 percent and help reduce abdominal fat content over a period of approximately 6 months. Evidence Category A.*

Rationale: A decrease in calorie intake is the most important dietary component of weight loss and maintenance. LCDs have been shown to reduce total body weight by an average of 8 percent over a period of 6 months, accompanied by significant reductions in waist circumference. Since this represents an average that includes individuals who did not lose weight, an individual average goal of 10 percent is feasible. When weight loss occurs, the loss consists of about 75 percent fat and 25 percent lean tissue. [556, 557] A deficit of 500 to 1,000 kcal/day will produce a weight loss of 70 to 140 grams/day, or 490 to 980 grams/week (1 to 2 lb/week). A deficit of 300 to 500 kcal/day will produce a weight loss of 40 to 70 grams/day, or 280 to 490 grams/week (1/2 to 1 lb/week) A patient may choose a diet of 1,000 to 1,200 kcal for women and 1,200 to 1,500 kcal for men.

VLCDs (less than 800 kcal/day) are not recommended for weight loss therapy because the deficits are too great, and nutritional inadequacies will occur unless VLCDs are supplemented with vitamins and minerals. [558] Moreover, clinical trials show that LCDs are just as effective as VLCDs in producing weight loss after 1 year. [437] Although more weight is initially lost with VLCDs, more is usually regained. Further, rapid weight reduction does not allow for gradual acquisition of changes in eating behavior. Successful behavior therapy is the key to long-term maintenance of weight at a reduced level. Finally, patients using VLCDs are at increased risk for developing gallstones.

Successful weight reduction by LCDs is more likely to occur when consideration is given to a patient's food preferences in tailoring a particular diet. Care should be taken to be sure that all of the recommended dietary allowances are met; this may require use of a dietary supplement. Dietary education is a necessary ingredient in achieving adjustment to an LCD. Educational efforts should pay particular attention to the following topics:

- energy value of different foods;
- food composition—fats, carbohydrates (including dietary fiber), and proteins;
- reading nutrition labels to determine caloric content and food composition;
- new habits of purchasing—preference to low-calorie foods;
- food preparation—avoiding adding high-calorie ingredients during cooking (e.g., fats and oils);

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- avoiding overconsumption of high-calorie foods (both high-fat and high-carbohydrate foods);
- maintain adequate water intake
- reducing portion sizes; and
- limiting alcohol consumption.

The Step I Diet in ATP II provides an appropriate nutrient composition for an LCD diet. The composition of the diet is presented in Table IV-3. Additional practical dietary advice for patients is included in Appendix VI.

RECOMMENDATION: *A diet that is individually planned to help create a deficit of 500 to 1,000 kcal/day should be an integral part of any program aimed at achieving a weight loss of 1 to 2 lb/week. Evidence Category A.*

RECOMMENDATION: *Reducing dietary fat alone without reducing calories is not sufficient for weight loss. However, reducing dietary fat, along with reducing dietary carbohydrates, can facilitate caloric reduction. Evidence Category A.*

Evidence Statement: *Optimally, dietary therapy should last at least 6 months. Evidence Category A.*

Rationale: Many studies suggest that the rate of weight loss diminishes after about 6 months. Shorter periods of dietary therapy usually result in lesser weight reductions. Therapeutic efforts should be directed toward behavior therapy as well as maintaining LCDs. [486, 570, 571]

Evidence Statement: *During dietary therapy, frequent contacts between professional counselors and patients promote weight loss and maintenance. Evidence Category C.*

Rationale: Frequent clinical encounters during the initial 6 months of weight reduction appear to facilitate reaching the goals of therapy. During the period of active weight loss, regular visits of at least once per month and preferably more often with a health professional for the purposes of reinforcement, encouragement, and monitoring will facilitate weight reduction. Weekly group meetings can be conducted at a low cost, and can contribute to favorable behavior changes. However, no clinical trials have been specifically designed to test the relative efficacy of different frequencies of encounters with physicians, dietitians, or others in the weight loss team. [487]

Evidence Statement: *The amount of time spent with the patient favorably affects weight change in overweight or obese adults given dietary therapy. Evidence Category D.*

Rationale: Training of a health professional in techniques of weight reduction, especially in behavior therapy and dietary principles, is expected to facilitate weight reduction. Further, adequate time must be made available to the patient to convey the information necessary, to reinforce behavioral and dietary messages, and to monitor the patient's response. Despite these judgments, none of the studies reviewed were designed to specifically address the type or qualifications of the health professional who implemented the various weight loss approaches. Many of the studies differed in the types of

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TABLE IV-3:

Low-Calorie Step I Diet

Nutrient	Recommended Intake
Calories[1]	Approximately 500 to 1,000 kcal/day reduction from usual intake
Total Fat[2]	30 percent or less of total calories
Saturated Fatty Acids[3]	8 to 10 percent of total calories
Monounsaturated Fatty Acids	Up to 15 percent of total calories
Polyunsaturated Fatty Acids	Up to 10 percent of total calories
Cholesterol[3]	< 300 mg/day
Protein[4]	Approximately 15 percent of total calories
Carbohydrate[5]	55 percent or more of total calories
Sodium Chloride	No more than 100 mmol per day (approximately 2.4 g of sodium or approximately 6 g of sodium chloride)
Calcium[6]	1,000 to 1,500 mg
Fiber[5]	20 to 30 g

1. A reduction in calories of 500 to1,000 kcal/day will help achieve a weight loss of 1 to 2 lbs/week. Alcohol provides unneeded calories and displaces more nutritious foods. Alcohol consumption not only increases the number of calories in a diet but has been associated with obesity in epidemiological studies [559-562] as well as in experimental studies. [563-566] The impact of alcohol calories on a person's overall caloric intake needs to be assessed and appropriately controlled.

2. Fat-modified foods may provide a helpful strategy for lowering total fat intake but will only be effective if they are also low in calories and if there is no compensation of calories from other foods.

3. Patients with high blood cholesterol levels may need to use the Step II diet to achieve further reductions in LDL-cholesterol levels; in the Step II diet, saturated fats are reduced to less than 7 percent of total calories, and cholesterol levels to less than 200 mg/day. All of the other nutrients are the same as in Step I.

4. Protein should be derived from plant sources and lean sources of animal protein.

5. Complex carbohydrates from different vegetables, fruits, and whole grains are good sources of vitamins, minerals, and fiber. A diet rich in soluble fiber, including oat bran, legumes, barley, and most fruits and vegetables may be effective in reducing blood cholesterol levels. A diet high in all types of fiber may also aid in weight management by promoting satiety at lower levels of calorie and fat intake. Some authorities recommend 20 to 30 grams of fiber daily, with an upper limit of 35 grams. [546, 567, 568]

6. During weight loss, attention should be given to maintaining an adequate intake of vitamins and minerals. Maintenance of the recommended calcium intakes of 1,000 to 1,500 mg/day is especially important for women who may be at risk of osteoporosis. [569]

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dietary intervention provided. Most programs involved dietitians and nutritionists as primary therapists and used group therapy rather than individual sessions. The length of time spent during each session and the nature of the practitioner/patient interaction tended not to be provided.

RECOMMENDATION: *The literature suggests that weight loss and weight maintenance therapies that provide a greater frequency of contacts between the patient and the practitioner and are provided over the long term should be put in place. This can lead to more successful weight loss and weight maintenance. Evidence Category C.*

2. Physical Activity

An increase in physical activity is an important component of weight loss therapy since it leads to increased expenditure of energy. Increased physical activity may also inhibit food intake in overweight patients. Physical activity can also be helpful in maintaining a desirable weight. In addition, sustained physical activity has the benefit of reducing overall CHD risk beyond that produced by weight reduction alone.

Several experts believe that a progressive decrease in the amount of energy expended for work, transportation, and personal chores is a major cause of obesity in the United States. These authorities note that total caloric intake has not increased over the last few decades; instead, the caloric imbalance leading to overweight and obesity is the result of a substantial decrease in physical activity and, consequently, a decrease in daily energy expenditure. However, this hypothesis is difficult to prove because appropriate data are lacking. Successful restoration of normal weight in many overweight and obese persons requires a higher level of energy expenditure. Increased regular physical activity is the way to achieve this goal of augmenting daily energy expenditure.

Evidence Statement: *Physical activity contributes to weight loss, both alone and when it is combined with dietary therapy. Evidence Category A.*

Rationale: Increased physical activity alone can create a caloric deficit and can contribute to weight loss. However, efforts to achieve weight loss through physical activity alone generally produce an average of a 2 to 3 percent decrease in body weight or BMI. Even so, increased physical activity is a useful adjunct to LCDs in promoting weight reduction.

Evidence Statement: *Physical activity in overweight and obese adults increases cardiorespiratory fitness independent of weight loss. Evidence Category A.*

Rationale: There is strong evidence that increased physical activity increases cardiorespiratory fitness, with or without weight loss. [346, 363, 369, 375, 401, 404, 406, 432, 434, 445, 447, 448] Improved cardiovascular fitness also improves the quality of life in overweight patients by improving mood, self-esteem, and physical function in daily activities. [572]

Evidence Statement: *Physical activity independently reduces CVD risk factors (Evidence Category A), and reduces risk for cardiovascular disease. Evidence Category C.*

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Rationale: There is considerable evidence that physical inactivity is an independent risk factor for CVD and diabetes. [572] Furthermore, the more active an individual is, the lower the risk. By the same token, increased physical activity appears to independently reduce risk for CVD morbidity and mortality, and diabetes. [411, 548, 573, 574] Physical activity reduces elevated levels of CVD risk factors, including blood pressure and triglycerides, increases HDL-cholesterol, and improves glucose tolerance with or without weight loss. [572]

Evidence Statement: *Physical activity contributes to a decrease in body fat, including a modest effect on abdominal fat. Evidence Category B.*

Rationale: Physical activity appears to have a favorable effect on distribution of body fat. [572] Several large cross-sectional studies in Europe, [464] Canada, [575] and the United States [466-468] showed an inverse association between energy expenditure through physical activity and several indicators of body fat distribution, such as WHR and waist-to-thigh circumference ratio. Fewer data are available on the effects of physical activity on waist circumference, although the ratio changes noted above suggest a decrease in abdominal obesity. Only a few randomized controlled trials that have tested the effect of physical activity on weight loss measured waist circumference. In some (but not all) studies, physical activity was found to produce only modest weight loss and decreased waist circumference. [365, 369, 375] However, it is not known whether the effects of physical activity on abdominal fat are independent of weight loss.

2.a. Strategies to increase physical activity

Many people live sedentary lives, have little training or skills in physical activity, and are difficult to motivate toward increasing their activity. For these reasons, starting a physical activity regimen may require supervision for some people. The need to avoid injury during physical activity is high. Extremely obese persons may need to start with simple exercises that can gradually be intensified. The practitioner must decide whether exercise testing for cardiopulmonary disease is needed before embarking on a new physical activity regimen. This decision should be based on a patient's age, symptoms, and concomitant risk factors.

For most obese patients, physical activity should be initiated slowly, and the intensity should be increased gradually. Initial activities may be walking or swimming at a slow pace. With time, depending on progress, the amount of weight lost, and functional capacity, the patient may engage in more strenuous activities. Some of these include fitness walking, cycling, rowing, cross-country skiing, aerobic dancing, and rope jumping. Jogging provides a high-intensity aerobic exercise, but can lead to orthopedic injury. If jogging is desired, the patient's ability to do this must first be assessed. The availability of a safe environment for the jogger is also a necessity. Competitive sports, such as tennis and volleyball, can provide an enjoyable form of physical activity for many, but again, care must be taken to avoid injury, especially in older people. As the examples listed in Table IV-4 show, a moderate amount of physical activity can be achieved in a variety of ways. People can select activities that they enjoy and that fit into their daily lives. Because amounts of activity are functions of duration, intensity, and frequency, the same amounts of activity can be obtained in longer sessions of moderately intense activities (such as brisk walking) as in shorter sessions of more strenuous activities (such as running).

A regimen of daily walking is an attractive form of physical activity for many people, particularly those who are overweight or obese. The patient

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TABLE IV-4:

Examples of Moderate Amounts of Activity*

Washing and waxing a car for 45-60 minutes
Washing windows or floors for 45-60 minutes
Playing volleyball for 45 minutes
Playing touch football for 30-45 minutes
Gardening for 30-45 minutes
Wheeling self in wheelchair for 30-40 minutes
Walking 1¾ miles in 35 minutes (20 min/mile)
Basketball (shooting baskets) for 30 minutes
Bicycling 5 miles in 30 minutes
Dancing fast (social) for 30 minutes
Pushing a stroller 1½ miles in 30 minutes
Raking leaves for 30 minutes
Walking 2 miles in 30 minutes (15 min/mile)
Water aerobics for 30 minutes
Swimming laps for 20 minutes
Wheelchair basketball for 20 minutes
Basketball (playing a game) for 15-20 minutes
Bicycling 4 miles in 15 minutes
Jumping rope for 15 minutes
Running 1½ miles in 15 minutes (10 min/mile)
Shoveling snow for 15 minutes
Stairwalking for 15 minutes

* A moderate amount of physical activity is roughly equivalent to physical activity that uses approximately 150 calories of energy per day, or 1,000 calories per week.

** Some activities can be performed at various intensities; the suggested durations correspond to expected intensity of effort.

can start by walking 10 minutes, 3 days a week, and can build to 30 to 45 minutes of more intense walking at least 5 days a week and preferably most, if not all, days. [577, 578] With this regimen, an additional 100 to 200 calories per day of physical activity can be expended. Caloric expenditure will vary depending on the individual's body weight and intensity of the activity (see Table IV-5).

This regimen can be adapted to other forms of physical activity, but walking is particularly attractive because of its safety and accessibility.

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With time, a larger weekly volume of physical activity can be performed that would normally cause a greater weight loss if it were not compensated by a higher caloric intake.

Reducing sedentary time is another approach to increasing activity. Patients should be encouraged to build physical activities into each day. Examples include leaving public transportation one stop before the usual one, parking further than usual from work or shopping, and walking up stairs instead of taking elevators or escalators. New forms of physical activity should be suggested, e.g., gardening, walking a dog daily, or new athletic activities. Engaging in physical activity can be facilitated by identifying a safe area to perform the activity, e.g., community parks, gyms, pools, and health clubs. However, when these sites are not available, an area of the home can be identified and perhaps outfitted with equipment such as a stationary bicycle or a treadmill.

Health professionals should encourage patients to plan and schedule physical activity 1 week in advance, budget the time necessary to do it, and document their physical activity by keeping a diary and recording the duration and intensity of exercise.

RECOMMENDATION: *Physical activity should be an integral part of weight loss therapy and weight maintenance. Evidence Category A. Initially, moderate levels of physical activity for 30 to 45 minutes, 3 to 5 days per week should be encouraged. All adults should set a long-term goal to accu-*

TABLE IV-5:

DURATION OF VARIOUS ACTIVITIES TO EXPEND 150 KILOCALORIES FOR AN AVERAGE 70 KG (154 LB) ADULT

Intensity	Activity	Approximate duration in minutes
Moderate	Volleyball, noncompetitive	43
Moderate	Walking, moderate pace (3mph, 20 min/mile)	37
Moderate	Walking, brisk pace (4mph, 15 min/mile)	32
Moderate	Table tennis	32
Moderate	Raking leaves	32
Moderate	Social dancing	29
Moderate	Lawn mowing (powered push mower)	29
Hard	Jogging (5 mph, 12 min/mile)	18
Hard	Field hockey	16
Very Hard	Running (6 mph, 10 min/mile)	13

Source: Surgeon General's Report on Physical Activity and Health

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mulate at least 30 minutes or more of moderate-intensity physical activity on most, and preferably all, days of the week. Evidence Category B.

3. Behavior Therapy

Behavioral strategies to reinforce changes in diet and physical activity can produce a weight loss in obese adults in the range of 10 percent of baseline weight over 4 months to 1 year. Unless a patient acquires a new set of eating and physical activity habits, long-term weight reduction is unlikely to succeed. The acquisition of new habits is particularly important for long-term weight maintenance at a lower weight. Most patients return to baseline weights in the absence of continued intervention. Thus, the physician or staff members must become familiar with techniques for modifying life habits of overweight or obese patients.

The goal of behavior therapy is to alter the eating and activity habits of an obese patient. Techniques for behavior therapy have been developed to assist patients in modifying their life habits.

Evidence Statement: *Behavior therapy, in combination with an energy deficit, provides additional benefits in assisting patients to lose weight short-term (1 year). Its effectiveness for long-term weight maintenance has not been shown in the absence of continued behavioral intervention. Evidence Category B.*

Rationale: The primary assumptions of behavior therapy are that:

- by changing eating and physical activity habits, it is possible to change body weight;
- patterns of eating and physical activity are learned behaviors and can be modified; and
- to change these patterns over the long term, the environment must be changed.

Behavior therapies provide methods for overcoming barriers to compliance with dietary therapy and/or increased physical activity, and are thus important components of weight loss therapy. Most weight loss programs incorporating behavioral strategies do so as a package that includes education about nutrition and physical activity. However, this standard "package" of management should not ignore the need for individualizing behavioral strategies. [579]

3.a. Behavior Therapy Strategies Used in Weight Loss and Weight Maintenance Programs

Studies reviewed for this report examined a range of modalities of behavioral therapy. No single method or combination of behavioral methods proved to be clearly superior. Thus, various strategies can be used by the practitioner to modify patient behavior. The aim is to change eating and physical activities behaviors over the long term. Such change can be achieved either on an individual basis or in group settings. Group therapy has the advantage of lower cost. Specific behavioral strategies include the following:

- Self-monitoring of both eating habits and physical activity—Objectifying one's own behavior through observation and recording is a key step in behavior therapy. Patients should be taught to record the amount and types of food they eat, the caloric values, and nutrient composition. Keeping a record of the frequency, intensity, and type of physical activity likewise will add insight to personal behavior. Extending records to time, place, and feelings related to eating and physical activity will help to bring previously unrecognized behavior to light. [580]

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- Stress management—Stress can trigger dysfunctional eating patterns, and stress management can defuse situations leading to overeating. Coping strategies, meditation, and relaxation techniques all have been successfully employed to reduce stress.
- Stimulus control—Identifying stimuli that may encourage incidental eating enables individuals to limit their exposure to high-risk situations. Examples of stimulus control strategies include learning to shop carefully for healthy foods, keeping high-calorie foods out of the house, limiting the times and places of eating, and consciously avoiding situations in which overeating occurs. [580]
- Problem solving—This term refers to the self-correction of problem areas related to eating and physical activity. Approaches to problem solving include identifying weight-related problems, generating or brainstorming possible solutions and choosing one, planning and implementing the healthier alternative, and evaluating the outcome of possible changes in behavior. [580] Patients should be encouraged to reevaluate setbacks in behavior and to ask "What did I learn from this attempt?" rather than punishing themselves.
- Contingency management—Behavior can be changed by use of rewards for specific actions, such as increasing time spent walking or reducing consumption of specific foods. [44] Verbal as well as tangible rewards can be useful, particularly for adults. Rewards can come from either the professional team or from the patients themselves. For example, self-rewards can be monetary or social and should be encouraged.
- Cognitive restructuring—Unrealistic goals and inaccurate beliefs about weight loss and body image need to be modified to help change self-defeating thoughts and feelings that undermine weight loss efforts. Rational responses designed to replace negative thoughts are encouraged. [580] For example, the thought, "I blew my diet this morning by eating that doughnut; I may as well eat what I like for the rest of the day," could be replaced by a more adaptive thought, such as, "Well, I ate the doughnut this morning, but I can still eat in a healthy manner at lunch and dinner."
- Social support—A strong system of social support can facilitate weight reduction. Family members, friends, or colleagues can assist an individual in maintaining motivation and providing positive reinforcement. Some patients may benefit by entering a weight reduction support group. Overweight patients should be asked about (possibly) overweight children and family weight control strategies. Parents and children should work together to engage in and maintain healthy dietary and physical activity habits.

3.b. Treatment of Obese Individuals with Binge Eating Disorder

If a patient suffers from binge eating disorder (BED), consideration can be given to referring the patient to a health professional who specializes in BED treatment. Behavioral approaches to BED associated with obesity have been derived from cognitive behavior therapy (CBT) used to treat bulimia nervosa. [227] Among the techniques are self-monitoring of eating patterns, encouraging regular patterns of eating (three meals a day plus planned snacks), cognitive restructuring, and relapse prevention strategies. [581]

RECOMMENDATION: *Behavior therapy strategies to promote diet and physical activity should be used routinely, as they are helpful in achieving weight loss and weight maintenance. Evidence Category B.*

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4. Combined Therapy

To achieve the greatest likelihood of success from weight loss therapy, the combination of dietary therapy with an LCD, increased physical activity, and behavior therapy will be required. Inclusion of behavior therapy and increased physical activity in a weight loss regimen will provide the best opportunity for weight loss, and hopefully for long-term weight control. In order to achieve weight loss, such a regimen should be maintained for at least 6 months before considering pharmacotherapy.

Evidence Statement: *Combined intervention of an LCD, increased physical activity, and behavior therapy provides the most successful therapy for weight loss and weight maintenance. Evidence Category A.*

Rationale: Clinical trials have demonstrated that combining behavior therapy, LCDs, and increased physical activity provides better outcomes for long-term weight reduction than programs that use only one or two of these modalities. A lower-fat diet markedly improves the potential of physical activity to achieve a negative energy balance. [317, 369, 434, 444, 582] In addition, lower-fat diets that are also low in saturated fats reduce serum cholesterol levels, which would reduce CVD risk. It is difficult to achieve a negative energy balance and weight loss with physical activity of moderate duration and intensity in individuals who consume a high-fat diet and alcohol. [583, 584]

RECOMMENDATION: *Weight loss and weight maintenance therapy should employ the combination of LCDs, increased physical activity, and behavior therapy. Evidence Category A.*

5. Pharmacotherapy

Drug therapy has undergone radical changes in the last 2 years. With the publication of the trials with phentermine and fenfluramine by Weintraub in 1992 (210 weeks), drug therapy began to change from short-term to long-term use. Both dexfenfluramine and fenfluramine alone, as well as the combination of phentermine/fenfluramine, were used long term. However, concerns about recently reported unacceptable side effects, such as valvular lesions of the heart causing significant insufficiency of the valves, [658] have led to the withdrawal of the drugs dexfenfluramine and fenfluramine from the market in September 1997. [761] No drugs remained that were approved by the Food and Drug Administration (FDA) for use longer than 3 months. In November 1997, the FDA approved a new drug, sibutramine, for use in obesity and is in the process of evaluating orlistat for long-term use.

Evidence Statement: *Appropriate weight loss drugs can augment diet, physical activity, and behavior therapy in weight loss. Evidence Category B.*

Rationale: The purpose of weight loss and weight maintenance is to reduce health risks. If weight is regained, health risks increase once more. The majority of persons who lose weight regain it, [585] so the challenge to the patient and the practitioner is to maintain the weight loss. Because of the tendency to regain weight after weight loss, the use of long-term medication to aid in the treatment of obesity may be indicated in carefully selected patients.

The drugs used to promote weight loss have been anorexiants or appetite suppressants. Three classes of anorexiant drugs have been developed, all of which affect neurotransmitters in the

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brain: those that affect catecholamines, those that affect serotonin, and those that affect both. They work by increasing the secretion of dopamine, norepinephrine, or serotonin into the synaptic neural cleft, or by inhibiting the reuptake of these neurotransmitters back into the neuron, or by both mechanisms. The new agent sibutramine has norepinephrine and serotonin effects. Another new agent, orlistat, has a different mechanism of action, the blockage of fat absorption. Very few trials longer than 6 months have been done with any drug. The ones tested for at least 1 year that received FDA approval for long-term use are shown in Table IV-6.

These drugs are effective but modest in their ability to produce weight loss. Net weight loss attributable to drugs generally has been reported to be in the range of 2 to 10 kg (4.4 to 22 lb), although some patients lose significantly more weight. It is not possible to predict how much weight an individual may lose. Most of the weight loss usually occurs in the first 6 months of therapy.

Adverse effects include primary pulmonary hypertension with fenfluramine and dexfenfluramine, [395, 586, 587] valvular heart disease with dexfenfluramine and fenfluramine, [658] and increases in blood pressure and pulse with sibutramine. [510] With orlistat, there is a possible decrease in the absorption of fat-soluble vitamins; overcoming this may require vitamin supplementation. People with a history of high blood pressure, CHD, congestive heart failure, arrhythmias, or history of stroke should not take sibutramine, and all patients taking the medication should have their blood pressure monitored on a regular basis. Depression has been described with the serotonergic drugs but it is generally not clinically significant. Neurotoxic effects with neuronal atrophy have been described with high doses of dexfenfluramine in rats and primates, but not in humans. [588] The risks for using

TABLE IV-6:

WEIGHT LOSS DRUGS+

Drug	Action	Adverse Effects
dexfenfluramine* fenfluramine*	serotonin reuptake inhibitor serotonin releaser	valvular heart disease primary pulmonary hypertension neurotoxicity
sibutramine	norepinephrine, dopamine, and serotonin reuptake inhibitor	increase in heart rate and blood pressure
orlistat±	inhibits pancreatic lipase, decreases fat absorption	decrease in absorption of fat-soluble vitamins soft stools and anal leakage possible link to breast cancer

+ Ephedrine and caffeine, and, fluoxetine have also been tested for weight loss, but are not approved for use in the treatment of obesity. Mazindol, phentermine, benzphetamine, and phendimetrazine are approved for only short-term use for the treatment of obesity.

* FDA approval withdrawn

± FDA approval pending

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appetite suppressant drugs during pregnancy is unknown.

Evidence Statement: *Weight loss drugs approved by the FDA for long-term use may be useful as an adjunct to diet and physical activity for patients with a BMI of ≥ 30 with no concomitant obesity-related risk factors or diseases, and for patients with a BMI of ≥ 27 with concomitant obesity-related risk factors or diseases. Evidence Category B.*

Rationale: If after at least 6 months on a weight loss regimen of an LCD, increased physical activity, and behavior therapy, the patient has not lost the recommended 1 lb/week, careful consideration may be given to pharmacotherapy. There are few long-term studies evaluating the safety or effectiveness of many currently approved weight loss medications. At present, sibutramine is available for long-term use. (Note: FDA approval for orlistat is pending a resolution of labeling issues and results of Phase III trials.) Their risk/benefit ratio is such that they can be recommended for use with the degree of obesity outlined above. [589] Weight loss medications should be used only by patients who are at increased medical risk because of their weight and should not be used for "cosmetic" weight loss. The risk factors and diseases considered serious enough to warrant pharmacotherapy at BMI of 27 to 29.9 are hypertension, dyslipidemia, CHD, type 2 diabetes, and sleep apnea.

Not every patient responds to drug therapy. Tests with weight loss drugs have shown that initial responders tend to continue to respond, while initial nonresponders are less likely to respond even with an increase in dosage. [395, 507] If a patient does not lose 2 kg (4.4 lb) in the first 4 weeks after initiating therapy, the likelihood of long-term response is very low. [507] This finding may be used as a guide to treatment, either continuing medication in the responders or stopping it in the nonresponders. If weight is lost in the initial 6 months of therapy or is maintained after the initial weight loss phase, this should be considered a success, and the drug may be continued. It is important to remember that the major role of medications should be to help patients stay on a diet and physical activity plan while losing weight. Medication cannot be expected to continue to be effective in weight loss or weight maintenance once it has been stopped. [590, 591] The use of the drug may be continued as long as it is effective and the adverse effects are manageable and not serious. There are no indications for specifying how long a weight loss drug should be continued. Therefore, an initial trial period of several weeks with a given drug or combination of drugs may help determine their efficacy in a given patient. If a patient does not respond to a drug with reasonable weight loss, the physician should reassess the patient to determine adherence to the medication regimen and adjunctive therapies, or consider the need for dosage adjustment. If the patient continues to be unresponsive to the medication, or serious adverse effects occur, the physician should consider its discontinuation. [592]

Evidence Statement: *Adverse side effects from the use of weight loss drugs have been observed in patients. Evidence Category A.*

Rationale: The potential for side effects from the use of weight loss drugs is of great concern. Adverse effects with sibutramine include increased blood pressure and tachycardia. [590] With orlistat there are oily and loose stools and some fat-soluble vitamin malabsorption. [389] Thus, a multivitamin supplement is recom-

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mended. Side effects are generally mild and may improve with continued use, although their persistence may result in discontinuation of the drug.

There is a great interest in weight loss drugs among consumers. Because of the possibility of serious adverse effects, it is incumbent on the practitioner to use drug therapy with caution. Practitioners should be sure that patients are not taking drugs that have been withdrawn from the market for safety reasons, and herbal medications are not recommended as part of a weight loss program. These preparations have unpredictable amounts of active ingredients and unpredictable and potentially harmful effects. *In those patients with a lower level of obesity risk, nonpharmacological therapy is the treatment of choice.* It is important for the physician to monitor both the effectiveness and the side effects of the drug.

Evidence Statement: *Using weight loss drugs singly (not in combination) and starting with the lowest effective doses can decrease the likelihood of adverse effects. Evidence Category C.*

Rationale: Given the fact that adverse events may increase in association with combination drug therapy, it seems wise that, until further safety data are available, using weight loss drugs singly would be more prudent. Some patients will respond to lower doses, so that full dosage is not always necessary. The short-term use of drugs (< 3 months) has not generally been found to be effective.

Drugs should be used only as part of a comprehensive program that includes behavior therapy, diet, and physical activity. Appropriate monitoring for side effects must be continued while drugs are part of the regimen. Patients will need to return for followup in 2 to 4 weeks, then monthly for 3 months, and then every 3 months for the first year after starting the medication. After the first year, the doctor will advise the patient on appropriate return visits. The purposes of these visits are to monitor weight, blood pressure, and pulse, discuss side effects, conduct laboratory tests, and answer questions.

Since obesity is a chronic disorder, the short-term use of drugs is not helpful. The health professional should include drugs only in the context of a long-term treatment strategy. [593] The risk/benefit ratio cannot be predicted at this time, since not enough long-term data (> 1 year) are available on any of the available drugs.

RECOMMENDATION: *Weight loss drugs approved by the FDA may only be used as part of a comprehensive weight loss program, including dietary therapy and physical activity, for patients with a BMI of ≥ 30 with no concomitant obesity-related risk factors or diseases, and for patients with a BMI of ≥ 27 with concomitant obesity-related risk factors or diseases. Weight loss drugs should never be used without concomitant lifestyle modifications. Continual assessment of drug therapy for efficacy and safety is necessary. If the drug is efficacious in helping the patient lose and/or maintain weight loss and there are no serious adverse effects, it can be continued. If not, it should be discontinued. Evidence Category B.*

6. Surgery for Weight Loss

Surgery is one option for weight reduction for some patients with severe and resistant obesity. The aim of surgery is to modify the gastrointestinal tract to reduce net food intake. Most authorities agree that weight loss surgery should be reserved for patients with severe obesity, in whom efforts at other therapy have failed, and

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who are suffering from the complications of obesity.

Considerable progress has been made in developing safer and more effective surgical procedures for promoting weight loss. Surgical interventions commonly used include gastroplasty, gastric partitioning, and gastric bypass. These procedures are designed primarily to reduce food consumption. They have replaced previous procedures that were designed to promote malabsorption of nutrients. The latter procedures were fraught with side effects that made their use impractical or dangerous.

Evidence Statement: *Gastrointestinal surgery (gastric restriction [vertical gastric banding] or gastric bypass [Roux-en Y]) can result in substantial weight loss, and therefore is an available weight loss option for well-informed and motivated patients with a BMI ≥ 40 or ≥ 35, who have comorbid conditions and acceptable operative risks. Evidence Category B.*

Rationale: According to the National Institutes of Health's Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity, [523] the risk for morbidity and mortality accompanying obesity increases with the degree of overweight. Thus, treatment of clinically severe obesity involves an effort to create a caloric deficit sufficient to result in weight loss and reduction of weight-associated risk factors or comorbidities. Surgical approaches can result in substantial weight loss, i.e., from 50 kg (110 lb) to as much as 100 kg (220 lb) over a period of 6 months to 1 year. A major limitation of nonsurgical approaches is the failure to maintain reduced body weight in many individuals.

Surgical procedures in current use (gastric restriction [vertical gastric banding] and gastric bypass [Roux-en Y]) can induce substantial weight loss, and serve to reduce weight-associated risk factors and comorbidities. Compared to other interventions available, surgery has produced the longest period of sustained weight loss. Assessing both perioperative risk and long-term complications is important and requires assessing the risk/benefit ratio in each case. Patients whose BMI equals or exceeds 40 kg/m^2 are potential candidates for surgery if they strongly desire substantial weight loss, because obesity severely impairs the quality of their lives. Less severe obese patients (BMIs between 35 and 39.9 kg/m^2) also may be considered for surgery. This group primarily includes those patients with high-risk comorbid conditions (cardiovascular, sleep apnea, uncontrolled type 2 diabetes) or weight-induced physical problems interfering with performance of daily life activities.

A recent retrospective study of severely overweight patients with noninsulin-dependent diabetes, who were referred for consideration of a gastric bypass procedure, allowed for a comparison of those who opted for the surgical procedure versus those who did not undergo the procedure because of personal preference or refusal of insurance payment. Patients undergoing the surgical procedure had a decrease in mortality rate for each year of follow up. [594] This latter observation provides initial documentation of the significant impact that reduction in weight may have on mortality.

Most of the surgery studies primarily included women of childbearing age. Caution should be exercised in selecting candidates for surgery to treat obesity, as pregnancy demands increase nutritional needs and a normal need for weight gain. Women with reproductive potential should be advised to avoid pregnancy until their weight has stabilized postoperatively and potential micronutrient deficiencies have been identified and treated.

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Of special note is that many of the studies reported to date have not had population samples representative of the general severely overweight population with respect to race, ethnicity, cultural or socioeconomic background, or gender.

Evidence Statement: *Patients opting for surgical intervention should be followed by a multidisciplinary team (medical, behavioral, and nutritional). Evidence Category D.*

Rationale: As for all other interventions for obesity, an integrated program should be in place that will provide guidance concerning the necessary dietary regimen, appropriate physical activity, and behavioral and social support both prior to and after the surgical procedure.

Evidence Statement: *Lifelong medical surveillance after surgical therapy is a necessity. Evidence Category C.*

Rationale: Since surgical procedures result in some loss of absorptive function, the long-term consequences of potential nutrient deficiencies must be recognized and adequate monitoring must be performed, particularly with regard to vitamin B_{12}, folate, and iron. Some patients may develop other gastrointestinal symptoms such as "dumping syndrome" or gallstones. Occasionally, patients may have postoperative mood changes or their presurgical depression symptoms may not be improved by the achieved weight loss. Thus, surveillance should include monitoring of indices of inadequate nutrition and modification of any preoperative disorders. Table IV-7 illustrates some of the complications that can occur following gastric bypass surgery.

TABLE IV-7:

GASTRIC BYPASS SURGERY COMPLICATIONS: 14-YEAR FOLLOW UP

Vitamin B_{12} deficiency	239	39.9 percent
Readmit for various reasons	229	38.2 percent
Incisional hernia	143	23.9 percent
Depression	142	23.7 percent
Staple line failure	90	15.0 percent
Gastritis	79	13.2 percent
Cholecystitis	68	11.4 percent
Anastomotic problems	59	9.8 percent
Dehydration, malnutrition	35	5.8 percent
Dilated pouch	19	3.2 percent

Data derived from source (Pories WJ[595]) and modified based on personal communication.

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RECOMMENDATION: *Weight loss surgery is an option for carefully selected patients with* clinically severe *obesity (BMI ≥ 40 or ≥ 35 with comorbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality. Evidence Category B.*

COMMENTARY: Adapting Weight Loss Programs To Meet the Needs of Diverse Patient Populations.

Standard obesity treatment approaches should be tailored to the needs of patients. It is, however, difficult to determine from the literature how often this occurs and whether it makes weight loss programs more effective. Very few published reports of such adapted programs can be identified, particularly when a distinction is made from reports that include or focus on special populations but do not report any particular steps taken to modify the intervention for these populations. In addition, it is impossible to compare directly the amount of weight lost using specially adapted programs with that achieved when more standard approaches are used. Studies reporting these programs are sometimes pilot studies or descriptive reports that do not meet the standards of evidence set forth elsewhere in these guidelines. Where randomized controlled trials or quasi-experiments are available, they usually do not include an internal comparison with a program involving no adaptations. Appendix III illustrates the types of adaptations that have been reported.

Large individual variation exists within any social or cultural group; furthermore, there is substantial overlap among subcultures within the larger society. There is, therefore, no "cookbook" or standardized set of rules to optimize weight reduction with a given type of patient. A theoretical and qualitative analysis of cultural appropriateness in obesity treatment programs has been conducted, and it provides some guidance for incorporating patient characteristics and perspectives when designing and delivering weight loss programs. [257] *Some examples follow:*

- *Adapt the setting and staffing to the patient population. The setting should:*
  - *be physically accessible to the patient;*
  - *have features likely to be familiar to the patient;*
  - *be free of negative psychosocial connotations;*
  - *be devoid of aspects that create a large social distance among patients or between patient and practitioner; and*
  - *promote active patient participation and high patient self-esteem and self-efficacy.*

  The staff should be culturally self-aware and culturally competent in working with persons of diverse cultural backgrounds and income or educational levels. For example, cultural adaptation of programs has been approached with the assumption that community centers may be preferable to hospitals or medical offices as venues for conducting lifestyle weight reduction programs. Or, some programs have included peer educators as a possible way of helping to overcome background and social class differences by providing a bridge of knowledge, experience, and perspective between patients and practitioners (see Appendix III).
  - *List assumptions about the type of patient for whom the program will be best suited and evaluate the extent to which these assumptions are appropriate for prospective patients. Where appropriate, modify the program to avoid the need for certain assumptions. Consider patients'—*
    - *preexisting knowledge base;*
    - *day-to-day routine;*
    - *discretionary time;*

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- *financial resources and living situation; and*
- *cultural preferences for types of food and activity.*

  For example, redesign printed materials to be suitable for patients with low literacy skills or poor vision. Offer dietary and physical activity recommendations that will be feasible for low-income patients living in inner-city areas with limited access to supermarkets or with high crime rates.

- *Consider how the obesity treatment program fits in other aspects of the health care and self-care of the patient(s), and integrate other aspects where appropriate. For example, for those patients with diabetes, information about weight reduction should be aligned with other diabetes management advice.*
- *Expect and allow for program modifications based on patient feedback and preferences. Program appropriateness can be increased when patients can express their needs and preferences, and the program is then adapted to those needs and preferences. This is especially applicable when practitioners have limited common experience with patients.*

In recent years, a fat acceptance, nondieting advocacy group has developed. This has emerged from concerns about weight cycling and its possible adverse effects on morbidity and mortality. However, recent evidence suggests that intentional weight loss is not associated with increased morbidity and mortality. For this reason, the guidelines have been made explicit on the importance of intervention for weight loss and maintenance in the appropriate patient groups.

COMMENTARY: Weight Reduction After Age 65—What Are the Issues?

- *Are the indications for treating obesity in older adults the same as those for younger adults?*
- *Does weight loss reduce risk factors in older adults?*
- *Does weight reduction prolong the lives of older adults?*
- *Are there risks associated with obesity treatment that are unique to older adults?*

The higher prevalence of cardiovascular risk factors in overweight versus nonoverweight persons is clearly observed at older ages. [596, 597] *In addition, obesity is a major predictor of functional limitations and mobility impairments in older adults.* [596, 598-600] *Both observational data* [596] *and applicable randomized controlled trials cited in these guidelines suggest that weight loss reduces risk factors and improves functional status in older persons in the same manner as in younger adults.*

The question of whether weight reduction leads to increased survival among older adults has been raised because of observations that weight reduction after age 60 or 65 years may be unable to reverse the deleterious effects of longstanding obesity. [288, 596, 601, 602] *Also, weight loss at older ages has been associated with increased mortality.* [318, 603-607] *Some of the association of weight loss with higher mortality may be due to the increased frequency at older ages of involuntary weight loss due to identified or occult illness. In any case, the association of weight loss with higher mortality applies most clearly to individuals who enter old age with a BMI in the lower part of the range. It is not clear that it applies to overweight older persons with CVD risk factors. This issue has been difficult to clarify in observational data, but there are no randomized trials in which the effects of obesity treatment on mortality can be directly assessed, at any age.*

The wisdom or importance of treating obesity at older ages has also been questioned because of epidemiological observations suggesting a decreased significance of obesity-related relative risks at older ages (see chapter 2.3.b.). However, these relative-risk data are not a useful reference point for considering whether obese older persons will benefit.

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Relative risks are influenced by the characteristics of the comparison group. In this case, the comparison group is lower-weight older persons who have also had high morbidity and mortality.

Concerns about potential adverse effects of obesity treatment in older adults have been raised with respect to bone health and to dietary adequacy. Weight reduction may accelerate aging-related bone loss and thereby increase the risk of osteoporotic fractures in high-risk groups such as older white women. [608-610] *This concern is more relevant to weight loss in thin persons than in obese persons. Some evidence suggests that including resistance training and moderate weight-bearing exercise as a part of a weight reduction program may help maintain bone integrity.* [611, 612]

The general nutritional safety of weight reduction at older ages is of interest because restrictions on overall food intake due to dieting could result in inadequate intakes of protein or essential vitamins and minerals. In addition, involuntary weight loss indicative of occult disease might be mistaken for success in voluntary weight reduction. These concerns can be alleviated by providing proper nutritional counseling and regular body weight monitoring for older persons for whom weight reduction is prescribed.

Evidence Statement: *Age alone should not preclude treatment for obesity in adult men and women. Evidence Category D.*

Rationale: There is little evidence at present to indicate that obesity treatment should be withheld from adult men and women on the basis of age alone up to 80 years of age.

RECOMMENDATION: *A clinical decision to forego obesity treatment in an older adult should be guided by an evaluation of the potential benefits of weight reduction for day-to-day functioning and reduction of the risk of future cardiovascular events, as well as the patient's motivation for weight reduction. Care must be taken to ensure that any weight reduction program minimizes the likelihood of adverse effects on bone health or other aspects of nutritional status. Evidence Category D.*

I Smoking Cessation in the Overweight or Obese Patient

Cigarette smoking is a major risk factor for cardiopulmonary disease. Because of its attendant high risk, smoking cessation is a major goal of risk-factor management. This aim is especially important in the overweight or obese patient, who usually carries excess risk from obesity-associated risk factors. Thus, smoking cessation in such patients becomes a high priority for risk reduction.

Evidence Statement: *Smoking and obesity together increase cardiovascular risk, but fear of weight gain upon smoking cessation is an obstacle for many patients who smoke. Evidence Category C.*

Rationale: Both smoking and obesity are accompanied by increased risks for cardiovascular disease. Many well-documented health benefits are associated with smoking cessation, but a major obstacle to successful smoking cessation has been the attendant weight gain observed in about 80 percent of quitters. This weight gain averages 4.5 to 7 lb, but in 13 percent of women and 10 percent of men, weight gains in excess of 28 lb have been noted among quitters. [613-615] Weight gain is an important barrier to smoking cessation, particularly in women. [616, 617]

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Weight gain that accompanies smoking cessation so far has been relatively resistant to most dietary, behavioral, or physical activity interventions. [618, 619] Postcessation weight gain has been associated with a reduction in energy expenditure of up to 100 kcal/day, accounting for approximately one-third of the weight gain after smoking cessation. [620, 621] The reduction in energy expenditure appears to be the result of a decrease in the resting metabolic rate. [614] In general, no differences in the level of physical activity have been observed after smoking cessation. About two-thirds of the weight gain after smoking cessation appears to result from increased caloric intake. [621-623] However, dietary counseling programs combined with smoking cessation programs have not been very successful. There are several products that reduce postcessation weight gain during drug administration, including nicotine replacement therapy, [624] phenylpropanolamine, [625] and bupropion. [626] No matter what the drug, however, it appears that these drugs merely delay rather than prevent postcessation weight gain. That is, while providing weight gain suppression during drug administration, subjects on these drugs experience a rebound of weight gain once they go off the products and long-term weight gain is equal to that in those not receiving these drugs. [624, 626]

The weight gained with smoking cessation is less likely to produce negative health consequences than would continued smoking. For this reason, smoking cessation should be strongly reinforced in persons regardless of their baseline weight. Smoking is not an acceptable weight control therapy, although it seems to be used for this purpose by a great many people. Overweight patients, as well as all others, should be counseled to quit smoking. For practical reasons, it may be prudent to avoid initiating smoking cessation and weight loss therapy simutaneously. Prevention of weight gain through diet and physical activity should be stressed. If weight gain ensues after smoking cessation, it should be managed vigorously according to the guidelines outlined in this report. Although short-term weight gain is a common side effect of smoking cessation, this gain does not rule out the possibility of long-term weight control. There are no clinical trials to test whether ex-smokers are less likely to successfully achieve long-term weight reduction than those who never smoked.

RECOMMENDATION: *All smokers, regardless of their weight status, should quit smoking. Evidence Category A. Prevention of weight gain should be encouraged and if weight gain does occur, it should be treated through dietary therapy, physical activity, and behavior therapy, maintaining the primary emphasis on the abstinence from smoking. Evidence Category C.*

J Role of Health Professionals in Weight Loss Therapy

Evidence Statement: *A number of health professionals can play an important role in a weight loss and management program. Evidence Category B.*

Rationale: Various randomized controlled trials were reviewed that highlighted the role of the nutritionists, [413, 476] exercise physiologists and physical education instructors, [401, 447] nurses, [413] and psychologists [476, 487] in addition to the physician in providing assessment, treatment, and follow up during weight loss. As a result, it is suggested that the health professionals avail themselves of the various disciplines that offer expertise in dietary counseling, physical activity, and behavior change. The relationship between the physician and these disciplines can be a direct,

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formal one or a more indirect referral. It is important to emphasize that a positive attitude of support and encouragement from all professionals is crucial to continuing success. [627]

RECOMMENDATION: *A weight loss and maintenance program can be conducted by a practitioner without specialization in weight loss so long as that person has the requisite interest and knowledge. However, various health professionals with different expertise are available and helpful to a practitioner who would like assistance. Evidence Category B.*

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Summary of Recommendations

A Advantages of Weight Loss

- Weight loss is recommended to lower elevated blood pressure in overweight and obese persons with high blood pressure. Evidence Category A.
- Weight loss is recommended to lower elevated levels of total cholesterol, low-density lipoprotein cholesterol, and triglycerides and to raise low levels of high-density lipoprotein cholesterol in overweight and obese persons with dyslipidemia. Evidence Category A.
- Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes. Evidence Category A.

B Measurement of Degree of Overweight and Obesity

- Practitioners should use the body mass index (BMI) to assess overweight and obesity. Body weight alone can be used to follow weight loss, and to determine efficacy of therapy. Evidence Category C.
- The BMI should be used to classify overweight and obesity and to estimate relative risk for disease compared to normal weight. Evidence Category C.
- The waist circumference should be used to assess abdominal fat content. Evidence Category C.
- For adult patients with a BMI of 25 to 34.9 kg/m^2, sex-specific waist circumference cutoffs should be used in conjunction with BMI to identify increased disease risks. Evidence Category C.

C Goals for Weight Loss

- The initial goal of weight loss therapy should be to reduce body weight by approximately 10 percent from baseline. With success, further weight loss can be attempted, if indicated, through further assessment. Evidence Category A.
- Weight loss should be about 1 to 2 lb/week for a period of 6 months, with the subsequent strategy based on the amount of weight lost. Evidence Category B.

D How To Achieve Weight Loss

1. Dietary Therapy

- Low-calorie diets are recommended for weight loss in overweight and obese persons. Evidence Category A. Reducing fat as part of a low-calorie diet is a practical way to reduce calories. Evidence Category A.
- Reducing dietary fat alone without reducing calories is not sufficient for weight loss. However, reducing dietary fat, along with reducing dietary carbohydrates, can facilitate caloric reduction. Evidence Category A.
- A diet that is individually planned to help create a deficit of 500 to 1,000 kcal/day should be an integral part of any program aimed at achieving a weight loss of 1 to 2 lb/week. Evidence Category A.

2. Physical Activity

- Physical activity is recommended as part of a comprehensive weight loss therapy and weight maintenance program because it: (1) modestly contributes to weight loss in overweight and

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obese adults (Evidence Category A), (2) may decrease abdominal fat (Evidence Category B), (3) increases cardiorespiratory fitness (Evidence Category A), and (4) may help with maintenance of weight loss (Evidence Category C).

- Physical activity should be an integral part of weight loss therapy and weight maintenance. Evidence Category A. Initially, moderate levels of physical activity for 30 to 45 minutes, 3 to 5 days per week should be encouraged. All adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most, and preferably all, days of the week. Evidence Category B.
- The combination of a reduced calorie diet and increased physical activity is recommended since it produces weight loss, decreases abdominal fat, and increases cardiorespiratory fitness. Evidence Category A.

3. Behavior Therapy

- Behavior therapy is a useful adjunct when incorporated into treatment for weight loss and weight maintenance. Evidence Category B.
- Practitioners need to assess the patient's motivation to enter weight loss therapy; assess the readiness of the patient to implement the plan and then take appropriate steps to motivate the patient for treatment. Evidence Category D.
- Behavior therapy strategies to promote diet and physical activity should be used routinely, as they are helpful in achieving weight loss and weight maintenance. Evidence Category B.

4. Combined Therapy

- Weight loss and weight maintenance therapy should employ the combination of low-calorie diets, increased physical activity, and behavior therapy. Evidence Category A.

5. Pharmacotherapy

- Weight loss drugs approved by the FDA may be used as part of a comprehensive weight loss program including diet and physical activity for patients with a BMI of ≥ 30 with no concomitant obesity- related risk factors or diseases, and for patients with a BMI of ≥ 27 with concomitant obesity-related risk factors or diseases. Drugs should never be used without concomitant lifestyle modification. Continual assessment of drug therapy for efficacy and safety is necessary. If the drug is efficacious in helping the patient lose and/or maintain weight loss and there are no serious adverse effects, it can be continued. If not, it should be discontinued. Evidence Category B.

6. Weight Loss Surgery

- Weight loss surgery is an option in carefully selected patients with *clinically severe* obesity (BMI ≥ 40 or ≥ 35 with comorbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality. Evidence Category B.

E Goals for Weight Loss Maintenance

- After successful weight loss, the likelihood of weight loss maintenance is enhanced by a program consisting of dietary therapy, physical activity, and behavior therapy, which should be continued indefinitely. Drug therapy can also be used. However, drug safety and efficacy beyond 1 year of total treatment have not been established. Evidence Category B.
- A weight maintenance program should be a priority after the initial 6 months of weight loss therapy. Evidence Category B.

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F How To Maintain Weight Loss

- The literature suggests that weight loss and weight maintenance therapies that provide a greater frequency of contacts between the patient and the practitioner and are provided over the long term should be put in place. This can lead to more successful weight loss and weight maintenance. Evidence Category C.
- A weight loss and maintenance program can be conducted by a practitioner without specialization in weight loss so long as that person has the requisite interest and knowledge. However, various health professionals with different expertise are available and helpful to a practitioner who would like assistance. Evidence Category B.

G Special Treatment Groups

- All smokers, regardless of their weight status, should quit smoking. Evidence Category A. Prevention of weight gain should be encouraged and if weight gain does occur, it should be treated through diet, physical activity, and behavior therapy, maintaining the primary emphasis on the abstinence from smoking. Evidence Category C.
- A clinical decision to forego obesity treatment in older adults should be guided by an evaluation of the potential benefits of weight reduction for day-to-day functioning and reduction of the risk of future cardiovascular events, as well as the patient's motivation for weight reduction. Care must be taken to ensure that any weight reduction program minimizes the likelihood of adverse effects on bone health or other aspects of nutritional status. Evidence Category D.
- The possibility that a standard approach to weight loss will work differently in diverse patient populations must be considered when setting expectations about treatment outcomes. Evidence Category B.

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6 Future Research

Obesity is a heterogeneous chronic disorder that has many causes, although the fundamental basis is an imbalance between energy intake and energy expenditure. Future research needs to examine the most effective ways to treat and prevent obesity, the causes of obesity and their mechanisms, the influence of fat distribution on health risk, and the development of better methods for assessing energy intake and energy expenditure.

A Intervention Approaches

Considerable research is needed on intervention approaches to treat and prevent obesity. Increased research on behavioral theory specifically addressing obesity treatment and prevention for all individuals, including children and adolescents, needs to be conducted. Intervention methods to prevent weight gain with smoking cessation are of particularly high priority in helping achieve smoking cessation.

More research is needed on behavioral intervention methods conducted in various settings, particularly the primary care setting. Effective programs to treat or prevent obesity in culturally, ethnically, and socioeconomically diverse populations need to be developed and tested. Simple screening tools should be tested for their predictive value in achieving lifestyle modifications that lead to weight loss or weight control practices. Research is needed on identifying appropriate and successful intervention content; for example, magnitude of weight loss goals (smaller changes versus larger changes), and goals for the rate of weight loss (1 lb versus 2 lb per week; initial weight loss goal of 5 percent of body weight and, subsequently, an additional 5 percent versus a single initial goal of 10 percent at the outset). Of particular importance is research on the optimal amount of physical activity to promote weight loss, the maintenance of weight loss, and the prevention of obesity. Also important are strategies which preserve muscle and bone in the face of weight loss. More research is needed on identifying the characteristics of individuals who have successfully maintained their weight loss over the long term.

Research on surgical interventions for weight loss should include evaluating surgical risk, including not only complications, morbidity, and mortality, but also long-term postoperative surveillance to monitor vitamin and mineral nutritional adequacy. Evaluation of the health benefits of weight loss from surgery should include changes in fat distribution; cardiorespiratory fitness; obesity-related comorbidities, including blood pressure, blood lipids, and glucose tolerance; and degree of success in long-term weight loss maintenance. Finally, research is needed on techniques for integrating behavioral methods to promote long-term maintenance of weight loss after surgical treatment. Likewise, research on pharmacologic interventions for weight loss should include evaluating changes in fat distribution, cardiorespiratory fitness, obesity-related comorbidities, and the degree of success of long-term weight loss maintenance. Better methods for integrating behavioral methods, along with pharmacologic treatment, should also be investigated.

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Finally, research is needed on environmental and population-based intervention methods, including community- and school-based interventions, to augment public health approaches toward promoting weight maintenance and preventing obesity in the general population.

B Causes and Mechanisms of Overweight and Obesity

The regulation of energy balance needs to be explored, including the neuroendocrine factors that control energy intake, energy expenditure, and the differentiation of adipose tissue resulting from excess calories. The genes that are important in human obesity need to be identified. These include those that alter eating and physical activity behaviors, those that affect thermogenesis, and those associated with the comorbidities of obesity. The roles of environmental and behavioral influences on metabolic factors important in obesity, as well as gene-environment interactions, need to be studied. Predictive factors should be examined to identify who is most at risk of developing obesity, and whether there are critical periods of life when these factors are most operative. In addition, the influence of the intrauterine environment on the development of obesity needs to be investigated, particularly to determine whether early deprivation leads to a later propensity for overweight and associated comorbidities, such as insulin resistance, or if high maternal weight gain and high birth weight are related to the risk of obesity and its comorbidities.

C Abdominal Fat, Body Weight and Disease Risk

The influence of abdominal fat independent of total body fat on health risk needs to be further defined. More information is needed on the relationship between differential body fat compartments and increased risk, the distribution of body fat compartments among various racial group populations, and the relationship between abdominal fat and disease risk in racial groups. Weight loss studies should include measurements of abdominal fat, as well as cardiorespiratory fitness, to better assess health improvement. Intentional weight loss treatments need to be examined in terms of their acute and chronic effect on the development and progression of diabetes, heart disease, and overall mortality. Large prospective studies are needed to examine the relationship of body mass index and body fat distribution to overall mortality.

D Assessment Methods

Much of the current research is hampered by the lack of good methods to accurately, objectively, and economically assess energy intake and expenditure, including physical activity, body composition and fat distribution, and behavioral and psychological variables. More research is therefore needed to focus on measures to assess intake of fat and other dietary components, levels of physical activity, energy metabolism, and body fat and visceral obesity. In addition, better methods for assessment of psychological, behavioral, and psychosocial variables that may be related to behavioral risk factors for obesity (such as poor diet and inactive lifestyle) are needed, and particularly so for special population segments based on race, ethnicity, and socioeconomic status. Methods for assessing culture, social integration, and psychological stress should also be developed.

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Appendices

1 Appendix I.A.1. Guidelines Development Methodology

The panel has attempted to provide primary care practitioners with recommendations regarding effective strategies to evaluate and treat overweight and obesity in adults. The panel anticipates that the recommendations also will be followed by the large proprietary weight loss industry in the United States. The guideline is based on a systematic review of the scientific literature published in MEDLINE from January 1980 through September 1997. This was done in the interest of time and economy. This information was supplemented by material provided by the panel and a search of appropriate references in eligible articles. The panel identified randomized controlled trials as the strongest level of evidence for the evaluation of treatment efficacy. Thus, evidence from randomized controlled trials (RCTs) serves as the basis for many of the recommendations contained in this guideline. However, in some instances, the panel had to make recommendations in the absence of RCTs. Each evidence statement (other than those with no available evidence) and each recommendation is categorized by level of evidence (A through D) as described on page 108. Statements for which there is no available evidence are so indicated.

1.a. Panel Selection

The National Heart, Lung, and Blood Institute (NHLBI) Obesity Education Initiative Task Force recommended panel members representing the various expertise required to deal with the issues of cardiovascular disease and body weight. The executive director of the American Academy of Family Physicians (AAFP) also provided recommendations for the primary care practitioner who would represent AAFP. The panel members include primary care practitioners, clinicians from academic medical centers, nutritionists, exercise physiologists, pulmonologists, cardiologists, psychologists, behaviorists, epidemiologists, and experts on cost issues. Some of the panel members were also members of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Task Force on the Prevention and Treatment of Obesity. The funding source for the guidelines was primarily the NHLBI, with the cooperation of the NIDDK of the National Institutes of Health.

1.b. Topics Included in the Guidelines

The panel decided to focus on *all* adult (18 years of age and older) overweight and obese patients with a body mass index (BMI) ≥ 25, and particularly those with cardiovascular risk factors. Excluded from the analysis were patients with known genetic or hormonal syndromes and pharmacologically induced obesity.

In addition, since pediatric obesity contributes to about one-third of adult obesity, the panel felt that some attention needed to be focused on the issue of overweight in children and adolescents (see Appendix III). Treatment issues surrounding overweight children and adolescents are quite different from the treatment of adults. The panel recommended that this issue warrants its own project as soon as possible.

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The therapeutic interventions requiring examination included diet, physical activity, behavior therapy, pharmacological therapy, surgery, and combinations of these. No clinical interventions were excluded at the outset. Because of the importance and complexity of the primary prevention of obesity, the panel decided not to deal with these concerns in detail and that the issue be addressed in a separate document. However, clinical interventions to prevent further weight gain in patients already overweight, or those patients not currently overweight at high risk for becoming overweight, were considered relevant therapeutic interventions. The guideline also contains some information on the cost of obesity.

In terms of reliable diagnostic measures, the panel decided to concentrate on useful tools readily available in a physician's office, i.e., weight, height and BMI. The panel did not search for evidence to prove that measures of body composition or metabolic rate are useful tools; however, they did include studies using these diagnostic measures.

1.c. Development of the Evidence Model

The panel determined the evidence model used to develop the guidelines for the evaluation and treatment of obesity (Figure 7, and Figures 7a and 7b). The model contains two broad categories, the association of weight to cardiovascular and noncardiovascular mortality and morbidity in the population and the clinical issues related to the treatment of the overweight individual. The population portion of the model addresses such questions as, "Is there an association between weight and cardiovascular risk factors?", and "Is there an association between weight and cardiovascular and noncardiovascular morbidity and mortality?" The patient portion of the model focuses on the clinical setting and addresses such questions as, "Does a reduction in weight result in a decrease in cardiovascular morbidity and mortality?"

The model illustrates the areas requiring a thorough examination of the relevant scientific literature through data abstraction and evaluation (the hollow shaded arrows), the areas where the literature has been firmly established (the hollow arrows), and the areas requiring a consideration of the preexisting evidence for minority populations (the crosshatched arrows). The arrows in the model represent the questions the panel considered when looking at the evidence (see the Evidence Model questions on pages 110 to 111).

1.d. Search and Review of the Literature

The literature was searched and systematically reviewed by

- establishing *a priori* eligibility criteria for inclusion of studies;
- reviewing titles and abstracts to select promising articles;
- reviewing these full articles; and
- compiling evidence tables summarizing those articles that met the inclusion criteria.

The panel decided on the parameters for the literature search, particularly for the search dealing with the model linking treatment to weight loss. The parameters of the search included year of publication, country, language, study design, length of the study, outcome measures (which, what, and when), and patient characteristics (age and weight).

The panel decided to limit its search to English-language studies, but included foreign studies that provide an English abstract and are randomized controlled clinical trials. The search included human studies only published in MEDLINE from January 1980 to September 1997. No editorials, letters, or case reports were accepted. The panel was aware that two books published in the early 1980s coded the bulk of the obesity literature written to that point.

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Figure 7
Evidence Model

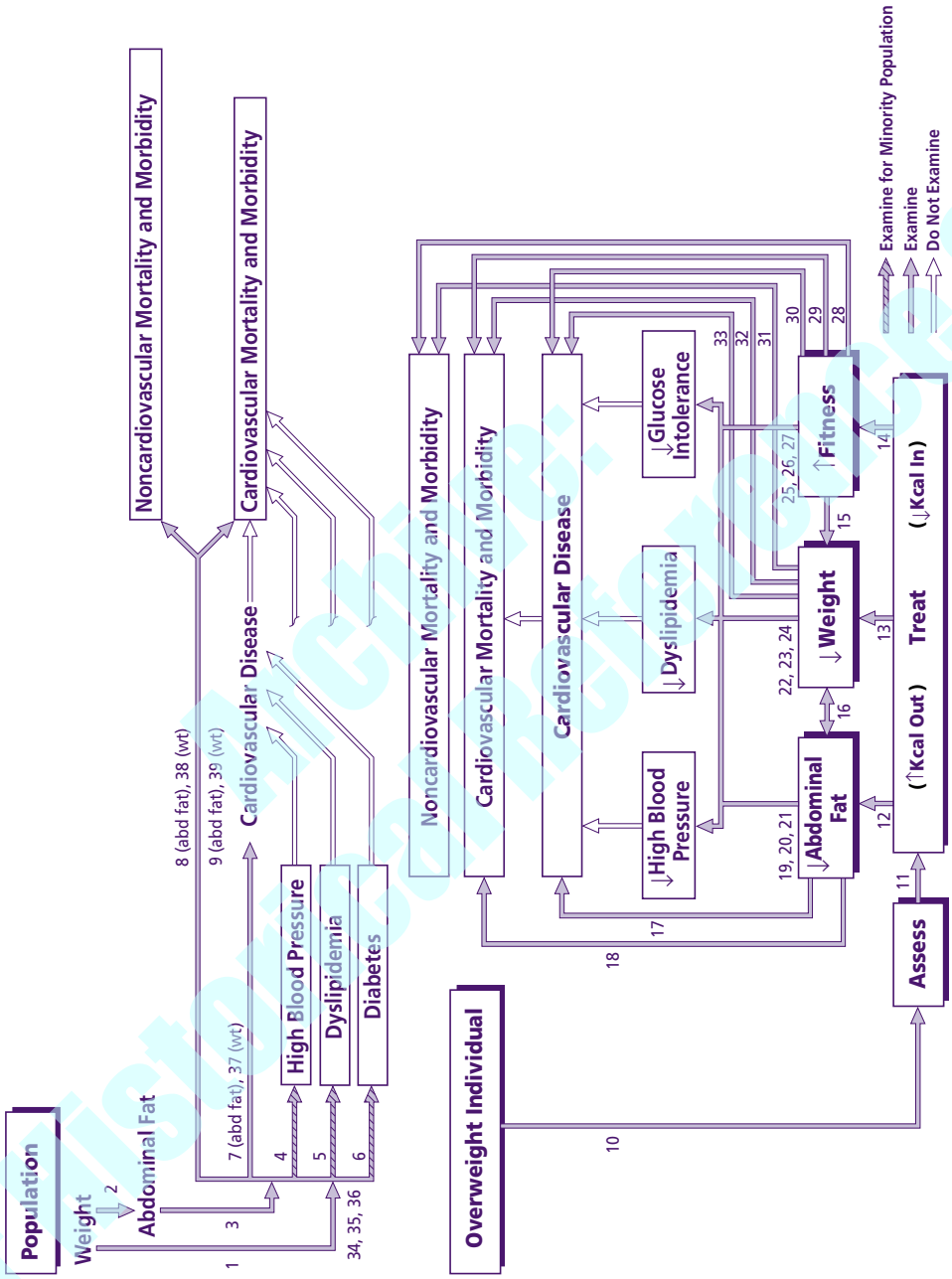

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Figure 7a
Treatment Evidence Model

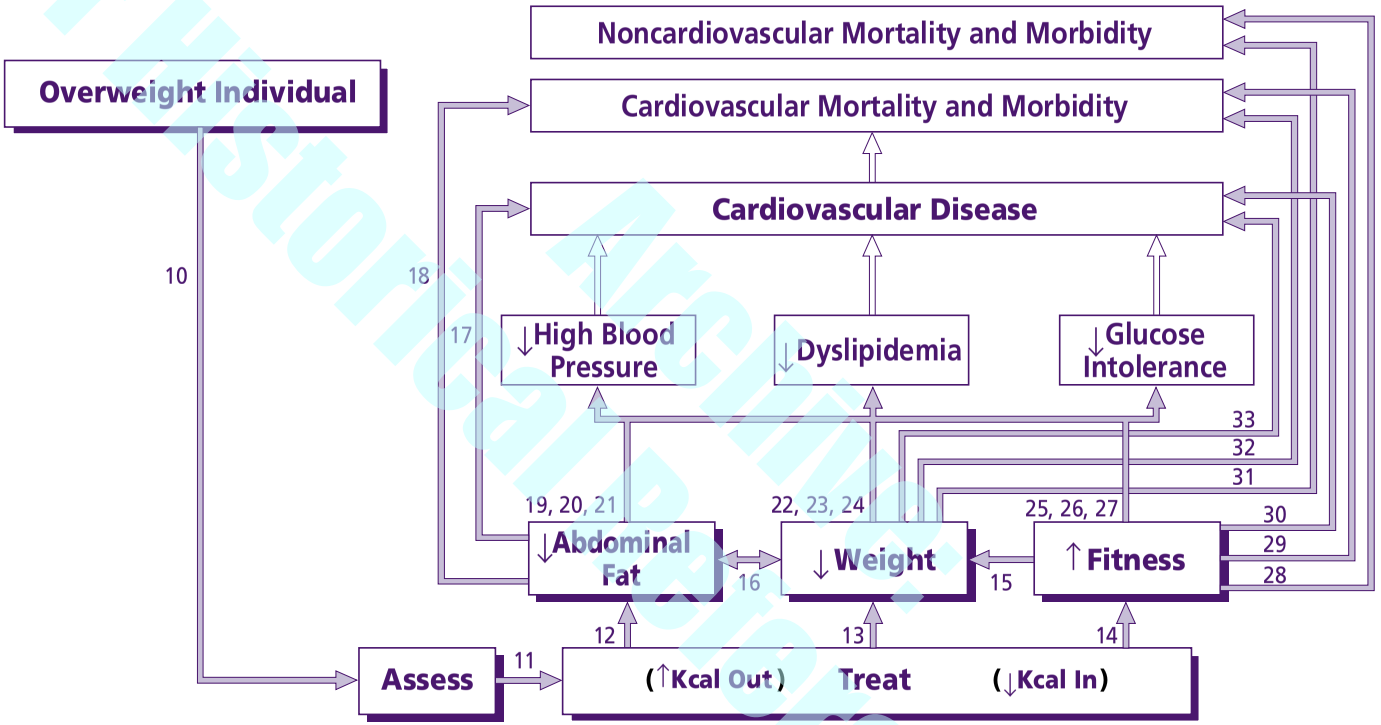

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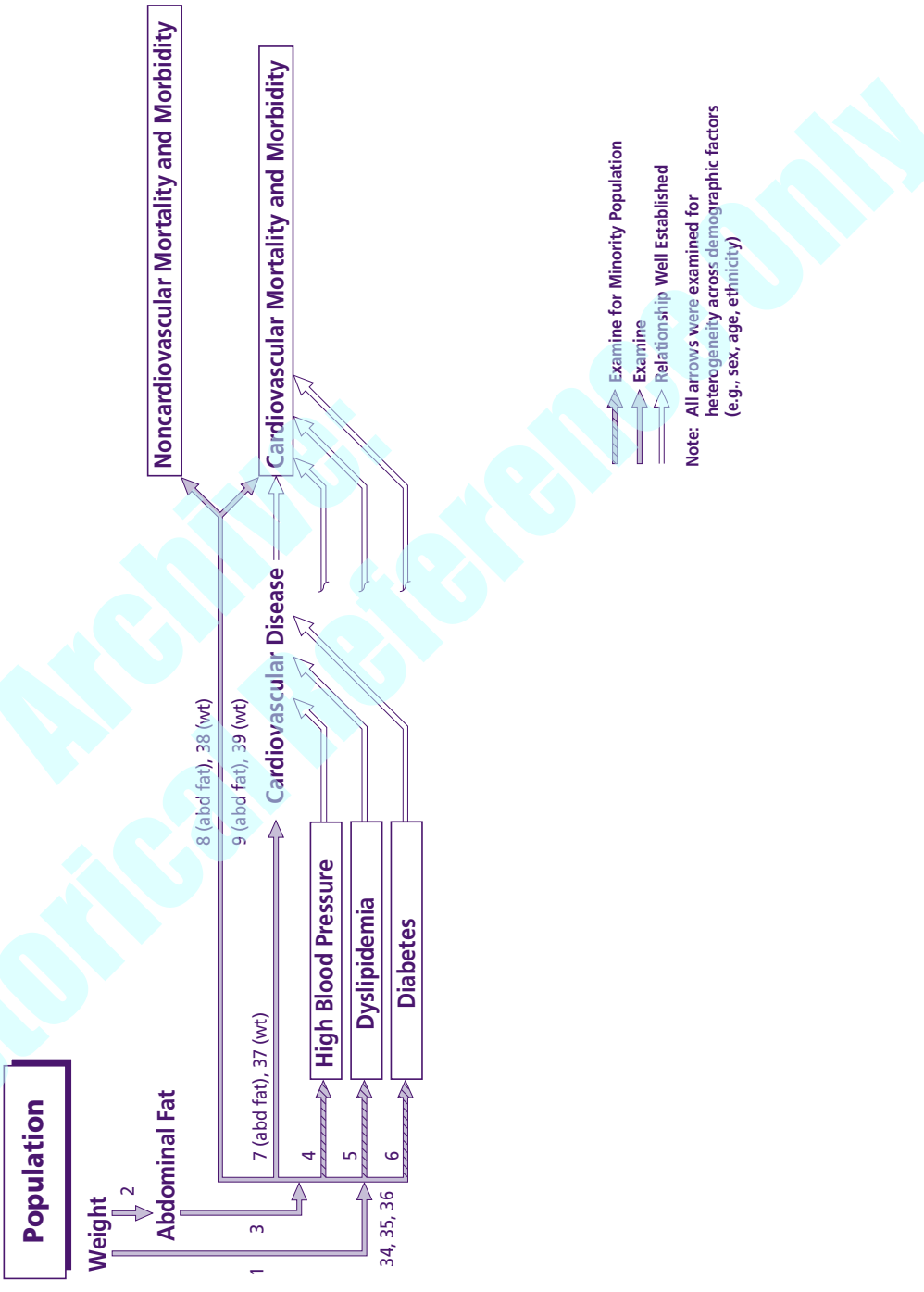
Figure 7b
Evidence Model
Association of Weight to Cardiovascular and Noncardiovascular Mortality and Morbidity



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Panel staff and librarians at the National Library of Medicine's National Information Center for Health Services Research determined the medical subject heading terms used in the literature review. The number of citations found by topic area is provided in Appendix I.A.2.

Figure 8 illustrates the various steps used to collect the evidence. Of the 43,627 titles acquired from the MEDLINE search, 18,217 were duplicates, leaving 25,410 titles to be considered. Using the ProCite reference database, the 25,410 titles were screened by two reviewers and ultimately marked for their appropriateness. Abstracts for the appropriate 8,040 remaining titles were then screened for relevance in two rounds. Two individuals independently reviewed each abstract using the inclusion and exclusion criteria developed by the panel. A third reviewer would sporadically check the quality of the screening. This review led to 2,440 possibly relevant abstracts. Due to the greater quality of the evidence, the decision was made that randomized controlled trials pertinent to the treatment portion of the model be the top priority for data abstraction. Ultimately, 394 articles of randomized controlled trials were reviewed for data abstraction.

1.e. Literature Abstraction and Preparation of Evidence Tables

In order to abstract the correct data related to the treatment portion of the model in a consistent manner, a 25-page form called the "Critical Review Status Sheet (CRSS)" was developed. The CRSS was reviewed and approved by the panel. It took into account the inclusion and exclusion criteria described below and allowed for (1) the collection of data on the study's purpose and design; (2) the intervention parameters, including the format, setting, practitioners, population demographics, and detailed descriptions of the intervention per se, be it dietary, physical activity, behavioral, pharmacotherapy, or other types of interventions (surgery, acupuncture, hypnosis, etc.); and (3) outcome measures, including the method of determining the outcome, and adverse events. The CRSS was pilot-tested by staff as well as by staff of the San Antonio Cochrane Center.

The San Antonio Cochrane Center is one of 12 centers around the world that comprise the Cochrane Collaboration. The Cochrane Collaboration is an international organization established in 1993 whose mission is to prepare, maintain, and disseminate systematic reviews and meta-analysis of health care interventions. The San Antonio Center provides advice on multiple aspects of systematic review, including searching and selecting materials, abstracting materials, organizing materials into evidence tables, and performing meta-analysis.

Inclusion and exclusion criteria—The appropriateness of an article was determined by applying criteria determined by the panel. These criteria included the time frame for the study, i.e., the minimum amount of time that must pass before the outcome measure is made; how body weight was reported; and the type and size of the study. In defining the time frame, the panel needed to clarify if the important outcome was weight loss or sustained weight loss. Due to the importance of both outcomes, the panel decided to include studies that considered the effects during the acute phase of weight loss, and those that examined effects during the maintenance phase. Both types of studies were deemed important, and two cutpoints were considered appropriate for follow-up. At a minimum, studies had to have a time frame from start to finish of at least 4 months. However, in order to consider the question of long-term maintenance, studies with outcome data provided at approximately 1 year or longer were examined. The panel decided to exclude studies that used only self-reported weights for their measurement. No exclusion of studies was made by study size.

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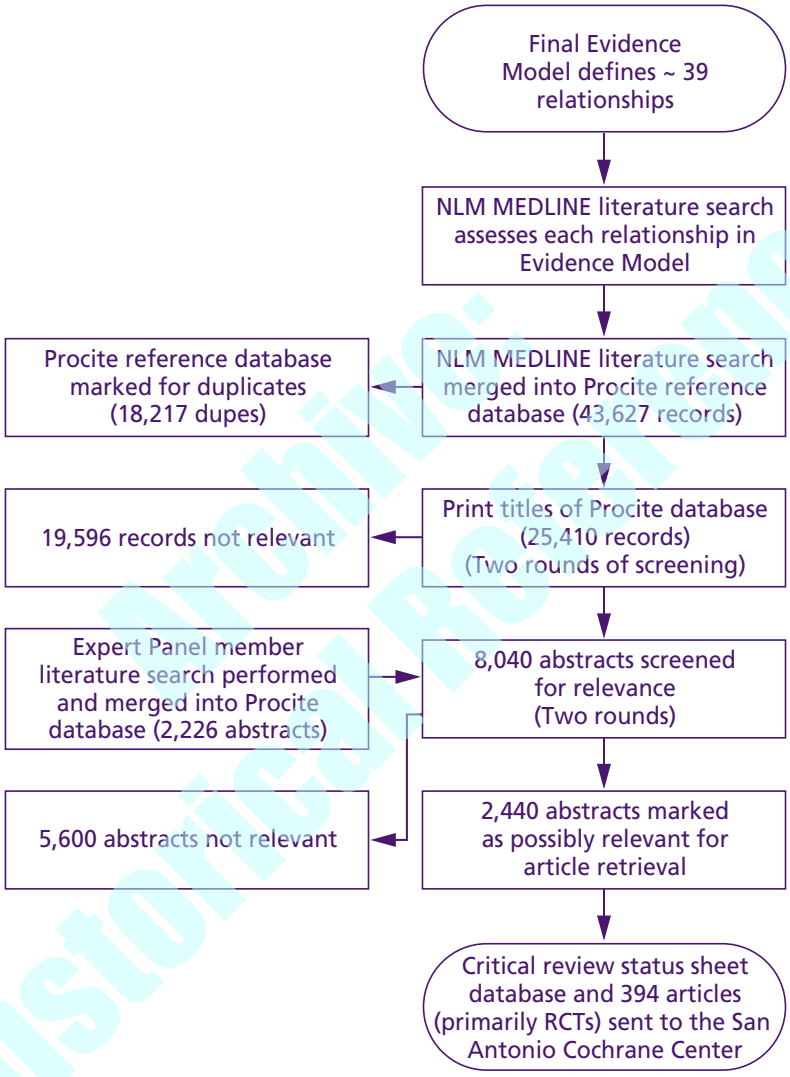
Figure 8
Obesity Guideline Development Process
Evidence Collection Schema



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Preparation of evidence tables—Of the 394 articles of randomized controlled trials considered for data abstraction by the San Antonio Cochrane Center, 158 were rejected for a variety of reasons; i.e., randomization was not adequate or subjects were not all overweight or obese. Ultimately, 236 articles were abstracted by two separate reviewers who independently read and abstracted each article according to the CRSS. The reviewers met, compared coding, and resolved discrepancies. The data were then compiled into individual evidence tables developed for each RCT. In addition, summary tables were developed to compile the evidence necessary to address the 23 questions relevant to the treatment portion of the model. All of the evidence tables will be available for online retrieval (see information regarding availability of the full obesity evidence report and other resources related to weight control on pages 165-167, and 226-228.

1.f. The Formulation of the Evidence into the Guidelines

In order to consider the evidence for each of the 23 questions, the panel met in groups of 6 to 10 members. During the first round of considering the evidence, 12 small groups of panel members were randomly assigned to consider the evidence for 2 or 3 questions. They developed evidence statements and determined the strength of the evidence using the criteria noted on page 108. Their recommendations were presented to the full panel, which then made additional recommendations regarding their conclusions.

After considering additional studies for questions where adequate RCTs were not available, another iteration of evidence statements and recommendations was developed. The full panel met again to consider this iteration, which was considered by small groups assigned to focus on either a specific treatment modality or outcome measure. The small groups brought their recommendations back to the full panel for their final consideration. The panel weighed the evidence based on a thorough examination of the threshold or magnitude of the treatment effect.

Criteria:

Each evidence statement (other than those with no available evidence) and each recommendation is categorized by a level of certainty (A through D) as described on the next page. The consensus process used for drawing conclusions and writing the recommendations was a group process that took into account all opinions. Conclusions reflect the widest possible agreement of the panel.

1.g. Consideration of Special Populations and Situations

The panel also evaluated population factors and clinical situations that might potentially influence the physiological, medical, behavioral, or sociocultural context for obesity identification and treatment. Evidence on special populations and situations was captured from non-RCT evidence when available, but in many cases such evidence was meager. Population factors selected for special consideration with respect to obesity classification and treatment were age, gender, race/ethnicity, socioeconomic status, pregnancy, eating disorders, sleep apnea, extreme obesity, concurrent treatment of other major conditions (such as heart disease or diabetes), and treatment of obesity in conjunction with smoking cessation.

These considerations were addressed in all stages of guideline development. Persons with relevant special expertise were invited to serve on the panel. The search for evidence was formulated to ascertain studies that include special populations. Studies evaluated were coded to permit analysis of the extent to which the special populations or situations of interest had been included and whether findings for these populations and situations deviated from those for the majority populations in these studies. In the numerous cases where evidence on these special

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Evidence Categories

Evidence Category	Sources of Evidence	Definition
A	Randomized controlled trials (rich body of data)	Evidence is from endpoints of well-designed RCTs (or trials that depart only minimally from randomization) that provide a consistent pattern of findings in the population for which the recommendation is made. Category A therefore requires substantial numbers of studies involving substantial numbers of participants.
B	Randomized controlled trials (limited body of data)	Evidence is from endpoints of intervention studies that include only a limited number of RCTs, post hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, and the trial results are somewhat inconsistent, or the trials were undertaken in a population that differs from the target population of the recommendation.
C	Nonrandomized trials Observational studies	Evidence is from outcomes of uncontrolled or nonrandomized trials or from observational studies.
D	Panel Consensus Judgment	Expert judgment is based on the panel's synthesis of evidence from experimental research described in the literature and/or derived from the consensus of panel members based on clinical experience or knowledge that does not meet the above-listed criteria. This category is used only in cases where the provision of some guidance was deemed valuable but an adequately compelling clinical literature addressing the subject of the recommendation was deemed insufficient to justify placement in one of the other categories (A through C).

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issues was insufficient to meet standards for inclusion in the main text of the guideline, potentially important issues were identified for the user and cross-referenced to an appendix or discussed in sidebar text.

1.h. External Review of the Guidelines

The external review of the guidelines included 115 reviewers from 59 government agencies, professional societies, and consumer groups represented on the Coordinating Committees of the National Cholesterol Education Program and the National High Blood Pressure Education Program, as well as the NIDDK's National Task Force on the Prevention and Treatment of Obesity, and selected members of the North American Association for the Study of Obesity.

Reviewers were asked to evaluate the guideline based on five criteria: validity, clarity, flexibility, completeness, and clinical applicability. Reviewers were also encouraged to provide additional comments. Comments of the peer reviewers were evaluated by the panel and panel staff, and were incorporated into the guideline where appropriate.

1.i. Caveats to Recommendation Use

In applying these guideline recommendations, the reader should note some caveats:

- The emphasis of these guidelines was to identify effective interventions, not to rank-order interventions in terms of relative efficacy or effectiveness. The panel chose not to emphasize comparisons among interventions, because there were few studies that compared long-term outcomes, and, since patient preference often dictates choice of therapy, we wished to present a menu of options rather than a ranked list of choices.
- When no evidence was available on the efficacy of various treatments, the panel usually rendered no opinion. An absence of studies should not be confused with an absence of effect. While clinicians may wish to use proven therapies in preference to untested therapies, the lack of testing does not prove that the untested therapy does not work.
- The limitations of RCTs must be kept in mind. The RCT is the primary method for demonstrating efficacy. Often, patients enrolled in RCTs differ from the patients in a primary care practice, and effectiveness in the community may differ from efficacy as measured in an RCT. The potential exists for misinterpretation of clinical trial results. Analysis of endpoints not specified at the outset, post hoc, or subgroup analyses should be viewed as hypothesis-generating rather than hypothesis-testing.

Appendix I.A.2. Literature Review

The results of the literature search are provided below in terms of the population (top) and clinical (bottom) portions of the evidence model. A total of 43,627 records were obtained from the search; the following notes the number of records per topic.

Population model search citations by topic area (22,017 total):

cardiovascular disease	3,675 citations
hypertension	93 citations
diabetes	65 citations
dyslipidemia	73 citations
cardiovascular morbidity and mortality	225 citations
noncardiovascular morbidity and mortality	4,272 citations

Clinical model search citations by topic area (11,268 total):

cardiovascular disease	1,866 citations
hypertension	616 citations
diabetes	380 citations
dyslipidemia	917 citations

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Evidence Model Questions
Population Model (Top)

Arrow Number	Question
1	Not considered
2	What is the evidence that relates weight to abdominal fat?
3	Not considered
4	What is the evidence that relates abdominal fat to high blood pressure in minority populations?
5	What is the evidence that relates abdominal fat to dyslipidemia in minority populations?
6	What is the evidence that relates abdominal fat to diabetes in minority populations?
7	What is the evidence that relates abdominal fat to cardiovascular disease?
8	What is the evidence that relates abdominal fat to noncardiovascular mortality and morbidity?
9	What is the evidence that relates abdominal fat to cardiovascular mortality and morbidity?
34	What is the evidence that relates weight to high blood pressure in minority populations?
35	What is the evidence that relates weight to dyslipidemia in minority populations?
36	What is the evidence that relates weight to diabetes in minority populations?
37	What is the evidence that relates weight to cardiovascular disease?
38	What is the evidence that relates weight to noncardiovascular mortality and morbidity?
39	What is the evidence that relates weight to cardiovascular mortality and morbidity?

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Evidence Model Questions
Clinical Model (Bottom)

Arrow Number	Question
10	Not considered
11	Not considered
12	What is the evidence that treatment directly affects abdominal fat?
13	What is the evidence that treatment directly affects weight loss?
14	What is the evidence directly relating treatment and fitness?
15	What is the evidence that fitness is directly related to weight loss?
16	What is the evidence that weight loss directly affects abdominal fat?
17	What is the evidence that a reduction of abdominal fat is directly related to cardiovascular disease?
18	What is the evidence that a reduction of abdominal fat is directly related to cardiovascular mortality and morbidity?
19	What is the evidence that a reduction in abdominal fat directly affects high blood pressure?
20	What is the evidence that a reduction in abdominal fat directly affects dyslipidemia (cholesterol)?
21	What is the evidence that a reduction in abdominal fat directly affects glucose tolerance?
22	What is the evidence that weight loss directly affects high blood pressure?
23	What is the evidence that weight loss directly affects dyslipidemia (cholesterol)?
24	What is the evidence that weight loss directly affects glucose tolerance?
25	What is the evidence that fitness directly affects high blood pressure?
26	What is the evidence that fitness directly affects dyslipidemia (cholesterol)?
27	What is the evidence that fitness directly affects glucose tolerance?
28	What is the evidence that fitness is directly related to noncardiovascular mortality?
29	What is the evidence that fitness is directly related to cardiovascular mortality and morbidity?
30	What is the evidence that fitness is directly related to cardiovascular disease?
31	What is the evidence directly relating weight loss and noncardiovascular mortality and morbidity?
32	What is the evidence directly relating weight loss and cardiovascular mortality and morbidity?
33	What is the evidence directly relating weight loss and cardiovascular disease?

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cardiovascular morbidity and mortality	71 citations
noncardiovascular morbidity and mortality	6,507 citations

Note: The number of citations per topic do not add up to the total citations per top or bottom model or the overall NLM search. The total number includes all of those listed above plus the citations for fitness, weight loss, and abdominal fat.

2 Appendix II. Description of Evidence

A. Why Treat Overweight and Obesity?

Blood Pressure

To evaluate the effect of weight loss on blood pressure and hypertension, 76 articles reporting randomized controlled trials (RCTs) were reviewed. Of these, 60 were lifestyle trials that studied diet and/or physical activity and 16 were pharmacotherapy trials of anorexiants. The 60 lifestyle trials were: [346-352, 354-380, 405, 470, 473, 484, 490, 674-694] The 16 articles on pharmacotherapy trials of anorexiants were: [386-395, 512, 695-699]

Lifestyle Trials

Of the 60 lifestyle trials reviewed, 35 were accepted and 25 were not included for these reasons:

- the no-treatment control group also lost weight; [470, 473, 484, 490, 675-680, 683, 684, 688, 690, 692, 693]
- there was no appropriate control group; [687]
- the dropout rate was more than 35 percent; [685, 686]
- the results were not compared according to randomized treatment assignments; [681]
- the population at baseline was not overweight; [689-691]
- blood pressure was not reported as a primary or secondary outcome; [405] or
- the intervention period was less than 4 weeks. [674]

Pharmacotherapy Trials

Of the 16 pharmacotherapy trials reviewed, 10 were accepted and 6 were not included because:

- the drug that was tested is not recommended for weight loss [695] [ephedrine alone] [696] [a beta-adrenoceptor agonist] [697] [ephedrine combined with caffeine] [698] [testosterone] [699] [cimetidine], or
- only very short-term data are available. [512]

Serum/Plasma Lipids and Lipoproteins

Sixty-five RCT articles were evaluated for the effect of weight loss on serum/plasma concentrations of total cholesterol, low-density lipoprotein cholesterol, very low-density lipoprotein cholesterol, triglycerides, and high-density lipoprotein cholesterol. In 52 of these trials weight loss was induced by various lifestyle modifications, including diet modification and increased physical activity. [356, 365, 367-370, 373, 380, 384, 399-406, 412, 431, 433, 434, 440, 446, 447, 469, 470, 473, 475, 484, 490, 677-679, 681, 683-685, 688-690, 693, 694, 700-709]

Thirteen RCT articles were reviewed that considered the effects of pharmacological therapy on weight loss and subsequent changes in total serum cholesterol level. [386, 390-393, 395, 407, 408, 696-698, 710, 711]

Lifestyle Trials

Of the 52 lifestyle trials:

- 27 RCT articles examined the effect on plasma lipids of weight loss induced by diet alone, i.e., these studies simply included a diet intervention without a formal physical activity program or medications. [356, 368-370, 373, 399, 400, 402, 412, 431, 433, 440, 484, 490, 677, 679, 683, 688-690, 693, 701, 702, 704, 706, 708, 709]
- 11 RCT articles examined weight loss induced by increased physical activity alone; [365, 401, 404, 406, 447, 678, 685, 700, 703, 705, 707] and
- 14 RCT articles considered the combination of caloric restriction and physical activity. [367, 380, 384, 403, 405, 434, 446, 469, 470, 473, 475, 681, 684, 694]

Of the 52 lifestyle trials reviewed, 14 met the criteria for inclusion. [365, 368, 370, 373, 380, 384, 399-406] The

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remaining 38 were not considered because:

- The no-treatment control group also lost weight. [434, 446, 469, 470, 473, 475, 484, 490, 677-679, 683, 684, 688, 690, 693, 694, 701, 705, 706, 708, 709]
- There was no appropriate control group; [431, 700]
- There was no difference in weight loss between the treatment and control group; [447, 702, 703]
- The dropout rate was more than 35 percent; [685]
- The population was not overweight; [689, 690]
- The results were not reported according to randomized treatment; [681]
- The outcome measures were not reported separately for the overweight and not overweight groups; [440]
- There was no measure of at least one lipoprotein fraction or measure of change in lipids between the beginning and end of treatment; [356, 367, 412, 433, 704] or
- Lipoprotein concentrations could not be determined from the figures in the paper, [707] or it was difficult to get precise measures. [369]

Pharmacotherapy Trials

The effects of pharmacological therapy on weight loss and subsequent changes in total serum cholesterol levels were evaluated by examining 13 RCT articles: 5 on the effect of dexfenfluramine; [386, 390- 393] 2 on fluoxetine; [408, 711] 1 on the combination of phentermine and fenfluramine (phen/fen); [395] 2 on orlistat; [407, 710] 1 on testosterone decanoate; [698] 1 on ephedrine alone or in combination with caffeine; [697] and 1 on a beta adrenoceptor agonist. [696] Of the 13 pharmacotherapy trials reviewed, 8 were accepted and 5 were not considered for these reasons:

- The main outcome of the treatment was not weight loss; [698]
- The drug in question is not currently being recommended for weight loss; [696-698]
- The dropout rate was more than 35 percent; [711] or
- It was a marginal 12-week study. [710]

Impaired Glucose Tolerance and Diabetes

Forty-nine articles on RCTs were reviewed to evaluate the effect of weight loss on fasting blood glucose and fasting insulin. [70, 362, 367, 369, 373, 386, 387, 390-393, 403, 404, 408, 412-415, 439, 440, 446, 470, 473, 474, 482, 485, 490, 492, 493, 576, 676-678, 681, 683, 684, 689, 690, 693, 694, 696-698, 700-702, 708, 709, 712]

Studies were conducted in individuals with normal blood glucose levels (fasting plasma glucose < 115 mg/dL [< 6.4mmol/L]), [367, 373, 386, 387, 390-393, 403, 412, 415, 677, 678, 681, 683, 684, 689, 690, 694, 696-698, 700] in individuals with impaired glucose tolerance (fasting plasma glucose of < 140 mg/dL [7.8 mmol/L] or 2 hours postprandial plasma glucose of ≥ 140 to < 200 mg/dL [7.8 to 11.1 mmol/L]), [70, 369] or in individuals with diabetes (fasting plasma glucose of > 140 mg/dL or 2 hours postprandial plasma blood glucose ≥ 200mg/dL). [362, 404, 408, 413, 414, 439, 440, 446, 470, 473, 474, 482, 485, 490, 492, 493, 576, 676, 693, 701, 702, 708, 709, 712*]

Lifestyle Trials

Of the 38 trials reviewed on the role of lifestyle in weight loss and subsequent changes in blood glucose levels, 16 were on diet alone, [70, 373, 412, 413, 415, 439, 440, 576, 677, 683, 689, 693, 701, 702, 708, 709] 8 dealt with physical activity alone [70, 369, 404. 474, 676, 678, 690, 700], 8 focused on diet plus physical activity, [70, 362, 403, 446, 470, 473, 681, 684] and 5 examined the role of behavior therapy. [367, 482, 485, 490, 493] One study included diet, behavior therapy and physical activity. [694] One study included diet, behavior therapy and physical activity. [694] One study [414] included diet, behavioral therapy and drug therapy. Of the 38 trials, 9 were accepted, and 29 were not considered for these reasons:

- There was a control group that had a weight loss intervention or there was no difference in weight loss between the treatment and control

* The reviewed articles used the "old" definitions of the American Diabetes Association (ADA) for impaired glucose tolerance and diabetes. As of November 1997, the new ADA definitions define "impaired fasting glucose" as those individuals having a fasting plasma glucose of 110 to 125 mg/dL, and "diabetes" as those individuals having a fasting plasma glucose of ≥ 126 mg/dL or 2 hours postprandial plasma glucose of ≥ 200 mg/dL.

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groups; [439, 446, 470, 473, 474, 482, 485, 490, 492, 493, 576, 676-678, 683, 684, 690, 693, 694, 701, 702, 708, 709]

- The dropout rate was more than 35 percent; [415]
- The results were not reported according to randomized treatment assignments; [681]
- Outcome measures were not reported separately for the obese and nonobese people who lost weight; [440]
- There was no appropriate control group; [700] or
- The population was not overweight. [689, 690]

Pharmacotherapy Trials

Of the 12 pharmacotherapy trials reviewed, 8 were accepted and 4 were excluded for these reasons:

- The main outcome of the treatment was not weight loss; [698] or
- The drug used is not currently being recommended for weight loss. [696-698, 712]

B. What Treatments Are Effective?

Dietary Therapy

Of the 86 RCT articles evaluated for the effectiveness of dietary therapy on weight loss, 49 were accepted; 37 were not considered for the following reasons:

- Diet alone was not evaluated; [376, 405]
- There was no control group; [442, 446, 675, 676, 680, 683, 686, 688, 693, 702, 709, 713-720]
- There was no appropriate control group; [677, 704]
- The dropout rate was more than 35 percent; [415]
- The weight loss intervention was less than 12 weeks; [402, 474, 477, 576, 674, 708, 714, 721-723]
- The study did not provide specific information to assess the diet; [724] or
- The patients were not overweight. [689-691]

Physical Activity

Twenty-three RCT articles were reviewed for the effect of physical activity on weight loss, body fat distribution (abdominal fat), and fitness level; of these, 13 were accepted and 10 were not considered. The 23 RCTs were: [346, 363, 365, 369, 375, 401, 404, 406, 432, 434, 445-447,474, 475,678, 685, 700, 705, 707, 725-727] Of the 23 RCTs, 11 were conducted on overweight or obese populations with an average body mass index > 25 kg/m^2. [346, 365, 369, 401, 434, 445-447, 685, 700, 725] Four RCTs were conducted on an overweight or obese population with an average weight of 120 percent to 160 percent of ideal body weight. [363, 406, 432, 475] One RCT was conducted on obese or overweight populations with a percent of body fat > 25 for men or > 30 for women. [678]

Nine RCT articles presented results on men, [363, 365, 369, 406, 432, 700, 705, 707, 726] six RCTs were conducted on women, [434, 445, 446, 678, 685, 725] and seven RCTs covered both men and women. [346, 401, 404, 447, 474, 475, 727]

One RCT article included hypertensive individuals, [346] three RCTs included people with type 2 diabetes, [404, 446, 474] and one RCT included individuals with hyperlipidemia. [685]

Ten RCT articles were not included because:

- The population at baseline was not overweight, [705, 727] or it was not clear if the population was overweight; [707, 726]
- The intervention period was less than 12 weeks; [474]
- There was no appropriate control group; [475, 678, 700, 725] and
- The dropout rate was more than 35 percent. [685]

Combined Therapy

Twenty-three RCT articles investigated the effects on body weight of a combination of a reduced-calorie diet with increased physical activity. The control groups used diet alone or exercise alone. [346, 365, 375-377, 380, 384, 405, 434, 435, 445, 448, 469-475,

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[681, 684, 728, 729] Of the 23, 15 were accepted and 8 were not considered for the following reasons:

- There was no exercise-alone or diet-alone comparison group; [376, 405, 475, 681, 684, 728, 729] or
- The intervention was less than 12 weeks. [474]

Behavior Therapy

Additional Benefits Beyond Other Weight Loss Approaches

Thirty-six RCT articles were reviewed to evaluate whether behavior therapy provides additional benefit beyond other weight loss approaches. Of the 36, 4 were accepted and 32 were not considered. The 36 trials were: [350, 373, 376, 379, 395, 399, 400, 412, 414, 415, 436-438, 443,444, 469, 470, 473, 476,-478, 490, 510, 677, 679, 688, 700,708, 709, 730-736]

Four RCT articles that compared behavior therapy plus another weight loss strategy to that weight loss strategy without behavior therapy, and that met the inclusion criteria, were accepted. Three of the accepted studies compared behavior therapy to a dietary intervention. [436, 476,477] No studies were found that compared behavior therapy to either exercise or to a combination of diet and exercise. One study was found that compared behavior therapy to drug therapy. [478]

Thirty-two of the articles were not considered because:

- Either behavior therapy was not used or it was not possible to ascertain whether it was used; [412, 490, 677, 730]
- Behavior therapy was used either alone or as part of an intervention, but the comparison groups used did not allow for determining the unique effect of behavior therapy; [350, 373, 376, 399, 400, 414, 415, 444, 470, 700, 732, 735] or
- Behavior therapy was integrated into all of the intervention groups, making it impossible to detect the unique effect of behavior therapy. [379, 395, 437, 438, 443, 469, 473, 510, 679, 688, 708, 709, 731, 733, 734, 736]

Comparison of Behavior Therapy Strategies

Another way to examine the efficacy of behavior therapy in the treatment of obesity is to evaluate studies that compare various behavioral techniques to one another. These studies are primarily from the behavioral psychology literature.

Thirty-one RCT articles were reviewed that compared one or more behavioral interventions. [367, 445, 476, 479-495, 632, 680, 694, 737-744] Most of the trials used a group format and followed subjects over time; three included booster sessions. [484, 487, 491] Twelve of the studies provided 1 year or more of follow-up weights. Most studies lacked a pure, no-treatment, control group. There were limited intervention data on special populations, including various ethnic groups and populations with low income and education. Men and women were well represented. The majority of patients were young and middle-aged adults.

Nine of the trials studied special patient populations: subjects with type 2 diabetes; [482, 485, 489, 490, 492 493, 739] subjects at high risk for coronary artery disease; [484] and subjects with binge eating disorder. [494] Trials with subjects with type 2 diabetes used behavioral approaches to increase adherence to the American Diabetes Association diet and improve glycemic control, rather than to lose weight as the primary objective (although all reported an effect on weight).

Of the 31 articles reviewed, 19 were accepted and the following 12 were not included because:

- The results were not presented by treatment group; [694]
- The dropout rate was more than 35 percent; [445, 632, 742, 744]
- Self-reported body weight was used; [741]
- There was no control group; [680]
- The treatment duration was less than 12 weeks; [737-739, 743] or
- The population was not overweight. [740]

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Pharmacotherapy

Forty RCTs evaluated the effect of pharmacotherapy on weight loss. In most studies, advice or behavioral therapy that promoted reduced energy intake and increased physical activity was included in all treatment arms, including the placebo group. The RCTs addressed the following pharmacotherapies: BRL 26830A, [696] cimetidine, [699] dexfenfluramine, [386, 387, 390-393, 414, 478, 506-508, 711, 745, 746] ephedrine, [695, 697, 747] fenfluramine, [478] fenfluramine and phentermine, [395, 514, 748, 749] femoxetine, [750] fluoxetine, [408, 712, 730, 734, 751, 752] mianserine, [753] orlistat, [407, 710] phenylpropanolamine, [511, 512] phentermine, [176, 754] testosterone, [698] yohimbine, [755] and sibutramine. [510] Most of the patients in these trials weighed more than 120 percent of their ideal body weight or had a BMI of 25 to 30.

RCTs that examined cimetidine, mianserine, yohimbine, testosterone, femoxetine, and BRL 26830A were not considered either because they are not now being studied for obesity treatment or because they are not approved by the Food and Drug Administration (FDA) for obesity treatment. Fluoxetine, and other selective serotonin reuptake inhibitors commonly used for the treatment of depression, have not been approved for use as antiobesity agents. Ephedrine has been tested alone and in combination with caffeine. Although a significant 3.4 kg difference was found at 6 months in patients treated with this combination compared with those on placebo [695], the ephedrine/caffeine combination is not approved by the FDA for use in the United States. In addition, studies with a dropout rate greater than 35 percent were not considered [711]. As of September 1997, two FDA-approved drugs, dexfenfluramine and fenfluramine, were withdrawn from the market by the manufacturer due to an observed association with valvular heart disease in patients taking the combination of phentermine/fenfluramine, or "Redux." The panel's deliberations on the evidence regarding these drugs are included in the report for informational purposes only.

Weight Loss Surgery

Fourteen RCTs compared the weight-reducing effect of different surgical interventions. [515-522, 524, 692, 706, 733, 756, 757] One study compared the effectiveness of a very low-calorie diet to surgery. [515] Another study compared the effectiveness of horizontal-banded to vertical-banded gastroplasty in a pretreated, very low-calorie formula diet group. [516] Six studies compared two or more of the following procedures: gastroplasty (vertical or horizontal), gastric bypass, and gastric partitioning. [517-522] Seven studies reported long-term (1 year or more) follow up. [515, 517-522] Two studies looked at comorbidity factors associated with weight loss. [517, 519]

Of these 14 RCT studies, the following five were not included because:

- Two studies looked at the effect on weight loss of jejunoileostomy, a procedure that is no longer recommended; they were not included because of the complications associated with this procedure; [692, 706] and
- Three studies compared the use of the gastric balloon to sham procedures; [733, 756, 757] however, this procedure is no longer utilized except in research studies.

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3 Appendix III. Special Populations

A.1. Prevalence of Overweight/Obesity in U.S. Children

a. Number and percentage of children (ages 6 to 11 years) and adolescents (ages 12 to 17 years) who were overweight, by gender and race/ethnicity—United States, Third National Health and Nutrition Examination Survey (NHANES III), 1988-1994.

b. Prevalence of overweight (BMI ≥ 85th percentile) in Native American school-age children by gender and age, 1990-1991.

c. Selected studies describing the prevalence of overweight in Native Americans, 1981-1993.

A.2.Overweight or BMI Data for Puerto Rican-Americans, Cuban-Americans, and Selected Samples of American Indians, Asians, and Pacific Islanders.

a. Percentage of overweight Cuban and Puerto Rican males and females, age 20 to 74, 1982-1984.

b. Selected studies describing the prevalence of overweight in Native Americans, 1981-1993.

c. Prevalence of overweight (BMI ≥ 85th percentile) and obesity (BMI ≥ 95th percentile) in American Indians and Alaska Natives and United States all races, by gender and age, 1987.

d. Overweight prevalence and BMI data for Asian-Americans (n = 13,031) examined in a northern California HMO, 1978-1985.

e. Body mass index in four groups of adult Samoans, by age and gender.

f. Prevalence of obesity (BMI ≥ 30 kg/m^2) in 1991, by age, sex, and western Samoa location.

A.3. Socioeconomic Status Differences in the Prevalence of Overweight/Obesity

a. Prevalence of overweight in U.S. adults by race/ethnicity, gender, and education, 1988-1991.

b. Prevalence of overweight in U.S. adults by race/ethnicity, gender, and annual family income, 1988-1991.

c. Prevalence of overweight in U.S. adults by age, race/ethnicity, gender, and occupation, 1988-1991.

d. Age-adjusted percentage of people 20 years of age and older who are overweight (high BMI) by gender, race/ethnicity, and income level, 1988-1991.

e. Percentage of medicare beneficiaries who are overweight by race, gender, and education, 1991.

f. Percentage of medicare beneficiaries who are overweight by race, gender, and annual family income, 1991.

Note: Due to the fact that the prevalence estimates in this appendix are based on available published data, the definitions used to define overweight and obesity are not the same as those used by the panel.

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TABLE III.A.1.a:

Number and Percentage of Children (aged 6-11 years) and Adolescents (aged 12-17 years) who were Overweight[1], by gender and Race/Ethnicity[2]

United States, Third National Health and Nutrition Examination Survey (NHANES III), 1988-1994

Characteristic	Children No.	(%)	(95% CI)[3]	Adolescents[4] No.	(%)	(95% CI)
Males						
White, non-Hispanic	446	(13.2)	(8.7%-17.6%)	281	(11.6)	(7.6%-15.6%)
Black, non-Hispanic	584	(14.7)	(11.2%-18.3%)	412	(12.5)	(9.2%-15.8%)
Mexican-American	565	(18.8)	(14.6%-23.0%)	406	(15.0)	(10.8%-19.1%)
Total	1,673	(14.7)	(11.5%-17.9%)	1,154	(12.3)	(9.3%-15.3%)
Females						
White, non-Hispanic	428	(11.9)	(7.2%-16.5%)	342	(9.6)	(5.5%-13.6%)
Black, non-Hispanic	538	(17.9)	(14.5%-21.2%)	447	(16.3)	(11.9%-20.8%)
Mexican-American	581	(15.8)	(10.3%-21.3%)	412	(14.0)	(6.8%-21.2%)
Total	1,606	(12.5)	(9.4%-15.7%)	1,274	(10.7)	(7.7%-13.7%)
Total[5]	3,279	(13.7)	(11.4%-15.9%)	2,428	(11.5)	(9.0%-14.0%)

[1] Overweight is defined as a BMI (kg/m^2) at or above gender- and age-specific 95th-percentile BMI cutoff points calculated at 6-month age intervals, derived respectively from National Health Examination Survey, cycles 2 and 3.

[2] Numbers for other racial/ethnic groups were too small for meaningful analysis.

[3] Confidence interval

[4] Excludes pregnant females and one person with an outlier sample weight.

[5] Total estimates include racial/ethnic groups not shown.

Source: *MMWR*, 3-7-97[759].

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TABLE III.A.1.b:

Prevalence of Overweight (BMI≥85th percentile) in Native American School-age Children by Gender and Age, 1990-91*

Age	Boys		Girls	
	Number	%	Number	%
5	364	36.0	404	30.3
6	539	30.6	494	37.0
7	482	46.5	538	43.1
8	524	42.6	495	42.2
9	511	45.2	469	38.8
10	493	40.5	404	37.6
11	419	36.0	384	35.4
12	369	47.4	311	41.8
13	281	43.8	231	42.4
14	246	35.4	228	36.4
15	249	39.0	209	55.0
16	204	26.5	181	39.8
17	165	35.8	152	40.4
18	75	32.0	43	39.5

* Adapted from Jackson MY and Strauss KF.

Source: Broussard et al. Toward comprehensive obesity prevention programs in Native American communities. *Obesity Res* 1995;3:289-97S. [26]

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TABLE III.A.1.c:

Selected Studies Describing the Prevalence of Overweight in Native Americans, 1981-1993

Population	Source	Age	Year	Definition of Overweight *	Percentage		
					Total	Males	Females
Preschool children							
Native Americans, national	Measured	<5	1988	a	11.2		
Mescalero Apache, NM	Measured	1-5	1988	a	19.5		
School-age children							
Native Americans, national	Measured	5-18	1990-1991	b	39.3		
Devils Lake Sioux, ND	Measured	9-13	1989	b		32.1	30.6
Winnebago and Omaha, NE	Measured	7-17	1990	b		32.7	34.4
Pueblo Indians, NM	Measured	9-13	1988-1991	b	40.4		
Navajo Indians, NM	Measured	9-13	1988-1991	b	29.1		
Navajo Indians, NM & AZ	Measured	5-17	1989	c		12.5	11.2
Navajo Indians, NM & AZ	Measured	14-18	1988-1990	b		25.0	33.0

* Definition of Overweight:
a=Weight-for height>95th percentile NCHS reference population
b=BMI ≥ 85th% NHANES II reference population
c=Weight-for-age > 95th NCHS reference population

Source: Broussard et al. Toward comprehensive obesity prevention programs in Native American communities. *Obesity Res* 1995;3:289-97S. [26]

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TABLE III.A.2.a:

Percentage of Overweight Cuban and Puerto Rican Males and Females, Ages 20-74, 1982-1984

Gender/Age	Cubans	Puerto Ricans
Males		
20-74 yrs	29.4	25.2
20-74 yrs (age adjusted*)	28.5	25.7
20-24 yrs	21.2	15.8
25-34 yrs	27.9	18.9
35-44 yrs	25.8	33.4
45-54 yrs	34.6	32.9
55-64 yrs	31.7	26.4
65-74 yrs	31.1	31.6
20-29 yrs**	23.5	15.6
Females		
20-74 yrs	34.1	37.3
20-74 yrs (age adjusted*)	31.9	39.8
20-24 yrs	13.6	23.6
25-34 yrs	23.8	26.5
35-44 yrs	32.7	42.7
45-54 yrs	37.2	50.2
55-64 yrs	51.4	49.0
65-74 yrs	39.6	61.0
20-29 yrs**	16.2	22.5

* Age adjusted by the direct method to the 1980 census population 20 to 74 years of age using 6 age groups.

** Overweight is defined as a sex-specific body mass index (kilograms divided by height in meters squared) equal to or greater than the 95th percentile for examinees 20 to 29 years of age examined in the second National Health and Nutrition Examination Survey (NHANES II).

Note: Excludes pregnant women.

Source: Najjar MF, Kuczmarski RJ. 1989. Anthropometric data and prevalence of overweight for Hispanics: 1982-1984. National Center for Health Statistics. *Vital Health Stat* 11(239). [27]

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TABLE III.A.2.b:

Selected Studies Describing the Prevalence of Overweight in Native Americans, 1981-1993

Population	Source	Age	Year	Definition of Overweight *	Total	Percentage Males	Percentage Females
Adults							
Native Americans, national	Self-report	18+	1987	a		33.7	40.3
Native Americans by region	Self-report	18+	1985-1988	a			
Southwest						30.0	28.5
Plains						27.8	35.7
West						22.7	26.8
Other regions						24.0	23.9
Alaskan Yup'ik Eskimos	Measured	18+	1987-1988	a		34.0	56.0
Alaskan Athabascan Indians	Measured	18+	1987-1988	a		29.0	55.0
Cherokee Indians, NC	Measured	18-27	1982	c			59.1
Navajo Indians, NM & AZ	Measured	20+	1988	a	43.7	33.1	50.7
Navajo Indians, NM & AZ	Measured	20-74	1986-1987	d		42.1	54.7
Penobscot Indians, ME	Self-report	18+	1981	c	35.0		
Pima Indians, AZ	Measured	20-54	1981-1988	a		61-78	81-87
		55+	1981-1988	a		31-53	44-74
Zuni Indians, NM	Measured	20-39	1987	e	40.0	33.8	56.2
		40-59	1987	e	70.7	55.6	79.2

* Definition of overweight and obesity used by NHANES/NCHS:
a=BMI≥85th%NHANES II reference population
b=Weight-for-age>95th NCHS reference population
c=>120% desirable weight for height, NHANES I
d=BMI > 85th% NHANES I reference population
e=BMI > 27 kg/m^2 for males, BMI > 26 kg/m^2 for females

Source: Broussard et al. Toward comprehensive obesity prevention programs in Native American communities. *Obesity Res* 1995;3:289-97S. [26]

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TABLE III.A.2.c:

Prevalence of Overweight (BMI≥85th percentile) and Obesity (BMI≥95th percentile) in American Indians and Alaska Natives and U.S. all races, by Gender and Age, 1987*

Age	Overweight		Obese	
	American Indians and Alaska Natives	U.S. All Races	American Indians and Alaska Natives	U.S. All Races
Males				
Total (18+)	33.7	24.1**	13.8	9.1**
18-24	21.5	13.1**	11.0	5.5***
25-34	31.8	19.5**	11.2	7.6
35-44	37.8	27.0**	11.2	10.4
45-54	49.1	33.8**	28.2	14.1**
55-64	45.5	33.1**	16.5	13.0***
65+	25.2	23.0**	11.1	5.4***
Females				
Total (18+)	40.3	25.0**	16.6	8.2**
18-24	25.2	11.5**	11.7	3.9**
25-34	45.1	17.4**	13.8	6.0**
35-44	48.5	28.1**	19.7	10.8**
45-54	54.0	32.0**	18.7	10.9
55-64	45.6	36.2**	18.8	11.5
65+	45.6	30.1**	20.7	7.7**

* Agency for Health Care Policy and Research, 1987 National Medical Expenditure Survey (NMES). American Indians and Alaska Natives who are eligible for care through the Indian Health Service (IHS) and who live on or near reservations. BMI, body mass index in kg/m^2.

** Statistically significant at $\alpha=0.05$.

*** Relative SE greater ≥ 30%

Source: Broussard et al. Prevalence of obesity in American Indians and Alaska Natives. *Am J Clin Nutr* 1991;53:1535-42S. [628]

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TABLE III.A.2.d:

Overweight Prevalence and BMI Data for Asian-Americans (n=13,031) Examined in a Northern California HMO, 1978-1985

Trait	Chinese	Filipino	Japanese	Other Asian
Age (mean ± SD)				
Males	40.2 ± 14.2	39.2 ± 13.4	42.1 ± 14.1	35.9 ± 10.4
Females	38.0 ± 13.6	36.8 ± 11.6	40.9 ± 13.4	34.1 ± 10.5
BMI ≥ 24.4 kg/m^2				
Males	26.9	41.8	38.0	28.9
Females	12.8	25.5	18.0	14.6
Mean BMI*				
Males	22.9	23.9	23.7	23.6
Females	21.2	22.8	21.6	22.2

* Adjusted for age, marital status, education, and alcohol intake.

Source: Klatsky AL, Armstrong MA. Cardiovascular risk factors among Asian-Americans living in Northern California. *Am J Public Health* 1991;81:1423-1428. [51]

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TABLE III.A.2.e:

BMI in Four Groups of Adult Samoans, by Age and Gender*

Gender/Age	Western Samoa	Manu'a	Tutuila	Hawaii
Males				
20-24	24.6 ± 2.8	26.4 ± 2.6	26.5 ± 3.6	30.4 ± 4.6
25-34	25.1 ± 3.2	30.7 ± 4.4	30.2 ± 5.0	31.3 ± 6.0
35-44	26.5 ± 4.3	29.2 ± 4.7	30.4 ± 5.5	32.6 ± 5.4
45-54	27.1 ± 4.9	27.2 ± 4.7	32.0 ± 6.4	31.3 ± 5.7
55-64	28.8 ± 5.4	28.0 ± 5.9	28.8 ± 5.5	32.1 ± 5.0
65-74	26.5 ± 3.9	28.7 ± 4.5	28.6 ± 6.2	31.6 ± 8.9
Total	26.2 ± 4.2	28.6 ± 5.0	29.8 ± 5.7	31.6 ± 5.7
Females				
20-24	25.3 ± 3.9	29.5 ± 7.9	27.9 ± 4.9	29.9 ± 5.8
25-34	26.7 ± 4.1	32.3 ± 6.0	32.4 ± 6.6	34.3 ± 7.8
35-44	29.0 ± 4.7	35.1 ± 5.8	34.4 ± 6.6	35.8 ± 7.7
45-54	29.6 ± 4.8	33.8 ± 7.4	35.3 ± 6.7	34.7 ± 6.5
55-64	31.0 ± 8.4	30.7 ± 6.1	33.3 ± 7.5	34.1 ± 5.5
65-74	28.6 ± 4.1	29.5 ± 5.8	32.3 ± 5.9	33.4 ± 6.9
Total	27.7 ± 4.8	32.7 ± 6.9	33.0 ± 6.9	33.6 ± 7.2

* SD. BMI in kg/m^2.

Source: McGarvey ST. Obesity in Samoans and a perspective on its etiology in Polynesians. *Am J Clin Nutr* 1991;53:1586S-94S. [50]

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TABLE III.A.2.f:

PREVALENCE OF OBESITY (BMI≥ 30KG/M²) IN 1991, BY AGE, GENDER, AND WESTERN SAMOA LOCATION

	Apia		Poutasi		Tuasivi	
Gender/Age	**No.**	**(%)**	**No.**	**(%)**	**No.**	**(%)**
Males						
25-34	71	45.1	58	36.2	51	21.6
35-44	77	70.1	58	43.1	58	46.6
45-54	64	67.2	48	52.1	51	45.1
55-64	78	51.3	40	57.5	44	40.9
65+	40	60.0	28	32.1	30	43.3
Overall	330	58.5	232	44.4	234	39.3
Age-std*		56.9		43.5		35.9
95% CI		51.2 - 62.6		36.9 - 50.1		29.7 - 42.1
Females						
25-34	97	57.7	74	52.7	61	52.5
35-44	83	89.2	48	66.7	77	57.9
45-54	120	84.2	40	70.0	63	66.7
55-64	96	86.5	34	64.7	40	52.5
65+	43	62.8	27	63.0	30	46.7
Overall	439	77.7	223	61.9	271	57.2
Age-std*		74.3		61.5		56.5
95% CI		69.9 - 78.7		55.1 - 68.0		50.2 - 62.7

* Age-std=age standardized by direct method to 1986 census population.

Source: Hodge AM, Dowse GK, Toelupe P, Collins VR, Imo T, Zimmet PZ. Dramatic increase in the prevalence of obesity in Western Samoa over the 13-year period 1978-1991. *Int J Obesity* 1994;18:419-428. [629]

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TABLE III.A.3.a:

Prevalence of Overweight* in U.S. Adults, by Race/Ethnicity, Gender, and Education, 1988-1991

	Black				Mexican American				White			
Gender	<12y	12y	>12y	Total	<12y	12y	>12y	Total	<12y	12y	>12y	Total
Males	29	29	36	31	39	43	40	40	39	36	30	34
Females	55	51	49	52	53	40	47	49	39	38	30	35

* Overweight is defined as ≥ 27.8 kg/m² for men and ≥ 27.3 kg/m² for women.
Source: NCHS/CDC NHANES III Phase 1, 1988-1991. [760]

TABLE III.A.3.b:

Prevalence of Overweight* in U.S. Adults, by Race/Ethnicity, Gender, and Annual Family Income, 1988-1991

	Black					Mexican American					White				
Gender	<$10K	$10-29,999	$30-49,999	$50,001+	Total	<$10K	$10-29,999	$30-49,999	$50,001+	Total	<$10K	$10-29,999	$30-49,999	$50,001+	Total
Males	23	31	34	42	31	33	39	45	48	40	33	35	36	31	34
Females	53	50	54	49	52	52	51	43	42	49	43	35	37	27	35

* Overweight is defined as ≥ 27.8 kg/m² for men and ≥ 27.3 kg/m² for women.
Source: NCHS/CDC NHANES III Phase 1, 1988-1991. [760]

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TABLE III.A.3.c:

Prevalence of Overweight* in U.S. Adults, by Age, Race/Ethnicity, Gender, and Occupation, 1988-1991

	Black					Mexican American					White				
Gender/Age	White Collar	Blue Collar	Farm	Service	Total	White Collar	Blue Collar	Farm	Service	Total	White Collar	Blue Collar	Farm	Service	Total
Males															
25-44	28	35	15	32	31	46	32	30	36±	35	30	31	24	30±	30
45-64	44	35	15	38±	37	41	58	38	54±	51	38	38±	47	21±	37
Females															
25-44	47	48		55	48	48	40		41	46	27	38		31	29
45-64	56	55		66	60±	55	55		58	57	41	45±		43	42

* Overweight is defined as ≥ 27.8 kg/m^2 for men and ≥ 27.3 kg/m^2 for women.

± Estimate not reliable because of small sample size.

Source: NCHS/CDC NHANES III Phase 1, 1988-1991. [760]

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TABLE III.A.3.d:

Age-Adjusted Percentage of People 20 Years of Age and Older who are Overweight (High BMI), by Gender, Race/Ethnicity, and Income Level, 1988-1991

Sex and Poverty	Total Population*			Non-Hispanic White			Non-Hispanic Black			Mexican American		
	Sample	Percent	SE	Sample	Percent	SE	Sample	Percent	SE	Sample	Percent	SE
Males												
Below poverty	712	30.4	2.24	142	29.8	3.02	211	29.6	2.53	338	36.9	4.22
At or above poverty	3,069	31.9	1.00	1,625	32.3	1.02	724	32.8	1.65	621	40.6	1.02
Under 131% poverty	1,034	32.8	2.49	238	33.3	3.18	313	28.4	2.20	453	37.2	3.44
131-350% poverty	1,793	32.7	1.38	865	33.6	1.64	460	33.2	2.26	401	41.4	1.75
Over 350% poverty	954	29.0	1.34	664	28.7	1.39	162	36.4	3.31	105	46.1	5.72
Females												
Below poverty	850	47.3	2.70	189	46.9	5.12	290	50.0	3.96	347	50.5	3.02
At or above poverty	2,710	32.2	1.20	1,442	30.1	1.34	637	49.0	1.61	540	44.4	2.89
Under 131% poverty	1,185	46.1	2.11	321	44.7	3.88	390	51.1	3.42	441	50.3	2.79
131-350% poverty	1,643	33.8	1.49	806	31.9	1.54	421	49.0	2.12	349	44.4	4.21
Over 350% poverty	732	28.0	2.30	504	26.4	2.39	116	46.1	3.11	97	40.0	6.81

* Includes data for racial/ethnic groups not shown separately.

Note: BMI is an index used to relate weight to stature. For this analysis, overweight in men is defined as a BMI ≥27.8 kg/m^2; for women, it is defined as a BMI ≥ 27.3 kg/m^2.

Source: HHS, NHANES III, 1988-1991. [760]

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TABLE III.A.3.e:

PERCENTAGE OF MEDICARE BENEFICIARIES WHO ARE OVERWEIGHT*, BY RACE, GENDER, AND EDUCATION, 1991

Gender/ Age	Black <HS	Black HS	Black >HS	Black Total	White <HS	White HS	White >HS	White Total
Males								
65-74	32.1	33.9**	47.5**	34.0	34.0	30.1	25.5	29.8
75+	20.1	14.9**	16.6**	21.8	18.1	11.1	11.1	15.0
All ages	27.4	26.5	35.5**	28.9	27.8	22.7	19.9	23.8
Females								
65-74	61.8	45.7	45.0**	54.1	40.6	34.5	27.9	34.6
75+	44.7	12.3	43.9	40.2	29.2	21.9	19.6	24.7
All ages	55.2	32.7	44.6	48.7	36.2	29.6	24.6	30.9

* Overweight is defined as a BMI ≥ 27.8 kg/m^2 for males and ≥ 27.3 kg/m^2 for females.
** Based on samples of fewer than 30 persons.
Source: Medicare Current Beneficiary Survey: 1991, Non-Institutionalized Persons only (N=9,721). [630]

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TABLE III.A.3.f:

Percentage of Medicare Beneficiaries who are Overweight*, by Race, Gender, and Annual Family Income, 1991

Gender/ Age	Black ≤$10,000	$10,001-30,000	$30,001-50,000	$50,001+	Unknown/ not rep	Total	White ≤$10,000	$10,001 30,000	$30,001-50,000	$50,001+	Unknown/ not rep	Total
Males												
65-74	24.0	41.7	27.2	59.02**	0.0**	34.0	26.2	32.3	30.7**	23.9	25.6	29.8
75+	17.8	27.9	—	—	0.0	21.8	16.1	17.3	9.9	9.3	11.5	15.0
All ages	20.6	35.2	11.3	0.0**	0.0**	28.9**	22.0	26.3	22.7	18.0	19.8	23.8
Females												
65-74	59.1	46.1	27.2	34.0**	0.0	54.1	43.2	36.3	25.7**	20.8	25.3	34.6
75+	43.4	28.1	23.0	100.0**	0.0	40.2	27.7	24.4**	20.1**	18.2	20.0	24.7
All ages	53.0	38.2	29.3	30.5**	0.0	48.7**	37.9	31.4	23.1	20.6	23.8	30.9

* Overweight is defined as ≥ 27.8 kg/m² for men and ≥ 27.3 kg/m² for women.
** Based on samples of fewer than 30 persons.
Source: Medicare Current Beneficiary Survey: 1991, Non-Institutionalized Persons only (N=9,721). [630]

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A.4. Annotated Bibliography of Studies Specifically Designed To Achieve Weight Reduction in Special Populations.

The following annotations describe weight reduction studies in special populations or situations. From the total number of studies identified in which minorities or other special populations were included, the studies listed below are those for which the treatment or intervention program included design features specifically geared to the needs of a minority population or other special population of interest. Thus, these studies provide examples of ways in which researchers or service practitioners have attempted to adapt conventional weight reduction approaches to the needs of diverse client groups. The annotations highlight the published reports with respect to the setting and the nature of the program. Study results are not included because relatively few studies are randomized controlled trials, several are pilot studies or program descriptions, and many do not lend themselves to a clear evaluation of success rates. Boldface material indicates the particular population or situation studied.

Agurs-Collins TD, Kumanyika SK, TenHave TR, Adams-Campbell LL. A randomized controlled trial of weight reduction and exercise for diabetes management in ***older African-American subjects.*** Diabetes Care *1997;20:1503-1511.* [362]

A randomized controlled trial conducted at an urban hospital in Washington, DC. The intervention group was offered 12 weekly group sessions, 1 individual session, and 6 biweekly group sessions; the usual care group was offered one class and two informational mailings. Participants were recruited through various clinics and through community outreach, including announcements in newsletters and church bulletins, flyers distributed at clinics and churches, and presentations at community gatherings. Program materials depicted African-American individuals, families, and community settings and reflected language, social values, and situations relevant to older Americans or African-Americans. All guidance about foods and recipes was based on types of foods and flavorings characteristic in African-American communities. Recipes were provided by participants and used in direct instruction. Ample time was allowed for the participants to discuss and work through dietary adherence issues unique to their social contexts (e.g., church meals).

Avila P, Hovell MF. Physical activity training for weight loss in ***Latinas****: A controlled trial.* Int J Obes *1994;18:476-482.* [631]

A 10-week physical activity program designed for obese Latino women in San Diego, California. Volunteers were recruited through flyers that were distributed in a low-income community medical clinic, the local church, English as a Second Language classes, and the local grocery store. Sessions focused on self-change behavior, nutrition education, gaining support from a "buddy," and an exercise component. The sessions were led by a bicultural, bilingual physician.

Cousins JH, Rubovits DS, Dunn JK, Reeves RS, Ramirez AG, Foreyt JP. Family versus individually-oriented intervention for weight loss in ***Mexican American women.*** Public Health Rep *1992;107(5):549-555.* [632]

A study that compared three groups of obese Mexican American women in Texas, ages 18 to 45 years. Families were recruited through media promotion and local contacts within the community, primarily through churches and health agencies. The comparison group received a bilingual manual with information on nutrition, exercise, and behavioral principles for weight loss. The manual was designed to reflect the cultural values of the population. The comparison group also received a cookbook with recipes for fat-modified traditional Mexican American foods. The *individual* group received the same printed materials and attended weekly classes led by bilingual registered dietitians. Classes provid-

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ed individual and group activities. The *family* group received the materials and attended classes that emphasized a family-oriented approach to making changes in eating habits and exercise behavior; spouses and children were invited. Family group members received a modified version of the manual with additional information on partner support and parenting skills to encourage family changes in eating and exercise behaviors. Spouses were encouraged to attend classes with the participants, and separate classes were held for preschool-age children.

Daniel EL. A multi-intervention weight management program for ***low-income rural women.*** J Am Diet Assoc *1989;89:1310-1311.* [633]

A pilot weight management program involving low-income rural women who were enrolled in the Special Supplemental Food Program for Women, Infants and Children (WIC) and/or food stamp programs in rural western New York State. The program included five biweekly sessions that focused on nutrition, behavior modification, aerobic exercise, and stress management. Handouts were designed for low-literacy or non-English-speaking adults, and plastic food models were used to discuss serving sizes and portion control. Suggestions for healthful eating were based on WIC foods whenever possible. Exercise focused on aerobic dance because it can done at home with no special equipment or child care needed and can be adapted to almost any kind of music.

Domel SB, Alford BB, Cattlett HN, Gench BE. Weight control for ***black women.*** J Am Diet Assoc *1992;92(3):346-348.* [634]

A program for black women with low educational levels at four literacy program sites in economically disadvantaged areas of Dallas, Texas. The program consisted of 11 weekly sessions taught by a registered dietitian and included nutrition education, behavior modification, active learner participation, and self-responsibility. It stressed practical, lifelong methods for weight control. Materials were geared toward low-literacy participants; for example, a green traffic light was used for low-calorie foods, and a yellow traffic light was used for high-calorie foods. Shopping tips included ways to save money and decrease calories; audiocassettes included a radio show format with disk jockey, guest speaker, and "phoned-in" questions from listeners.

Domel SB, Alford BB, Cattlett HN, Rodriguez ML, Gench BE. A pilot weight control program for ***Hispanic women.*** J Am Diet Assoc *1992 Oct;92(10):1270-1.* [635]

A 10-session pilot weight control program for Hispanic women in Dallas, Texas. Modifications to fit the Hispanic culture included adding appropriate ethnic foods and recipes, stressing the importance of health for the entire family, and reformatting some of the materials. To this end, some of the pamphlets were changed to a comic book format, and audiocassetes were changed from a radio show format to a dialog between two *comadres.* The program was taught in Spanish by a bilingual Hispanic dietitian at a local church. Handouts were available in English and Spanish. Participants were recruited through articles in Spanish and English newspapers, public service announcements on Spanish radio stations, church bulletins, and various flyers. A promotional event was also held at each site 1 week before the program began.

Fox RA, Haniotes H, Rotatori A. A streamlined weight loss program for ***moderately retarded adults*** *in a sheltered workshop setting.* Appl Res Ment Retard *1984;5(1):69-79.* [636]

A 15-week behavioral weight loss program for obese, moderately retarded adults that included 10 weeks of treatment and 5 weeks of maintenance. The program was conducted in the sheltered workshop where all of the participants worked, and participants were given time off during the day to attend sessions. Picture materials were developed to facilitate the learning and

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practice of the behavioral weight loss strategies; no reading skills were required. All participants in the study lived with their parents, and all parents were instructed in the behavioral weight reduction techniques and the forms so that they could provide guidance and support to their child at home during the course of the program. Daily homework assignments were given so that participants could practice behavioral strategies outside of the training setting. Bimonthly phone calls to the parents were made to discuss their child's progress and difficulties in implementing behavior techniques. To encourage attendance, at each session, participants were entered into a drawing to win small prizes, and awards were also given for each pound of weight lost. Follow-up was conducted for 1 year.

*Glasgow RE, Toobert DJ, Hampson SE, Brown JE, Lewinsohn PM, Donnely J. Improving self-care among **older patients with type 2 diabetes.** The "Sixty-Something..." Study. Patient Educ Couns 1992;19:61-74.* [482]

A 10-session, self-management training program designed for persons older than 60 years of age. Recruitment was conducted through local diabetes care professionals, presentations, mailings, newsletters of local and State diabetes associations, presentations at health fairs, flyers distributed at grocery stores and pharmacies, and local television and radio advertising. The program was offered at no cost, and participants were provided glucose testing materials and a coupon for a pair of walking shoes. Sessions were held during daylight hours in well-known, accessible, and pleasant facilities that earlier focus group participants thought were most convenient. In response to focus group feedback, the program focused on dietary and exercise self-care behaviors. The group was led by an interdisciplinary team of psychologists, a registered dietitian, certified exercise leaders, and other educators. Group meetings were kept small and focused on developing individualized plans to overcome barriers to adherence. Participants chose the specific self-care area on which they wished to focus. Follow-up was conducted for 6 months.

*Heath GW, Wilson RH, Smith J, Leonard BE. Community-based exercise and weight control. Diabetes risk reduction and glycemic control in **Zuni Indians.*** Am J Clin Nutr *1991;53:1642S-1646S.* [637]

A 2-year exercise intervention in the Zuni Indian community in western New Mexico. Participants were recruited through personal invitation, recommendation from the medical staff, and a general community advertising campaign. Community events such as foot races were offered throughout the year, supported by community agencies and local businesses. The program was coordinated by a health educator, two health education assistants, and 48 Zuni Indians who were trained in exercise and group leadership.

*Kanders BS, Ullmann-Joy P, Foreyt JP, Heymsfield SB, Heber D, Elashoff RM, Ashley JM, Reeves RS, Blackburn GL. The black American lifestyle intervention (BALI): The design of a weight loss program for **working-class African-American women.*** J Am Diet Assoc *1994;94(3):310-312.* [638]

A 10-week weight loss program for obese, low-income African-American women ages 40 to 64 years in Boston, New York, Houston, and Los Angeles. The program focused on diet, exercise, and behavior modification using information obtained from interviews of obese African-American women concerning these issues. Participants were placed on a culturally appropriate, low-fat diet, including two free meal replacement shakes. Lactaid was provided to those participants who were lactose intolerant. Group sessions involving goal-setting, problem-solving, and role-playing were led by a female African-American nutritionist. All educational materials, recipes, and menu plans were reviewed by minority health professionals to ensure cultural appropriateness.

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Kumanyika SK, Brancato J, Brewer A, Carnaghi M, Doroshenko LH, Rosen R, Rosofsky W, Self MS. Interventions in the Trials of Nonpharmacologic Intervention in the Elderly. Effective approaches to weight and sodium reduction among ***older adults.*** Circulation *1996;94(8):I-690.* [639]

The Trials of Nonpharmacologic Intervention in the Elderly (TONE) was a randomized comparison of weight reduction, sodium reduction, and combined weight/sodium reduction programs versus a no-treatment control group conducted in four university research centers located in Maryland, North Carolina, New Jersey, and Tennessee. Education and counseling addressed relevant nutrition knowledge and behavior change skills. Contacts were weekly for 4 months, biweekly for 4 months, and then monthly. The study addressed challenges that an older population faces, such as literacy limitations, and used oral and visual examples to explain new concepts; concrete, step-by-step instruction; limited use of complex sentences; and minimal need for abstract reasoning. Only a small amount of information was given at one time to prevent overload. Easy-to-read typeface was used, as well as generous use of graphics. Physical changes of aging (e.g., impaired hearing, vision, or memory and speed of absorbing new information) were addressed by using simultaneous oral and visual presentation and seating and room arrangements to accommodate those who wished to be close to the speaker. Large typeface was used in all visual materials, and the room was arranged to avoid glare. Graphics and text references were chosen to depict older persons, and counseling was geared to build on previously learned nutrition practices, preferences, and food-related attitudes.

Kumanyika SK, Charleston JB. Lose weight and win: A church-based weight loss program for blood pressure control among ***black women.*** Patient Educ Couns *1992;19(1):19-32.* [640]

A behaviorally oriented weight control program offering eight weekly diet counseling/exercise sessions. The program was a component of the Baltimore Church High Blood Pressure Program (CHBPP), which encompassed black churches in the Baltimore, Maryland, black community. Recruitment was through CHBPP networks, including lay volunteers from each congregation who had also been trained as blood pressure measurement specialists. Advertisement of the program was by word of mouth as well as by presentations at meetings of the ministerial alliance. Announcements were also placed in church bulletins. The meetings were held on church property, often following other scheduled church activities such as choir practice. The group format emphasized an unrushed, supportive, relaxed environment and included a diet component led by a registered dietitian and an exercise component consisting of low-impact aerobics.

Lasco RA, Curry RH, Dickson VJ, Powers J, Menes S, Merritt RK. Participation rates, weight loss, and blood pressure changes among ***obese women*** *in a nutrition-exercise program.* Public Health Rep *1989;104(6):640-646.* [641]

A 10-week exercise and nutrition intervention targeted to obese residents of a **black urban community** in Atlanta between the ages of 18 and 59 years. Free transportation and child care were provided to encourage participation. Classes on nutrition, community resources, and exercise were offered, including low-impact aerobic dance, water exercises, and walking. Home visits by a public health educator were planned to build family support and alleviate spousal concerns. Participants were asked to comment on the program, and their suggestions were incorporated into the special interest sessions. Participation was monitored, and absentees were called and encouraged to attend the next session.

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McNabb W, Quinn M, Kerver J, Cook S, Karrison T. The Pathways church-based weight loss program for urban ***African-American women at risk for diabetes.*** Diabetes Care *1997;20:1518-1523.* [642]

A randomized, 14-week, church-based weight loss program targeting urban, obese African-American women. The program was developed using locally conducted focus groups with the target population and administered by trained lay facilitators recruited from urban churches. Facilitators assisted participants in identifying and providing solutions for their dietary problems. Aspects of the program included emphasizing weight loss for general well-being and health rather than improved physical appearance, achieving culturally appropriate body size, and using ethnic foods and food combinations.

McNabb WL, Quinn MT, Rosing L. Weight loss program for ***inner-city black women*** *with non-insulin-dependent diabetes mellitus: PATHWAYS.* J Am Diet Assoc *1993;93(1):75-77.* [643]

An 18-week weight loss program, including 12 core weekly sessions that focused on nutrition information and behavior modification and 6 follow-up or "reinforcement" sessions that provided support and strategies for overcoming obstacles the women faced along the way. The program was designed to deal with the obstacles obese, inner-city black women face in trying to exercise and lose weight and was partly based on feedback from a sample of women who were interviewed before the study was designed. An expert panel composed of local minority health care professionals reviewed program materials, which were written at a low-literacy level. Participants were provided with information about foods, including ethnic and regional foods such as greens, salt pork, and ham hocks.

Mount MA, Kendrick OW, Draughon M, Stitt KR, Head D, Mount R. Group participation as a method to achieve weight loss and blood glucose control. J Nutr Educ *1991;23:25-29.* [644]

A biweekly, 10-session nutrition, diabetes, and weight loss education program with 30 **black adults in rural west Alabama**. The program used self-help groups to assist participants with diabetes management by providing peer interaction and support. Groups were led by a public health nutritionist, nutrition graduate student, and a lay facilitator chosen from each group. Topics included definition of diabetes, meal planning, diet modification to reduce complications, and weight control.

Mulrow C, Bailey S, Sönksen PH, Slavin B. Evaluation of an ***audiovisual diabetes education*** *program. Negative results of a randomized trial of patients with non-insulin dependent diabetes mellitus.* J Gen Intern Med *1987;2:215-219.* [645]

A randomized, controlled trial conducted at a hospital in central London. The intervention focused on improving glucose and weight control in **low-income, low-literacy obese patients** with non-insulin dependent diabetes. The trial excluded those patients who were taking insulin and patients who were older than 70 years of age. Of the 120 patients recruited, 55 percent were female, and 49 percent were **West Indian black**. Patients within the intervention group participated in monthly group sessions that included materials specifically designed for diabetic patients with low literacy or monthly group sessions without low-literacy materials. Low-literacy sessions used standardized audiovisual lessons and written materials and included common West Indian foods.

Pleas J. Long-term effects of a lifestyle-change obesity treatment program with ***minorities.*** J Natl Med Assoc *1988;80(7):747-752.* [646]

A 12-week weight management program with lifestyle change as its central focus (n=12) located at a neighborhood YMCA. Recruiting was conducted through articles and announcements

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in local newspapers and church bulletins. The weekly sessions lasted 2 hours, with the first hour devoted to lectures on nutrition, behavioral change, and weight loss; the second hour involved exercise, which included endurance exercises and walking.

Shintani TT, Hughes CK, Beckham S, O'Connor HK. Obesity and cardiovascular risk intervention through the ad libitum feeding of ***traditional Hawaiian diet****.* Am J Clin Nutr *1991;53:1647S-1651S.* [647]

Under the premise that, historically, **Native Hawaiians** have been thin due to their traditional diet, a diet intervention for Native Hawaiians was conducted with traditional Hawaiian foods on the western coast of the island of Oahu. Recruitment was conducted through newspaper advertisements, articles, flyers, and a public presentation about the program. The selection of food for the program consisted of foods available in Hawaii before Western contact, such as taro, poi, sweet potatoes, yams, breadfruit, greens, fruit, seaweed, fish, and chicken. Foods were prepared in the traditional manner. Breakfast was eaten together, and cultural or health education sessions were conducted during the group dinner session.

Sullivan J, Carter JP. A nutrition-physical fitness intervention program for ***low-income black parents.*** J Natl Med Assoc *1985;77(1):39-43.* [648]

An 8-week intervention for obese, low-income black mothers (n=10) of children younger than 3 years was conducted at the Parent Child Development Center of the Urban League in New Orleans, Louisiana. Aerobic exercise with soul music was incorporated into the sessions because it was thought to appeal to the population and because dancing can be done safely in the home with no special equipment. Child care was provided for the mothers during the sessions.

4 Appendix IV. Obesity and Sleep Apnea

Obstructive sleep apnea is defined as an absence of breathing during sleep. Currently, it is recognized that sleep apnea is part of a continuum from health to disease. [649, 650] Apnea is currently defined as cessation of airflow for at least 10 seconds and is characterized as either central (if no respiratory effort occurs), obstructive (if continued effort is noted), or mixed (if both central and obstructive components are present). [651-653] Apnea is associated with either a fall in oxyhemoglobin desaturation or an arousal from sleep. Hypopneas, which are defined as partial reductions in airflow associated with falls in oxygen saturation or arousals from sleep, are also recorded.

The sleep apnea syndrome has been clinically defined as recurrent apnea or hypopnea associated with clinical impairment usually manifested as increased daytime sleepiness or altered cardiopulmonary function. In general, the average number of episodes of apnea and hypopnea per hour are reported as an index (AHI) or as a respiratory disturbance index (RDI). Classically, an AHI of greater than five episodes per hour has been the definition of the presence of the sleep apnea syndrome. [651, 652] Other commonly used cutoff points are an AHI of 10 or 15 episodes per hour or an overnight total of 30 apneic-hypopneic episodes. [653]

There are several correlates of sleep apnea. It is well recognized that it is more prevalent in males, although the difference is less pronounced in population-based studies than in laboratory-based studies. [20] Some studies have suggested that the prevalence of sleep apnea in women increases after menopause. Snoring also correlates with sleep apnea, increasing up to late middle age and decreasing thereafter. [20, 282, 654, 655] The other major correlate of sleep apnea is obesity [20, 653, 654, 656] in both men and women. In general, women have to be significantly more obese than men for the clinical syndrome to be apparent. [657] At present, no published epidemiologic studies

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have examined the relationship between race and sleep apnea. Given the high prevalence of obesity among specific populations and minorities, sleep apnea may be highly prevalent in these groups.

The major pathophysiologic consequences of severe sleep apnea include severe arterial hypoxemia, recurrent arousals from sleep, increased sympathetic tone, pulmonary and systemic hypertension, and cardiac arrhythmias. [658] These phenomena may result in acute hemodynamic and chronic structural change in the coronary arteries, possibly associated with relative myocardial ischemia, rupture of atheromatous plaques, and increased risk for thrombosis at the site of any unstable plaque. [659] Similar mechanisms acting in the cerebrovascular system may be involved in an increased risk of stroke. Finally, the sympathetic tone may be associated with hypertension as well as increased platelet aggregability. [660]

The primary goal for treatment of individuals with sleep apnea is to reduce the severity of the respiratory events that are associated with oxyhemoglobin desaturation and arousal from sleep. There are only two cohort studies in clinic-based populations that demonstrate a significant reduction in cardiovascular mortality among sleep apnea patients who are treated progressively compared to those who are treated conservatively. [661, 662] However, both of these studies were retrospective and suffered from a significant bias of ascertainment.

The evidence that treatment of obesity ameliorates obstructive sleep apnea is reasonably well established. Although the studies are small, both surgical and medical approaches to weight loss have been associated with a consistent but variable reduction in the number of respiratory events, as well as improvement in oxygenation. In general, surgical interventions, which have included a gastric bypass or jejunoileostomy, have been reserved for people who are severely obese. [663-666] While this approach to weight reduction was commonly used in patients with severe obstructive sleep apnea, they recently have been abandoned because of complications and side effects. However, the use of surgical gastric procedures has been successful in improving sleep apnea in a number of studies.

On the other hand, weight reduction has been associated with comparable reduction in the severity of sleep apnea, as well as improved evidence of renal function and hypertension [667-671] Both medical and surgical studies have demonstrated that as little as 10-percent weight reduction is associated with a more than 50-percent reduction in the severity of sleep apnea. Moreover, more recent data suggest a possible "threshold" effect that is directly related to the collapsibility of the upper airway. Those individuals who demonstrate a minimally collapsible upper airway apparently achieve a greater effect for the same percentage of weight reduction. [672]

Finally, there is evidence that standard treatments for sleep apnea do reduce specific cardiovascular risk factors. Specifically, the most commonly employed treatment, continuous positive airway pressure, has been shown to reduce waking arresting carbon dioxide and reduced heart rate, and pulmonary artery pressure decreased hematocrit and improved ventricular ejection fraction. [673] Other standard surgical approaches that have been employed to widen the upper airway have been shown to reduce the severity of the apnea, but there are no data examining the associated cardiovascular risk factors. No studies have specifically examined the effects of treatment of sleep apnea on obesity, but it generally has been noted that all nonweight loss treatments of sleep apnea have not been associated with any significant weight loss other than might be accrued from surgical interventions that temporarily reduce the ability to eat in the immediate postoperative period.

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5 Appendix V. Body Mass Index—How to Measure Obesity

Body mass index (BMI) is usually measured with the Quetelet index as follows: weight divided by height squared (W/H^2 [kg/m^2]).

To use the table, find the appropriate height in the left-hand column. Move across to a given weight. The number at the top of the column is the BMI at that height and weight. Pounds have been rounded off. [758]

Body Mass Index

Height (inches)	Body Weight (pounds)																
	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287

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Body Mass Index

Height (inches)	Body Weight (pounds)																		
	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
58	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

To use the table, find the appropriate height in the left-hand column. Move across to a given weight. The number at the top of the column is the BMI at that height and weight. Pounds have been rounded off.[758]

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6 Appendix VI. Practical Dietary Therapy Information

A.1. Shopping—What To Look For

a. Low-Calorie Shopping List

b. Low-Calorie, Lower-Fat Alternatives

c. Fat-Free Versus Regular—Calorie Comparisons

d. Good Sources of Calcium

A.2. Food Preparation—What To Do

■ Low-Calorie, Low-Fat Cooking/Serving Methods

A.3. Dining Out—How To Choose

a. General Tips for Healthy Dining Out

b. Tips for Healthy Multicultural Dining Out

A.4. Sample Reduced-Calorie Menus

a. Traditional American Cuisine—Reduced Calorie

b. Asian-American Cuisine—Reduced Calorie

c. Southern Cuisine—Reduced Calorie

d. Mexican-American Cuisine—Reduced Calorie

e. Lacto-Ovo Vegetarian Cuisine—Reduced Calorie

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VI. A.1. Shopping—What To Look For

A.1.a. Low-Calorie Shopping List

Make a shopping list. Include the items you need for your menus and any low-calorie basics you need to restock in your kitchen.

Dairy case

❑ Low-fat (1%) or fat-free (skim) milk

❑ Low-fat or reduced-fat cottage cheese

❑ Fat-free cottage cheese

❑ Low-fat cheeses

❑ Low-fat or nonfat yogurt

❑ Light or diet margarine (tub, squeeze or spray)

❑ Reduced-fat or fat-free sour cream

❑ Fat-free cream cheese

❑ Eggs/Egg substitutes

❑ _____

❑ _____

❑ _____

Breads, muffins, rolls

❑ Bread, bagels, pita bread

❑ English muffins

❑ Yeast breads (whole wheat, rye, pumpernickel, multi-grain, raisin)

❑ Corn tortillas (not fried)

❑ Low-fat flour tortillas

❑ Fat-free biscuit mix

❑ Rice crackers

❑ Challah

❑ _____

❑ _____

Cereals, crackers, rice, noodles, and pasta

❑ Plain cereal, dry or cooked

❑ Saltines, soda crackers (low sodium or unsalted tops)

❑ Graham crackers

❑ Other low-fat crackers

❑ _____

❑ _____

❑ _____

❑ Rice (brown, white, etc.)

- ❑ Pasta (noodles, spaghetti)
- ❑ Bulgur, couscous, kasha
- ❑ Potato mixes (made without fat)
- ❑ Rice mixes (made without fat)
- ❑ Other
- ❑ Wheat mixes
- ❑ Tabouli grain salad
- ❑ Hominy
- ❑ Polenta
- ❑ Polvillo
- ❑ Hominy grits
- ❑ Quinoa
- ❑ Millet
- ❑ Aramanth
- ❑ Oatmeal
- ❑ _____
- ❑ _____

Meat case

- ❑ White meat chicken and turkey (skin-off)
- ❑ Fish (not battered)
- ❑ Beef, round or sirloin
- ❑ Extra lean ground beef such as ground round
- ❑ Pork tenderloin
- ❑ 95% fat-free lunch meats or low-fat deli meats
- ❑ Meat equivalents:
  - ❑ Tofu (or bean curd)
  - ❑ Beans (see bean list)
  - ❑ Eggs/egg substitutes (see dairy list)
  - ❑ _____
  - ❑ _____
  - ❑ _____

Fruit (fresh, canned, and frozen)

Fresh Fruit:

- ❑ Apples
- ❑ Bananas
- ❑ Peaches
- ❑ Oranges
- ❑ Pears
- ❑ Grapes
- ❑ Grapefruit
- ❑ Apricot
- ❑ Dried Fruits
- ❑ Cherries
- ❑ Plums
- ❑ Melons
- ❑ Lemons
- ❑ Limes
- ❑ Plantains
- ❑ Mango
- ❑ Papaya
- ❑ _____
- ❑ _____

Exotic Fresh Fruit:

- ❑ Kiwi
- ❑ Olives
- ❑ Figs
- ❑ Quinces
- ❑ Currants
- ❑ Persimmons
- ❑ Pomegranates
- ❑ Anon
- ❑ Caimito
- ❑ Chirimoya

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- ❑ Guanabana
- ❑ Mamey
- ❑ Papayas
- ❑ Zapote
- ❑ Guava
- ❑ Starfruit
- ❑ Ugli fruit
- ❑ Dried pickled plums
- ❑ Litchee nuts
- ❑ Winter melons
- ❑ _____
- ❑ _____

Canned Fruit (in juice or water):

- ❑ Canned pineapple
- ❑ Applesauce
- ❑ Other canned fruits (mixed or plain)
- ❑ _____

Frozen Fruits (without added sugar):

- ❑ Frozen blueberries
- ❑ Frozen raspberries
- ❑ Frozen 100% fruit juice
- ❑ _____

Dried Fruit:

- ❑ Raisins/dried fruit (these tend to be higher in calories than fresh fruit)

Vegetables (fresh, canned, frozen)

Fresh Vegetables:

- ❑ Broccoli
- ❑ Peas
- ❑ Corn
- ❑ Cauliflower
- ❑ Squash
- ❑ Green Beans
- ❑ Green Leafy Vegetables
- ❑ Spinach
- ❑ Lettuce
- ❑ Cabbage
- ❑ Artichokes
- ❑ Cucumber
- ❑ Asparagus
- ❑ Mushrooms
- ❑ Carrots or celery
- ❑ Onions
- ❑ Potatoes
- ❑ Tomatoes
- ❑ Green peppers
- ❑ Chilies
- ❑ Tomatillos
- ❑ _____

Canned Vegetables: (low sodium or no salt added)

- ❑ Canned tomatoes
- ❑ Tomato sauce or pasta
- ❑ Other canned vegetables
- ❑ Canned vegetable soup, reduced sodium

Frozen Vegetables: (without added fats)

- ❑ Frozen broccoli
- ❑ Frozen spinach
- ❑ Frozen mixed medley, etc.
- ❑ Frozen yucca
- ❑ _____

Exotic Fresh Vegetables

- ❑ Okra

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- ❑ Dandelions
- ❑ Eggplant
- ❑ Grape leaves
- ❑ Mustard greens
- ❑ Kale
- ❑ Leeks
- ❑ Boniato
- ❑ Chayote
- ❑ Borenjena
- ❑ Plaintain
- ❑ Cassava
- ❑ Prickly pear cactus
- ❑ Bamboo shoots
- ❑ Chinese celery
- ❑ Water chestnuts
- ❑ Bok choy
- ❑ Burdock root
- ❑ Napa cabbage
- ❑ Taro
- ❑ Seaweed
- ❑ Bean sprouts
- ❑ Amaranth
- ❑ Choy sum
- ❑ Calabacita
- ❑ Sea vegetables
- ❑ Rhubarb
- ❑ _____

Beans and legumes (if canned, no salt added)

- ❑ Lentils
- ❑ Black beans
- ❑ Red beans (kidney beans)
- ❑ Navy beans
- ❑ Black beans
- ❑ Pinto beans
- ❑ Blackeyed peas
- ❑ Fava beans
- ❑ Mung beans
- ❑ Italian white beans
- ❑ Great white northern beans
- ❑ Chickpeas (garbanzo beans)
- ❑ Dried beans, peas, and lentils (without flavoring packets)
- ❑ Canned bean soup

Baking items

- ❑ Flour
- ❑ Sugar
- ❑ Imitation butter (flakes or buds)
- ❑ Nonstick cooking spray
- ❑ Canned evaporated milk—fat free (skim) or reduced-fat (2%)
- ❑ Nonfat dry milk powder
- ❑ Cocoa powder, unsweetened
- ❑ Baking powder
- ❑ Baking soda
- ❑ Cornstarch
- ❑ Unflavored gelatin
- ❑ Gelatin, any flavor (reduced calorie)
- ❑ Pudding mixes (reduced calorie)
- ❑ Angel food cake mix
- ❑ Other low-fat mixes
- ❑ Other
- ❑ _____
- ❑ _____

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Frozen foods

- ❑ Frozen fish fillets— unbreaded
- ❑ Egg substitute
- ❑ Frozen 100 percent fruit juices (no sugar added)
- ❑ Frozen fruits (no sugar added)
- ❑ Frozen vegetables (plain)
- ❑ Other frozen foods
- ❑ _____

Condiments, sauces, seasonings, and spreads

- ❑ Low-fat or nonfat salad dressings
- ❑ Mustard (Dijon, etc.)
- ❑ Catsup
- ❑ Barbecue sauce
- ❑ Other low-fat sauces
- ❑ _____
- ❑ _____
- ❑ Jam, jelly, or honey
- ❑ Spices _____
- ❑ _____
- ❑ Flavored vinegars
- ❑ Hoisin sauce, plum sauce
- ❑ Salsa or picante sauce
- ❑ Canned green chilies
- ❑ Soy sauce (low sodium)
- ❑ Bouillon cubes/granules (low sodium)
- ❑ Other
- ❑ _____

Beverages

- ❑ No-calorie drink mixes
- ❑ Reduced-calorie juices
- ❑ Unsweetened iced tea
- ❑ Carbonated water
- ❑ Water

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Low-Calorie Shopping List

We live in a fast-moving world. To reduce the time you spend in the kitchen you can improve your organization by using a shopping list and keeping a well-stocked kitchen. Shop for quick low-fat food items, and fill your kitchen cupboards with a supply of low-calorie basics.

Read labels as you shop. Pay attention to the serving size and the servings per container. All labels list total calories in a serving size of the product. **Compare the total calories in the product you choose with others like it; choose the one that is lowest in calories.** Below is a label that identifies important information.

Product:

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 250 Calories from Fat 110

	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 20% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrates 4 • Protein 4

Check for:

- Serving size
- Number of servings
- Calories
- Total fat in grams
- Saturated fat in grams
- Cholesterol in milligrams
- Sodium in milligrams

Here, the label gives the amounts for the different nutrients in one serving. Use it to help you keep track of how many calories, fat, saturated fat, cholesterol, and sodium you are getting from different foods.

The "% Daily Value" shows you how much of the recommended amounts the food provides in one serving, if you eat 2,000 calories a day. For example, one serving of this food gives you 18 percent of your total fat recommendation.

Here you can see the recommended daily amount for each nutrient for two calorie levels. If you eat a 2,000 calorie diet, you should be eating less than 65 grams of fat and less than 20 grams of saturated fat. If you eat 2,500 calories a day, you should eat less than 80 grams of fat and 25 grams of saturated fat. Your daily amounts may vary higher or lower depending on the calories you eat.

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VI. A.1.b. Low-Calorie, Lower-Fat Alternatives

These low-calorie alternatives provide new ideas for old favorites. When making a food choice, remember to consider vitamins and minerals. Some foods provide most of their calories from sugar and fat but give you few if any vitamins and minerals.

This guide is not meant to be an exhaustive list. We stress reading labels to find out just how many calories are in the specific products you decide to buy.

HIGHER-FAT FOODS	LOWER-FAT FOODS
Dairy Products	
❑ Evaporated whole milk	❑ Evaporated fat-free (skim) or reduced-fat (2%) milk
❑ Whole milk	❑ Low-fat (1%), reduced-fat (2%), or fat-free (skim) milk
❑ Ice cream	❑ Sorbet, sherbet, low-fat or fat-free frozen yogurt, or ice milk (check label for calorie content)
❑ Whipping cream	❑ Imitation whipped cream (made with fat-free [skim] milk) or low-fat vanilla yogurt
❑ Sour cream	❑ Plain low-fat yogurt
❑ Cream cheese	❑ Neufchatel or "light" cream cheese or fat-free cream cheese
❑ Cheese (Cheddar, Swiss, Jack)	❑ Reduced-calorie cheese, low-calorie processed cheeses, etc.
❑ American cheese	❑ Fat-free cheese
❑ Regular (4%) cottage cheese	❑ Fat-free American cheese or other types of fat-free cheeses ❑ Low-fat (1%) or reduced-fat (2%) cottage cheese
❑ Whole milk mozzarella cheese	❑ Part-skim milk, low-moisture mozzarella cheese
❑ Whole milk ricotta cheese	❑ Part-skim milk ricotta cheese
❑ Coffee cream (½ and ½) or nondairy creamer (liquid, powder)	❑ Low-fat (1%) or reduced-fat (2%) milk or non-fat dry milk powder
Cereals, Grains, and Pasta	
❑ Ramen noodles	❑ Rice or noodles (spaghetti, macaroni, etc.)
❑ Pasta with white sauce (alfredo)	❑ Pasta with red sauce (marinara)
❑ Pasta with cheese sauce	❑ Pasta with vegetables (primavera)
❑ Granola	❑ Bran flakes, crispy rice, etc.
	❑ Cooked grits or oatmeal
	❑ Reduced-fat granola

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HIGHER-FAT FOODS	LOWER-FAT FOODS
	Meat, Fish, and Poultry
❑ Coldcuts or lunch meats (bologna, salami, liverwurst, etc.)	❑ Low-fat coldcuts (95 to 97% fat-free lunch meats, low-fat pressed meats)
❑ Hot dogs (regular)	❑ Lower-fat hot dogs
❑ Bacon or sausage	❑ Canadian bacon or lean ham
❑ Regular ground beef	❑ Extra lean ground beef such as ground round or ground turkey (read labels)
❑ Chicken or turkey with skin; duck, or goose	❑ Chicken or turkey without skin (white meat)
❑ Oil-packed tuna	❑ Water-packed tuna (rinse to reduce sodium content)
❑ Beef (chuck, rib, brisket)	❑ Beef (round, loin) (trimmed of external fat) (choose select grades)
❑ Pork (spareribs, untrimmed loin)	❑ Pork tenderloin or trimmed, lean smoked ham
❑ Frozen breaded fish or fried fish (homemade or commercial)	❑ Fish or shellfish, unbreaded (fresh, frozen, canned in water)
❑ Whole eggs	❑ Egg whites or egg substitutes
❑ Frozen TV dinners (containing more than 13 grams of fat per serving)	❑ Frozen TV dinners (containing less than 13 grams of fat per serving and lower in sodium)
❑ Chorizo sausage	❑ Turkey sausage, drained well (read label)
	❑ Vegetarian sausage (made with tofu)
	Baked Goods
❑ Croissants, brioches, etc.	❑ Hard french rolls or soft brown 'n serve rolls
❑ Donuts, sweet rolls, muffins, scones, or pastries	❑ English muffins, bagels, reduced-fat or fat-free muffins or scones
❑ Party crackers	❑ Low-fat crackers (choose lower in sodium)
	❑ Saltine or soda crackers (choose lower in sodium)
❑ Cake (pound, chocolate, yellow)	❑ Cake (angel food, white, gingerbread)
❑ Cookies	❑ Reduced-fat or fat-free cookies (graham crackers, ginger snaps, fig bars) (compare calorie level)

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HIGHER-FAT FOODS	LOWER-FAT FOODS
Snacks and Sweets	
❑ Nuts	❑ Popcorn (air-popped or light microwave), fruits, vegetables
❑ Ice cream, e.g., cones or bars	❑ Frozen yogurt, frozen fruit or chocolate pudding bars
❑ Custards or puddings (made with whole milk)	❑ Puddings (made with skim milk)
Fats, Oils, and Salad Dressings	
❑ Regular margarine or butter	❑ Light spread margarines, diet margarine, or whipped butter, tub or squeeze bottle
❑ Regular mayonnaise	❑ Light or diet mayonnaise or mustard
❑ Regular salad dressings	❑ Reduced-calorie or fat-free salad dressings, lemon juice, or plain or herb flavored or wine vinegar
❑ Butter or margarine on toast or bread	❑ Jelly, jam, or honey on bread or toast
❑ Oils, shortening, or lard	❑ Nonstick cooking spray for stir-frying or sautéing
	❑ As a substitute for oil or butter, use applesauce or prune puree in baked goods
Miscellaneous	
❑ Canned cream soups	❑ Canned broth-based soups
❑ Canned beans and franks	❑ Canned baked beans in tomato sauce
❑ Gravy (homemade with fat and/or milk)	❑ Gravy mixes made with water or homemade with the fat skimmed off and fat-free milk
❑ Fudge sauce	❑ Chocolate syrup
❑ Avocado on sandwiches	❑ Cucumber slices or lettuce leaves
❑ Guacamole dip or refried beans with lard	❑ Salsa

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VI. A.1.c. Fat-Free Versus Regular—Calorie Comparison

A calorie is a calorie is a calorie…whether it comes from fat or carbohydrate. Anything eaten in excess can lead to weight gain. You can lose weight by eating less calories and by increasing your physical activity. Reducing the amount of fat and saturated fat that you eat is one easy way to limit your overall calorie intake. However, eating fat-free or reduced-fat foods isn't always the answer to weight loss. For example, if you eat twice as many fat-free cookies as regular cookies you may not have reduced your overall calorie intake. The following list of foods and their fat-free varieties will show you that just because a product is fat-free, it doesn't mean that it is "calorie-free." And, calories do count!

Fat-Free or Reduced Fat	Calories	Regular	Calories
Reduced-Fat Peanut Butter, 2 tablespoons	190	Regular Peanut Butter, 2 tablespoons	190
Cookies:		Cookies:	
Reduced-Fat Chocolate Chip Cookie, 1 cookie	128	Regular Chocolate Chip Cookie, 1 cookie	136
Fat-Free Fig Cookie, 1 cookie	70	Fig Cookie, 1 cookie	50
Ice Cream:		Ice Cream:	
Premium Nonfat Frozen Yogurt ½ cup	190	Regular Ice Cream ½ cup	180
Premium Reduced-Fat Ice Cream ½ cup	190	Regular Ice Cream ½ cup	180
Fat-Free Caramel Topping, 2 tablespoons	130	Butterscotch Caramel Topping, 2 tablespoons	130
Reduced-Fat Granola Cereal, ¼ cup	110	Granola Cereal, ¼ cup	130
Reduced-Fat Croissant Roll, 1 roll	110	Regular Croissant Roll, 1 roll	130
Baked Tortilla Chips, 1 ounce	110	Regular Tortilla Chips, 1 ounce	130
Reduced-Fat Breakfast Bar, 1 bar	140	Breakfast Bar, 1 bar	130

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VI. A.1.d. Good Sources of Calcium

Calcium is not just for growing children. It is an important mineral that adults also need to keep their bones and teeth strong and their muscles functioning. Many people do not eat enough calcium everyday. The following is a list of good sources of calcium and tips on how to include more calcium in your diet everyday.

Source	Calcium (milligrams)
Milk (1 cup)	
Whole	300
2% reduced-fat	300
1%* low-fat	300
Fat free*	300
Yogurt* (1 cup)	
Plain, low-fat	415
Flavored, low-fat	315
Plain, fat free	315
Cheese (1 ounce)	
Reduced-fat Cheddar*	120
American	175
Swiss Cheese	270
Mozzarella, part-skim	185
Cottage Cheese (½ cup)	
2% reduced-fat	75
Calcium fortified cottage cheese	300
Ice Cream	
Regular, ½ cup	90
Low-fat, ½ cup	100
Frozen Yogurt	
Low-fat, ½ cup	100
Beans, dried cooked, 1 cup	90
Salmon, with bones, 3 ounces	205
Tofu, processed with calcium sulfate, ½ cup	435
Spinach, fresh cooked	244
Turnip Greens, fresh cooked, 1 cup	100
Kale, fresh cooked	94
Broccoli, fresh cooked	75
Waffle, 7" diameter	180
Pancakes, (2) 4" diameter	115
Pizza, with vegetables, ¼ 12" pie	180

* Low-fat and nonfat varieties of foods are still good sources of calcium.

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Calcium Requirements

Age	Women	Men
19-24	1,200 mg	1,200 mg
25-50	1,000 mg	800 mg

Tips for Fitting in Calcium

- Eat cereal with fat-free milk. Try adding fresh fruit.
- Drink an extra glass of milk every day; try calcium-fortified milk.
- Spread calcium-fortified cottage cheese* on crackers or bagel. Add fresh fruit.
- Drink calcium-fortified orange juice.*
- Blend a yogurt smoothie with low-fat or fat-free yogurt and milk, and fresh or frozen fruit.
- Make instant pudding with low-fat or fat-free milk.
- Choose frozen yogurt for dessert instead of cake or cookies.
- Add a slice of low-fat or fat-free cheese to sandwiches.
- Substitute calcium fortified tofu in stir-fries for chicken, shrimp, or beef.
- Sauté greens (kale, bok choy, collard greens) in cooking spray and lemon juice and herbs.

*Read food labels for products with added calcium

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VI. A.2. Food Preparation—What to Do

Low-Calorie, Low-Fat Cooking/ Serving Methods

Cooking low-calorie, low-fat dishes may not take a long time, but best intentions can be lost with the addition of butter or other added fats at the table. It is important to learn how certain ingredients can add unwanted calories and fat to low-fat dishes—making them no longer lower in calories and lower in fat! The following list provides examples of lower fat-cooking methods and tips on how to serve your low-fat dishes.

Low-Fat Cooking Methods

These cooking methods tend to be lower in fat:

- Bake
- Broil
- Microwave
- Roast—for vegetables and/or chicken without skin
- Steam
- Lightly stir-fry or sauté in cooking spray, small amounts of vegetable oil, or reduced sodium broth
- Grill seafood, chicken or vegetables

How To Save Calories and Fat

Look at the following examples for how to save calories and fat when preparing and serving foods. You might be surprised at how easy it is!

- Two tablespoons of butter on a baked potato can add an *extra* 200 calories and 22 grams of fat! However, ¼ cup salsa only adds 18 calories and no fat!
- Two tablespoons of regular clear Italian salad dressing will add an *extra* 136 calories and 14 grams of fat. Reduced fat Italian dressing only adds 30 calories and 2 grams of fat!

Try These Low-Fat Flavorings—added during preparation or at the table

- Herbs—oregano, basil, cilantro, thyme, parsley, sage, or rosemary
- Spices—cinnamon, nutmeg, pepper, or paprika
- Reduced-fat or fat-free salad dressing
- Mustard
- Catsup
- Fat-free or reduced-fat mayonnaise
- Fat-free or reduced-fat sour cream
- Fat-free or reduced-fat yogurt
- Reduced sodium soy sauce
- Salsa
- Lemon or lime juice
- Vinegar
- Horseradish
- Fresh ginger
- Sprinkle of butter flavor (not made with real butter)
- Red pepper flakes
- Sprinkle of parmesan cheese (stronger flavor than most cheese)
- Sodium-free salt substitute
- Jelly or fruit preserves on toast or bagels

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VI. A.3. Dining Out—How to Choose

VI. A.3.a. General Tips for Healthy Dining Out

Whether or not you're trying to lose weight, you can eat healthy when dining out or bringing in food, if you know how. The following tips will help you move toward healthier eating as you limit your calories, as well as fat, saturated fat, cholesterol, and sodium when eating out.

You Are the Customer -

- Ask for what you want! Most restaurants will honor your requests.
- Ask questions! Don't be intimidated by the menu - your server will be able to tell you how foods are prepared or suggest substitutions on the menu.
- If you wish to reduce portion sizes - try ordering appetizers as your main meal.

General Tips: Limiting your calories and fat can be easy as long as you know what to order. Try asking these questions when you call ahead or before you order. Ask the restaurant "Do you or would you on request...":

- Serve margarine (rather than butter) with the meal?
- Serve fat-free (skim) milk rather than whole milk or cream?
- Use less oil when cooking?
- Trim visible fat off poultry or meat?
- Leave all butter, gravy, or sauces off a side dish or entree?
- Serve salad dressing on the side?
- Accommodate special requests if made in advance by telephone or in person?
- Above all else, don't get discouraged. There are usually several healthy choices to choose from at most restaurants.

Reading the Menu -

- Choose lower-calorie, low-fat cooking methods. Look for terms like steamed, in its own juice (au jus), garden fresh, broiled, baked, roasted, poached, tomato juice, dry boiled (in wine or lemon juice), and lightly sautéed or stir-fried.
- Be aware of foods high in calories, fat, and saturated fat. Watch out for terms like butter sauce, fried, crispy, creamed, in cream or cheese sauce, au gratin, au fromage, escalloped, parmesan, hollandaise, bernaise, marinated (in oil), stewed, basted, sautéed, stir-fried, casserole, hash, prime, pot pie and pastry crust.

Specific Tips for Healthy Choices

Breakfast

- Fresh fruit or small glass of citrus juice
- Whole grain bread, bagel or English muffin with jelly or honey
- Whole grain cereal with low-fat (1%) or fat-free milk
- Oatmeal with fat-free milk topped with fruit
- Omelet made with egg whites or egg substitute
- Multigrain pancakes without butter on top
- Nonfat yogurt (try adding cereal or fresh fruit)

Beverages

- Water with lemon
- Flavored sparkling water (noncaloric)
- Juice spritzer (half fruit juice and half sparkling water)
- Iced tea
- Tomato juice (reduced sodium)

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Bread

Most bread and breadsticks are low in calories and low in fat. The calories add up when you add butter, margarine, or olive oil to the bread. Also, eating a lot of bread in addition to your meal will fill you up with extra unwanted calories and not leave enough room for fruits and vegetables.

Appetizers

- Steamed seafood
- Shrimp* cocktail (limit cocktail sauce - it's high in sodium)
- Melons or fresh fruit
- Bean soups
- Salad with reduced fat dressing (or add lemon juice or vinegar)

*If you are on a cholesterol-lowering diet, eat shrimp and other shellfish in moderation.

Entree

- Poultry, fish, shellfish and vegetable dishes are healthy choices
- Pasta with red sauce or with vegetables (primavera)
- Look for terms like baked, broiled, steamed, poached, lightly sautéed or stir-fried
- Ask for sauces and dressings on the side
- Limit the amount of butter, margarine, and salt you use at the table

Salads/Salad Bars

- Fresh greens, lettuce and spinach
- Fresh vegetables - tomato, mushroom, carrots, cucumber, peppers, onion, radishes, and broccoli
- Beans, chick peas and kidney beans
- Skip the nonvegetable choices: deli meats, bacon, egg, cheese, croutons
- Choose lower-calorie, reduced-fat or fat-free dressing, lemon juice, or vinegar

Side Dish

- Plain vegetables and starches (rice, potato, noodles) make good additions to meals and can also be combined for a lower-calorie alternative to higher-calorie entrees
- Ask for side dishes without butter or margarine
- Ask for mustard, salsa or low-fat yogurt instead of sour cream or butter

Dessert/Coffee

- Fresh fruit
- Nonfat frozen yogurt
- Sherbet or fruit sorbet (these are usually fat free, but check the calorie content)
- Try sharing a dessert
- Ask for low-fat milk for your coffee (instead of cream or half-'n-half)

VI. A.3.b. Tips for Healthy Multicultural Dining Out

If you're dining out or bringing in, it is easy to find healthy foods. Knowing about American food terms, as well as other ethnic cuisines can help make your dining experience healthy and enjoyable! The following list includes healthy food choices (lower in calories and fat) and terms to look for when making your selection.

Chinese

Choose More Often...

- Steamed
- Jum (poached)
- Chu (boiled)
- Kow (roasted)
- Shu (barbecued)
- Hoison sauce with assorted Chinese vegetables: broccoli, mushroom, onion, cabbage, snow peas, scallions, bamboo shoots, water chestnuts, asparagus

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- Oyster sauce (made from seafood)
- Lightly stir-fried in mild sauce
- Cooked in light wine sauce
- Hot and spicy tomato sauce
- Sweet and sour sauce
- Hot mustard sauce
- Reduced sodium soy sauce
- Dishes without MSG added
- Garnished with spinach or broccoli
- Fresh fish filets, shrimp, scallops
- Chicken, without skin
- Lean beef
- Bean curd (tofu)
- Moo Shu vegetable, chicken or shrimp
- Steamed rice
- Lychee fruit

French

Choose More Often...

- Dinner salad with vinegar or lemon juice dressing (or other reduced fat dressing)
- Crusty bread without butter
- Fresh fish, shrimp, scallops, steamed mussels (without sauces)
- Chicken breast, without skin
- Rice and noodles without cream or added butter or other fat
- Fresh fruit for dessert

Italian

Choose More Often...

- Lightly sautéed with onions
- Shallots
- Peppers and mushrooms
- Artichoke hearts
- Sun-dried tomatoes
- Red sauces - spicy marinara sauce (arrabiata), marinara sauce or cacciatore
- Light red sauce or light red or white wine sauce
- Light mushroom sauce
- Red clam sauce
- Primavera (no cream sauce)
- Lemon sauce
- Capers
- Herbs and spices - garlic and oregano
- Crushed tomatoes and spices
- Florentine (spinach)
- Grilled (often fish or vegetables)
- Piccata (lemon)
- Manzanne (eggplant)

Middle Eastern

Choose More Often ...

- Lemon dressing, lemon juice
- Blended or seasoned with Middle Eastern spices
- Herbs and spices
- Mashed chickpeas
- Fava beans
- Smoked eggplant
- With tomatoes, onions, green peppers and cucumbers
- Spiced ground meat
- Special garlic sauce
- Basted with tomato sauce
- Garlic

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- Chopped parsley and/or onion
- Couscous (grain)
- Rice or bulgur (cracked wheat)
- Stuffed with rice and imported spices
- Grilled on a skewer
- Marinated and barbecued
- Baked
- Charbroiled or charcoal broiled
- Fresh fruit

Japanese

Choose More Often...

- House salad with fresh ginger and cellophane (clear rice) noodles
- Rice
- Nabemono
- Chicken, fish or shrimp teriyaki, broiled in sauce
- Menrui or soba noodles, often used in soups
- Yakimono (broiled)
- Tofu or bean curd
- Grilled vegetables

Indian

Choose More Often...

- Tikka (pan roasted)
- Cooked with or marinated in yogurt
- Cooked with green vegetables, onions, tomatoes, peppers, and mushrooms
- With spinach (saag)
- Baked leavened bread
- Masala
- Tandoori
- Paneer
- Cooked with curry, marinated in spices
- Lentils, chick beans, garbanzo beans, beans
- Garnished with dried fruits
- Chickpeas (garbanzo) and potatoes
- Basmati rice (pullao)
- Matta (peas)
- Chicken or shrimp kebab

Mexican

Choose More Often...

- Shredded spicy chicken
- Rice and black beans
- Rice
- Ceviche (fish marinated in lime juice and mixed with spices)
- Served with salsa (hot red tomato sauce)
- Served with salsa verde (green chili sauce)
- Covered with enchilada sauce
- Topped with shredded lettuce, diced tomatoes and onions
- Served with or wrapped in a corn or wheat flour (soft) tortilla
- Grilled
- Marinated
- Picante sauce
- Simmered with chili vegetarian tomato sauce

Thai

Choose More Often...

- Barbecued, sautéed, broiled, boiled, or steamed, braised, marinated
- Charbroiled
- Basil sauce, basil or sweet basil leaves
- Lime sauce or lime juice
- Chili sauce or crushed dried chili flakes

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- Thai spices
- Served in hollowed-out pineapple
- Fish sauce
- Hot sauce
- Napa, bamboo shoots, black mushrooms, ginger, garlic
- Bed of mixed vegetables
- Scallions, onions

Steakhouses

Choose More Often...

- Lean broiled beef (no more than 6 ounces) - London broil, filet mignon, round and flank steaks
- Baked potato without added butter, margarine or sour cream. Try low-fat yogurt or mustard.
- Green salad with reduced fat dressing
- Steamed vegetables without added butter or margarine. Try lemon juice and herbs.
- Seafood dishes (usually indicated as "surf" on menus)

Fast Food

- Grilled chicken breast sandwich without mayonnaise
- Single hamburger without cheese
- Grilled chicken salad with reduced-fat dressing
- Garden salad with reduced-fat dressing
- Low-fat or nonfat yogurt
- Fat-free muffin
- Cereal with low-fat milk

Deli/Sandwich Shop

Choose More Often...

- Fresh sliced vegetables in pita bread with low-fat dressing, yogurt or mustard
- Cup of bean soup (lentil, minestrone)
- Turkey breast sandwich with mustard, lettuce, tomato
- Fresh fruit

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Sample Reduced-Calorie Menus

	Calories	Total CHO % kcal	Total Fat % kcal	Sodium (mg)	SFA % kcal	Cholesterol (mg)	Protein % kcal
Traditional Cuisine							
1,600	1,613	55	29	1,341	8	142	19
1,200	1,247	58	26	1,043	7	96	19
Asian-American Cuisine							
1,600	1,609	56	27	1,296	8	148	20
1,200	1,220	55	27	1,043	8	117	21
Southern Cuisine							
1,600	1,653	53	28	1,231	8	172	20
1,200	1,225	50	31	867	9	142	21
Mexican-American Cuisine							
1,600	1,638	56	27	1,616	9	143	20
1,200	1,239	58	26	1,364	8	91	19
Lacta-Ovo Vegetarian Cuisine							
1,600	1,650	56	27	1,829	8	82	19
1,200	1,205	60	25	1,335	7	44	18

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TABLE VI.A.4.a:

Sample Menu: Traditional American Cuisine, Reduced Calorie

	1,600 Calories	1,200 Calories
Breakfast		
Whole Wheat Bread	1 slice	1 slice
Jelly, regular	2 tsp	2 tsp
Cereal, Shredded Wheat	1 cup	½ cup
Milk, 1% low-fat	1 cup	1 cup
Orange Juice	¾ cup	¾ cup
Coffee, Regular	1 cup	1 cup
Milk, 1% low-fat	1 oz	—
Lunch		
Roast Beef Sandwich		
Whole Wheat Bread	2 slices	2 slices
Lean Roast Beef, unseasoned	2 oz	2 oz
American Cheese, low-fat, low-sodium	1 slice (¾ oz)	—
Lettuce	1 leaf	1 leaf
Tomato	3 slices	3 slices
Mayonnaise, low-calorie	2 tsp	1 tsp
Apple	1 medium	1 medium
Water	1 cup	1 cup
Dinner		
Salmon	3 oz	2 oz
Vegetable Oil	1½ tsp	1½ tsp
Baked Potato	¾ medium	¾ medium
Margarine	1 tsp	1 tsp
Carrots seasoned with	½ cup	½ cup
margarine	½ tsp	—
Green Beans seasoned with	½ cup	½ cup
margarine	½ tsp	½ tsp
White Dinner Roll	1 medium	1 small
Ice Milk	½ cup	—
Iced Tea, unsweetened	1 cup	1 cup
Water	2 cups	2 cups
Snack		
Popcorn, air popped	2½ cups	2½ cups
Margarine	1½ tsp	¾ tsp

Calories:	1,613	Calories:	1,247
Total Carb, % kcals:	55	Total Carb, % kcals:	58
Total Fat, % kcals:	29	Total Fat, % kcals:	26
*Sodium, mg:	1,341	*Sodium, mg:	1,043
SFA, % kcals:	8	SFA, % kcals:	7
Cholesterol, mg:	142	Cholesterol, mg:	96
Protein, % kcals:	19	Protein, % kcals:	19

1,600: 100% RDA met for all nutrients except: Vit E 99%, Iron 73%, Zinc 91%
1,200: 100% RDA met for all nutrients except: Vit E 80%, Vit B_2 96%, Vit B_6 94%, Calcium 68%, Iron 63%, Zinc 73%
* No salt added in recipe preparation or as seasoning. Consume at least 32 oz. water.

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TABLE VI.A.4.b:

Sample Menu: Asian-American Cuisine, Reduced Calorie

	1,600 Calories	1,200 Calories
Breakfast		
Banana	1 small	1 small
Whole Wheat Bread	2 slices	1 slice
Margarine	1 tsp	1 tsp
Orange Juice	¾ cup	¾ cup
Milk, 1% low-fat	¾ cup	¾ cup
Lunch		
Beef Noodle Soup, canned, low-sodium	½ cup	½ cup
Chinese Noodle and Beef Salad		
Beef Roast	3 oz	2 oz
Peanut Oil	1½ tsp	1 tsp
Soy Sauce, low-sodium	1 tsp	1 tsp
Carrots	½ cup	½ cup
Zucchini	½ cup	½ cup
Onion	¼ cup	¼ cup
Chinese Noodles, soft-type	¼ cup	¼ cup
Apple	1 medium	1 medium
Tea, unsweetened	1 cup	1 cup
Dinner		
Pork Stir-fry with Vegetables		
Pork Cutlet	2 oz	2 oz
Peanut Oil	1 tsp	1 tsp
Soy Sauce, low-sodium	1 tsp	1 tsp
Broccoli	½ cup	½ cup
Carrots	1 cup	½ cup
Mushrooms	¼ cup	½ cup
Steamed White Rice	1 cup	½ cup
Tea, unsweetened	1 cup	1 cup
Snack		
Almond Cookies	2 cookies	—
Milk, 1% low-fat	¾ cup	¾ cup
Calories:	1,609	1,220
Total Carb, % kcals:	56	55
Total Fat, % kcals:	27	27
*Sodium, mg:	1,296	1,043
SFA, % kcals:	8	8
Cholesterol, mg:	148	117
Protein, % kcals:	20	21

1,600: 100% RDA met for all nutrients except: Zinc 95%, Iron 87%, Calcium 93%
1,200: 100% RDA met for all nutrients except: Vit E 75%, Calcium 84%, Magnesium 98%, Iron 66%, Zinc 77%
* No salt added in recipe preparation or as seasoning. Consume at least 32 oz. water.

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TABLE VI.A.4.c:

SAMPLE MENU: SOUTHERN CUISINE, REDUCED CALORIE

	1,600 Calories	1,200 Calories
Breakfast		
Oatmeal, prepared with 1% low-fat milk	½ cup	½ cup
Milk, 1% low-fat	½ cup	½ cup
English Muffin	1 medium	—
Cream Cheese, light, 18% fat	1 T	—
Orange Juice	¾ cup	½ cup
Coffee	1 cup	1 cup
Milk, 1% low-fat	1 oz	1 oz
Lunch		
Baked Chicken, without skin	2 oz	2 oz
Vegetable Oil	1 tsp	½ tsp
Salad		
Lettuce	½ cup	½ cup
Tomato	½ cup	½ cup
Cucumber	½ cup	½ cup
Oil and Vinegar Dressing	2 tsp	1 tsp
White Rice, seasoned with	½ cup	¼ cup
margarine, diet	½ tsp	½ tsp
Baking Powder Biscuit, prepared with vegetable oil	1 small	½ small
Margarine	1 tsp	1 tsp
Water	1 cup	1 cup
Dinner		
Lean Roast Beef	3 oz	2 oz
Onion	¼ cup	¼ cup
Beef Gravy, water-based	1 T	1 T
Turnip Greens, seasoned with	½ cup	½ cup
margarine, diet	½ tsp	½ tsp
Sweet Potato, baked	1 small	1 small
Margarine, diet	½ tsp	¼ tsp
Ground Cinnamon	1 tsp	1 tsp
Brown Sugar	1 tsp	1 tsp
Cornbread prepared with margarine, diet	½ medium slice	½ medium slice
Honeydew Melon	¼ medium	⅛ medium
Iced Tea, sweetened with sugar	1 cup	1 cup
Snack		
Saltine Crackers, unsalted tops	4 crackers	4 crackers
Mozzarella Cheese, part-skim, low-sodium	1 oz	1 oz

Calories:	1,653	Calories:	1,225
Total Carb, % kcals:	53	Total Carb, % kcals:	50
Total Fat, % kcals:	28	Total Fat, % kcals:	31
*Sodium, mg:	1,231	*Sodium, mg:	867
SFA, % kcals:	8	SFA, % kcals:	9
Cholesterol, mg:	172	Cholesterol, mg:	142
Protein, % kcals:	20	Protein, % kcals:	21

1,600: 100% RDA met for all nutrients except: Vit E 97%, Magnesium 98%, Iron 78%, Zinc 90%

1,200: 100% RDA met for all nutrients except: Vit E 82%, Vit B_1 & B_2 95%, Vit B_3 99%, Vit B_6 88%, Magnesium 83%, Iron 56%, Zinc 70%

* No salt added in recipe preparation or as seasoning. Consume at least 32 oz. water.

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TABLE VI.A.4.d:

Sample Menu: Mexican-American Cuisine, Reduced Calorie

	1,600 Calories	1,200 Calories
Breakfast		
Cantaloupe	1 cup	½ cup
Farina, prepared with 1% low-fat milk	½ cup	½ cup
White Bread	1 slice	1 slice
Margarine	1 tsp	1 tsp
Jelly	1 tsp	1 tsp
Orange Juice	1½ cup	¾ cup
Milk, 1% low-fat	½ cup	½ cup
Lunch		
Beef Enchilada		
Tortilla, corn	2 tortillas	2 tortillas
Lean Roast Beef	2 ½ oz	2 oz
Vegetable Oil	⅔ tsp	⅔ tsp
Onion	1 T	1 T
Tomato	4 T	4 T
Lettuce	½ cup	½ cup
Chili Peppers	2 tsp	2 tsp
Refried Beans, prepared with vegetable oil	¼ cup	¼ cup
Carrots	5 sticks	5 sticks
Celery	6 sticks	6 sticks
Milk, 1% low-fat	½ cup	—
Dinner		
Chicken Taco		
Tortilla, corn	1 tortilla	1 tortilla
Chicken Breast, without skin	2 oz	1 oz
Vegetable Oil	⅔ tsp	⅔ tsp
Cheddar Cheese, low-fat, low-sodium	1 oz	½ oz
Guacamole	2 T	1 T
Salsa	1 T	1 T
Corn, seasoned with margarine	½ cup ½ tsp	½ cup —
Spanish Rice without meat, seasoned without margarine	½ cup	½ cup
Banana	1 large	½ large
Coffee	1 cup	1 cup
Milk 1%	1 oz	1oz
	Calories: 1,638 Total Carb, % kcals: 56 Total Fat, % kcals: 27 *Sodium, mg: 1,616 SFA, % kcals: 9 Cholesterol, mg: 143 Protein, % kcals: 20	Calories: 1,239 Total Carb, % kcals: 58 Total Fat, % kcals: 26 *Sodium, mg: 1,364 SFA, % kcals: 8 Cholesterol, mg: 91 Protein, % kcals: 19

1,600: 100% RDA met for all nutrients except: Vit E 97%, Zinc 84%

1,200: 100% RDA met for all nutrients except: Vit E 71%, Vit B_1 & B_3 91%, Vit B_2 & Iron 90%, Calcium 92%, Magnesium 95%, Zinc 64%

* No salt added in recipe preparation or as seasoning. Consume at least 32 oz. water.

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TABLE VI.A.4.e:

SAMPLE MENU: LACTO-OVO VEGETARIAN CUISINE, REDUCED CALORIE

	1,600 Calories	1,200 Calories
Breakfast		
Orange	1 medium	1 medium
Pancakes, made with 1% low-fat milk, egg whites	3 4" circles	2 4" circles
Pancake Syrup	2 T	1 T
Margarine, diet	1½ tsp	1½ tsp
Milk, 1% low-fat	1 cup	½ cup
Coffee	1 cup	1 cup
Milk, 1% low-fat	1 oz	1 oz
Lunch		
Vegetable Soup, canned, low-sodium	1 cup	½ cup
Bagel	1 medium	½ medium
Processed American Cheese, low-fat and low sodium	¾ oz	—
Spinach Salad		
Spinach	1 cup	1 cup
Mushrooms	⅛ cup	⅛ cup
Salad Dressing, regular calorie	2 tsp	2 tsp
Apple	1 medium	1 medium
Iced Tea, unsweetened	1 cup	1 cup
Dinner		
Omelette		
Egg Whites	4 large eggs	4 large eggs
Green Pepper	2 T	2 T
Onion	2 T	2T
Mozzarella Cheese, made from part-skim milk, low-sodium	1½ oz	1 oz
Vegetable Oil	1 T	½ T
Brown Rice, seasoned with	½ cup	½ cup
margarine, diet	½ tsp	½ tsp
Carrots, seasoned with	½ cup	½ cup
margarine, diet	½ tsp	½ tsp
Whole Wheat Bread	1 slice	1 slice
Margarine, diet	1 tsp	1 tsp
Fig Bar Cookie	1 bar	1 bar
Tea	1 cup	1 cup
Honey	1 tsp	1 tsp
Snack		
Milk, 1% low-fat	¾ cup	¾ cup
Calories:	1,650	1,205
Total Carb, % kcals:	56	60
Total Fat, % kcals:	27	25
*Sodium, mg:	1,829	1,335
SFA, % kcals:	8	7
Cholesterol, mg:	82	44
Protein, % kcals:	19	18

1,600: 100% RDA met for all nutrients except: Vit E 92%, Vit B_3 97%, Vit B_6 67%, Magnesium 98%, Iron 73%, Zinc 68%
1,200: 100% RDA met for all nutrients except: Vit E 75%, Vit B_1 92%, Vit B_3 69%, Vit B_6 59%, Iron 54%, Zinc 46%
* No salt added in recipe preparation or as seasoning. Consume at least 32 oz. water.

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7 Appendix VII. Resource List

For additional information on overweight and obesity, and related conditions or diseases, you may wish to contact the professional organizations listed below.

The Federal consumer health information gateway, healthfinder, (www.healthfinder.gov) offers convenient access to these and many other resources.

American Dietetic Association
216 West Jackson Boulevard
Chicago, IL 60606-6995
(800) 877-1600
FAX: (312) 899-1979
http://www.eatright.org
- Eat Right America program
- List of nutrition resources
- Find a dietitian, 1-800-366-1655

American College of Sports Medicine
P.O. Box 1440
Indianapolis, IN 46206-1440
(317) 637-9200
FAX: (317) 634-7817
http://www.acsm.org
- Health and Fitness Summit and Exposition
- National Coalition for Promoting Physical Activity
- Public information

National Heart, Lung, and Blood Institute
Education Programs Information Center
P.O. Box 30105
Bethesda, MD 20824-0105
(301) 251-1222
FAX: (301) 251-1223
http://www.nhlbi.nih.gov/nhlbi/nhlbi.htm (general NHLBI site)
- Online publications on blood pressure, overweight, cholesterol, heart disease, sleep disorders, and asthma

National Institute of Diabetes and Digestive and Kidney Diseases
31 Center Drive, MSC-2560
Building 31, Room 9A-04
Bethesda, MD 20892-2560
(301) 496-3583
FAX: (301) 496-7422
http://www.niddk.nih.gov
- Many online patient information publications on diabetes
- Many online publications on nutrition and obesity
- WIN — the Weight-Control Information Network 1-800-WIN-8098

The Weight-Control Information Network
National Institute of Diabetes and Digestive and Kidney Diseases
1 WIN WAY
Bethesda, MD 20892-3665
(301) 570-2177
FAX: (301) 570-2186
1-800-WIN-8098

National Digestive Diseases Information Clearinghouse (NIDDK)
2 Information Way
Bethesda, MD 20892-3570
(301) 654-3810
FAX: (301) 907-8906

National Kidney and Urologic Diseases Information Clearinghouse (NIDDK)
3 Information Way
Bethesda, MD 20892-3580
(301) 654-4415
FAX: (301) 907-8906

National Diabetes Information Clearinghouse (NIDDK)
1 Information Way
Bethesda, MD 20892-3560
(301) 654-3327
FAX: (301) 907-8906

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American Diabetes Association
1660 Duke Street
Alexandria, VA 22314
1-800 DIABETES
http://www.diabetes.org
- List of publications

American Cancer Society
Atlanta, GA
1-800-ACS-2345
http://www.cancer.org
- Dietary guidelines online
- List of publications

National Cancer Institute
Office of Cancer Communications
9000 Rockville Pike
Building 31, Room 10A-24
Bethesda, MD 20892
(800) 4-CANCER (800-422-6237)
http://www.nci.nih.gov
- Many publications online, including those on nutrition and cancer

National Eating Disorders Organization
6655 South Yale Avenue
Tulsa, OK 74136
(918) 481-4044
FAX: (918) 481-4076
http://www.laureate.com/aboutned.html
- Publications list
- Online descriptive information

Eating Disorders Awareness and Prevention, Inc.
603 Stewart Street, Suite 803
Seattle, WA 98101
(206) 382-3587
http://members.aol.com/edapinc/home.html
- Online descriptive information
- Publications list

American Anorexia/Bulimia Association, Inc.
165 West 46th Street #1108
New York, NY 10036
(212) 575-6200
http://members.aol.com/amanbu/index.html
- Online descriptive information

National Association of Anorexia Nervosa and Associated Disorders
P.O.Box 7
Highland Park, IL 60035
(847) 831-3438
FAX: (847) 433-4632
http://www.medpatients.com/Health%20Resources/NAANAD.htm

American Heart Association
7272 Greenville Avenue
Dallas, TX 75231-4596
(214) 706-1220
FAX: (214) 706-1341
1-800-AHA-USA1 (800-242-8721)
http://www.americanheart.org
- Publications list
- Online information
- Stroke Connection 1-800-553-6321

Hypertension Network, Inc.
http://www.bloodpressure.com
- Online information
- Weekly research updates

National Institute of Neurological Disorders and Stroke
P.O. Box 5801
Bethesda, MD 20824
(301) 496-5751
http://www.ninds.nih.gov
- Online publications on stroke
- Publications list

National Center on Sleep Disorders Research
National Heart, Lung, and Blood Institute
Two Rockledge Centre, Suite 7024
6701 Rockledge Drive, MSC 7920
Bethesda, MD 20892-7920
(301) 435-0199
FAX: (301) 480-3451

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American Sleep Disorders Association
1610 14th Street NW, Suite 300
Rochester, MN 55901
(507) 287-6006
Fax: (507) 287-6008
http://www.asda.org
- List of member centers
- Online descriptive information

The Sleep Medicine Home Page
http://www.users.cloud9.net/~thorpy
- List of internet resources
- List of centers
- Online descriptive information

National Mental Health Association
1201 Prince Street
Alexandria, VA 22314-2971
(703) 684-7722
Fax: (703) 684-5968
800/969-NMHA Information Center
http://www.nmha.org

North American Association for the Study of Obesity (NAASO)
8630 Fenton Street
Suite 412
Silver Spring, MD 20910
(301) 563-6526
Fax: (301) 587-2365
http://www.naaso.org

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8 Appendix VIII. Glossary of Terms

Abdominal fat: Fat (adipose tissue) that is centrally distributed between the thorax and pelvis and that induces greater health risk.

Absolute risk: The observed or calculated probability of an event in a population under study, as contrasted with the relative risk.

Aerobic exercise: A type of physical activity that includes walking, jogging, running, and dancing. Aerobic training improves the efficiency of the aerobic energy-producing systems that can improve cardiorespiratory endurance.

Age-adjusted: Summary measures of rates of morbidity or mortality in a population using statistical procedures to remove the effect of age differences in populations that are being compared. Age is probably the most important and the most common variable in determining the risk of morbidity and mortality.

Anorexiant: A drug, process, or event that leads to anorexia.

Anthropometric measurements: Measurements of human body height, weight, and size of component parts, including skinfold measurement. Used to study and compare the relative proportions under normal and abnormal conditions.

Atherogenic: Causing the formation of plaque in the lining of the arteries.

Behavior therapy: Behavior therapy constitutes those strategies, based on learning principles such as reinforcement, that provide tools for overcoming barriers to compliance with dietary therapy and/or increased physical activity.

Biliopancreatic diversion: A surgical procedure for weight loss that combines a modest amount of gastric restriction with intestinal malabsorption.

BMI: Body mass index; the body weight in kilograms divided by the height in meters squared (wt/ht^2) used as a practical marker to assess obesity; often referred to as the Quetelet Index. An indicator of optimal weight for health and different from lean mass or percent body fat calculations because it only considers height and weight.

Body composition: The ratio of lean body mass (structural and functional elements in cells, body water, muscle, bone, heart, liver, kidneys, etc.) to body fat (essential and storage) mass. Essential fat is necessary for normal physiological functioning (e.g., nerve conduction). Storage fat constitutes the body's fat reserves, the part that people try to lose.

BRL 26830A: An atypical B adrenoreceptor agonist drug that in obese rodents showed an increased metabolic rate and caused a reduction in weight by decreasing body lipid content. It is not approved as a weight loss drug by FDA.

Carbohydrates: A nutrient that supplies 4 calories/gram. They may be simple or complex. Simple carbohydrates are called sugars, and complex carbohydrates are called starch and fiber (cellulose). An organic compound—containing

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carbon, hydrogen, and oxygen—that is formed by photosynthesis in plants. Carbohydrates are heat producing and are classified as monosaccharides, disaccharides, or polysaccharides.

Cardiovascular disease (CVD): Any abnormal condition characterized by dysfunction of the heart and blood vessels. CVD includes atherosclerosis (especially coronary heart disease, which can lead to heart attacks), cerebrovascular disease (e.g., stroke), and hypertension (high blood pressure).

Central fat distribution: The waist circumference is an index of body fat distribution. Increasing waist circumference is accompanied by increasing frequencies of overt type 2 diabetes, dyslipidemia, hypertension, coronary heart disease, stroke, and early mortality. In the body fat patterns called android type (apple shaped) fat is deposited around the waist and upper abdominal area and appears most often in men. Abdominal body fat is thought to be associated with a rapid mobilization of fatty acids rather than resulting from other fat depots, although it remains a point of contention. If abdominal fat is indeed more active than other fat depots, it would then provide a mechanism by which we could explain (in part) the increase in blood lipid and glucose levels. The latter have been clearly associated with an increased risk for cardiovascular disease hypertension and type 2 diabetes mellitus. The gynoid type (pear-shaped) of body fat is usually seen in women. The fat is deposited around the hips, thighs, and buttocks, and presumably is used as energy reserve during pregnancy and lactation.

Cholecystectomy: Surgical removal of the gallbladder and gallstones, if present.

Cholecystitis: Inflammation of the gallbladder, caused primarily by gallstones. Gallbladder disease occurs most often in obese women older than 40 years of age.

Cholesterol: A soft, waxy substance manufactured by the body and used in the production of hormones, bile acid, and vitamin D and present in all parts of the body, including the nervous system, muscle, skin, liver, intestines, and heart. Blood cholesterol circulates in the bloodstream. Dietary cholesterol is found in foods of animal origin.

Cimetidine: A weight loss drug that is thought to work by suppression of gastric acid or suppression of hunger by blocking histamine H_2 receptors. It is not approved by the FDA.

Cognitive behavior therapy: A system of psychotherapy based on the premise that distorted or dysfunctional thinking, which influences a person's mood or behavior, is common to all psychosocial problems. The focus of therapy is to identify the distorted thinking and to replace it with more rational, adaptive thoughts and beliefs.

Cognitive rehearsal: A technique used in cognitive behavior therapy. In a weight loss program, for example, individuals first imagine the situation that is causing temptation (such as eating a high fat food), describe the thoughts and feelings that accompany the imagined situation, and make positive self-statements about the situation (e.g., "I am feeling good about choosing a low calorie drink rather than the high fat cheese."). Then the next step is to follow the positive self-statement with an adaptive behavior (such as walking away from the buffet line to chat with a friend). Finally, individuals are encouraged to reward themselves for doing well in a difficult situation, with either positive statements or material rewards, or both. The idea is to rehearse one's thoughts and behaviors prior to experiencing the potentially difficult situation, and to be armed with healthy adaptive responses.

Cognitive restructuring: A method of identifying and replacing fear-promoting, irrational beliefs with more realistic and functional ones.

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Comorbidity: Two or more diseases or conditions existing together in an individual.

Computed tomography (CT) scans: A radiographic technique for direct visualization and quantification of fat that offers high image contrast and clear separation of fat from other soft tissues. CT can estimate total body adipose tissue volume and identify regional, subcutaneous, visceral, and other adipose tissue depots. Radiation exposure, expense, and unavailability restrict the epidemiologic use of CT.

Confounding: Extraneous variables resulting in outcome effects that obscure or exaggerate the "true" effect of an intervention.

Coronary heart disease (CHD): A type of heart disease caused by narrowing of the coronary arteries that feed the heart, which needs a constant supply of oxygen and nutrients carried by the blood in the coronary arteries. When the coronary arteries become narrowed or clogged by fat and cholesterol deposits and cannot supply enough blood to the heart, CHD results.

Cue avoidance: A stimulus control technique often used in weight loss programs in which individuals are asked to reduce their exposure to certain food cues by making a variety of changes in their habits. The rationale is to make it easier on oneself and reduce temptation by reducing contact with food cues. For example, coming home from work and feeling tired is a time when many people reach for the high fat foods if they are available. By not having the high fat foods within reach, one can avoid eating them.

Dexfenfluramine: A serotonin agonist drug used to treat obesity. FDA approval has been withdrawn.

Diabetes: A complex disorder of carbohydrate, fat, and protein metabolism that is primarily a result of relative or complete lack of insulin secretion by the beta cells of the pancreas or a result of defects of the insulin receptors.

Diastolic blood pressure: The minimum pressure that remains within the artery when the heart is at rest.

Diethylproprion: An appetite suppressant prescribed in the treatment of obesity.

Dopamine: A catecholamine neurotransmitter that is found primarily in the basal ganglia of the central nervous system. Major functions include the peripheral inhibition and excitation of certain muscles; cardiac excitation; and metabolic, endocrine and central nervous system actions.

Dual energy X-ray absortiometry (DEXA): A method used to estimate total body fat and percent of body fat. Potential disadvantages include whole body radiation and the long time required for scanning while the subject lies on a hard table.

Dyslipidemia: Disorders in the lipoprotein metabolism; classified as hypercholesterolemia, hypertriglyceridemia, combined hyperlipidemia, and low levels of high-density lipoprotein (HDL) cholesterol. All of the dyslipidemias can be primary or secondary. Both elevated levels of low-density lipoprotein (LDL) cholesterol and low levels of HDL cholesterol predispose to premature atherosclerosis.

Efficacy: The extent to which a specific intervention, procedure, regimen, or service produces a beneficial result under ideal conditions. Ideally, the determination of efficacy is based on the results of a randomized control trial.

Energy balance: Energy is the capacity of a body or a physical system for doing work. Energy balance is the state in which the total energy intake equals total energy needs.

Energy deficit: A state in which total energy intake is less than total energy need.

Ephedrine: A sympathomimetic drug that stimulates thermogenesis in laboratory animals and

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humans. Animal studies show that it may reduce fat content and, therefore, body weight by mechanisms that probably involve increased expenditure and reduced food intake.

Extreme obesity: A body mass index ≥ 40.

Femoxetine: A selective serotonin reuptake inhibitor drug used in obese patients for weight loss.

Fenfluramine: A serotonin agonist drug used in the treatment of obesity. FDA approval has been withdrawn.

Fibrinogen: A plasma protein that is converted into fibrin by thrombin in the presence of calcium ions. Fibrin is responsible for the semisolid character of a blood clot.

Fluoxetine: An antidepressant drug used to promote weight loss whose action is mediated by highly specific inhibition of serotonin reuptake into presynaptic neurons. Serotonin acts in the brain to alter feeding and satiety by decreasing carbohydrate intake, resulting in weight reduction.

Framingham Heart Study: Study begun in 1948 to identify constitutional, environmental, and behavioral influences on the development of cardiovascular disease. Framingham data show that increased relative weight and central obesity are associated with elevated levels of risk factors (e.g., cholesterol, blood pressure, blood glucose, uric acid), increased incidence of cardiovascular disease, and increased death rates for all causes combined.

Gallstones: Constituents in the gallbladder that are not reabsorbed, including bile salts and lipid substances such as cholesterol that become highly concentrated. They can cause severe pain (obstruction and cramps) as they move into the common bile duct. Risk factors for cholesterol gallstone formation include female gender, weight gain, overweight, high energy intake, ethnic factors (Pima Indians and Scandinavians), use of certain drugs (clofibrate, estrogens, and bile acid sequestrants), and presence of gastrointestinal disease. Gallstones sometimes develop during dieting for weight reduction. There is an increased risk for gallstones and acute gallbladder disease during severe caloric restriction.

Gastric banding: Surgery to limit the amount of food the stomach can hold by closing part of it off. A band made of special material is placed around the stomach near its upper end, creating a small pouch and a narrow passage into the larger remainder of the stomach. The small outlet delays the emptying of food from the pouch and causes a feeling of fullness.

Gastric bubble/balloon: A free-floating intragastric balloon used in the treatment of obesity.

Gastric bypass: A surgical procedure that combines the creation of small stomach pouches to restrict food intake and the construction of bypasses of the duodenum and other segments of the small intestine to cause food malabsorption. Patients generally lose two-thirds of their excess weight after 2 years.

Gastric exclusion: Same as gastric partitioning and Roux-en Y bypass. A small stomach pouch is created by stapling or by vertical banding to restrict food intake. A Y-shaped section of the small intestine is attached to the pouch to allow food to bypass the duodenum as well as the first portion of the jejunum.

Gastric partitioning: See gastric exclusion.

Gastroplasty: See also jejuno-ileostomy. A surgical procedure that limits the amount of food the stomach can hold by closing off part of the stomach. Food intake is restricted by creating a small pouch at the top of the stomach where the food enters from the esophagus. The pouch initially holds about 1 ounce of food and expands to 2-3 ounces with time. The pouch's lower outlet usually has a diameter of about 1/4 inch. The

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small outlet delays the emptying of food from the pouch and causes a feeling of fullness.

Genotype: The entire genetic makeup of an individual. The fundamental constitution of an organism in terms of its hereditary factors. A group of organisms in which each has the same hereditary characteristics.

Glucose tolerance: The power of the normal liver to absorb and store large quantities of glucose and the effectiveness of intestinal absorption of glucose. The glucose tolerance test is a metabolic test of carbohydrate tolerance that measures active insulin, a hepatic function based on the ability of the liver to absorb glucose. The test consists of ingesting 100 grams of glucose into a fasting stomach; blood sugar should return to normal in 2 to 2½ hours after ingestion.

Hemoglobin A_{1c}: One of the fractions of glycosylated hemoglobin A. Glycosylated hemoglobin is formed when linkages of glucose and related monosaccharides bind to hemoglobin A and its concentration represents the average blood glucose level over the previous several weeks. HbA_{1C} levels are used as a measure of long-term control of plasma glucose (normal, 4 to 6 percent). In controlled diabetes mellitus, the concentration of glycosylated hemoglobin A is within the normal range, but in uncontrolled cases the level may be 3 to 4 times the normal concentration. Generally, complications are substantially lower among patients with HbA_{1C} levels of 7 percent or less than in patients with HbA_{1C} levels of 9 percent or more.

Hemorrhagic stroke: A disorder involving bleeding within ischemic brain tissue. Hemorrhagic stroke occurs when blood vessels that are damaged or dead from lack of blood supply (infarcted), located within an area of infarcted brain tissue, rupture and transform an "ischemic" stroke into a hemorrhagic stroke. Ischemia is inadequate tissue oxygenation caused by reduced blood flow; infarction is tissue death resulting from ischemia. Bleeding irritates the brain tissues, causing swelling (cerebral edema). Blood collects into a mass (hematoma). Both swelling and hematoma will compress and displace brain tissue.

Heritability: The proportion of observed variation in a particular trait that can be attributed to inherited genetic factors in contrast to environmental ones.

High-density lipoproteins (HDL): Lipoproteins that contain a small amount of cholesterol and carry cholesterol away from body cells and tissues to the liver for excretion from the body. Low-level HDL increases the risk of heart disease, so the higher the HDL level, the better. The HDL component normally contains 20 to 30 percent of total cholesterol, and HDL levels are inversely correlated with coronary heart disease risk.

Hirsutism: Presence of excessive body and facial hair, especially in women; may be present in normal adults as an expression of an ethnic characteristic or may develop in children or adults as the result of an endocrine disorder. Apert's hirsutism is caused by a virilizing disorder of adrenocortical origin. Constitutional hirsutism is mild-to-moderate hirsutism present in individuals exhibiting otherwise normal endocrine and reproductive functions; it appears to be an inheritable form of hirsutism and commonly is an expression of an ethnic characteristic. Idiopathic hirsutism is of uncertain origin in women, who may exhibit menstrual abnormalities and sterility. Some authorities believe the hirsutism reflects hypersecretion of adrenocortical androgens.

Hypercholesterolemia (high blood cholesterol): Cholesterol is the most abundant steroid in animal tissues, especially in bile and gallstones. The relationship between the intake of cholesterol and its manufacture by the body to its utiliza-

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tion, sequestration, or excretion from the body is called the cholesterol balance. When cholesterol accumulates, the balance is positive; when it declines, the balance is negative. In 1993, the NHLBI National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults issued an updated set of recommendations for monitoring and treatment of blood cholesterol levels. The NCEP guidelines recommended that total cholesterol levels and subfractions of high-density lipoprotein (HDL) cholesterol be measured beginning at age 20 in all adults, with subsequent periodic screenings as needed. Even in the group of patients at lowest risk for coronary heart disease (total cholesterol <200 mg/dL and HDL >35 mg/dL), the NCEP recommended that rescreening take place at least once every 5 years or upon physical examination.

Hypertension: High blood pressure (i.e., abnormally high blood pressure tension involving systolic and/or diastolic levels). The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure defines hypertension as a systolic blood pressure of 140 mm Hg or greater, a diastolic blood pressure of 90 mm Hg or greater, or taking hypertensive medication. The cause may be adrenal, benign, essential, Goldblatt's, idiopathic, malignant PATE, portal, postpartum, primary, pulmonary, renal or renovascular.

Hypertriglyceridemia: An excess of triglycerides in the blood that is an autosomal dominant disorder with the phenotype of hyperlipoproteinemia, type IV. The National Cholesterol Education Program defines a high level of triglycerides as being between 400 and 1,000 mg/dL.

Incidence: The rate at which a certain event occurs (i.e., the number of new cases of a specific disease occurring during a certain period).

Insulin-dependent diabetes mellitus (type I diabetes): A disease characterized by high levels of blood glucose resulting from defects in insulin secretion, insulin action, or both. Autoimmune, genetic, and environmental factors are involved in the development of type I diabetes.

Ischemic stroke: A condition in which the blood supply to part of the brain is cut off. Also called "plug-type" strokes. Blocked arteries starve areas of the brain controlling sight, speech, sensation, and movement so that these functions are partially or completely lost. Ischemic stroke is the most common type of stroke, accounting for 80 percent of all strokes. Most ischemic strokes are caused by a blood clot called a thrombus, which blocks blood flow in the arteries feeding the brain, usually the carotid artery in the neck, the major vessel bringing blood to the brain. When it becomes blocked, the risk of stroke is very high.

Jejuno-ileostomy: See gastroplasty.

J-shaped relationship: The relationship between body weight and mortality.

Lipoprotein: Protein-coated packages that carry fat and cholesterol throughout the bloodstream. There are four general classes: high-density, low-density, very low-density, and chylomicrons.

Locus/loci: A general anatomical term for a site in the body or the position of a gene on a chromosome.

Longitudinal study: Also referred to as a "cohort study" or "prospective study"; the analytic method of epidemiologic study in which subsets of a defined population can be identified who are, have been, or in the future may be exposed or not exposed, or exposed in different degrees, to a factor or factors hypothesized to influence the probability of occurrence of a given disease or other outcome. The main feature of this type of study is to observe large numbers of subjects over an extended time, with comparisons of

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incidence rates in groups that differ in exposure levels.

Low-calorie diet (LCD): Caloric restriction of about 800 to 1,500 calories (approximately 12 to 15 kcal/kg of body weight) per day.

Low-density lipoprotein (LDL): Lipoprotein that contains most of the cholesterol in the blood. LDL carries cholesterol to the tissues of the body, including the arteries. A high level of LDL increases the risk of heart disease. LDL typically contains 60 to 70 percent of the total serum cholesterol and both are directly correlated with CHD risk.

Lower-fat diet: An eating plan in which 30 percent or less of the day's total calories are from fat.

Macronutrients: Nutrients in the diet that are the key sources of energy, namely protein, fat, and carbohydrates.

Magnetic resonance imaging (MRI): Magnetic resonance imaging uses radio frequency waves to provide direct visualization and quantification of fat. The sharp image contrast of MRI allows clear separation of adipose tissue from surrounding nonlipid structures. Essentially the same information provided by CT is available from MRI, including total body and regional adipose tissue, subcutaneous adipose, and estimates of various visceral adipose tissue components. The advantage of MRI is its lack of ionizing radiation and hence its presumed safety in children, younger adults, and pregnant women. The minimal present use of MRI can be attributed to the expense, limited access to instrumentation, and long scanning time.

Menopause: The cessation of menstruation in the human female, which begins at about the age of 50.

Meta-analysis: Process of using statistical methods to combine the results of different studies. A frequent application is pooling the results from a set of randomized controlled trials, none of which alone is powerful enough to demonstrate statistical significance.

Mianserine: An antidepressant sometimes used in the pharmacotherapy of bulimia nervosa.

Midaxillary line: An imaginary vertical line that passes midway between the anterior and posterior axillary (armpit) folds.

Monounsaturated fat: An unsaturated fat that is found primarily in plant foods, including olive and canola oils.

Myocardial infarction (MI): Gross necrosis of the myocardium as a result of interruption of the blood supply to the area; it is almost always caused by atherosclerosis of the coronary arteries, upon which coronary thrombosis is usually superimposed.

NHANES: National Health and Nutrition Examination Survey; conducted every 10 years by the National Center for Health Statistics to survey the dietary habits and health of U.S. residents.

Neural tube defects: These defects include problems stemming from fetal development of the spinal cord, spine, brain, and skull, and include birth defects such as spina bifida, anencephaly, and encephalocele. Neural tube defects occur early in pregnancy at about 4 to 6 weeks, usually before a woman knows she is pregnant. Many babies with neural tube defects have difficulty walking and with bladder and bowel control.

Neuronal atrophy: Nerve cell death and functional loss.

Obesity: The condition of having an abnormally high proportion of body fat. Defined as a body mass index (BMI) of greater than or equal to 30. Subjects are generally classified as obese when body fat content exceeds 30 percent in women and 25 percent in men. The operational definition of obesity in this document is a BMI ≥ 30.

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Observational study: An epidemiologic study that does not involve any intervention, experimental or otherwise. Such a study may be one in which nature is allowed to take its course, with changes in one characteristic being studied in relation to changes in other characteristics. Analytical epidemiologic methods, such as case-control and cohort study designs, are properly called observational epidemiology because the investigator is observing without intervention other than to record, classify, count, and statistically analyze results.

Orlistat: A lipase inhibitor used for weight loss. Lipase is an enzyme found in the bowel that assists in lipid absorption by the body. Orlistat blocks this enzyme, reducing the amount of fat the body absorbs by about 30 percent. It is known colloquially as a "fat blocker." Because more oily fat is left in the bowel to be excreted, Orlistat can cause an oily anal leakage and fecal incontinence. Orlistat may not be suitable for people with bowel conditions such as irritable bowel syndrome or Crohn's disease.

Osteoarthritis: Noninflammatory degenerative joint disease occurring chiefly in older persons, characterized by degeneration of the articular cartilage, hypertrophy of bone at the margins, and changes in the synovial membrane. It is accompanied by pain and stiffness.

Overweight: An excess of body weight but not necessarily body fat; a body mass index of 25 to 29.9 kg/m^2.

Peripheral regions: Other regions of the body besides the abdominal region (i.e., the gluteal-femoral area).

Pharmacotherapy: A regimen of using appetite suppressant medications to manage obesity by decreasing appetite or increasing the feeling of satiety. These medications decrease appetite by increasing serotonin or catecholamine—two brain chemicals that affect mood and appetite.

Phenotype: The entire physical, biochemical, and physiological makeup of an individual as determined by his or her genes and by the environment in the broad sense.

Phentermine: An adrenergic isomeric with amphetamine, used as an anorexic; administered orally as a complex with an ion-exchange resin to produce a sustained action.

Polyunsaturated fat: An unsaturated fat found in greatest amounts in foods derived from plants, including safflower, sunflower, corn, and soybean oils.

Postprandial plasma blood glucose: Glucose tolerance test performed after ingesting food.

Prevalence: The number of events, e.g., instances of a given disease or other condition, in a given population at a designated time. When used without qualification, the term usually refers to the situation at specific point in time (point prevalence). Prevalence is a number not a rate.

Prospective study: An epidemiologic study in which a group of individuals (a cohort), all free of a particular disease and varying in their exposure to a possible risk factor, is followed over a specific amount of time to determine the incidence rates of the disease in the exposed and unexposed groups.

Protein: A class of compounds composed of linked amino acids that contain carbon, hydrogen, nitrogen, oxygen, and sometimes other atoms in specific configurations.

Randomization: Also called random allocation. Is allocation of individuals to groups, e.g., for experimental and control regimens, by chance. Within the limits of chance variation, random allocation should make the control and experimental groups similar at the start of an investigation and ensure that personal judgment and prejudices of the investigator do not influence allocation.

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Randomized clinical trial (RCT): An epidemiologic experiment in which subjects in a population are randomly allocated into groups, usually called study and control groups, to receive or not to receive an experimental prevention or therapeutic product, maneuver, or intervention. The results are assessed by rigorous comparison of rates of disease, death recovery, or other appropriate outcome in the study and control groups, respectively. RCTs are generally regarded as the most scientifically rigorous method of hypothesis testing available in epidemiology.

Recessive gene: A gene that is phenotypically expressed only when homozygous.

Refractory obesity: Obesity that is resistant to treatment.

Relative risk: The ratio of the incidence rate of a disease among individuals exposed to a specific risk factor to the incidence rate among unexposed individuals; synonymous with risk ratio. Alternatively, the ratio of the cumulative incidence rate in the exposed to the cumulative incidence rate in the unexposed (cumulative incidence ratio). The term relative risk has also been used synonymously with odds ratio. This is because the odds ratio and relative risk approach each other if the disease is rare (<5 percent of population) and the number of subjects is large.

Resting metabolic rate (RMR): RMR accounts for 65 to 75 percent of daily energy expenditure and represents the minimum energy needed to maintain all physiological cell functions in the resting state. The principal determinant of RMR is lean body mass (LBM). Obese subjects have a higher RMR in absolute terms than lean individuals, an equivalent RMR when corrected for LBM and per unit surface area, and a lower RMR when expressed per kilogram of body weight. Obese persons require more energy for any given activity because of a larger mass, but they tend to be more sedentary than lean subjects.

Risk: The probability that an event will occur. Also, a nontechnical term encompassing a variety of measures of the probability of a generally unfavorable outcome.

Roux-en Y bypass: See gastric exclusion; the most common gastric bypass procedure.

Saturated fat: A type of fat found in greatest amounts in foods from animals, such as fatty cuts of meat, poultry with the skin, whole-milk dairy products, lard, and in some vegetable oils, including coconut, palm kernel, and palm oils. Saturated fat raises blood cholesterol more than anything else eaten. On a Step I Diet, no more than 8 to 10 percent of total calories should come from saturated fat, and in the Step II Diet, less than 7 percent of the day's total calories should come from saturated fat.

Secular trends: A relatively long-term trend in a community or country.

Serotonin: A monoamine vasoconstrictor, found in various animals from coelenterates to vertebrates, in bacteria, and in many plants. In humans, it is synthesized in the intestinal chromaffin cells or in the central or peripheral neurons and is found in high concentrations in many body tissues, including the intestinal mucosa, pineal body, and central nervous system. Produced enzymatically from tryptophan by hydroxylation and decarboxylation, serotonin has many physiologic properties (e.g., inhibits gastric secretion, stimulates smooth muscle, serves as central neurotransmitter, and is a precursor of melatonin).

Sibutramine: A drug used for the management of obesity that helps reduce food intake and is indicated for weight loss and maintenance of weight loss when used in conjunction with a reduced-calorie diet. It works to suppress the appetite primarily by inhibiting the reuptake of the neurotransmitters norepinephrine and serotonin. Side effects include dry mouth, headache,

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constipation, insomnia, and a slight increase in average blood pressure. In some patients it causes a higher blood pressure increase.

Sleep apnea: A serious, potentially life-threatening breathing disorder characterized by repeated cessation of breathing due to either collapse of the upper airway during sleep or absence of respiratory effort.

Social pressure: A strategy used in behavior therapy in which individuals are told that they possess the basic self-control ability to lose weight, but that coming to group meetings will strengthen their abilities. The group is asked to listen and give advice, similar to the way many self-help groups, based on social support, operate.

Stoma size: The size of a new opening created surgically between two body structures.

Stress incontinence: An involuntary loss of urine that occurs at the same time that internal abdominal pressure is increased, such as with laughing, sneezing, coughing, or physical activity.

Stress management: A set of techniques used to help an individual cope more effectively with difficult situations in order to feel better emotionally, improve behavioral skills, and often to enhance feelings of control. Stress management may include relaxation exercises, assertiveness training, cognitive restructuring, time management, and social support. It can be delivered either on a one-to-one basis or in a group format.

Stroke: Sudden loss of function of part of the brain because of loss of blood flow. Stroke may be caused by a clot (thrombosis) or rupture (hemorrhage) of a blood vessel to the brain.

Submaximal heart rate test: Used to determine the systematic use of physical activity. The submaximal work levels allow work to be increased in small increments until cardiac manifestations such as angina pain appear. This provides a more precise manipulation of workload and gives a reliable and quantitative index of a person's functional impairment if heart disease is detected.

Surgical procedures: See jejuno-ileostomy, gastroplasty, gastric bypass, gastric partitioning, gastric exclusion, Roux-en Y bypass and gastric bubble.

Systolic blood pressure: The maximum pressure in the artery produced as the heart contracts and blood begins to flow.

Triglyceride: A lipid carried through the bloodstream to tissues. Most of the body's fat tissue is in the form of triglycerides, stored for use as energy. Triglycerides are obtained primarily from fat in foods.

Type 2 diabetes mellitus: Usually characterized by a gradual onset with minimal or no symptoms of metabolic disturbance and no requirement for exogenous insulin. The peak age of onset is 50 to 60 years. Obesity and possibly a genetic factor are usually present.

Validity: The degree to which the inferences drawn from study results, especially generalization extending beyond the study sample, are warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn.

Vertical banded gastroplasty: A surgical treatment for extreme obesity; an operation on the stomach that involves constructing a small pouch in the stomach that empties through a narrow opening into the distal stomach and duodenum.

Very low-calorie diet (VLCD): The VLCD of 800 (approximately 6-10 kcal/kg body weight) or fewer calories per day is conducted under physician supervision and monitoring and is restricted to severely obese persons.

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Very low-density lipoprotein (VLDL): The lipoprotein particles that initially leave the liver, carrying cholesterol and lipid. VLDLs contain 10 to 15 percent of the total serum cholesterol along with most of the triglycerides in the fasting serum; VLDLs are precursors of LDL, and some forms of VLDL, particularly VLDL remnants, appear to be atherogenic.

Visceral fat: One of the three compartments of abdominal fat. Retroperitoneal and subcutaneous are the other two compartments.

VO_2 max: Maximal oxygen uptake is known as VO_2 max and is the maximal capacity for oxygen consumption by the body during maximal exertion. It is used as an indicator of cardiorespiratory fitness.

Waist circumference: To define the level at which the waist circumference is measured, a bony landmark is first located and marked. The subject stands, and the technician, positioned to the right of the subject, palpates the upper hip bone to locate the right ileum. Just above the uppermost lateral border of the right ileum, a horizontal mark is drawn and then crossed with a vertical mark on the midaxillary line. The measuring tape is then placed around the trunk, at the level of the mark on the right side, making sure that it is on a level horizontal plane on all sides. The tape is then tightened slightly without compressing the skin and underlying subcutaneous tissues. The measure is recorded in centimeters to the nearest millimeter.

Waist-hip-ratio (WHR): The ratio of a person's waist circumference to hip circumference. WHR looks at the relationship between the differences in the measurements of waist and hips. Most people store body fat in two distinct ways, often called the "apple" and "pear" shapes, either the middle (apple) or the hips (pear). For most people, carrying extra weight around their middle increases health risks more than carrying extra weight around their hips or thighs. Overall obesity, however, is still of greater risk than body fat storage locations or WHR. A WHR ≥ 1.0 is in the danger zone, with risks of heart disease and other ailments connected with being overweight. For men, a ratio of .90 or less is considered safe, and for women .80 or less.

Yohimbine: An alkaloid that possesses adrenergic-blocking properties and is used in arteriosclerosis and angina pectoris, formerly used as a local anesthetic and mydriatic and for its purported aphrodisiac properties.

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List of Abbreviations

AAFP	American Academy of Family Physicians
ADA	American Diabetes Association
AHCPR	Agency for Health Care Policy and Research
AHI	Apnea and Hypopnea Index
ATP II	Second Report of the Expert Panel on the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II)
BED	Binge Eating Disorder
BMI*	Body Mass Index
BN	Bulimia Nervosa
CAD	Coronary Artery Disease
CARDIA	Coronary Artery Risk Development in Young Adults
CDC	Centers for Disease Control and Prevention
CHD*	Coronary Heart Disease
CHF	Congestive Heart Failure
CPAP	Continuous Positive Airway Pressure
CRSS	Critical Review Status Sheet
CT*	Computed Tomography
CVD	Cardiovascular Disease
DEXA*	Dual-Energy X-ray Absorpiometry
DNA	Deoxyribonucleic Acid
FDA	Food and Drug Administration
HDL*	High-Density Lipoprotein
HHANES	Hispanic Health and Nutrition Examination Survey
HMO	Health Maintenance Organization
IGT	Impaired Glucose Tolerance
INDEX trial	International Dexfenfluramine Study
INTERSALT	International study of SALT
IOM	Institute of Medicine
JNC VI	Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
LCD*	Low-Calorie Diets
LDL*	Low-Density Lipoprotein
MEDLINE	MEDLARS (Medical Literature Analysis and Retrieval System) On-Line
MeSH	Medical Subject Headings
MMPI	Minnesota Multiphasic Personality Inventory
MRI*	Magnetic Resonance Imaging
NAASO	North American Association for the Study of Obesity

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NCEP	National Cholesterol Education Program
NCHS	National Center for Health Statistics (CDC)
NHANES*	National Health and Nutrition Examination Survey
NHBPEP	National High Blood Pressure Education Program
NHES	National Health Examination Survey
NHIS	National Health Interview Survey
NHLBI	National Heart, Lung, and Blood Institute
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
NLM	National Library of Medicine
RCTs*	Randomized Controlled Trials
RDI	Respiratory Disturbance Index
SOS	Swedish Obesity Study
SSRIs	Selective Serotonin Reuptake Inhibitors
TAIM	Trial of Antihypertensive Interventions and Management
TOHP I	Trials of Hypertension Prevention (Phase 1)
TOHP II	Trials of Hypertension Prevention (Phase 2)
TONE	Trial of Nonpharmacologic Interventions in the Elderly
VLCD*	Very Low-Calorie Diets
VLDL*	Very Low-Density Lipoprotein
VO_2max*	Oxygen Consumption
WHR*	Waist-to-Hip Ratio

*Terms defined in the glossary.

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Publication List

Reports and Materials on Cardiovascular Health from the National Heart, Lung, and Blood Institute

Unless otherwise noted, contact the NHLBI Information Center for the price and availability of the publications listed below:

NHLBI Information Center
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Obesity and Physical Activity

Strategy Development Workshop for Public Education on Weight and Obesity--Summary Report. Summary of a 1992 workshop held to identify issues in educating the public, identifying priority audiences, approaches, and communications channels for weight and physical activity. *Available at http: //www.nhlbi.nih.gov/nhlbi/cardio/obes/prof/obeshc.htm*

Methods for Voluntary Weight Loss and Control (National Institutes of Health Technology Assessment Conference). An edited summary of a 1992 NIH Technology Assessment Conference on American weight loss practices, success of methods of weight loss and control, short- and long-term benefits and adverse effects of weight loss, principles for selecting a weight loss and control strategy, and future directions for research. *Available at http://text.nlm.nih.gov/nih/ta/www/10.html*

[Full proceedings available in Danford, D., Fletcher, S.W. Methods for Voluntary Weight Loss and Control, National Institutes of Health Technology Assessment Conference. Annals of Internal Medicine Supplement, 119(7pt2)641-770(1993).]

NIH Consensus Development Conference on Physical Activity and Cardiovascular Health. An edited summary of a 1995 NIH Consensus Development Conference which examined the accumulating evidence on the role of physical activity in the prevention and treatment of cardiovascular disease and its risk factors. *Available at http: //odp.od.nih.gov/consensus/ statements/cdc/intros/physact_intro.html*

[Full proceedings available from Leon, A. (ed.) Physical Activity and Cardiovascular Health: A National Consensus. Human Kinetics:1995.]

High Blood Pressure

The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNCVI). Provides guidance for primary care clinicians on the prevention, detection, treatment, and control of high blood pressure. Lifestyle modification and pharmacotherapy are discussed. Treatment algorithms and patient handouts are included.

Working Group Report on Hypertension in Diabetes. Guides clinicians in the care of persons with hypertension and diabetes. Addresses epidemiological, diagnostic, clinical consideration, and special concerns, such as kidney disease, sexual dysfunction, obesity, and pregnancy.

Working Group Report on Hypertension in the Elderly. Assists clinicians in their care of elderly patients with high blood pressure and health care professionals in hypertension control programs that serve the elderly. Presents the prevalence and epidemiology, benefits of antihypertensive therapy, detection and evaluation, therapy, and management considerations for the fastest growing special population in the United States.

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Controlling High Blood Pressure in Older Women: Clinical Reference Manual. Assists clinicians in the care of older patients with high blood pressure, especially women. Presents the benefits of anithypertensive therapy, detection, evaluation, and treatment strategies. Includes charts to help clinicians improve patient adherence to therapy and select antihypertensive drug therapy.

High Blood Cholesterol

Second Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP II). Provides guidelines for detecting, evaluating, and treating high blood cholesterol in adult patients. Discusses classification of blood cholesterol, patient evaluation, and dietary and drug treatment. Includes helpful tools for the clinician including a dietary questionnaire, menus, and patient handouts.

Cholesterol Lowering in the Patient with Coronary Heart Disease: Physician Monograph. Reviews the scientific evidence that cholesterol lowering in patients with coronary heart disease produces dramatic benefits. Provides guidance on implementing dietary and drug treatment and improving patient adherence to lowering cholesterol in the patient with coronary heart disease.

Enhance your Patient Education with NHLBI Materials

Obesity and Physical Activity

Check Your Weight and Heart Disease I.Q. A true/false quiz that helps the public determine what they know about weight and heart disease. Correct answers are explained on the back of the quiz sheet.

Check Your Physical Activity and Heart Disease I.Q. Uncovers exercise myths and provides information on ways to improve heart health through physical activity.

Exercise and Your Heart: A Guide to Physical Activity. Provides your patients with information on the effects of physical activity on their heart, and practical guidelines for starting and staying on their own exercise program. The benefits, risks, and common myths about exercise are discussed, and tips and sample activity programs are included.

High Blood Pressure

High Blood Pressure: Treat It For Life. Helps patients take action against high blood pressure, by losing weight if overweight, increasing physical activity, choosing foods lower in salt and sodium, limiting alcohol, and taking medication as prescribed. Includes information for women taking birth control pills, older persons, African Americans, and people with diabetes or high blood cholesterol. A sample walking program, menu ideas, and recipes are included.

Eat Right to Help Lower Your High Blood Pressure. Presents practical information in an easy to read (5th grade level) conversational text brochure presented in large type with colorful illustrations. Helps patients reduce high blood pressure by losing weight, being more active, drinking less alcohol, and using less salt and sodium.

Facts About The DASH Diet. Describes the eating plan from the "Dietary Approaches to Stop Hypertension" (DASH) study, which was shown to lower blood pressure. The diet is rich in fruits, vegetables, and lowfat dairy products, and lower in saturated fat, total fat, and cholesterol. A full week's menu, recipes, and helpful tips are included.

Controlling High Blood Pressure: A Woman's Guide. Explains how high blood pressure affects women's health and tells the simple steps used to prevent and control high blood pressure, as well as the types of medication used to treat the condition. A table of generic names of blood pressure medications and a chart for recording blood pressure readings are given.

High Blood Cholesterol

So You Have High Blood Cholesterol. Gives patients the information on what they need to know about and what they need to do to lower their high blood cholesterol level. Diet, physical activity, weight loss strategies, and medications are discussed. Case studies highlight stategies for action.

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Step by Step: Eating To Lower Your High Blood Cholesterol. Advises patients on how to make diet and lifestyle changes to lower their high blood cholesterol levels. Explains the Step I and Step II diets and gives practical tips for buying and preparing foods, eating out, increasing physical activity and selecting a weight loss program. Sample menus at two calorie levels and nutrient content tables of a wide variety of foods are included.

Eat Right to Lower Your High Blood Cholesterol. Provides practical information on dietary changes to high blood cholesterol in an easy-to-read (5th grade) conversation style. Includes shopping and cooking tips, sample menu and snack suggestions, and a tear-off shopping guide.

Live Healthier, Live Longer: Lowering Cholesterol for the Person With Heart Disease. Gives the patient with coronary heart disease information on how to lower high blood cholesterol through diet, physical activity and weight control to prevent future heart attacks and improve the quality of life. Practical information included on choosing foods lower in saturated fat, total fat, and cholesterol.

Multiple Risk Factors

Healthy Heart Handbook for Women. Tells women (both with and without heart disease) how to take action to make their hearts healthier. Topics include how to talk to the doctor, blood pressure and blood cholesterol, physical activity, weight loss, hormone replacement therapy, heart attack symptoms, and heart-healthy eating.

Package of Eight Easy-To-Read Booklets in Spanish and English on Preventing Heart Disease. Written especially for Latino families, these booklets include: Watch Your Weight, Stay Active and Feel Better, Cut Down on Fat--Not Taste, Take Steps--Prevent High Blood Pressure, Cut Down on Salt and Sodium, Learn Your Cholesterol Number, Protect Your Heart--Lower Your Blood Cholesterol, and Kick the Smoking Habit.

Delicious Heart-Healthy Latino Recipes (bilingual). Provides 23 traditional Latino recipes lower in calories, fat, saturated fat, cholesterol, and sodium.

Improving Cardiovascular Health in African Americans--Package of Seven Easy-To-Read Booklets. Written especially for African Americans, these booklets include: Lose Weight If You Are Overweight--Embrace Good Health, Stay Physically Active--Energize Yourself, Prevent High Blood Pressure--Protect Your Heart, Eat Less Salt and Sodium--Spice Up Your Life, Learn Your Cholesterol Number--Empower Yourself, Eat Foods Lower in Saturated Fat and Cholesterol--Be Heart Smart, Stop Smoking--Refresh Yourself.

Heart-Healthy Home Cooking--African American Style. Provides 20 favorite African American recipes lower in calories, fat, saturated fat, cholesterol, and sodium.

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U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Public Health Service
National Institutes of Health
National Heart, Lung, and Blood Institute

NIH Publication No. 98-4083
September 1998

EXHIBIT 24

NON-PROFIT

Applicant:

Financial Worksheet (A)

Please provide one year of actual results and three years of projections of **Total Entity** revenue, expense and volume statistics without, incremental to and with the CON proposal in the following reporting format:

LINE	Total Entity: Description	(1) FY14 Actual Results	(2) FY16 Projected W/out CON	(3) FY16 Projected Incremental	(4) FY16 Projected With CON	(5) FY17 Projected W/out CON	(6) FY17 Projected Incremental	(7) FY17 Projected With CON	(8) FY18 Projected W/out CON	(9) FY18 Projected Incremental	(10) FY18 Projected With CON	(11) FY19 Projected W/out CON	(12) FY19 Projected Incremental	(13) FY19 Projected With CON
A.	**OPERATING REVENUE**													
1	Total Gross Patient Revenue	$701,705,462	$731,122,624	$ 4,912,149	**$736,034,773**	$747,632,886	$ 4,948,868	**$752,581,754**	$767,951,019	$ 5,115,932	**$773,066,951**	$792,316,091	$ 5,177,577	**$797,493,668**
2	Less: Allowances	$394,788,265	$435,386,060	$0	**$435,386,060**	$441,848,601	$0	**$441,848,601**	$452,555,857	$0	**$452,555,857**	$465,267,039	$0	**$465,267,039**
3	Less: Charity Care	$5,263,975	$4,598,489	$0	**$4,598,489**	$4,722,041	$0	**$4,722,041**	$4,858,096	$0	**$4,858,096**	$5,007,362	$0	**$5,007,362**
4	Less: Other Deductions	$0	$0	$0	**$0**	$0	$0	**$0**	$0	$0	**$0**	$0	$0	**$0**
	Net Patient Service Revenue	**$301,653,222**	**$291,138,075**	**$4,912,149**	**$296,050,224**	**$301,062,244**	**$4,948,868**	**$306,011,112**	**$310,537,066**	**$5,115,932**	**$315,652,998**	**$322,041,689**	**$5,177,577**	**$327,219,266**
5	Medicare	$288,445,183	$302,832,158	$2,468,542	**$305,300,700**	$308,949,741	$2,486,995	**$311,436,736**	$317,063,295	$2,570,951	**$319,634,246**	$327,301,001	$2,601,930	**$329,902,931**
6	Medicaid	$141,904,568	$151,379,026	$561,032	**$151,940,058**	$154,989,666	$565,226	**$155,554,892**	$159,277,105	$584,307	**$159,861,412**	$164,283,071	$591,348	**$164,874,418**
7	CHAMPUS & TriCare	$11,079,023	$10,459,864	$0	**$10,459,864**	$10,722,453	$0	**$10,722,453**	$11,024,196	$0	**$11,024,196**	$11,367,447	$0	**$11,367,447**
8	Other	$4,069,609	$4,670,826	$37,402	**$4,708,228**	$4,757,209	$37,682	**$4,794,891**	$4,879,008	$38,954	**$4,917,962**	$5,038,523	$39,423	**$5,077,947**
	Total Government	**$445,498,383**	**$469,341,874**	**$3,066,976**	**$472,408,851**	**$479,419,069**	**$3,089,902**	**$482,508,971**	**$492,243,605**	**$3,194,211**	**$495,437,816**	**$507,990,043**	**$3,232,700**	**$511,222,743**
9	Commercial Insurers	$235,544,515	$240,070,451	$1,795,303	**$241,865,754**	$245,906,159	$1,808,723	**$247,714,882**	$252,751,523	$1,869,782	**$254,621,305**	$260,668,285	$1,892,312	**$262,560,597**
10	Uninsured	$0	$0	$0	**$0**	$0	$0	**$0**	$0	$0	**$0**	$0	$0	**$0**
11	Self Pay *(part of uninsured)*	$13,017,856	$12,356,868	$49,870	**$12,406,738**	$12,673,626	$50,242	**$12,723,868**	$13,032,837	$51,938	**$13,084,775**	$13,437,018	$52,564	**$13,489,582**
12	Workers Compensation	$7,644,708	$9,353,430	$0	**$9,353,430**	$9,634,033	$0	**$9,634,033**	$9,923,054	$0	**$9,923,054**	$10,220,746	$0	**$10,220,746**
13	Other	$0	$0	$0	**$0**	$0	$0	**$0**	$0	$0	**$0**	$0	$0	**$0**
	Total Non-Government	**$256,207,079**	**$261,780,749**	**$1,845,173**	**$263,625,922**	**$268,213,817**	**$1,858,966**	**$270,072,783**	**$275,707,414**	**$1,921,721**	**$277,629,135**	**$284,326,048**	**$1,944,877**	**$286,270,925**
	Net Patient Service Revenue[a] (Government+Non-Government)	**$701,705,462**	**$731,122,624**	**$4,912,149**	**$736,034,773**	**$747,632,886**	**$4,948,868**	**$752,581,754**	**$767,951,019**	**$5,115,932**	**$773,066,951**	**$792,316,091**	**$5,177,577**	**$797,493,668**
14	Less: Provision for Bad Debts	$8,035,283	$8,719,355	$196,486	**$8,915,841**	$8,953,625	$197,955	**$9,151,580**	$9,211,605	$204,637	**$9,416,242**	$9,494,633	$207,103	**$9,701,736**
	Net Patient Service Revenue less provision for bad debts	**$293,617,939**	**$282,418,720**	**$4,715,663**	**$287,134,383**	**$292,108,619**	**$4,750,913**	**$296,859,532**	**$301,325,461**	**$4,911,295**	**$306,236,756**	**$312,547,057**	**$4,970,474**	**$317,517,531**
15	Other Operating Revenue	$6,760,427	$9,552,257	$0	**$9,552,257**	$10,916,599	$0	**$10,916,599**	$11,023,423	$0	**$11,023,423**	$11,132,446	$0	**$11,132,446**
17	Net Assets Released from Restrictions	$287,246	$503,858	$0	**$503,858**	$521,493	$0	**$521,493**	$539,745	$0	**$539,745**	$558,636	$0	**$558,636**
	TOTAL OPERATING REVENUE	**$300,665,612**	**$292,474,835**	**$4,715,663**	**$297,190,498**	**$303,546,711**	**$4,750,913**	**$308,297,624**	**$312,888,629**	**$4,911,295**	**$317,799,924**	**$324,238,138**	**$4,970,474**	**$329,208,612**
B.	**OPERATING EXPENSES**													
1	Salaries and Wages	$110,166,889	$110,277,491	$1,535,674	**$111,813,165**	$114,137,203	$1,577,551	**$115,714,754**	$118,132,005	$1,623,809	**$119,755,814**	$122,266,625	$1,668,778	**$123,935,403**
2	Fringe Benefits	$21,447,489	$28,446,379	$42,965	**$28,489,344**	$29,940,616	$44,116	**$29,984,732**	$31,384,241	$45,299	**$31,429,540**	$32,879,512	$46,513	**$32,926,025**
3	Physicians Fees	$2,624,355	$2,668,969	$202,176	**$2,871,145**	$2,714,342	$204,048	**$2,918,390**	$2,760,485	$210,600	**$2,971,085**	$2,807,414	$213,408	**$3,020,822**
4	Supplies and Drugs	$39,451,269	$38,678,142	$1,003,020	**$39,681,162**	$39,794,984	$1,036,938	**$40,831,922**	$41,130,248	$1,100,936	**$42,231,184**	$42,546,532	$1,145,298	**$43,691,830**
5	Depreciation and Amortization	$15,651,354	$16,911,938	$424,940	**$17,336,878**	$14,839,633	$454,633	**$15,294,266**	$12,922,486	$485,329	**$13,407,815**	$12,865,481	$516,394	**$13,381,875**
6	Provision for Bad Debts-Other[b]	$0	$0	$0	**$0**	$0	$0	**$0**	$0	$0	**$0**	$0	$0	**$0**
7	Interest Expense	$2,992,001	$3,359,894	$0	**$3,359,894**	$3,326,712	$0	**$3,326,712**	$3,290,093	$0	**$3,290,093**	$3,249,152	$0	**$3,249,152**
8	Malpractice Insurance Cost	$1,363,097	$4,223,000	$0	**$4,223,000**	$4,349,690	$0	**$4,349,690**	$4,480,181	$0	**$4,480,181**	$4,614,586	$0	**$4,614,586**
9	Lease Expense	$1,609,189	$2,133,666	$0	**$2,133,666**	$2,169,938	$0	**$2,169,938**	$2,206,827	$0	**$2,206,827**	$2,244,343	$0	**$2,244,343**
10	Other Operating Expenses	$56,722,518	$53,127,531	$1,862,251	**$54,989,782**	$54,056,123	$1,891,444	**$55,947,567**	$54,999,599	$2,005,023	**$57,004,622**	$55,966,620	$2,085,840	**$58,052,460**
	TOTAL OPERATING EXPENSES	**$252,028,161**	**$259,827,010**	**$5,071,026**	**$264,898,036**	**$265,329,241**	**$5,208,730**	**$270,537,970**	**$271,306,166**	**$5,470,996**	**$276,777,162**	**$279,440,265**	**$5,676,231**	**$285,116,496**
	INCOME/(LOSS) FROM OPERATIONS	**$48,637,451**	**$32,647,825**	**($355,363)**	**$32,292,462**	**$38,217,470**	**($457,817)**	**$37,759,653**	**$41,582,462**	**($559,701)**	**$41,022,761**	**$44,797,873**	**($705,757)**	**$44,092,116**
	NON-OPERATING REVENUE	**$8,462,200**	**$8,100,000**	**$0**	**$8,100,000**	**$8,100,000**	**$0**	**$8,100,000**	**$8,100,000**	**$0**	**$8,100,000**	**$8,100,000**	**$0**	**$8,100,000**
	EXCESS/(DEFICIENCY) OF REVENUE OVER EXPENSES	**$57,099,651**	**$40,747,825**	**($355,363)**	**$40,392,462**	**$46,317,470**	**($457,817)**	**$45,859,653**	**$49,682,462**	**($559,701)**	**$49,122,761**	**$52,897,873**	**($705,757)**	**$52,192,116**
	Principal Payments	**$2,433,472**	$356,000	$0	**$356,000**	$387,000	$0	**$387,000**	$422,000	$0	**$422,000**	$461,000	$0	**$461,000**
C.	**PROFITABILITY SUMMARY**													
1	Hospital Operating Margin	**15.7%**	**10.9%**	**-7.5%**	**10.6%**	**12.3%**	**-9.6%**	**11.9%**	**13.0%**	**-11.4%**	**12.6%**	**13.5%**	**-14.2%**	**13.1%**
2	Hospital Non Operating Margin	**2.7%**	**2.7%**	**0.0%**	**2.7%**	**2.6%**	**0.0%**	**2.6%**	**2.5%**	**0.0%**	**2.5%**	**2.4%**	**0.0%**	**2.4%**
3	Hospital Total Margin	**18.5%**	**13.6%**	**-7.5%**	**13.2%**	**14.9%**	**-9.6%**	**14.5%**	**15.5%**	**-11.4%**	**15.1%**	**15.9%**	**-14.2%**	**15.5%**
D.	**FTEs**	**1,457**	1,439	2	**1,441**	1,439	2	**1,441**	1,439	2	**1,441**	1,439	2	**1,441**
E.	**VOLUME STATISTICS[c]**													
1	Inpatient Discharges	10,690	11,005	146	**11,151**	10,788	147	**10,935**	10,706	152	**10,858**	10,756	154	**10,910**
2	Outpatient Visits	413,579	416,474	70	**416,544**	428,968	71	**429,039**	441,837	73	**441,910**	455,092	74	**455,166**
	TOTAL VOLUME	**424,269**	**427,479**	**216**	**427,695**	**439,756**	**218**	**439,974**	**452,543**	**225**	**452,768**	**465,848**	**228**	**466,076**

[a]Total amount should equal the total amount on cell line "Net Patient Revenue" Row 14.

[b]Provide the amount of any transaction associated with Bad Debts not related to the provision of direct services to patients. For additional information, refer to FASB, No.2011-07, July 2011.

[c]Provide projected inpatient and/or outpatient statistics for any new services and provide actual and projected inpatient and/or outpatient statistics for any existing services which will change due to the proposal.

EXHIBIT 25

QUOTATION 1 AutoCAT 2 WAVE IABP

TO: **WILLIAM BACKUS HOSPITAL**
11 Murphy Road
North Franklin, CT 06254
Attn: Becky Durhan
Email: rebecca.durham@hhchealth.org

ARROW INTERNATIONAL

16 Elizabeth Drive
Chelmsford, MA 01824
978-250-5100
Toll-free: 800-343-3297
24-hr. Customer Support:
800-447-6961
Fax: 978-250-5105

OFFER VALID THROUGH OCTOBER 31, 2015

Quotation No:	JB090315	1 AUTOCAT 2 WAVE® IABP	
Date:	09/03/2015	Terr. :	John Bowman
Delivery Info:	30 Days ARO	Terms:	Net 30 Days FOB Shipping Point Freight Prepaid & Added to Invoice

Item #	Qty	Catalog #	Product Description	Unit Price	Extended Price
1	1	IAP-0500	**AutoCAT 2 WAVE®** Intra-Aortic Balloon Pump System with FiberOptix capability; Portable Modular System for in-hospital and transport use. Each system includes AutoPilot™ operational mode, WAVE® timing algorithm, a removable high resolution color LCD with operation keypad, interface communication cables. Display unit, dual channel multi-parameter strip chart recorder with one (1) box of chart paper (10 rolls), 5-lead ECG cable and cable for interfacing to remote monitors and arterial pressure. Pre-amplifier with cables for interfacing to remote monitors. Configuration also includes operator's manual, four (4) disposable helium tanks, accessory bag, dual hanger IV pole, initial on-site clinical in-service training, and one (1) year service warranty.	$84,000.00	
			Arrow Cardiac Care, a division of Teleflex, is pleased to provide one (1) AutoCAT 2 WAVE® Intra-Aortic Balloon Pump System to William Backus Hospital at the special Premier contract #PP-CA-246 Tier 1 price of $45,855 at a 10% discount for a net price of $41,269.50 each. This special pricing is valid for the first 12 months of the Premier contract #PP-CA-246 effective until 10/31/2015.		**$41,269.50**
			Please note that this special pricing includes all cash discounts and trade-in allowances.		
2	1	IAA-01003	AutoCAT 2 WAVE® Accessory Bag	$200.00	**NO CHARGE**
3	1	IAA-00175	Dual Hanger IV Pole	$500.00	**NO CHARGE**
			If you have any questions, please contact your local Teleflex representative, John Bowman 484-793-1761. Please send any Purchase Orders to John at John.Bowman@teleflex.com and Diane Crowley at Diane.Crowley@teleflex.com.		
				TOTAL	**$41,269.50**

1. All orders are subject to acceptance in writing by Arrow International, Everett MA
2. IMPORTANT-NOTE TERMS AND CONDITIONS ARE ATTACHED.
3. One (1) full year service warranty included on equipment.

For Teleflex

Quotation Accepted and Approved Date Purchase Order

TELEFLEX TERMS AND CONDITIONS OF SALE

Teleflex Medical Incorporated, a California Corporation with its principal place of business at 3015 Carrington Mill Blvd, Morrisville, North Carolina and Arrow International, Inc., with offices located at 2400 Bernville Road, Reading, Pennsylvania ("Arrow") ("Teleflex Medical Incorporated" and "Arrow" individually or collectively referred to herein as "Teleflex"). All entities purchasing products from Teleflex are referred to herein as "Buyer"

1. Contract. These terms and conditions will apply to all sales of products by Teleflex to Buyer(s). Teleflex's acceptance of Buyer's purchase order is expressly limited to the terms and conditions contained herein and any provisions of Buyer's purchase order which are consistent with the terms and conditions contained herein. Any and all other terms and conditions proposed by Buyer are objected to and rejected by Teleflex. Acceptance of products from Teleflex by Buyer shall be deemed to be an acceptance of these terms and conditions. Notwithstanding the foregoing, if at the time of Buyer's purchase of products there is in effect a supply, or purchasing, or distributorship agreement between Teleflex and Buyer, any of these terms and conditions which are inconsistent with the provisions of such supply or purchasing agreement shall be ineffective and the terms of the supply or purchasing agreement shall control.

2. Purchasing Account Acceptance. Buyer must establish a valid purchasing account with Teleflex prior to purchase order acceptance. If Buyer seeks open credit terms with Teleflex, Buyer must provide all requested information included in Teleflex's credit application. Teleflex is not responsible, nor offers any remedy to Buyer, for delays in order fulfillment due to Buyer delay in providing incomplete or incorrect information on their submitted credit application. Any change to Buyer purchasing account information, or addition of shipping facility locations, must be submitted in writing prior to Teleflex implementation of this change for subsequent purchase orders placed.

3. Payment Terms. Except as otherwise specified to Buyer, the terms of payment for each order of Buyer shall be net thirty (30) days from date of invoice. In the event of nonpayment of an invoice, all collection fees and/or legal fees incurred by Teleflex will be added to the balance owed on the account, as permitted by law.

4. Methods of Payment. Teleflex accepts payment via open credit terms (if extended by Teleflex, pursuant to section 8 of these Terms), or payment in advance with a cleared company check or pre-authorized credit card. Teleflex accepts Visa, MasterCard and American Express (excluding Arrow International, Inc., orders) credit cards.

5. Purchase Order Acceptance: Teleflex accepts Buyer purchase orders via telephone, fax, email and EDI. EDI connections must be requested in writing and accepted linkage made prior to acceptance of Buyer purchase orders via EDI. Purchase orders are recognized and order placement confirmed by Teleflex within 24 hours of the receipt of Buyer purchase order.

6. Purchase Order Cancellations. Teleflex allows Buyer the ability to cancel all or part of their purchase order, excluding any products already in the process of delivery, and products made to order, customized, or repaired for Buyer. All purchase order cancellation requests must be communicated to, and confirmed by Teleflex, prior to being accepted as cancelled. Teleflex offers no Remedy to Buyer for purchase order discrepancies caused by requested order cancellations that do not comply with provisions for order cancellation contained herein.

7. Shipping. Products will be shipped as FOB Origin, with risk of loss or damage passing to the Buyer at Teleflex's shipping point. Teleflex shall not fill orders with requested shipment directly to patients, any residential address, and any temporary or mobile site (hotel, construction site, storage unit, etc). All shipment locations must have Buyer staff on hand to accept and sign for delivered product during normal business hours. All applicable shipping charges are the responsibility of Buyer and will be prepaid by Teleflex and invoiced to Buyer or paid directly by Buyer.

7 a. Standard Freight Terms. Teleflex shall ship products via preferred standard ground service carriers, with charges prepaid and invoiced. When Buyer is paying freight, Buyer can select their preferred carrier and method of service.
Buyer is responsible for all applicable freight charges, including but not limited to, any special level of service, handling, packaging or freight charges, other than standard ground service, as requested by Buyer. These can include liftgate service, inside

delivery, special packaging requirements, special delivery appointments, etc.

7 b. Third Party Freight Payment. Buyers participating in a third party freight program can have applicable freight charges billed to their preferred third party freight collect account. Requests to change freight billing for a Buyer to a managed third party freight program must be provided in writing to Teleflex by Buyer, or the Third Party Managed Freight Program acting as the Buyer's Proxy, no later than five (5) business days prior to expectation of implementation of this service to Buyer. As part of this written request, Buyer, or Buyer's Proxy, must provide third party freight collect account number(s) to Teleflex, per facility to be added to this program, including any other special instructions needed to ensure compliance to Buyer's program. Teleflex shall not be liable for any disputed freight charged incorrectly, if the Buyer does not comply with provisions herein.

7c. Expedited Orders Expedited orders are only processed at the specific request of the Buyer, and when Buyer is specifically requesting at the time of ordering. Buyers request for expedited orders must include the exact level of service needed for the delivery (Next day, Second day, Saturday delivery, early AM, etc.) and a location with valid address that the Carrier can deliver to. Expedited orders are not eligible for free freight of any type, and Buyer is responsible for all freight charges either prepaid and added to the invoice, or through provision of a third party collect account number. Teleflex is not liable for the reliability or outcome of expedite requests, nor will offer Buyer any remedy, due to Carrier error, Carrier delay, Acts of God, and/or any other situations outlined in section 8 of these terms contained herein.

7d Other: Shipment of products is subject to availability of Teleflex's inventory. Products are shipped within five (5) to seven (7) business days once a Purchase Order is received. Teleflex reserves the right to fill orders with one or more shipments. Notification of short shipments and other shipping discrepancies must be reported to Teleflex Customer Service within seven (7) business days of signed receipt of order. Upon receipt of shipment, all products should be unpacked and inspected and any damage noted on the freight bill and reported to the carrier. Shipping requirements for Authorized Distributors are according to the Agreements with the Authorized Distributors.

8. Force Majeure. Teleflex shall not be responsible nor liable, to Buyer for any failure to perform its obligations to Buyer as a result of any strikes, work stoppages or labor unrest, earthquakes, fires, floods, storms or other natural disasters, shortages of materials or supplies or availability of goods or inventory, acts of war, terrorism, crimes, unrest or violence, shipping or other transportation delays or restraints, acts, laws, rules or regulations of any governmental or legal authority, or any other cause or circumstance beyond Teleflex's reasonable control.

9. Taxes. Any sales, use or excise taxes or other charges or levies which Teleflex is required to pay or collect under any applicable law, ordinance, rule or regulation (domestic or foreign), upon or with respect to the sale, shipping, delivery, storage or use of the products purchased by Buyer, shall be for the account of Buyer and Buyer agrees to pay the amount thereof to Teleflex, as invoiced or upon request.

10. Product Warranty. Teleflex warrants that its products sold to Buyer pursuant hereto, other than products which have been reconditioned or repaired for Buyer, will be free from defects in workmanship and materials from their date of shipment until (i) their expiration date, if they have an expiration date, or (ii) one (1) year after the date of original purchase, if they do not have an expiration date, provided they are not used in any application or manner not specified or recommended by Teleflex **in their Instructions For Use** or otherwise misused or abused. Teleflex makes no warranty whatsoever with respect to reprocessed or repaired products. Teleflex's sole liability and obligation to Buyer in the event of a breach of the foregoing warranty shall be to replace the defective product or products or, in its discretion, to provide a credit in the amount of the purchase price thereof.
EXCEPT AS EXPRESSLY SET FORTH HEREIN, TELEFLEX NEITHER MAKES, NOR SHALL HAVE ANY LIABILITY UNDER, ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR AN INTENDED USE OR PURPOSE. NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, MADE BY ANY REPRESENTATIVE, AGENT OR EMPLOYEE OF TELEFLEX WHICH IS NOT SPECIFICALLY SET FORTH HEREIN SHALL BE BINDING UPON TELEFLEX.
All claims for breach of the foregoing express warranty shall be made by Buyer (and no other party) in writing within thirty (30) days after discovery of the defect. The claim shall include a returned goods authorization number which may be obtained from Teleflex prior to assertion of the claim. In addition, the

claim must be accompanied by the return of the defective product or products to the destination specified by Teleflex within 60 days of Buyer's written claim. Any claim not made in compliance herewith shall be deemed to have been waived. Products for which a warranty claim is validly made under this Section 10 hereof shall be returned as specified in this Section 10 and Teleflex's Return Goods Policy .

11. LIMITATION OF LIABILITY. IN NO EVENT SHALL TELEFLEX BE LIABLE TO BUYER WITH RESPECT TO ANY SALES OF PRODUCTS, WHETHER UNDER THEORIES OF CONTRACT, TORT, INDEMNITY, PRODUCT LIABILITY, STRICT LIABILITY OR OTHERWISE, FOR ANY LOST PROFITS OR SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR EXEMPLARY DAMAGES, EVEN IF TELEFLEX HAS BEEN APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING.

12. Product Returns. Products shipped to Buyer may be returned within sixty (60) days of shipment for replacement or credit in the amount of the purchase price, as allowed in Teleflex's Return Goods Policy outlined in Exhibit A.

13. Minimum Order Requirement: Teleflex requires Buyer to meet the minimum order requirement of One Hundred dollars ($100.00) per Purchase Order. Teleflex at its sole discretion may charge a fee of Twenty Dollars ($20.00) to the Buyer for each Purchase Order less than One Hundred Dollars ($100.00). The minimum order requirement for Authorized Distributors shall be per Agreement with the Authorized Distributors.

14. Product Recalls. If any products shipped to and held by Buyer are or become subject to a recall mandated by the United States Food and Drug Administration (FDA), Buyer shall notify Teleflex immediately of possession of affected product, request a return authorization, and promptly return the affected product to the address designated by Teleflex. Teleflex will replace affected product with comparable products not subject to recall, or provide a credit in the amount of Buyer's original purchase price.

15. Adequate Assurance/Suspension of Orders. Teleflex may, at any time or times, suspend performance of any order to Buyer or require payment in cash, security or other adequate assurance satisfactory to Teleflex when, in Teleflex's opinion, the financial condition of Buyer or other grounds for insecurity warrant such action.

16. Assignment. Buyer shall not assign its rights nor delegate its duties with respect to any purchase order for Teleflex's products and/or its agreement with Teleflex without the prior written consent of Teleflex. Any such actual or attempted assignment without Teleflex's prior written consent shall entitle Teleflex to cancel all outstanding orders upon notice to Buyer.

17. Governing Law. These terms and conditions and the agreement between Teleflex and Buyer shall in all respects be governed by, and the parties respective rights and obligations enforced under, the laws of the Commonwealth of Pennsylvania without giving effect to the conflict of laws principles thereof.

18. Confidential Information. Certain information disclosed by Teleflex during the course of business dealings with Buyer may be confidential and proprietary information ("Confidential Information"). Confidential Information shall include all information not previously known to Buyer or not generally known or readily ascertainable and from which Buyer may obtain a business benefit or advantage. If Buyer questions whether any information is regarded as confidential, Buyer agrees to treat the information as Confidential Information until and unless Teleflex confirms in writing that it is not confidential. Absent express written consent to the contrary and until the Confidential Information becomes publicly known or otherwise legally available in some manner, other than as a result of a breach of this Agreement, Buyer will not use, disclose, transfer, duplicate, or reproduce Confidential Information in any form other than as necessary in the performance of this Agreement. Notwithstanding the provisions of this paragraph, Buyer party may disclose Confidential Information as required by a court order or other lawful process; provided that it notifies Teleflex of any such order or process promptly and shall attempt in good faith to allow Teleflex to contest such order or process. Teleflex may require Buyer to return all copies of documents containing Confidential Information. Buyer shall be liable Teleflex for any damages Teleflex may suffer if the Confidential Information is disclosed without Teleflex's authorization, whether such disclosure is due to negligence, intentional misconduct or any other reason.

19. Insurance. Teleflex will provide evidence of coverage upon request.

EXHIBIT A

TELEFEX MEDICAL INCORPORATED AND ARROW INTERNATIONAL INC.,
RETURN GOODS POLICY

A Return Goods Authorization (RGA) number must be received from Teleflex Medical Domestic Customer Service (866-246-6990) and (800-523-8446) for Arrow International Inc. Domestic Customer Service prior to returning any products. International customers may send their information by facsimile to 919-361-4111. Requests for return authorizations must be received by telephone, mail, email or facsimile within sixty (60) calendar days of invoice date and must include:

- Invoice number
- Purchase Order number
- Date of purchase
- Product number
- Quantity of items to be returned
- Lot or serial number
- Reason for return

All authorized return shipments must be shipped freight prepaid. Upon issuance of the RGA number, the customer will be advised as to which Distribution Center to ship the product. Goods returned without an RGA number will not be accepted or credited. Teleflex Medical will not accept any authorized return shipments after sixty (60) calendar days of the RGA issue date.

Acceptable Returns and Credit Schedule
Reason for Return
Defective product Invoiced price
Teleflex Medical shipping error Invoiced price
Teleflex Medical order error Invoiced price
Customer order error Invoiced price less 30%
Refused shipment (not Teleflex Medical error) Invoiced price less 30%
Customer stock reduction Invoiced price less 30%
Unacceptable Returns
Merchandise damaged in shipment. The carrier is responsible and should be contacted by the customer.
Custom or special order products.
Products not in the original packaging or in less than sales unit quantity.
Product not in saleable condition.
Obsolete or discontinued product.
Private labeled products.
Reusable goods over 60 days from invoice date
Sterile products
At the sole discretion of Teleflex Medical any return shipments that do not comply with the above policy may be refused and returned to the sender at their expense.

Customer Summary

PHILIPS

Reference #: 1-1B5BV8T	Rev: 1	Effective From:	To:

Presented To:
WILLIAM W BACKUS HOSPITAL
326 WASHINGTON ST
NORWICH, CT 06360-2714

Tel:

Alternate Address:

Presented By:
Michael Bousa
Account Manager
Tel: (603) 635-0470
Fax: (603) 589-1255

Regional Manager
Tel:
Fax:

Date Printed: 03-Sep-15

Submit Orders To:
22100 BOTHELL EVERETT HWY
BOTHELL WA 98021
Tel:
Fax:(425) 458-0390

The Service information contained in this Quote is subject to a separate service proposal.

The Lease Information contained in this Quote is subject to a separate leasing proposal.

Field Instructions:
1. This summary is not an approved quotation
2. This summary cannot be used for Order Entry purposes.
3. This summary contains confidential and proprietary information of Philips Healthcare, a division of Philips Electronics North America Corporation ("Philips") and is intended for use only by the customer whose name appears on this summary. It may not be disclosed to third parties without the prior written consent of Philips.
4. If this potential solution is agreeable to the parties, then Philips will issue a quotation for Customer to sign.

FOR INFORMATION PURPOSES ONLY
THIS IS A SUMMARY SHEET NOT A QUOTE

IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law including but not limited to 42 CFR 1001.952(h).

Line #	Product	Qty	Price
	100222 Upgrades CV	1	$79,555.00
		Equipment Total:	$79,555.00

Product	Qty	Each	Monthly	Price
100222 Upgrades CV	1	$79,555.00		$79,555.00
60 Month Equipment + Service Lease Fair Market Value	60		$1,579.80	

The Lease Information contained in this Quote is subject to a separate leasing proposal. If the trade-in equipment is leased with Philips Medical Capital, then the monthly payment does not apply.

Buying Group: **GNYHA** **Contract #:** **GNYHA-IM-016**

FOR INFORMATION PURPOSES ONLY
THIS IS A SUMMARY SHEET NOT A QUOTE

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Quote Summary

100222 Upgrade Quote Sample

Qty	Product
1	NCVB878 Interventional Tools Hardware
1	**NCVA567 StentBoost sw Rel. 2.0**
1	**NCVA086 Rotational Scan**
1	**NCVB209 Xper Swing**
1	**NCVA785 Coronary Quant.Sw pkg(Xper)**

FOR INFORMATION PURPOSES ONLY
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System Type: Upgrade
Freight Terms: FOB Destination
Warranty Terms: Part numbers beginning with two (2) asterisks (**) are covered by a ninety (90) day product warranty. All other part numbers are third (3rd) party items.
Special Notations: Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date. Any rigging costs are the responsibility of the Purchaser.
Additional Terms:

Line #	Part #	Description	Qty
1	**NCVB878	**Interventional Tools Hardware**	1

The Interventional hardware is the hardware for the 3D interventional tools and enables import and viewing of DICOM compatible data from other imaging modalities.

The Interventional Hardware comprises at least:
- Computer Workstation
- CR 19" display
- 16 GB memory
- 2 TB disk for the operating system, application software and application data
- Internal CD-Rom / DVD writer
- Mouse tablet to interact with all the interventional tools at the table side.

Conditionally:
FD Calibration Tool Kit for 3D-RA

Line #	Part #	Description	Qty
2	**NCVA567	**StentBoost sw Rel. 2.0**	1

StentBoost is a unique interventional tool to improve visualization of stents in the coronary arteries during interventions. This, Philips exclusive, innovative interventional tool produces a highly augmented image of a deployed stent in coronary arteries - while the catheter is still in place. The StentBoost image helps clinicians to make a thorough check of stent expansion, and stent position of stents in relation to other objects, like other stents, without the use of extra contrast or other 'expensive' consumables. This allows interventional cardiologists to immediately take any corrective action required while your patient is still in the examination room.
The way it works
StentBoost automatically detects the stent delivery markers image after image. In each image StentBoost aligns the markers with the markers of the previous image. By doing this all radiopaque material in the close proximity of the markers will be enhanced and items further away from the markers will be less visible.
The result provides enhanced contrast of the environment surrounding the markers, including the stent, while background noise is reduced.
StentBoost Workflow

1. Image acquisition
StentBoost is based on a maximum of 40 frames out of a cine run. Depending on the frames speed this takes the user 2-3 seconds.

2. Image transfer
The run will automatically be transferred to the interventional workstation and show up in the StentBoost software.
The Real time link (NCVA590) is a unique option within the Allura Xper FD10 R.2 and Allura Xper FD10/10 and allows instant access to the StentBoost image.

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3. Region of Interest definition
The StentBoost software shows the acquired run with a predefined Region of interest. With the

region of interest user has to indicate where the markers of the stent delivery markers are located in the image run.

4. StentBoost
After definition of the region of interest, the user presses next and within seconds, the boosted image shows up on the screen.
A real time operation user interface is available with StentBoost, providing:

- Review of StentBoost runs, before and after processing
- Viewing tools like Brightness/Contrast, Pan and Zoom to optimize the image displayed
- Automatic stent delivery system marker identification
- Reliability feedback regarding the enhanced run
- Manual quality improvement; Manual correction possibility for marker identification
- View patient info like, Birth date, Gender, Patient ID, Exam ID, Exam date, Run date, Run time, Hospital name, Physician name, RAO/LAO
- Creation of exportable items:
  - movies (AVI format)
  - snapshots (jpeg format)
  - The step 5, 6 and 7 are not mandatory.

5. Calibration
To create a StentBoost image no calibration is needed. For the measurement support tool four calibration methods are included:

- No calibration
- Auto calibration based on calibration data generated by the Allura Xper system when the autocall function is installed (MCV5681),
- Marker distance of the stent delivery markers,
- Catheter calibration

6. "Measurement"
"Measurement" an option within the StentBoost package supports the clinician in his/her decision-making in determining the percentage of remaining stenosis in the stent.

7. Archiving
Transfer to

- Optional Hard copy unit (DICOM Print)
- Optional third party station (snapshots images in DICOM Secondary Capture format)
- Any computer via a web server functionality with images in a standard file format (JPEG, AVI movies)
- One or multiple DVD's, CD-ROM(s) for easy archiving
- Store a subset of exportable objects (snapshots and AVI Movies) to a USB removable memory device.

8. StentBoost release 2.0 comprises:

- StentBoost release 2.0 Software Package
- User manual on compact disc

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Line #	Part #	Description	Qty

- Software release bulletin
- DICOM Conformance Statement
- StentBoost IQ verification Phantom

9. Compatible with:

- Allura Xper FD10 R 1.x
- Allura Xper FD20
- Allura Xper FD10 R. 2
- Allura Xper FD10/10

10. Pre-requisite for StentBoost R 2.0:

- Interventional Hardware (NCVA106)

3 **NCVA086 **Rotational Scan** 1

Rotational Scan provides real-time 3D impressions of complex vasculature and the coronary artery tree. It acquires multiple projections with just one contrast injection.

Rotational Scan can be used during screening procedures to quickly determine the optimal projection for the study as the angle (rotation/angulation) of the projection is indicated on each image.

Compared with traditional angiography Rotational Scan can save considerable time dose and contrast while providing image detail required for diagnostic and therapeutic decisions.

Rotational Scan is possiblewith the Allura Xper systems in the side position (ceiling mounted systems) and in the head position which provides the flexibility to perform procedures virtually from head to toe.

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With Allura Xper FD20

C-arm in side position:

- Max. rotation speed: 30°
- Max. rotation angle: 180°

C-arm in head position:

- Max. rotation Speed: 55°
- Max. rotation Angle: 305°

With Allura Xper FD10:

Poly G in side position (ceiling version):

- Max. rotation Speed: 30°
- Max. rotation Angle: 90°

Poly G in head position:

1421

Line #	Part #	Description	Qty

- Max. rotation Speed: 55°
- Max. rotation Angle: 240°

Maximum speeds are given by the framespeed specifications of the system configuration.

The speed and range of rotation are the highest available (see table). The very high speed allows using less contrast whereas the very wide rotation range provides a complete evaluation of the anatomy.

The stand is designed forvery high mechanical stability. It offers precise positioning and high reproducibility assuring you of high quality images and excellentstudies.

Operation of Rotational Scan is extremely easy. The procedure is selected set up and executed virtually within a matter of seconds supporting the highest patient throughput. A set of dedicated acquisition programs is available on the Xper Module and can be selected at the touch of a button. The rotation endand start positions are easily selected. The procedure is controlled from theexposure hand

- or foot-switch.

4 **NCVB209 Xper Swing 1

XperSwing allows dual-axis rotational coronary angiography to gather more information in less time and with less X-ray and contrast dose. XperSwing acquires simultaneous RAO/LAO cranial-caudal views in just one acquisition run by moving the C-arm in a curved trajectory instead of multiple acquisitions. XperSwing can be used during screening procedures to quickly determine the optimal projection for the study as the angle (rotation/angulation) of the projection is indicated on each image, providing image detail required for diagnostic and therapeutic decisions and to obtain a real-time 3D impression of the coronary artery tree.

In total seven pre-programmed trajectories are available:
• Three for Left coronary imaging
• Two for Right Coronary imaging,
• Two generic trajectories.
The choice depends on size and weight of the patient. These trajectories are designed to fully cover all conventional projections for a diagnostic coronary angiography. Rotation and angulation movements are combined in one complete scan trajectory, using the maximum rotation and angulation speed of the Allura system. (55 resp 30 degr/sec). XperSwing is possible in the side position (ceiling mounted systems) and in the head position

XperSwing functionality includes, but is not limited to

• 15 frames per seconds acquisition to allows using of less contrast.
• Wide rotation range provides a complete evaluation of the anatomy.
• Precise positioning and high reproducibility, assuring you of high quality images and excellent subtraction studies.
• Set up and executed in a matter of seconds.
• Set of dedicated acquisition programs with the trajectories available on the Xper Module
• The rotation end- and start-positions can be selected.
• Acquisition procedure is controlled from the exposure hand or footswitch.

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5 **NCVA785 Coronary Quant.Sw pkg(Xper) 1

1422

Line #	Part #	Description	Qty

Functions:

- diameter measurement along the selected segment
- cross sectional area
- %-stenosis
- pressure gradient values
- stenotic flow reserve
- calibration routines

In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.

Comprising:

- software license

Compatible with:
. Allura Xper FD 10 Rel 3 and FD10/10 Rel 2 onwards
. Allura Xper FD20 Rel 2, FD20/10 Rel 2 onwards

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1424

PHILIPS PRODUCT WARRANTY

CARDIOVASCULAR (CV) SYSTEMS

This product warranty document is an addition to the terms and conditions set forth in the quotation to which this warranty document is attached. The terms and conditions of the quotation are incorporated into this warranty document. The capitalized terms herein have the same meaning as set forth in the quotation.

TWELVE-MONTH SYSTEM WARRANTY
Philips warrants to Customer that the Philips Vascular and Cardiac Systems (the "System") as delivered to Customer will perform in substantial compliance with its performance specifications for a period of twelve (12) months upon first patient use. Any glassware or flat detectors provided with the System is subject to special warranty terms set forth below.

PLANNED MAINTENANCE
During the warranty period, Philips personnel will schedule planned maintenance visits, in advance, at a mutually agreeable time on weekdays, between 8:00 A.M. and 5:00 P.M. local time, excluding Philips observed holidays.

SYSTEM UPGRADES
Any commercially available upgrade to the System which is hereafter installed by Philips during the original term of the System warranty shall be subject to the warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire on the later of: a) upon termination of the initial twelve (12) month warranty period for the System on which the upgrade is installed or b) after ninety (90) days for parts only from the date of installation.

MRC X-RAY TUBES
Philips warrants to Customer, for the warranty periods further specified in this section, that the Philips X-Ray tube will be substantially free from defects in material and manufacturing workmanship, which impair performance under normal use as specified in Philips product descriptions and specifications.

The warranty period for MRC tubes provided with Customer's purchase of a new or refurbished X-ray system shall be the shorter of thirty-six (36) months after installation or thirty-eight (38) months after date of shipment from Philips. The warranty period for purchases of replacement tubes shall be the shorter of twelve (12) months after installation or fourteen (14) months after date of shipment from Philips.

MRC TUBE WARRANTY EXCLUSION
The above warranty shall not apply to X-ray tubes outside the United States and Canada. Philips' obligations under the product warranty do not apply to any product defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the product; or, to viruses or similar software interference resulting from the connection of the product to a network.

MRC TUBE WARRANTY REMEDIES
If a tube is found to fail during the warranty period, and if, in the best judgment of Philips, the failure is not due to neglect, accident, improper installation, use contrary to instructions, or the exclusions stated above, Philips' tube warranty liability hereunder is limited to, at Philips option, the repair or replacement of the tube. Any replacement tube would have a warranty period equal to the balance of the warranty period left on the tube replaced.

IMAGE INTENSIFIER TUBES
Philips warrants the image intensifier tubes provided with the System, if any, will be free from defects in material and manufacturing workmanship for twenty-four (24) months. Claims must be made within twenty-four (24) months after installation or twenty-seven (27) months after date of shipment from Philips, whichever occurs first. If an image intensifier tube fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the tube, Philips will provide a prorated credit towards the purchase of a replacement tube from Philips as follows:

USAGE				CREDIT
0	to within	12	months	100%
12	to within	13	months	50%
13	to within	14	months	46%
14	to within	15	months	42%
15	to within	16	months	37%
16	to within	17	months	33%
17	to within	18	months	29%
18	to within	19	months	25%
19	to within	20	months	21%
20	to within	21	months	17%
21	to within	22	months	12%
22	to within	23	months	8%
23	to within	24	months	4%

Tubes received by Philips under this warranty that are found to meet all test specifications will be returned to the Customer and the warranty will continue as to the original date of installation. Examination of the returned tube may necessitate its destruction, but Philips' liability shall, in any case, be limited to repair or replacement as aforesaid, only if in its sole opinion the tube has been properly used, installed and applied and has not been subjected to neglect, accident, improper installation or use. Transportation charges and risk of loss, both ways, of returned or replaced tubes shall be at the expense of the Customer.

DYNAMIC FLAT DETECTORS
Philips warrants the flat detectors provided with the System will be free from defects in material and manufacturing workmanship for twelve (12) months. Claims must be made within twelve (12) months after installation or fifteen (15) months after date of shipment from Philips, whichever occurs first. If a detector fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the detector, Philips will provide Customer a replacement detector at no additional charge.

SYSTEM SOFTWARE AND SOFTWARE UPDATES
The software provided with the System will be the latest version of the standard software available for that System as of the 90th day prior to the date the System is delivered to Customer. Updates to standard software for the System that do not require additional hardware or equipment modifications will be performed as a part of normal warranty service during the term of the warranty.

All software is and shall remain the sole property of Philips or its software suppliers. Use of the software is subject to the terms of a separate software license agreement. Customer must sign all such license agreements prior to or upon the delivery of the product. No license or other right is granted to Customer or to any other party to use the software except as set forth in the license agreements.

Any Philips maintenance or service software and documentation provided with the product and/or located at Customer's premises is intended solely to assist Philips and its authorized agents to install and to test the System, to assist Philips and its authorized agents to maintain and to service the System under a separate support agreement with Customer, or to permit Customer to maintain and service the System. Customer agrees to restrict the access to such software and documentation to Philips' employees and those of its authorized agents, and to authorized employees of Customer only.

WARRANTY LIMITATIONS
Philips' obligations under the System warranty are limited, at Philips' option, to the repair or the replacement of the System or a portion thereof, or to a credit or refund of a portion of the purchase price paid by Customer. Any refund or credit will be paid to Customer when the System is returned to Philips. Certain of the parts used in the manufacture or installation of, or in the replacement parts for, this System may contain refurbished components. If such components are used, they will be subject to the same quality control and inspection procedures as all other components in the System. Any System warranty is made on condition that Philips receives written notice of a System defect during the warranty period, and within thirty (30) days following the discovery of the defect by Customer. Philips' obligations under the System warranty do not apply to any System defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the System; or to viruses or similar software interference resulting from the connection of the product to a network. Philips does not provide a warranty for any such third party products furnished to Customer by Philips; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips described above are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a System warranty. Repairs or replacement parts do not extend the term of this warranty.

FOR INFORMATION PURPOSES ONLY
THIS IS A SUMMARY SHEET NOT A QUOTE

THE WARRANTIES SET FORTH IN THIS WARRANTY DOCUMENT WITH RESPECT TO THE SYSTEM (INCLUDING THE SOFTWARE PROVIDED WITH THE SYSTEM), GLASSWARE, AND DETECTORS ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE SYSTEM, SOFTWARE, GLASSWARE, DETECTORS, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ACCESS TO SYSTEM
Philips shall have full, free and safe access to the System and Customer's operation, performance and maintenance records for the System, on each scheduled or requested warranty service visit. Philips shall also have access to and use of any machine, service, attachment, features or other equipment required to perform the necessary service contemplated herein at no charge to Philips. Customer waives warranty service if it does not provide such access to the System and Customer's records. Should Philips be denied access to the System and Customer's records at the agreed upon time, a charge equal to the appropriate hourly rate will be accepted by Customer for "waiting time."

WARRANTY SERVICE
In the event it is not possible to accomplish warranty service within normal working hours (8:00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips observed holidays), or in the event Customer specifically requests that warranty service be performed outside of Philips normal working hours, Customer agrees to pay for such services at Philips standard service rates in effect. Maintenance Agreements are available for extended coverage.

TRANSFER OF SYSTEM
In the event Customer transfers or relocates the System, all obligations under this warranty will terminate unless Customer receives the prior written consent of Philips for the transfer or relocation. Upon any transfer or relocation, the System must be inspected and certified by Philips as being free from all defects in material, software and workmanship and as being in compliance with all technical and performance specifications. Customer will compensate Philips for these services at the prevailing service rates in effect as of the date the inspection is performed. Any System which is transported intact to pre-approved locations and is maintained as originally installed in mobile configurations will remain covered by this warranty.

CONDITIONS
This warranty is subject to the following conditions: the System (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips), (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips written instructions and for the purpose for which the products were intended, (c) is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the System, and (d) Customer is to notify Philips immediately in the event the System at any time fails to meet its printed performance specifications.

LIMITATIONS OF LIABILITY AND DISCLAIMERS
The liability, if any, of Philips AND ITS AFFILIATES for damages whether arising from breach of the terms in the quotation, breach of warranty, negligence, indemnity, strict liability or other tort, or otherwise with respect to the products and services is limited to an amount not to exceed the price of the product or service giving rise to the liability.

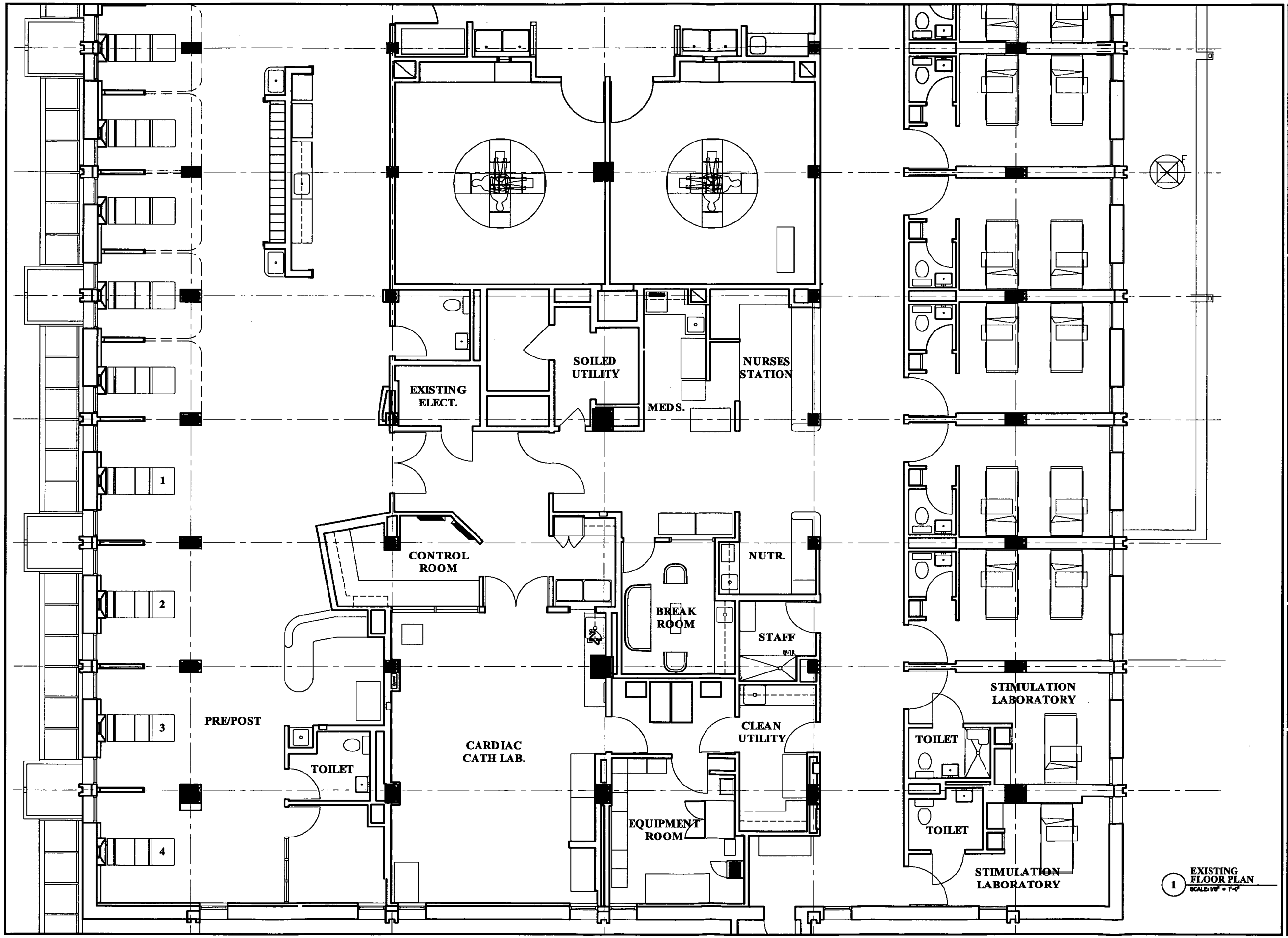
IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF THE TERMS IN THIS QUOTATION, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT. PHILIPS SHALL HAVE NO LIABILITY FOR ANY GRATUITOUS ADVICE PROVIDED TO THE CUSTOMER.

FORCE MAJEURE
Philips and Customer shall each be excused from performing its obligations arising from any delay or default caused by events beyond its reasonable control including, but not limited to: acts of God, acts of third parties, acts of the other party, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities.

Philips system specifications are subject to change without notice Document Number 4535 983 03234 999

FOR INFORMATION PURPOSES ONLY
THIS IS A SUMMARY SHEET NOT A QUOTE

EXHIBIT 26



1 EXISTING FLOOR PLAN
SCALE: 1/8" = 1'-0"

PROGRESS DRAWING
NOT FOR CONSTRUCTION
September 28, 2015

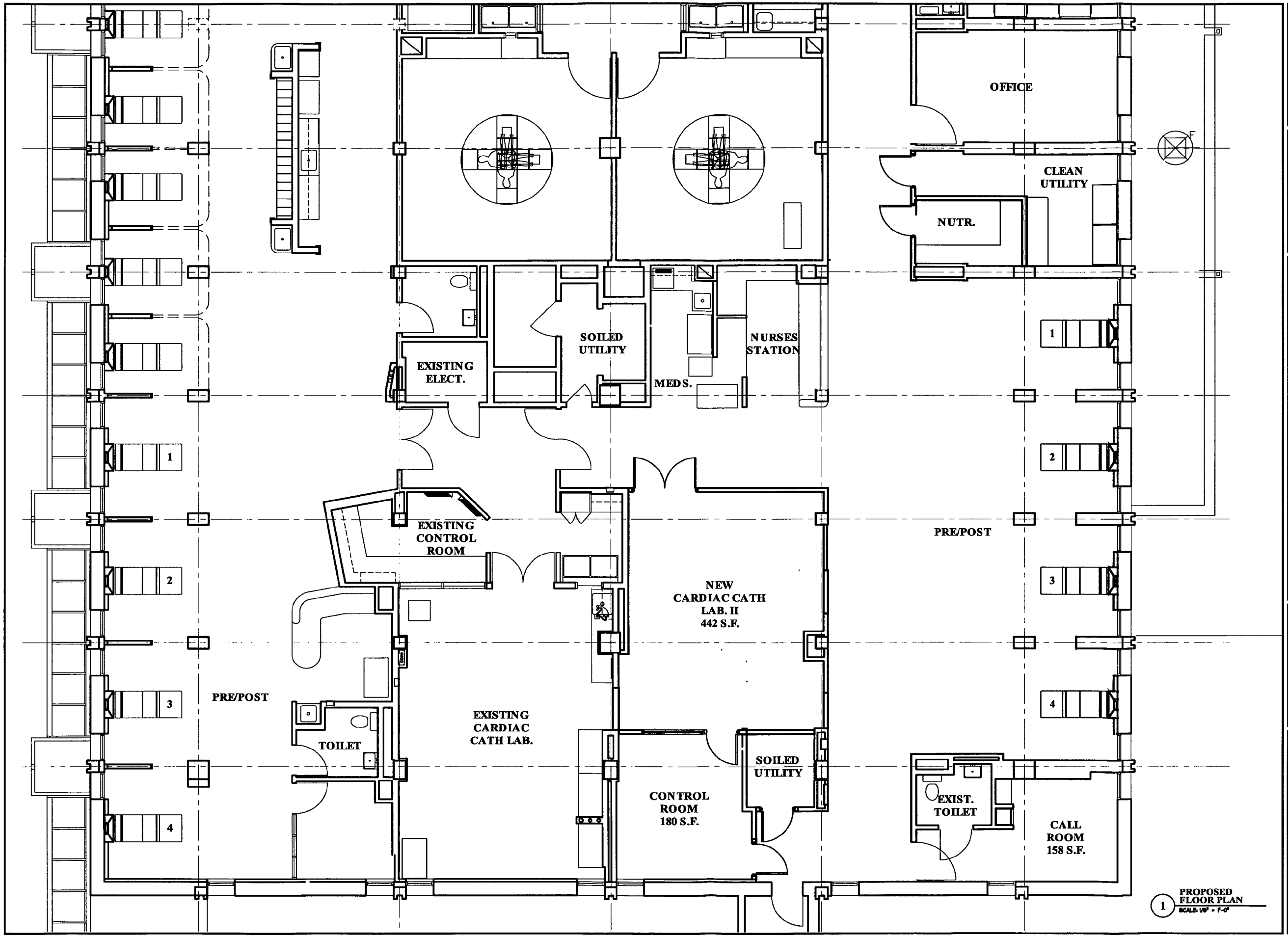
THE WILLIAM W. BACKUS HOSPITAL
RENOVATION TO:
CARDIAC CATH LAB II
NORWICH, CT

JACUNSKI HUMES ARCHITECTS, LLC
15 MASSIRIO DRIVE
SUITE 101
BERLIN, CT 06037
TEL 860-828-9231
FAX 860-828-9233

EXISTING FLOOR PLAN

PROJ. NO. J-1124
DRAWING NO. *E-1*
SCALE 1/8" = 1'-0"
DATE

1428



1 PROPOSED FLOOR PLAN
SCALE: 1/8" = 1'-0"

PROGRESS DRAWING
NOT FOR CONSTRUCTION
September 28, 2015

THE WILLIAM W. BACKUS HOSPITAL
RENOVATION TO:
CARDIAC CATH LAB II
NORWICH, CT

JACUNSKI HUMES ARCHITECTS, LLC
15 MASSIRIO DRIVE
SUITE 101
BERLIN, CT 06037
TEL 860-828-0231
FAX 860-828-0232

PROPOSED FLOOR PLAN

PROJ. NO. J1584
SCALE: 1/8" = 1'-0"
DATE:
DRAWING NO. A-1

EXHIBIT 27

U. S. TREASURY DEPARTMENT
INTERNAL REVENUE SERVICE
WASHINGTON 25, D. C.

Vault

IN REPLY REFER TO
T:E:E:4
VCJ

JAN 6 1960

Hartford Hospital
Hartford 15, Connecticut

Gentlemen:

This refers to your letter of November 13, 1959 in which you state that you received a ruling from this office dated August 11, 1953, exempting you from Federal income tax under the provisions of section 101(6) of the Internal Revenue Code. This ruling also had the effect of affirming prior rulings dated August 28, 1934, September 19, 1938 and January 27, 1941. You are now requesting that your status be brought up to date to conform with the 1954 Code, section 501(c)(3).

Treasury Regulations prescribed under the Internal Revenue Code of 1954 provide at section 1.501(a)-1(a)(2), as amended by Treasury Decision 6391, published June 26, 1959, for situations such as yours and read, in part, as follows:

> "Subject only to the Commissioner's inherent power to revoke rulings because of a change in the law or regulations or for other good cause, an organization that has been determined by the Commissioner or the district director to be exempt under section 501(a) or the corresponding provision of prior law may rely upon such determination so long as there are no substantial changes in the organization's character, purposes, or methods of operation. An organization which has been determined to be exempt under the provisions of the Internal Revenue Code of 1939 or prior law is not required to secure a new determination of exemption merely because of the enactment of the Internal Revenue Code of 1954 unless affected by substantive changes in law made by such Code."

In view of the present Regulations you are not required to have your existing exempt status affirmed under the 1954 Code in the absence of basic changes in your organization and/or operations. If you prefer, as a matter of convenience, to have a current ruling on your

status it will be necessary for you to file a new exemption application, Form 1023, with your District Director at Hartford, Connecticut, together with all supporting documents required by the application, as well as a statement in some detail concerning your activities subsequent to 1953. Inasmuch as we have on file the copies of your charter and by-laws submitted with your prior application, further copies of these documents need not be furnished, but any amendments subsequent to July 1953 should be supplied. For your use in this connection, there are enclosed three copies of Form 1023, two executed copies of which may be filed and the third may be retained for your use.

A cursory examination of your charter shows that it does not specify that you are organized as a nonprofit charitable hospital, contains no provision requiring you to be operated to the extent of your financial ability for those not able to pay for the services rendered, and other requirements of Revenue Ruling 56-185, published in Internal Revenue Bulletin 1956-1, page 202, which establishes the criteria to be met in determining whether a hospital qualifies for exemption as an organization described in section 501(c)(3) of the 1954 Code. Further, your charter does not contain any provision impressing your assets with a trust by providing that in the event of dissolution your assets are required to be distributed for one or more of the purposes described in section 501(c)(3). In this connection your attention is invited to section 1.501(c)(3)-1(b)(6) of the Regulations which reads, in part, as follows:

> "Applicability of the organizational test. A determination by the Commissioner or a district director that an organization is described in section 501(c)(3) and exempt under section 501(a) will not be granted after July 26, 1959 (regardless of when the application is filed), unless such organization meets the organizational test prescribed by this paragraph. If, before July 27, 1959, an organization has been determined by the Commissioner or district director to be exempt as an organization described in section 501(c)(3) or in a corresponding provision of prior law and such determination has not been revoked before such date, the fact that such organization does not meet the organizational test prescribed by this paragraph shall not be a basis for revoking such determination. Accordingly, an organization which has been determined to be exempt before July 27, 1959, and which does not seek a new determination of exemption is not required to amend its articles of organiza-

tion to conform to the rules of this paragraph, but any organization which seeks a determination of exemption after July 26, 1959, must have articles of organization which meet the rules of this paragraph.
* * *"

This office is also in receipt of a communication, dated April 16, 1959, from Shipmen & Goodwin, Counselors at law, Hartford, Connecticut, submitting in your behalf a request for a ruling on certain proposed transaction contemplated by you with respect to their effect on your exempt status. You are advised that our reply to this request will be held in abeyance pending receipt of advice from you as to what further action you intend to take with regard to having your status affirmed under the Internal Revenue Code of 1954.

Your reply should also contain information concerning any implementing action which you may have taken subsequent to April 1959 with regard to the proposed transactions.

Your reply should be directed to the attention of T:R:EO:4-VCS.

Very truly yours,

E. F. Wadley

Chief, Exempt Organizations Branch

Enclosure:
Form 1023 (3)

IRS Department of the Treasury
Internal Revenue Service

OGDEN UT 84201-0038

In reply refer to: 0438189331
Apr. 08, 2014 LTR 4168C 0
06-0250773 000000 00
00032217
BODC: TE

WILLIAM W BACKUS HOSPITAL
% PAYROLL
326 WASHINGTON ST
NORWICH CT 06360-2740

25619

Employer Identification Number: 06-0250773
Person to Contact: Vincent B. Fronberg
Toll Free Telephone Number: 1-877-829-5500

Dear Taxpayer:

This is in response to your Mar. 28, 2014, request for information regarding your tax-exempt status.

Our records indicate that you were recognized as exempt under section 501(c)(3) of the Internal Revenue Code in a determination letter issued in Dec 1951.

Our records also indicate that you are not a private foundation within the meaning of section 509(a) of the Code because you are described in section(s) 509(a)(1) and 170(b)(1)(A)(iii).

Donors may deduct contributions to you as provided in section 170 of the Code. Bequests, legacies, devises, transfers, or gifts to you or for your use are deductible for Federal estate and gift tax purposes if they meet the applicable provisions of sections 2055, 2106, and 2522 of the Code.

Please refer to our website www.irs.gov/eo for information regarding filing requirements. Specifically, section 6033(j) of the Code provides that failure to file an annual information return for three consecutive years results in revocation of tax-exempt status as of the filing due date of the third return for organizations required to file. We will publish a list of organizations whose tax-exempt status was revoked under section 6033(j) of the Code on our website beginning in early 2011.

IRS Department of the Treasury
Internal Revenue Service

OGDEN UT 84201-0038

025619.283918.17094.3852 1 AB 0.406 536

WILLIAM W BACKUS HOSPITAL
% PAYROLL
326 WASHINGTON ST
NORWICH CT 06360-2740

025619

CUT OUT AND RETURN THE VOUCHER AT THE BOTTOM OF THIS PAGE IF YOU ARE MAKING A PAYMENT, EVEN IF YOU ALSO HAVE AN INQUIRY.

The IRS address must appear in the window.

0438189331

BODCD-TE

Use for payments

Letter Number: LTR4168C
Letter Date : 2014-04-08
Tax Period : 000000

060250773

WILLIAM W BACKUS HOSPITAL
% PAYROLL
326 WASHINGTON ST
NORWICH CT 06360-2740

INTERNAL REVENUE SERVICE

OGDEN UT 84201-0038

060250773 QJ WILL 00 2 000000 670 00000000000

U. S. TREASURY DEPARTMENT
WASHINGTON 25

OFFICE OF
COMMISSIONER OF INTERNAL REVENUE

ADDRESS REPLY TO
COMMISSIONER OF INTERNAL REVENUE
AND REFER TO

IT:P:ER-TUC

DEC 14 1951

The William W. Backus Hospital

Norwich, Connecticut

Gentlemen:

It is the opinion of this office, based upon the evidence presented, that you are exempt from Federal income tax under the provisions of section 101(6) of the Internal Revenue Code and corresponding provisions of prior revenue acts, as it is shown that you are organized and operated exclusively for charitable purposes.

Accordingly, you will not be required to file income tax returns unless you change the character of your organization, the purposes for which you were organized, or your method of operation. Any such changes should be reported immediately to the collector of internal revenue for your district in order that their effect upon your exempt status may be determined.

You will be required, however, to file an information return, Form 990A, annually, with the collector of internal revenue for your district so long as this exemption remains in effect. This form may be obtained from the collector and is required to be filed on or before the fifteenth day of the fifth month following the close of your annual accounting period.

Contributions made to you are deductible by the donors in computing their taxable net income in the manner and to the extent provided by section 23(o) and (q) of the Internal Revenue Code, as amended, and corresponding provisions of prior revenue acts.

Bequests, legacies, devises, or transfers, to or for your use are deductible in computing the value of the net estate of a decedent for estate tax purposes in the manner and to the extent provided by sections 812(d) and 861(a)(3) of the Code and corresponding provisions of prior revenue acts. Gifts of property to you are deductible in computing net gifts for gift tax purposes in the manner and to the extent provided in section 1004(a)(2)(B) and 1004(b)(2) and (3) of the Code and corresponding provisions of prior revenue acts.

Form 6978—Rev. Dec. 1950
(1491M-1)

1436

16—61990-2 GPO

In the event you have not filed a waiver of exemption certificate in accordance with the provisions of section 1426(1) of the Code, no liability is incurred by your organization for the taxes imposed under the Federal Insurance Contributions Act. Tax liability is not incurred by your organization under the Federal Unemployment Tax Act by virtue of the provisions of section 1607(c)(8) of such Act.

The collector of internal revenue for your district is being advised of this action.

Bureau ruling dated September 19, 1934, in which you were held exempt under the provisions of section 103(6) of the Revenue Act of 1932 and corresponding provisions of prior revenue acts and Bureau ruling dated April 27, 1938, which affirmed that ruling under the Revenue Act of 1936 are hereby affirmed.

By direction of the Commissioner.

Very truly yours,

Deputy Commissioner

Greer, Leslie

From: Mercier, Carlene M. <CMercier@brownrudnick.com>
Sent: Friday, October 09, 2015 1:53 PM
To: User, OHCA
Cc: Anthony, Robert J.; Janette.Edwards@hhchealth.org
Subject: Docket No. 15-32031 / Add'l Letters of Support
Attachments: Lt - OHCA re_ Add_l Letters of Support 10_9_15.PDF

Good Afternoon,

Attached for filing are additional Letters of Support in Docket No. 15-32031 (Hartford/Backus CON for Angioplasty). The original was mailed via first class mail today.

Please let me know if you have any questions.

Best Regards,
Carlene Mercier

BROWNRUDNICK

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

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****

BROWNRUDNICK

ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

185 Asylum
Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

October 9, 2015

VIA FIRST CLASS MAIL &
E-MAIL (ohca@ct.gov)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON – Supplemental Letters of Support

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital, enclosed please find two additional Letters of Support (from State Representative Rovero and the Voluntown Fire Department) for the Applicants' Certificate of Need Application to establish and operate a Primary and Elective Angioplasty Program at Backus Hospital. An electronic copy of this filing has been emailed to the Office of Health Care Access.

Please do not hesitate to contact me if you have any questions.

Very truly yours,

BROWN RUDNICK LLP

By: Robert J. Anthony/cm
Robert J. Anthony

Enclosure

62198643 v1-WorksiteUS-032836/0001

brownrudnick.com

OCT - 2 2015

State of Connecticut
HOUSE OF REPRESENTATIVES
STATE CAPITOL
HARTFORD, CONNECTICUT 06106-1591

REPRESENTATIVE DANNY ROVERO
51ST ASSEMBLY DISTRICT

LEGISLATIVE OFFICE BUILDING
ROOM 4004
HARTFORD, CT 06106-1591

HOME: 860-774-3792
CAPITOL: 860-240-8585
TOLL FREE: 800-842-8267
E-MAIL: Danny.Rovero@cga.ct.gov

VICE CHAIR
AGING COMMITTEE

MEMBER
BANKS COMMITTEE
GENERAL LAW COMMITTEE
PUBLIC SAFETY AND SECURITY COMMITTEE

September 30, 2015

David A. Whitehead
President
The William W. Backus Hospital
326 Washington Street Norwich, CT 06360

Dear Mr. Whitehead,

Please accept this letter of support for the development of a Primary and Elective Percutaneous Cardiac Intervention (PCI) program at The William W. Backus Hospital.

Although I am not a healthcare expert, I have experienced angioplasty firsthand and do know that timing is everything when it comes to a cardiac emergency. As state representative, I fully support your proposal, which would give residents in the communities I represent timely access to PCI.

Currently, residents in Killingly, Putnam, and Thompson do not have access to a PCI-capable facility within a 30-minute drive time. This lack of access should not exist-our families, friends, and neighbors should not be at a disadvantage when it comes to their health, just because of where they live.

Having this service available at Backus Hospital would improve quality of life, make our region a more attractive place to live and, most importantly, save lives.

Please accept this letter of support-Backus should be applauded for its commitment to offering Percutaneous Cardiac Intervention, close to home for patients.

Sincerely,

Daniel Rovero
State Representative

1439

Voluntown Fire Department

P.O. BOX 10, 205 PRESTON CITY ROAD
VOLUNTOWN, CT 06384
(860) 376-0475

OCT - 5 2015

SER 09L0010015

9/08/2015

Dave Whitehead
President
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

Dear Mr. Whitehead:

We are excited to support The William W. Backus Hospital and its proposal to build and operate a Percutaneous Coronary Intervention program in Norwich.

This investment is much needed. Although currently many of our residents and neighbors utilize Backus Hospital healthcare services, many cardiac emergency situations mean our volunteer ambulance company and other emergency personnel must transport patients suffering from life-threatening conditions out of our community to more distant facilities. This distance means one call can tie up an emergency vehicle and its EMS personnel for a significant amount of time. Since we are a small community resources are limited and the extended away time can be crucial.

Your proposal to provide Percutaneous Coronary Intervention would improve patient safety and make our EMS network much more efficient. It is a service that we lack in our community, and that our residents deserve to have. Our community is currently at a disadvantage without such a vital program. The proposal to add such a program is yet another example of Backus Hospital's commitment to improving healthcare in the communities in which it serves.

We support the project wholeheartedly, and look forward to the project's approval and completion.

Sincerely,

Jody Grenier

Greer, Leslie

From: Armah, Olga
Sent: Friday, October 30, 2015 3:38 PM
To: Janette.Edwards@hhchealth.org
Cc: User, OHCA; Riggott, Kaila; Schaeffer-Helmecki, Jessica; Fernandes, David; Armah, Olga
Subject: 15-32031 CON - Backus PCI Program

Dear Ms. Edwards:

On September 30, 2015, OHCA received the Certificate of Need application of The William W. Backus Hospital and Hartford Hospital to establish a primary and elective percutaneous coronary intervention (PCI) program at Backus Hospital. OHCA requests additional information pursuant to Connecticut General Statutes §19a-639a(c). *Please electronically confirm receipt of this email as soon as you receive it.* Provide responses to the questions below in both a Word document and PDF format as an attachment to a responding email, at your earliest convenience.

Repeat each question before providing your response and paginate and date your response, i.e., each page in its entirety. Information filed after the initial CON application submission (e.g., completeness response letter, prefile testimony, late file submissions and the like) must be numbered sequentially from the Applicant's document preceding it. Begin your submission using **Page 1438** and reference "**Docket Number: 15-32031-CON**."

1. Explain the reasoning for 24% growth rate in PCIs (page 69), given declining state and national PCI trends. OHCA Hospital Reporting System Report 450 data indicates a 12% decline in CT primary and elective PCIs. The SCAI/ACC/AHA Expert Consensus Document 2014 Update (Exhibit 1 of application) also indicates that nationally, PCI volumes have dropped 30% due to factors such as increased emphasis on use of other treatment modalities including medical therapy and improved preventions efforts.

2. Explain the clear public need for the proposed service when statewide PCI discharge volumes are declining.

3. To what percentage of the projected PCI patients associated with the proposal do the DPH Regulations on page 93 apply? Discuss in detail how the regulations apply to elective angioplasty patients and the relevance of a 30-minute drive time.

4. Using the service area defined in the table below, update FY 2015 numbers through the end of the fiscal year for the tables on pages 46, 62, 101 102, 103 and 104. If full year data is unavailable, update the 2015 numbers through the most recent month available and identify that month.

5. Explain the decreases in the number of diagnostic catheterizations and transfers reflected on Figure 20 on page 62.

   The table below shows inpatient PCI discharges from Backus Hospital's primary services area+ towns:

FY 2014 PCI Discharges from Backus Hospital Primary Service Area+

	PCI Hospital						
Primary Service Area Patient Towns	Yale	Hartford	L&M	St. Francis	John Dempsey	Central CT	**Total**
Canterbury	<6	<6					**<6**
Colchester	<6	12		<6			**14**
Griswold & Lisbon	14	<6		<6			**20**
Ledyard	<6		10	<6			**16**

Montville	22	<6	6				**31**
Norwich	39	14	<6	<6			**56**
Sprague		<6		<6			**<6**
Preston	<6	<6	<6				**6**
Plainville		<6		<6	7	6	**18**
PSA Total Inpatient PCIs	**86**	**39**	**19**	**8**	**7**	**6**	**165**
Total Inpatient PCIs	1,201	716	134	535	189	81	**2,856**
PSA % Share of Hospital Inpatient PCI	**7%**	**5%**	**14%**	**1%**	**4%**	**7%**	**6%**

Source: *CT DPH Office of Health Care Access Acute Care Hospital Inpatient Discharge Database*

*ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06, 36.07 & 36.09

Please note: unduplicated counts utilizing all procedure codes

+Primary service area towns make up the top 75% of a hospital inpatient discharges.

Cells sizes less than six are masked for patient confidentiality

6. Given that Yale, Hartford and L+M are the PCI providers listed on page 46, as well as St. Francis, John Dempsey and Central CT shown in the table above also serve Backus' service area patients, explain:
    a. Why the proposal is not an unnecessary duplication of existing health care services currently available;
    b. How the proposal will not result in a shift in volumes from existing providers; and
    c. How there will be no impact on existing provider.

7. Discuss and describe the existing referral base (physicians and physician practices, specifically the interventionalists) in the service area defined in the table above.

8. Page 25 indicates physician alignment requirements have been met. Explain what the alignment is at Backus Hospital and its impact on the proposed services.

9. Describe in detail the proposed on-call system with physicians at Hartford Hospital and Hartford Cardiac Laboratory, P.C. and Dr. John Michael Chua Chiaco to ensure continuous 24/7 coverage.

10. Provide a copy of the on-call schedule for the physicians that will provide coverage for the proposed program.

11. In a table format, provide angioplasty volumes, separated by primary and elective procedures, for each of the physicians in the proposed program for the most recent full fiscal year, and indicate the year.

12. Table 6 on page 78 shows a projected 2% increase in PCIs from FY16 to FY18. Please elaborate on the assumptions used to arrive at the growth rate.

13. On page 459, PCIs are defined to include ICD-9 CM procedure code 17.55 and NSTEMIs to include ICD-9-CM diagnoses codes 426.2 – 426.3. Explain each inclusion and provide a source/citation.

14. Revise and resubmit the payer mix table on page 79 as the rows appear to have shifted downward and are not correctly aligned. In addition, provide the assumptions used for the projected population mix.

15. Page 67 indicates a capital expenditure of $4.8 M for an additional cath lab, software and equipment update and allowances for ongoing capital needs. Page 62 shows a 32% decline in cardiac caths between 2012 and 2014. Explain the need for an additional cath lab.

16. Confirm the projection of 385 PCIs in year 5 in order to achieve operating gains.

Note that pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request no later than sixty days from the date of this email transmission. Therefore, provide your written responses to OHCA no later than December 30, 2015, otherwise your application will be automatically considered withdrawn. ***Please email your responses to all of the following email addresses:*** **OHCA@ct.gov, jessica.schaeffer-helmecki@ct.gov,*olga.armah@ct.gov*, *kaila.riggott@ct.gov*; david.fernandes@ct.gov.** If you have any questions concerning this letter, feel free to contact me at 860-418 7070 or Jessica Schaeffer-Helmecki at (860) 509-8075.

Sincerely,

Olga Armah, M. Phil
Associate Research Analyst
Office of Health Care Access
CT Department of Public Health
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134

Phone: 860 418 7070
Fax: 860 418 7053
mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

Greer, Leslie

From: Edwards, Janette <Janette.Edwards@hhchealth.org>
Sent: Friday, October 30, 2015 4:24 PM
To: Armah, Olga
Cc: User, OHCA; Riggott, Kaila; Schaeffer-Helmecki, Jessica; Fernandes, David
Subject: RE: 15-32031 CON - Backus PCI Program
Attachments: image001.png

Thank you, Olga. I received the questions.

Janette

_____

From: Armah, Olga [Olga.Armah@ct.gov]
Sent: Friday, October 30, 2015 3:37 PM
To: Edwards, Janette
Cc: User, OHCA; Riggott, Kaila; Schaeffer-Helmecki, Jessica; Fernandes, David; Armah, Olga
Subject: 15-32031 CON - Backus PCI Program

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L&M

St. Francis

John Dempsey

Central CT

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<6

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14

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20

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10

<6

16

Montville

22

<6

6

31

Norwich

39

14

<6

<6

56

Sprague

<6

<6

<6

Preston

<6

<6

<6

6

Plainville

<6

<6

7

6

18

PSA Total Inpatient PCIs

86

39

19

8

7

6

165

Total Inpatient PCIs

1,201

716

134

535

189

81

2,856

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Sincerely,

Olga Armah, M. Phil
Associate Research Analyst
Office of Health Care Access
CT Department of Public Health
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134

Phone: 860 418 7070

Fax: 860 418 7053
mailto: olga.armah@ct.gov<mailto:olga.armah@po.state.ct.us>
Web: www.ct.gov/ohca<http://www.ct.gov/ohca>
[cid:image001.png@01D11320.EB10E810]

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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

TO: Kevin Hansted, Hearing Officer

FROM: Jewel Mullen, M.D., M.P.H., M.P.A., Commissioner

DATE: December 16, 2015

RE: Certificate of Need Application; Docket Number: 15-32031-CON
The William W. Backus Hospital
To Establish and Operate a Primary and Elective Angioplasty Program at The William W. Backus Hospital

---

I hereby designate you to sit as a hearing officer in the above-captioned matter to rule on all motions and recommend findings of fact and conclusions of law upon completion of the hearing.

Connecticut Department of Public Health

Phone: (860) 509-8000 • Fax: (860) 509-7184 • VP: (860) 899-1611
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

Greer, Leslie

From: Martone, Kim
Sent: Wednesday, December 30, 2015 3:25 PM
To: Greer, Leslie
Subject: FW: OHCA Docket 15-32031 Hartford Healthcare Backus Completeness Response 12-30-2015.pdf
Attachments: OHCA Docket 15-32031 Hartford Healthcare Backus Completness Response 12-30-2015.pdf; Hartford Hospital _ Backus Revised Exhibit 24 - Financial Schedule.xlsx; Completeness Responses - Hartford Hospital _ Backus 12_30_15 (5).DOCX

From: Teitelbaum, Claudia S. [mailto:CTeitelbaum@brownrudnick.com]
Sent: Wednesday, December 30, 2015 2:58 PM
To: User, OHCA; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: Anthony, Robert J.; Janette.Edwards@hhchealth.org; Mercier, Carlene M.
Subject: OHCA Docket 15-32031 Hartford Healthcare Backus Completeness Response 12-30-2015.pdf

-----Original Message-----
From: Teitelbaum, Claudia S.
Sent: Wednesday, December 30, 2015 2:52 PM
To: Teitelbaum, Claudia S.
Subject: Emailing: OHCA Docket 15-32031 Hartford Healthcare Backus Completness Response 12-30-2015.pdf

Your message is ready to be sent with the following file or link attachments:

OHCA Docket 15-32031 Hartford Healthcare Backus Completness Response 12-30-2015.pdf

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

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****

BROWNRUDNICK

ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

185 Asylum
Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

December 30, 2015

VIA E-MAIL
(ohca@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON
Revised CON Exhibit 24 - Financial Worksheet A
Completeness Responses with Exhibit 28 & Exhibit 29

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital, enclosed please find a revised copy of Exhibit 24 – Financial Worksheet A to the Certificate of Need application (originally page 1409 in the CON). The Applicants recently discovered the payor mix in Financial Worksheet A was calculated using gross revenue instead of net. A revised Exhibit 24 with the correction made is attached.

Also attached are the Applicants' Completeness Responses (and associated Exhibit 28 & Exhibit 29). Per Ms. Armah's October 30, 2015 request, this submission has been e-filed with the individuals identified above and no hard copies are being provided. A PDF version of the filing in its entirety as well as a Word version of the Completeness Response and an Excel version of the Revised Exhibit 24 are also included.

Please do not hesitate to contact me if you have any questions.

Very truly yours,

BROWN RUDNICK LLP

By: Robert J. Anthony /s/ cs
Robert J. Anthony

Enclosure

62268986 v1-WorkSiteUS-032836/0002

brownrudnick.com

REVISED
EXHIBIT 24

Applicant:

Financial Worksheet (A)

Please provide one year of actual results and three years of projections of **Total Entity** revenue, expense and volume statistics without, incremental to and with the CON proposal in the following reporting format:

LINE	Total Entity:	(1) FY14 Actual Results	(2) FY16 Projected W/out CON	(3) FY16 Projected Incremental	(4) FY16 Projected With CON	(5) FY17 Projected W/out CON	(6) FY17 Projected Incremental	(7) FY17 Projected With CON	(8) FY18 Projected W/out CON	(9) FY18 Projected Incremental	(10) FY18 Projected With CON	(11) FY19 Projected W/out CON	(12) FY19 Projected Incremental	(13) FY19 Projected With CON
	Description													
A.	**OPERATING REVENUE**													
1	Total Gross Patient Revenue	$701,705,462	$731,122,624	$ 4,912,149	$736,034,773	$747,632,886	$ 4,948,868	$752,581,754	$767,951,019	$ 5,115,932	$773,066,951	$792,316,091	$ 5,177,577	$797,493,668
2	Less: Allowances	$394,788,265	$435,386,060	$0	$435,386,060	$441,848,601	$0	$441,848,601	$452,555,857	$0	$452,555,857	$465,267,039	$0	$465,267,039
3	Less: Charity Care	$5,263,975	$4,598,489	$0	$4,598,489	$4,722,041	$0	$4,722,041	$4,858,096	$0	$4,858,096	$5,007,362	$0	$5,007,362
4	Less: Other Deductions	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
	Net Patient Service Revenue	**$301,653,222**	**$291,138,075**	**$4,912,149**	**$296,050,224**	**$301,062,244**	**$4,948,868**	**$306,011,112**	**$310,537,066**	**$5,115,932**	**$315,652,998**	**$322,041,689**	**$5,177,577**	**$327,219,266**
5	Medicare	$90,689,692	$92,136,226	$2,468,542	$94,604,768	$92,767,829	$2,486,995	$95,254,824	$94,193,784	$2,570,951	$96,764,735	$96,354,459	$2,601,930	$98,956,389
6	Medicaid	$42,190,169	$21,029,014	$561,032	$21,590,047	$21,403,318	$565,226	$21,968,544	$21,921,700	$584,307	$22,506,007	$22,582,495	$591,348	$23,173,843
7	CHAMPUS & TriCare	$3,190,096	$3,169,569	$0	$3,169,569	$3,246,126	$0	$3,246,126	$3,336,298	$0	$3,336,298	$3,440,919	$0	$3,440,919
8	Other	$1,468,169	$1,902,277	$37,402	$1,939,679	$1,929,500	$37,682	$1,967,182	$1,975,769	$38,954	$2,014,723	$2,042,342	$39,423	$2,081,765
	Total Government	**$137,538,126**	**$118,237,086**	**$3,066,976**	**$121,304,062**	**$119,346,773**	**$3,089,902**	**$122,436,676**	**$121,427,551**	**$3,194,211**	**$124,621,762**	**$124,420,215**	**$3,232,700**	**$127,652,915**
9	Commercial Insurers	$150,932,559	$154,926,488	$1,795,303	$156,721,791	$163,350,180	$1,808,723	$165,158,904	$170,251,040	$1,869,782	$172,120,823	$178,160,932	$1,892,312	$180,053,244
10	Uninsured	$0	$0	$0	$0	$2	$0	$2	$4	$0	$4	$6	$0	$6
11	Self Pay *(part of uninsured)*	$7,448,757	$3,262,200	$49,870	$3,312,069	$3,349,848	$50,242	$3,400,090	$3,446,367	$51,938	$3,498,305	$3,552,257	$52,564	$3,604,821
12	Workers Compensation	$5,733,780	$14,712,301	$0	$14,712,301	$15,015,438	$0	$15,015,438	$15,412,100	$0	$15,412,100	$15,908,274	$0	$15,908,274
13	Other	$0	$0	$0	$0	$2	$0	$2	$4	$0	$4	$6	$0	$6
	Total Non-Government	**$164,115,096**	**$172,900,989**	**$1,845,173**	**$174,746,161**	**$181,715,471**	**$1,858,966**	**$183,574,436**	**$189,109,515**	**$1,921,721**	**$191,031,235**	**$197,621,474**	**$1,944,877**	**$199,566,351**
	Net Patient Service Revenue[a] (Government+Non-Government)	**$301,653,222**	**$291,138,075**	**$4,912,149**	**$296,050,224**	**$301,062,244**	**$4,948,868**	**$306,011,112**	**$310,537,066**	**$5,115,932**	**$315,652,998**	**$322,041,689**	**$5,177,577**	**$327,219,266**
14	Less: Provision for Bad Debts	$8,035,283	$8,719,355	$196,486	**$8,915,841**	$8,953,625	$197,955	**$9,151,580**	$9,211,605	$204,637	**$9,416,242**	$9,494,633	$207,103	**$9,701,736**
	Net Patient Service Revenue less provision for bad debts	**$293,617,939**	**$282,418,720**	**$4,715,663**	**$287,134,383**	**$292,108,619**	**$4,750,913**	**$296,859,532**	**$301,325,461**	**$4,911,295**	**$306,236,756**	**$312,547,057**	**$4,970,474**	**$317,517,531**
15	Other Operating Revenue	$6,760,427	$9,552,257	$0	**$9,552,257**	$10,916,599	$0	**$10,916,599**	$11,023,423	$0	**$11,023,423**	$11,132,446	$0	**$11,132,446**
17	Net Assets Released from Restrictions	$287,246	$503,858	$0	**$503,858**	$521,493	$0	**$521,493**	$539,745	$0	**$539,745**	$558,636	$0	**$558,636**
	TOTAL OPERATING REVENUE	**$300,665,612**	**$292,474,835**	**$4,715,663**	**$297,190,498**	**$303,546,711**	**$4,750,913**	**$308,297,624**	**$312,888,629**	**$4,911,295**	**$317,799,924**	**$324,238,138**	**$4,970,474**	**$329,208,612**
B.	**OPERATING EXPENSES**													
1	Salaries and Wages	$110,166,889	$110,277,491	$1,535,674	$111,813,165	$114,137,203	$1,577,551	$115,714,754	$118,132,005	$1,623,809	$119,755,814	$122,266,625	$1,668,778	$123,935,403
2	Fringe Benefits	$21,447,489	$28,446,379	$42,965	$28,489,344	$29,940,616	$44,116	$29,984,732	$31,384,241	$45,299	$31,429,540	$32,879,512	$46,513	$32,926,025
3	Physicians Fees	$2,624,355	$2,668,969	$202,176	$2,871,145	$2,714,342	$204,048	$2,918,390	$2,760,485	$210,600	$2,971,085	$2,807,414	$213,408	$3,020,822
4	Supplies and Drugs	$39,451,269	$38,678,142	$1,003,020	$39,681,162	$39,794,984	$1,036,938	$40,831,922	$41,130,248	$1,100,936	$42,231,184	$42,546,532	$1,145,298	$43,691,830
5	Depreciation and Amortization	$15,651,354	$16,911,938	$424,940	$17,336,878	$14,839,633	$454,633	$15,294,266	$12,922,486	$485,329	$13,407,815	$12,865,481	$516,394	$13,381,875
6	Provision for Bad Debts-Other[b]	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
7	Interest Expense	$2,992,001	$3,359,894	$0	$3,359,894	$3,326,712	$0	$3,326,712	$3,290,093	$0	$3,290,093	$3,249,152	$0	$3,249,152
8	Malpractice Insurance Cost	$1,363,097	$4,223,000	$0	$4,223,000	$4,349,690	$0	$4,349,690	$4,480,181	$0	$4,480,181	$4,614,586	$0	$4,614,586
9	Lease Expense	$1,609,189	$2,133,666	$0	$2,133,666	$2,169,938	$0	$2,169,938	$2,206,827	$0	$2,206,827	$2,244,343	$0	$2,244,343
10	Other Operating Expenses	$56,722,518	$53,127,531	$1,862,251	$54,989,782	$54,056,123	$1,891,444	$55,947,567	$54,999,599	$2,005,023	$57,004,622	$55,966,620	$2,085,840	$58,052,460
	TOTAL OPERATING EXPENSES	**$252,028,161**	**$259,827,010**	**$5,071,026**	**$264,898,036**	**$265,329,241**	**$5,208,730**	**$270,537,970**	**$271,306,166**	**$5,470,996**	**$276,777,162**	**$279,440,265**	**$5,676,231**	**$285,116,496**
	INCOME/(LOSS) FROM OPERATIONS	**$48,637,451**	**$32,647,825**	**($355,363)**	**$32,292,462**	**$38,217,470**	**($457,817)**	**$37,759,653**	**$41,582,462**	**($559,701)**	**$41,022,761**	**$44,797,873**	**($705,757)**	**$44,092,116**
	NON-OPERATING REVENUE	**$8,462,200**	**$8,100,000**	**$0**	**$8,100,000**	**$8,100,000**	**$0**	**$8,100,000**	**$8,100,000**	**$0**	**$8,100,000**	**$8,100,000**	**$0**	**$8,100,000**
	EXCESS/(DEFICIENCY) OF REVENUE OVER EXPENSES	**$57,099,651**	**$40,747,825**	**($355,363)**	**$40,392,462**	**$46,317,470**	**($457,817)**	**$45,859,653**	**$49,682,462**	**($559,701)**	**$49,122,761**	**$52,897,873**	**($705,757)**	**$52,192,116**
	Principal Payments	**$2,433,472**	$356,000	$0	**$356,000**	$387,000	$0	**$387,000**	$422,000	$0	**$422,000**	$461,000	$0	**$461,000**
C.	**PROFITABILITY SUMMARY**													
1	Hospital Operating Margin	**15.7%**	**10.9%**	**-7.5%**	**10.6%**	**12.3%**	**-9.6%**	**11.9%**	**13.0%**	**-11.4%**	**12.6%**	**13.5%**	**-14.2%**	**13.1%**
2	Hospital Non Operating Margin	**2.7%**	**2.7%**	**0.0%**	**2.7%**	**2.6%**	**0.0%**	**2.6%**	**2.5%**	**0.0%**	**2.5%**	**2.4%**	**0.0%**	**2.4%**
3	Hospital Total Margin	**18.5%**	**13.6%**	**-7.5%**	**13.2%**	**14.9%**	**-9.6%**	**14.5%**	**15.5%**	**-11.4%**	**15.1%**	**15.9%**	**-14.2%**	**15.5%**
D.	**FTEs**	**1,457**	1,439	2	**1,441**	1,439	2	**1,441**	1,439	2	**1,441**	1,439	2	**1,441**
E.	**VOLUME STATISTICS[c]**													
1	Inpatient Discharges	10,690	11,005	146	**11,151**	10,788	147	**10,935**	10,706	152	**10,858**	10,756	154	**10,910**
2	Outpatient Visits	413,579	416,474	70	**416,544**	428,968	71	**429,039**	441,837	73	**441,910**	455,092	74	**455,166**
	TOTAL VOLUME	**424,269**	**427,479**	**216**	**427,695**	**439,756**	**218**	**439,974**	**452,543**	**225**	**452,768**	**465,848**	**228**	**466,076**

[a]Total amount should equal the total amount on cell line "Net Patient Revenue" Row 14.

[b]Provi

[c]Provide projected inpatient and/or outpatient statistics for any new services and provide actual and projected inpatient and/or outpatient statistics for any existing services which will change due to the proposal.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

IN RE:	**:**	**DOCKET NO. 15-32031-CON**
	:	
THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S CERTIFICATE OF NEED APPLICATION TO ESTABLISH A PRIMARY AND ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI) PROGRAM AT BACKUS HOSPITAL.	**:**	**December 30, 2015**

RESPONSES TO COMPLETENESS QUESTIONS

1. **Explain the reasoning for 24% growth rate in PCIs (page 69), given declining state and national PCI trends. OHCA Hospital Reporting System Report 450 data indicates a 12% decline in CT primary and elective PCIs. The SCAI/ACC/AHA Expert Consensus Document 2014 Update (Exhibit 1 of application) also indicates that nationally, PCI volumes have dropped 30% due to factors such as increased emphasis on use of other treatment modalities including medical therapy and improved preventions efforts.**

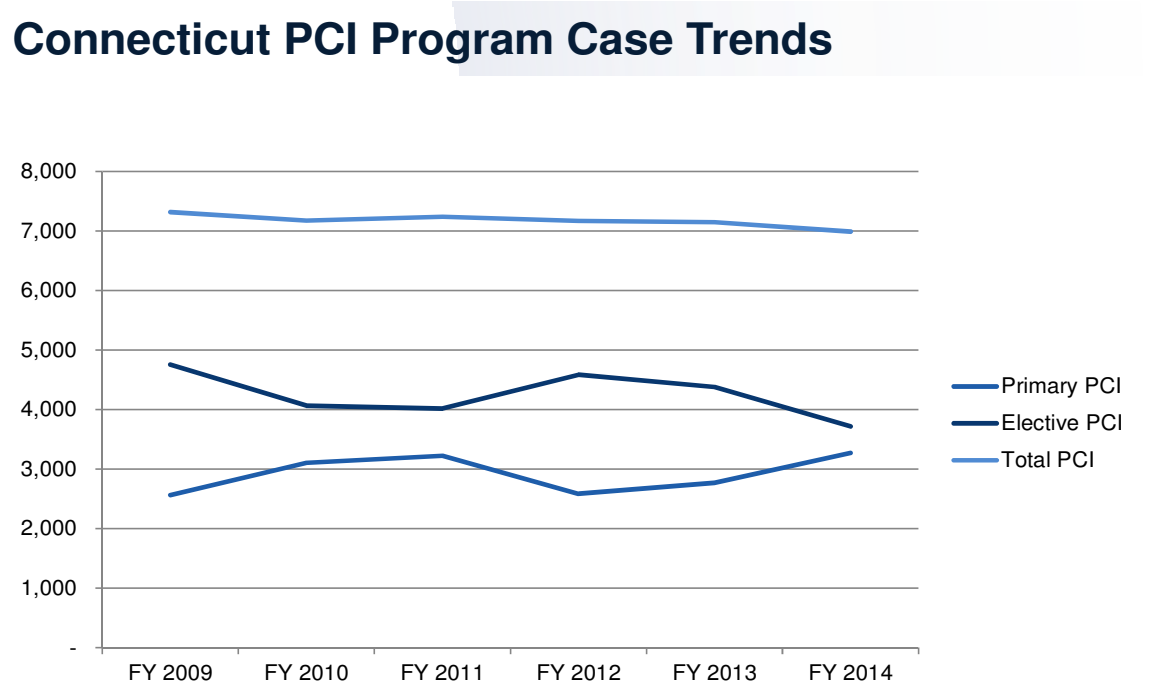
   The 24% growth rate is specific to the service area defined on page four (referred to as the Angioplasty Region) of the 3d Health Assessment (CON, Exhibit 8, Page 447), and was calculated by applying age-gender specific average use rates developed using six years (FY 2009 through FY 2014) of historic utilization data. The use rates do not incorporate state or national trends that may not be relevant to the healthcare landscape in Eastern Connecticut, but instead rely on the demographics and disease burden in the Angioplasty Region communities to predict need for PCI intervention.

   As shown on page 15 of the 3d Health Assessment (CON, Exhibit 8, Page , 462), Acute MI inpatient volumes in the defined service area have increased by more than twelve percent over the past six years. Additionally, the incidence rate of STEMI per 100,000 is significantly higher than both the state and national rates, as seen on page 16 of the 3d Health Assessment (CON, Exhibit 8, Page 463). Due to the lack of timely access to a PCI facility for the majority of service area residents, the rate of Primary PCI and Elective PCI as an intervention is less than both state and national levels, as depicted on page 17 (CON, Exhibit 8, Page 463), leading to an estimated 71 PCI patients either seeking care at a provider outside of those listed in the report or not receiving any care at all (see the Unmet Need/Other Outmigration 2014 estimates for Primary and Elective PCI, page 41 of the 3d Health Assessment (CON, Exhibit 8, Page 488). As a point of comparison, Lawrence + Memorial, whose PCI service area has a similar demographic composition and historic lack of access, reported

to OHCA total PCI volumes of 135 in FY 2013 (page 40, 3d Health Assessment (CON, Exhibit 8, Page 487), growing to 216[1] in FY 2015.

Further, data suggests that total PCI volumes in the State of Connecticut are not declining across the board. When analyzing the OHCA Report 450 for each PCI capable hospital in Connecticut (Bridgeport, Danbury, John Dempsey, Greenwich, Hartford, Lawrence + Memorial, Waterbury, St. Mary's, Norwalk, St. Francis, St. Vincent's, Stamford, and Yale) included within each facility's Twelve Month Filing from 2009-2014 (the most current year of data available) total PCI trends remained fairly flat.

Additionally, consistent trends in Primary and Elective PCI volumes could not be determined. That is, data indicates that PCI volume is up or down in any given year; trends were not up or consistently down between 2009-2014. None of the data obtained through the OHCA report 450 indicated a 12% decline in volume.



Source: State of Connecticut Department of Public Health Office of Health Care Access Report 450

[1] *The L+M volume of 216 cases is different than the 211 reported in the CON, as the L+M volume in the CON was annualized based on three quarters of complete data. The 216 represents full 2015 L+M volume.*

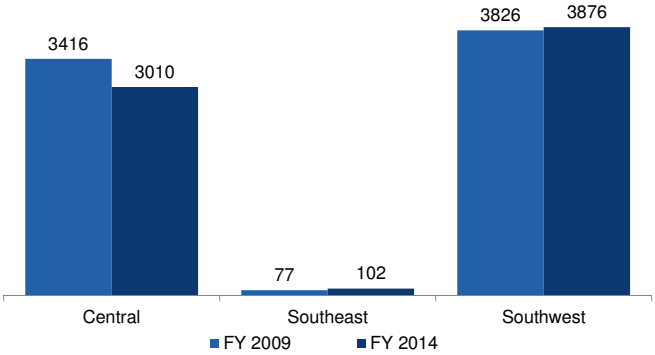
	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	Change FY 09-14
Primary PCI	2,562	3,106	3,224	2,586	2,770	3,273	28%
Elective PCI	4,757	4,067	4,017	4,584	4,378	3,715	(22%)
Total PCI	7,319	7,173	7,241	7,170	7,148	6,988	(5%)

Source: State of Connecticut Department of Public Health Office of Health Care Access Report 450

From 2009-2014 reported Primary PCI volumes grew by 28%. While reported Elective PCI volume declined, the reliability of the data was called into question, as this analysis revealed data integrity issues. Year-over- year hospital reporting was not consistent. For example, Lawrence + Memorial reported no Elective volume in FY 13 or 14, despite receiving approval for an Elective program in February of 2013. Lawrence + Memorial reported Elective volume, however, to OHCA per the stipulated conditions outlined within the Agreed Settlement in Docket No. 12-31768-CON, granting approval for its Elective program. This is only one example where data integrity issues were uncovered when analyzing Report 450 information. Regardless of the validity of the reported data, PCI volumes in totality only declined 5% over six years. This represents a Compound Annual Growth Rate of (.8%) per year, a modest change in volume overall.

Finally, the data found in OHCA Report 450 for Primary and Elective volume was analyzed by geographic region to determine if volume shifts existed within specific communities based on hospital location. This analysis revealed that declines in volume appear to take place in the Central part of the State (defined as aggregate volume seen by Hartford, HOCC, St. Francis, John Dempsey, Waterford, St. Mary's) while PCI volume grew over the same time period in the South East (Lawrence + Memorial Primary volume only) and the South West (defined as Yale, Bridgeport, Greenwich, Danbury, St. Vincent's, Stamford, Norwalk).

Connecticut PCI Program Case Trends by Region



Source: State of Connecticut Department of Public Health Office of Health Care Access Report 450

3

The South East region, as noted above, does not include any Elective PCI volume originating from Lawrence + Memorial , as they did not report volumes within their Twelve Month Filing. If this volume was included the growth in the South East would be even greater.

2. Explain the clear public need for the proposed service when statewide PCI discharge volumes are declining.

As discussed in response to Question 1 above, statewide PCI discharges are not consistently declining, and are not declining at all institutions. Clear public need exists in the North East corner of Connecticut for multiple reasons:

Residents in the Angioplasty Region are not receiving adequate care. *The rate of Primary PCI interventions for residents living in the Angioplasty Region defined in the 3d Health Assessment, page 4 (CON, Exhibit 8, Page 451) is **18% below** the statewide level and **8% below** the national level. The rate of Elective PCI interventions for this same population is **19% below** the statewide level and **41% below** the national level (3d Health Assessment, page 17 (CON, Exhibit 8, Page 464). These figures are especially disturbing given the characteristics of the population in this region: a larger percentage of older people as compared to state and national averages and poorer health statistics and health status, as further discussed below. In addition, MI volumes in this region have **increased 12.9%** since FY 2009 and the incidence of STEMI per 100,000 has also increased and is **significantly higher** than both the state and national levels. This region also has one of the highest coronary mortality rates in the state. Residents of the Angioplasty Region are not receiving the same level of care as the rest of the state, is in dire need of angioplasty services - and the above facts alone support such need.*

*It's also important to note that for this Region, the median door-to-balloon time for patients presenting to Backus and being treated for PCI intervention at a PCI facility was **134 minutes**, well above the recommended time of **90 minutes**; in fact, only 10% of the these patients were treated within 90 minutes. Door-in-door-out times were also calculated and found to **exceed** recommended guidelines **89% of the time** - only 11% of the time were patients treated within the recommended 30 minutes. These are life-saving, time sensitive treatments that would greatly improve the health and lives of the residents living in this isolated area. This geographic "dual standard of care" that exists today in Connecticut should not continue.*

Access to PCI services is severally restricted. *While it may be true that there is sufficient access to PCI services in many parts of Connecticut and in some areas there may actually be excess capacity and thus no need for additional PCI providers, this is not the case for residents living in the Angioplasty Region. In fact, in all of Eastern Connecticut only a small number, those in the South East region, have sufficient access to a PCI provider. Astonishingly, residents living in the Angioplasty Region, a population of more than 230,000, which makes up most of North/North East Connecticut, do not. These residents must travel significant distances for this life saving procedure. The table below shows drive time estimates to the closest PCI facility for communities centrally located within the Angioplasty Region. The drive times are minimums and reflect trips that take place during the very best conditions - outside of morning or evening rush hours and on dry roads. Traffic, construction and inclement weather are familiar and frequent challenges to Connecticut*

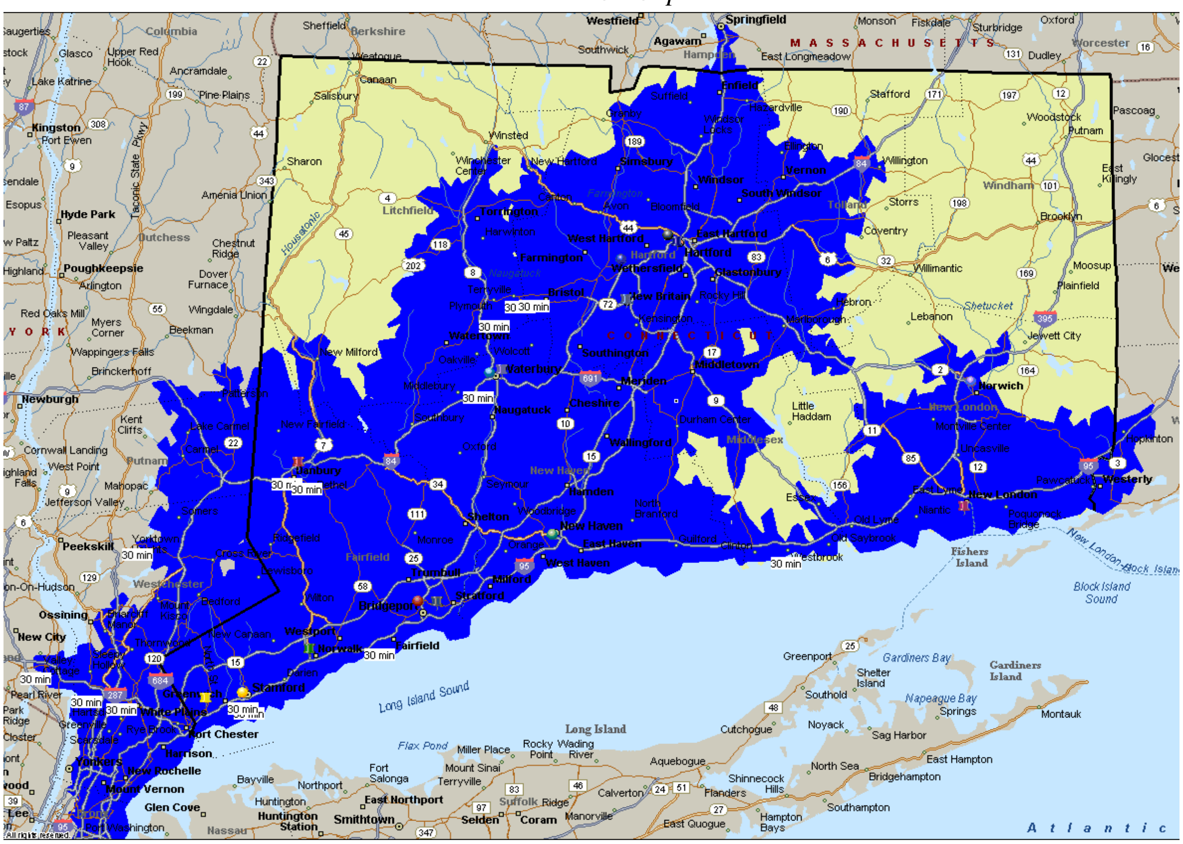
travelers. A PCI program at Backus would be a tremendous benefit to residents of the Angioplasty Region - 80% of whom live within 30 minutes of Backus and would have sufficient access to PCI services; and for the remaining 20%, Backus would be the closest provider of PCI services.

Average Drive Time			
	Brooklyn	***Plainfield***	***Windham***
Backus	*28 minutes*	*17 minutes*	*20 minutes*
Hartford	*55 minutes*	*57 minutes*	*43 minutes*
Lawrence + Memorial	*47 minutes*	*36 minutes*	*39 minutes*

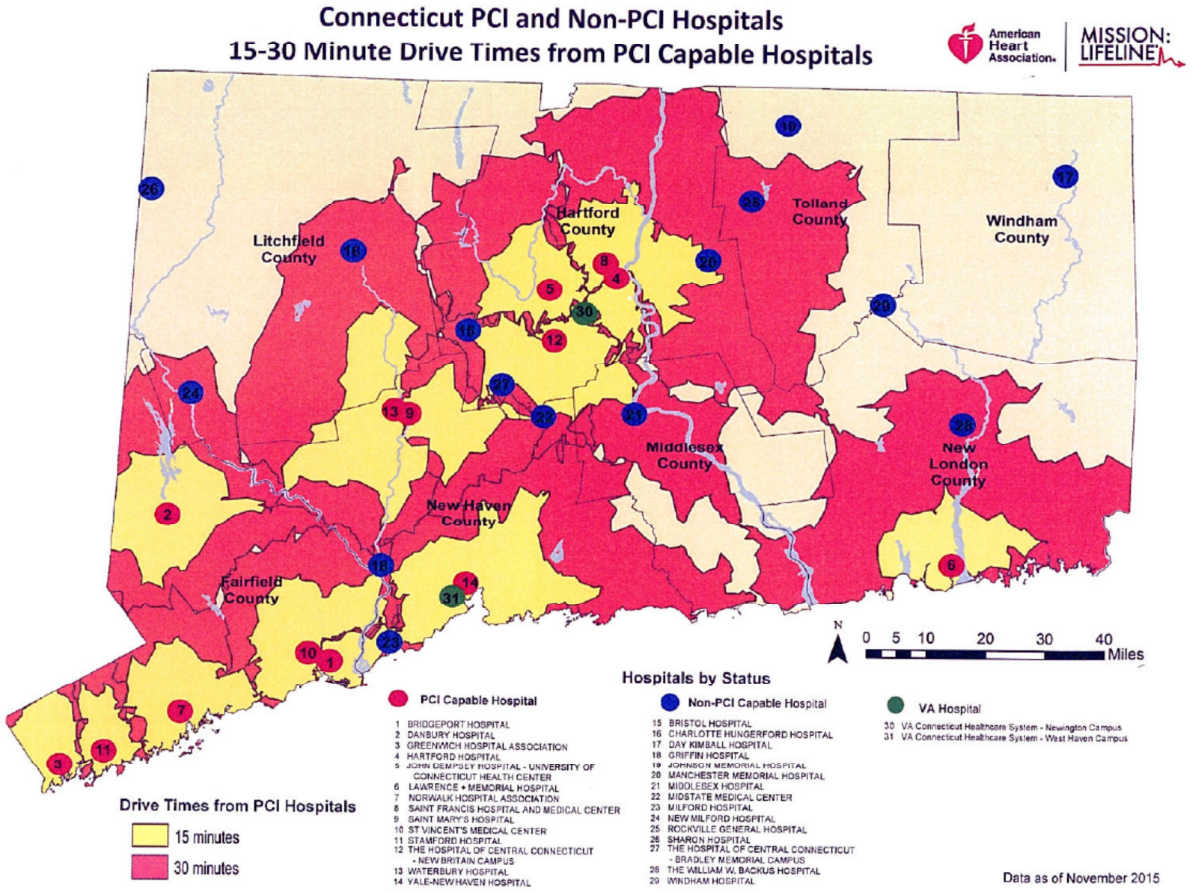
Source: 3d Health Assessment, page 34 (CON, Exhibit 8, Page 481)

The map below highlights the inequitable distribution of PCI services throughout Connecticut - there are twelve PCI providers in the western half of Connecticut and only one in the eastern half. Residents in many regions, such as Greater Hartford, Greater Waterbury and Greater New Haven, have immediate access to two or more PCI providers in or nearby the communities in which they live. In eastern Connecticut, only a small number, those in the southeast region, have a local PCI provider (Lawrence and Memorial), while residents living in the Angioplasty Region must travel significant distances for this life saving procedure.

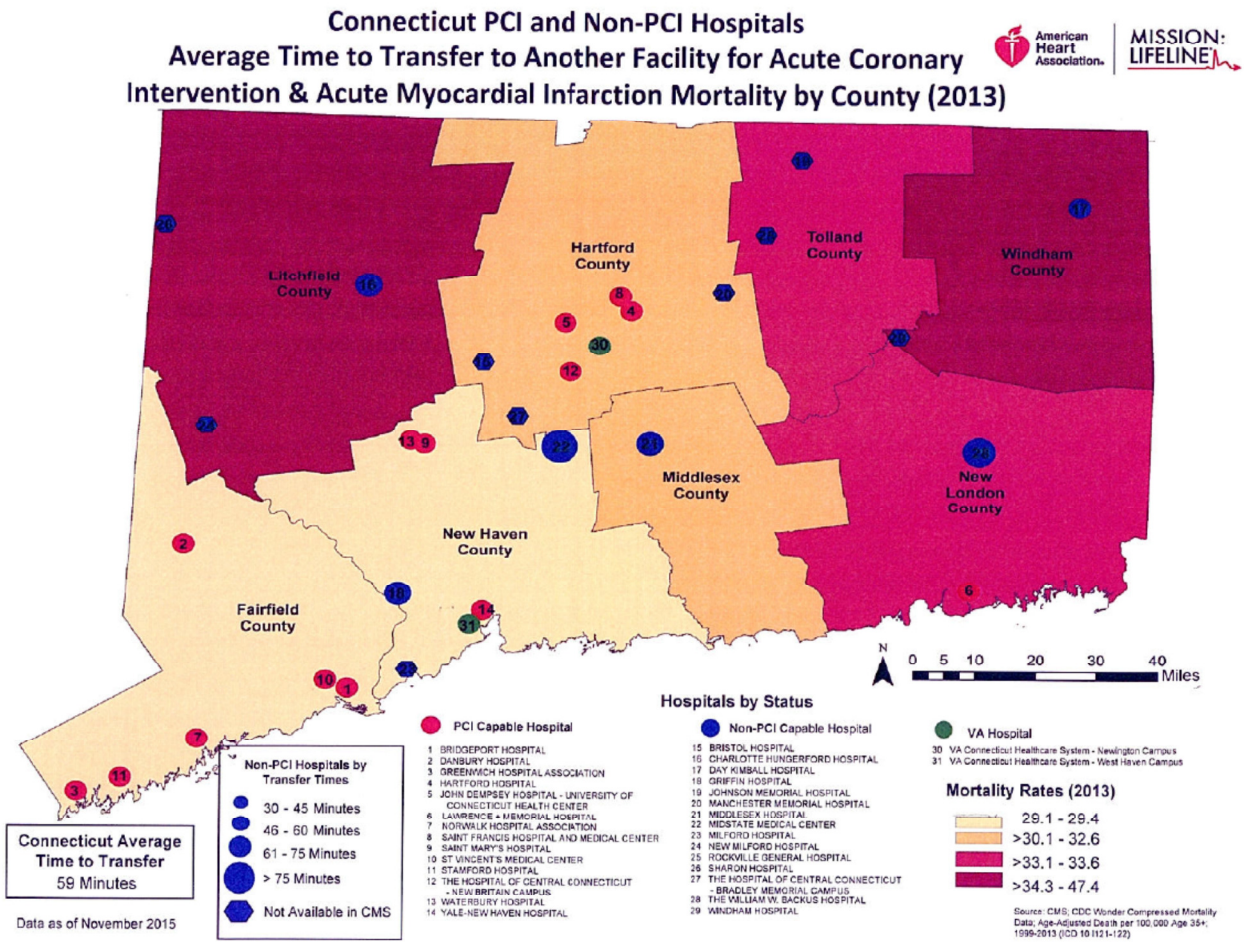
30 Minute Access to PCI-Capable Facilities



These facts are supported by The American Heart Association's 'Mission: LifeLine' data. Data as of November 2015 illustrate the drive time challenges faced by the Angioplasty Region.
The map below highlights 15 and 30 minute drive times from PCI capable hospitals. The majority of the Backus Angioplasty Region is outside a 15-30 minute drive time window.



'Mission: LifeLine' also analyzed the average time to transfer to another acute care facility for acute coronary intervention, and its impact on mortality. Backus Hospital, indicated on the map as having a greater than 75 minute transfer time, is located in a region with the third-highest mortality rate. This supports the argument that additional access is needed in New London County, as Lawrence + Memorial's program provides timely access to a limited population. Additionally, Windham County (which has no access to a PCI capable provider in Connecticut) has the highest mortality rate in the State at greater than 34.3-47.4 age adjusted deaths per 100,000. This mortality rate correlates with the map above. That is, areas outside of a 15-30 minute drive time (which mirrors the Angioplasty Region) have higher mortality rates. The establishment of a program at Backus Hospital will lower this mortality rate, and improve the access to this life saving standard of care to Eastern Connecticut residents.



Cost and safety factors. *As noted in the CON, the distances and travel times to a PCI facility can also be unmanageable or cost-prohibitive and thus, care is not sought. Within the Angioplasty Region, poor socioeconomics place further limits on residents. 43% of the Angioplasty Region has a median household income less than $50,000 per year, and fewer residents in the Backus Angioplasty Region have completed an undergraduate degree or post-graduate degree (26% vs. 36% and 29% in the State and Nation, respectively) (3d Health Assessment, p. 9-10 (CON, Exhibit 8, Pages 456-457). Patients who are transported from Backus to another facility for PCI must incur the expense associated with the transportation and duplication of services. It is estimated that a typical patient who is transported to another facility pays thousands of dollars in additional hospital expenses because of the transportation and duplication of services. These patients are also at increased risk of infections, bleeding complications, and other adverse events associated with multiple procedures at two facilities. Families of patients who are currently transferred face a financial burden as well due to costs of travel, parking and, at times, hotel accommodations, when the patient is admitted to the hospital. This clear service gap in PCI services for this region profoundly impacts patients and their families.*

Age, socioeconomic and health concerns. *As discussed more below, this is an area with a high and increasing demand for PCI services due to the aging population and poor health statistics and health status compared to state and national averages, yet as noted above, receive PCI interventions at a*

rate significantly below state and national levels. Residents of the Angioplasty Region also have a greater demand for cardiac services due to poorer cardiovascular health than the state and national averages as demonstrated by key statistics. They also have a high prevalence of key risk factors for coronary heart disease, including:

- *increased prevalence of high blood pressure (almost 36% of New London & Windham Counties compared to 31% for the state), diabetes, smoking, obesity, and physical inactivity - more than 85% of adults reported one or more risk factors (As found in the Hartford HeatlhCare's Eastern Region Community Health Needs Assessment, page 23 (CON, Exhibit 3, Page 153))*
- *high mortality and hospitalization rates for heart disease - between 2011 and 2013, the annual average age adjusted heart disease mortality rate was 167.5 deaths per 100,000 for Windham County versus 153.4 deaths per 100,000 for Connecticut*
- *low number of primary care physicians (an indication that residents are receiving insufficient preventative services) - 58.9/100,000 versus 84/100,000 statewide*
- *high rate of uninsured and underinsured*
- *low socioeconomic status*
- *high proportion of elderly residents which has large effect on the incidence of heart disease and the need for cardiac related services*

88.2% of individuals residing in Hartford HealthCare's Eastern Region (which includes the Angioplasty Region) have one or more cardiovascular risk factor (Hartford HeatlhCare's Eastern Region Community Health Needs Assessment, page 23 (CON, Exhibit 3, Page 155). The Burden of Cardiovascular Diseases in Connecticut ("BCVD"), cited previously in the CON (CON, Page 57), identifies two different categories for risk factors relating to cardiovascular diseases: modifiable and non-modifiable. Non-modifiable risk factors include indicators such as age and family history, whereas modifiable risk factors include such indicators as high blood pressure, high cholesterol, smoking, diabetes, obesity, and physical inactivity. As discussed in detail in the CON, the Angioplasty Region suffers disproportionately from all of these risk factors. The table below highlights specific risk factors and health outcomes for residents of Hartford HealthCare's Eastern Region, the Backus Hospital Service Area (which is the area most contiguous to Backus Hospital and includes towns from the Angioplasty Region), as compared to the State of Connecticut (Hartford HealthCare's Eastern Region, Community Health Needs Assessment CON, Exhibit 3, Page 155-162). An excerpt of the Backus Hospital Community Health Needs Assessment is included as ***Exhibit 28.*** *As demonstrated by the table, the Eastern Region and the Backus Service Area fares worse than the State across risk factors. The Backus Hospital Service Area has worse outcomes across most risk factors than the Eastern Region. These data illustrates the need for Backus Hospital to establish PCI services:*

Risk Factor	*Hartford HealthCare's Eastern Region*	*Backus Hospital Service Area*	*Connecticut*
% of Population with 1+ Cardiovascular Risk Factors	*85.1%*	*88.2%*	*No benchmark available*
% of Population with High Blood Pressure	*35.7%*	*39.5%*	*31.3%*
% of Population with High Cholesterol	*32.4%*	*31.7%*	*37.8%*
% of Population who are Current Smokers	*16.6%*	*18.9%*	*15.5%*
Diabetes Age Adjusted Death Rate	*15.8*	*16.4*	*14.8*
% of Population with Diabetes/High Blood Sugar	*11.0%*	*12.4%*	*11.7%*
% of Overweight Population (BMI 25+)	*66.2%*	*69.5%*	*62.6%*
% of Obese Population (BMI 30+)	*30.2%*	*32.4%*	*25%*
% of Population with no physical activity	*27.0%*	*28.5%*	*24.9%*
Diseases of the Heart Age Adjusted Death Rate	*165.7*	*169.0*	*153.4*
% of Population with Heart Disease (Heart Attack, Angina, Coronary Disease)	*5.9%*	*5.8%*	*No benchmark available*
*% of Population who experienced a heart attack**	*N/A*	*4.0*	*No benchmark available*

**Differences exist within the primary and secondary service areas of Backus Hospital. The Primary Service Area (the area most contiguous to Backus) has a higher prevalence of heart attack, with 5.5% of the population vs. 2.4% of the secondary service area.*

Based on the foregoing reasons, the need for PCI services in the Angioplasty Region is clear and evident - a void that this CON, if approved, will address. *As noted in the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, "It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will* ***clearly fill a void in the healthcare needs of the community****," (emphasis added) (CON, Exhibit 9) and further, in the 2014 ACC/SCAI Expert Consensus Document, "It behooves the cardiology community to foster [elective PCI without on-site surgery] programs…when such programs* ***improve access to a higher level of cardiovascular*** *care than would otherwise be available." (CON, Exhibit 1).*

3. To what percentage of the projected PCI patients associated with the proposal do the DPH Regulations on page 93 apply? Discuss in detail how the regulations apply to elective angioplasty patients and the relevance of a 30-minute drive time.

The DPH Regulations, (discussed in the CON on page 93), highlight the relationship of time with clinical outcomes in the case of patients requiring a PCI. These regulations set a standard of care for STEMI patients, who are identified in the field, to be transported to the closest PCI-capable facility, if there is one within a 30 minute drive time of the patient. The objective of these recommendations is to ensure, whenever possible, that the goal of a 90-minute door-to-balloon time is achieved. In the case of an Emergent PCI, time is muscle, and so a shorter transport time will likely reduce necrosis, ultimately improving patient outcomes. The Door-In-Door-Out and Door-to-

Balloon times for patients in the Angioplasty Region are outside acceptable windows. Thus, this is an indication that patients in the Angioplasty Region are not able to access the same high quality care available elsewhere in the State, as illustrated in the response to question 2. The establishment of a PCI program at Backus will fix this issue, improving access for all. In total, the establishment of a program at Backus will improve access to care for 6.4% of the State of Connecticut, and 59% of New London and Windham Counties.

In the case of non-Emergent, "Elective," PCI patients, time is still of the essence. Elective procedures are still time-sensitive, urgent, and necessary procedures. The guidelines aren't technically applicable to Elective patients, but the relevance of a 30 minute drive time will improve access to patients' ability to access services. Two scenarios are currently at play for patients requiring a non-Emergent PCI who reside within the Backus Hospital Angioplasty Region:

Patients must leave the service area for care. *Patients who undergo an Elective PCI have risk factors, or test results which show that if a PCI to correct the blockages causing the ischemia is not performed, the patient would be more likely to have a fatal myocardial infarction in the future. Unlike primary PCI, this procedure is scheduled, but ideally takes place within 24-48 hours of diagnosis to effectively reduce the risk of future cardiac events. Once these patients have their coronary intervention, their reoccurring symptoms are alleviated and they are able to return to their baseline health. The closest provider of this service today is Lawrence + Memorial Hospital, located in New London, Connecticut. Lawrence + Memorial however, is more than 45 minutes away from North Eastern Connecticut communities. For example, Lawrence + Memorial is 47 minutes from Brooklyn, Connecticut, more than 35 minutes away from Plainfield, Connecticut, and almost 40 minutes from Windham. This drive time, coupled with the socioeconomic factors of these communities, makes seeking care even 40 minutes away burdensome. If Backus is approved to establish a PCI program in Norwich, drive times would be cut in half; Brooklyn would be able to access services within 28 minutes, Plainfield within 17, and Windham residents within 20. These improved drive times not only benefit Primary PCI patients, but provide access to care close to home for Elective patients as well.*

Patients are transported via EMS from Backus Hospital's Catheterization Lab to a PCI facility. *Backus Hospital operates a diagnostic catheterization laboratory in Norwich. In Fiscal year 2015, 234 diagnostic catheterizations were performed at Backus. Often, patients who are undergoing a diagnostic procedure have an identified occlusion requiring a PCI. These patients are then transferred from Backus to a PCI capable facility via EMS. These patients then undergo a repeat catheterization to clear the blockages found in the initial procedure. Often this requires another groin or radial puncture to the patient. By having an elective PCI program at Backus patients will be able to have the diagnostic and elective procedure completed together, reducing the exposure to radiation and intravenous contrast used during the procedure. This will also reduce the burden placed on family members who must meet their loved one in an unfamiliar facility and city in an already stressful situation. These patients are choosing Backus for their care, but are unable to receive standard cardiovascular care as residents elsewhere in the State and in the Nation.*

The DPH regulations are only technically applicable to Primary PCI patient transports. This represents 79, or 36.5%, of projected patients in Year 1 of the program, a significant proportion of estimated volume. The establishment of a program at Backus, however, will improve care for all.

4. <u>Using the service area defined in the table below,</u> update FY 2015 numbers through the end of the fiscal year for the tables on pages 46, 62, 101 102, 103 and 104. If full year data is unavailable, update the 2015 numbers through the most recent month available and identify that month.

The table below shows inpatient PCI discharges from Backus Hospital's primary services area+ towns:

	PCI Hospital						
Primary Service Area Patient Towns	Yale	Hartford	L&M	St. Francis	John Dempsey	Central CT	**Total**
Canterbury	<6	<6					**<6**
Colchester	<6	12		<6			**14**
Griswold & Lisbon	14	<6		<6			**20**
Ledyard	<6		10	<6			**16**
Montville	22	<6	6				**31**
Norwich	39	14	<6	<6			**56**
Sprague		<6		<6			**<6**
Preston	<6	<6	<6				**6**
Plainville		<6		<6	7	6	**18**
PSA Total Inpatient PCIs	**86**	**39**	**19**	**8**	**7**	**6**	**165**
Total Inpatient PCIs	1,201	716	134	535	189	81	**2,856**
PSA % Share of Hospital Inpatient PCI	**7%**	**5%**	**14%**	**1%**	**4%**	**7%**	**6%**

Source: *CT DPH Office of Health Care Access Acute Care Hospital Inpatient Discharge Database*

*ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06, 36.07 & 36.09

Please note: unduplicated counts utilizing all procedure codes

+Primary service area towns make up the top 75% of a hospital inpatient discharges.

Cells sizes less than six are masked for patient confidentiality

The OHCA-defined primary service area definition for Backus Hospital, while consistent with most methodologies in defining a hospital's primary market as 75% of patients, is not contiguous and is absent consideration for patient travel times, which are critical for a PCI program.

Six towns (Gales Ferry, Ledyard, Mashantucket, Montville, Oakdale, and Uncasville) were excluded from the 3d Health-defined Backus Angioplasty Region due to their proximity being closer to Lawrence + Memorial. Even though those towns are also within a 30 minute drive-time to Backus Hospital and account for 11% of Backus' current inpatient origin, those PCI patients should receive more timely care at Lawrence + Memorial.

One town, Plainville, is considerably closer to Hartford Hospital. Backus Hospital only received two inpatients from that market in 2015.

Of the remaining towns included in the Angioplasty Region, all are either within a 30 minute drive-time and closest to Backus Hospital or currently have no access to a PCI facility within a 30 minute drive-time and are within a 45 minute drive-time to Backus Hospital.

Please see the detailed patient origin analysis, below, for more information. This table compares and contrasts the OHCA-defined service area with the Backus Angioplasty Region, and the traditional CMS Stark Defined Service Area. It provides, by town, the percentage of total Backus inpatient discharges as well as the Backus market share within each region. Finally, this table provides notes on why each city was either included or excluded from the Backus Angioplasty Region:

Service Area Comparison: Backus Angioplasty Region vs. OHCA Defined Service Area								
ZIP Code	***City***	***2015 Discharges***	***OHCA 75% Definition***	***Backus Angioplasty Region***	***CMS Stark 75% Definition***	***% of Total Discharges***	***Backus IP Market Share***	***Backus Angioplasty Service Area Definition Notes***
06360	*Norwich*	*3,212*	*SA*	*SA*	*SA*	*31.7%*	*71.8%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06351	*Jewett City*	*1,115*	*SA*	*SA*	*SA*	*11.0%*	*70.2%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06382	*Uncasville*	*565*	*SA*		*SA*	*5.6%*	*49.9%*	*Excluded - Closer to L&M*
06374	*Plainfield*	*538*		*SA*	*SA*	*5.3%*	*54.8%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06365	*Preston*	*322*	*SA*	*SA*	*SA*	*3.2%*	*57.2%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06415	*Colchester*	*287*	*SA*	*SA*	*SA*	*2.8%*	*22.3%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06370	*Oakdale*	*278*	*SA*		*SA*	*2.7%*	*38.5%*	*Excluded - Closer to L&M*
06331	*Canterbury*	*261*	*SA*	*SA*	*SA*	*2.6%*	*54.9%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06354	*Moosup*	*234*		*SA*	*SA*	*2.3%*	*43.0%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06380	*Taftville*	*232*	*SA*	*SA*	*SA*	*2.3%*	*68.3%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
ZIP Code	***City***	***2015 Discharges***	***OHCA 75% Definition***	***Backus Angioplasty Region***	***CMS Stark 75% Definition***	***% of Total Discharges***	***Backus IP Market Share***	***Backus Angioplasty Service Area Definition Notes***
06330	*Baltic*	*209*	*SA*	*SA*	*SA*	*2.1%*	*50.3%*	*Within 30 Minute Drive-Time of Backus; No Current Access*

06239	*Danielson*	*196*		*SA*	*SA*	*1.9%*	*10.3%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06334	*Bozrah*	*185*		*SA*	*SA*	*1.8%*	*59.3%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06249	*Lebanon*	*145*		*SA*		*1.4%*	*22.8%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06339	*Ledyard*	*142*	*SA*			*1.4%*	*21.9%*	*Excluded - Closer to L&M*
06384	*Voluntown*	*140*		*SA*		*1.4%*	*65.0%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06234	*Brooklyn*	*126*		*SA*		*1.2%*	*13.3%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06335	*Gales Ferry*	*104*	*SA*			*1.0%*	*18.2%*	*Excluded - Closer to L&M*
06377	*Sterling*	*102*		*SA*		*1.0%*	*46.5%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06254	*North Franklin*	*90*		*SA*		*0.9%*	*49.3%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06226	*Willimantic*	*81*		*SA*		*0.8%*	*5.0%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06241	*Dayville*	*56*		*SA*		*0.6%*	*9.7%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06280	*Windham*	*30*		*SA*		*0.3%*	*12.1%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06250	*Mansfield Center*	*28*		*SA*		*0.3%*	*6.0%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06260	*Putnam*	*28*		*SA*		*0.3%*	*3.4%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
ZIP Code	***City***	***2015 Discharges***	***OHCA 75% Definition***	***Backus Angioplasty Region***	***CMS Stark 75% Definition***	***% of Total Discharges***	***Backus IP Market Share***	***Backus Angioplasty Service Area Definition Notes***
06353	*Montville*	*23*	*SA*			*0.2%*	*54.2%*	*Excluded - Closer to L&M*
06256	*North Windham*	*17*		*SA*		*0.2%*	*4.5%*	*Within 30 Minute Drive-Time of Backus; No Current Access*

06247	*Hampton*	*15*		*SA*		*0.1%*	*9.4%*	*Within 40 Minute Drive-Time of Backus; No Current Access*
06231	*Amston*	*14*		*SA*		*0.1%*	*4.1%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06259	*Pomfret Center*	*13*		*SA*		*0.1%*	*6.4%*	*Within 40 Minute Drive-Time of Backus; No Current Access*
06281	*Woodstock*	*12*		*SA*		*0.1%*	*5.4%*	*Within 45 Minute Drive-Time of Backus; No Current Access*
06277	*Thompson*	*12*		*SA*		*0.1%*	*11.4%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06264	*Scotland*	*9*		*SA*		*0.1%*	*18.5%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06237	*Columbia*	*8*		*SA*		*0.1%*	*1.9%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06255	*North Grosvenordale*	*7*		*SA*		*0.1%*	*4.8%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06235	*Chaplin*	*6*		*SA*		*0.1%*	*2.4%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06336	*Gilman*	*6*		*SA*		*0.1%*	*100.0 %*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06423	*East Haddam*	*5*		*SA*		*0.0%*	*1.8%*	*Within 40 Minute Drive-Time of Backus; No Current Access*
06282	*Woodstock Valley*	*3*		*SA*		*0.0%*	*4.2%*	*Within 45 Minute Drive-Time of Backus; No Current Access*
ZIP Code	***City***	***2015 Discharges***	***OHCA 75% Definition***	***Backus Angioplasty Region***	***CMS Stark 75% Definition***	***% of Total Discharges***	***Backus IP Market Share***	***Backus Angioplasty Service Area Definition Notes***
06469	*Moodus*	*3*		*SA*		*0.0%*	*1.4%*	*Within 30 Minute Drive-Time of Backus; Backus Closest Facility*
06266	*South Windham*	*3*		*SA*		*0.0%*	*3.0%*	*Within 30 Minute Drive-Time of Backus; No Current Access*
06062	*Plainville*	*2*	*SA*			*0.0%*	*0.1%*	*Excluded - Closer to HHC*

06262	*Quinebaug*	*1*		*SA*		*0.0%*	-	*Within 45 Minute Drive-Time of Backus; No Current Access*
06338	*Mashantucket*	*1*	*SA*			*0.0%*	*0.1%*	*Excluded - Closer to L&M*
	All Other Areas	*1,260*						
	Total	***10,126***						

The updated tables with the OHCA defined service area are listed below. Additionally, some tables reflective of the entire Angioplasty Region were updated with complete FY2015 numbers.

Page 46 (revised to reflect only the OHCA defined service area and to include all Hospitals listed in OHCA's table, above. Includes the town of Plainville, as requested by OHCA.)

Facilities Providing PCI to the OHCA-Defined Service Area

FY 2015 Data	Hartford Hospital	John Dempsey Hospital	Lawrence + Memorial Hospital	Saint Francis Hospital	The Hospital of Central Connecticut	UMass Memorial - University	Yale-New Haven Hospital
Service Area Cases / Market Share: **Primary PCI**	14 cases / 19% share	0 cases / 0% share	28 cases / 36% share	4 cases / 5% share	10 cases / 13% share	5 cases / 6% share	12 cases / 16% share
Service Area Cases / Market Share: **Elective PCI**	36 cases / 12% share	30 cases / 10% share	23 cases / 7% share	20 cases / 6% share	5 cases / 2% share	49 cases / 16% share	133 cases / 43% share
Total Estimated Primary PCI Cases	476 cases	177 cases	121 cases	369 cases	70 cases	347 cases	635 cases
Total Estimated Elective PCI Cases	623 cases	222 cases	95 cases	415 cases	15 cases	~753 cases (OP estimated)	940 cases
Total Coronary Angioplasty (inpatient and outpatient)[2]	1,099 cases	399 cases	216 cases	784 cases	85 cases	~1,100 cases (OP estimated)	1,575 cases
Percent of all Hospital's Coronary Angioplasty (Primary + Elective) from the Service Area	4.5%	7.4%	23.6%	3.0%	17.6%	4.9%	9.2%

[1]UMass-University data from FY 2012; 33% of all elective estimated to be performed on an outpatient basis
[2]L&M data from OCHA filing
[3]Hartford data obtained directly
[4]YNNH, and St. Francis data per the CHA's Patient Census Report from October 2014 through September 2015

The OHCA-defined service area accounts for a small percentage of each provider's overall volumes, with the exception of Lawrence + Memorial. This is to be expected, however, as the towns of Gales Ferry, Ledyard, Mashantucket, Montville, Oakdale, and Uncasville are within closer proximity to Lawrence + Memorial, and have significant PCI volumes. These towns were excluded from Angioplasty Region, and their volumes were not included in the projections for the Backus program.

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Backus Hospital Diagnostic Catheterization Volume and Related Transfers Fiscal Year 2015			
Fiscal Year	***Total Volume***	***Angioplasty Region Volume***	***OHCA Defined Service Area Volume***

	Total	Transfers	% Transferred	Total	Transfers	% Transferred	Total	Transfers	% Transferred
2015 (10/1/14-9/30/15)	234	50	21.36%	208	44	21.15%	185	41	22.16%
% of Total				89%			79%		

Overall, diagnostic catheterizations have increased over 2014 by 16 procedures. This analysis indicates that the individuals residing in the Angioplasty Region account for 89% of the total diagnostic volume. This is interpreted to mean that residents of the Angioplasty Region, although outside of the OHCA defined service area, are choosing to receive their cardiac care at Backus. Further, the OHCA defined service area accounts for 79% of Backus diagnostic catheterization volume.

Page 101, Table A: Cardiac Historical Utilization by Zip Code

Hartford Hospital Primary & Elective PCIs, Backus Hospital Angioplasty Region					
Town	**Zip**	**2012**	**2013**	**2014**	**2015 (September)**
Windham	6226	20	19	19	20
Amston	6231	0	1	8	9
Killingly	6233	0	0	0	0
Brooklyn	6234	1	3	3	3
Chaplin	6235	3	4	4	1
Columbia	6237	6	8	6	5
Killingly	6239	3	0	1	2
Killingly	6241	0	0	1	1
Killingly	6243	0	0	0	0
Town	**Zip**	**2012**	**2013**	**2014**	**2015 (September)**
Scotland	6246	0	0	0	0
Hampton	6247	5	1	4	2
Lebanon	6249	2	5	9	14
Mansfield Center	6250	6	6	4	2
Mansfield Center	6251	0	0	0	0
Franklin	6254	0	1		2
Windham	6256	4	3	5	6
Pomfret	6258	0	0	0	0
Putnam	6260	1	0	2	0
Killingly	6263	0	0	0	0
Windham	6266	0	0	0	2
Mansfield Center	6268	7	2	5	2
Mansfield Center	6269	0	0	0	0

Thompson	*6277*	*0*	*0*	*0*	*0*
Windham	*6280*	*0*	*5*	*7*	*5*
Woodstock	*6281*	*0*	*0*	*0*	*2*
Sprague	*6330*	*0*	*0*	*1*	*1*
Canterbury	*6331*	*0*	*1*	*1*	*1*
Plainfield	*6332*	*0*	*0*	*1*	*0*
Bozrah	*6334*	*2*	*1*	*1*	*1*
Griswold/Lisbon	*6351*				*6*
Plainfield	*6354*	*0*	*3*	*1*	*1*
Norwich	*6360*	*3*	*5*	*13*	*12*
Preston	*6365*	*0*	*0*	*1*	*2*
Plainfield	*6374*	*2*	*2*	*6*	*4*
Sterling	*6377*	*0*	*2*	*2*	*2*
Norwich	*6380*	*0*	*0*	*2*	*4*
Voluntown	*6384*	*0*	*0*	*1*	*2*
Plainfield	*6387*	*0*	*0*	*0*	*0*
Norwich	*6389*	*0*	*0*	*0*	*0*
Colchester	*6415*	*17*	*12*	*20*	*14*
East Haddam	*6423*	*9*	*4*	*4*	*7*
Total		***91***	***88***	***132***	***135***

Page 101, Table B: Cardiac Historical Utilization by Inpatient/Outpatient

Hartford Hospital Volume Originating from the OHCA Defined Service Area		
Town	***Zip***	***2015 (September)***
Plainville	*06062*	*10*
Canterbury	*06331*	*1*
Colchester	*06415*	*14*
Griswold/Lisbon	*06351*	*6*
Norwich	*06360*	*12*
Norwich	*06380*	*4*
Norwich	*06389*	*0*
Preston	*06365*	*2*
Sprague	*06330*	*1*
Total		***50***

PCI volume at Hartford Hospital from the Angioplasty Service Area held constant from FY 2014-2015. The OHCA defined service area accounts for 50 cases performed at Hartford Hospital in FY 2015. This is to be expected, as referenced in the response above, some towns in the OHCA defined region are better served by other institutions, such as Lawrence + Memorial, Hartford of Central Connecticut, or John Dempsey, due to the proximity of the patient's origin to the PCI capable facility.

Page 102, Table B: Cardiac Historical Utilization by Inpatient/Outpatient

Hartford Hospital Primary & Elective PCIs Originating from the Backus Angioplasty Region				
Category - Inpatient/Outpatient	***Hartford Hospital Volume***			
	2012	***2013***	***2014***	***2015***
Inpatient PCI	*99*	*90*	*104*	*108*
Outpatient PCI	*3*	*12*	*34*	*27*
Total	***102***	***102***	***138***	***135***

Hartford Hospital Volume Originating from the OHCA Defined Service Area	
Category - Inpatient/Outpatient	***Fiscal Year 2015***
Inpatient PCI	*41*
Outpatient PCI	*9*
Total	***50***

Inpatient PCI continues to grow at Hartford Hospital from patients originating from the Backus Angioplasty Region. Inpatient PCI dominates the majority of cases originating from the OHCA defined service area.

Page 103, Table C: Cardiac Historical Utilization by Unique Physician Identifier

PCI Volume by Physician	***2015 Total Volumes***	***2015 OHCA Defined Service Area***
Physician 1	*124*	*6*
Physician 2	*165*	*9*
Physician 3	*258*	*9*
Physician 4	*86*	*2*
Physician 5	*129*	*5*
Physician 6	*107*	*4*
Physician 7	*113*	*5*
*Physician 8^*	*173*	*Not Available*
Total	***1,155***	***40***

Data for physicians 1-7 obtained directly, provided by internal data analytics. Reflective of Hartford Hospital volume only.
^Physician 8 data obtained directly and reflects 6 months of data not included in original CON application; data not available by zip code

Providers participating in the program are high volume operators, seasoned and high quality physicians. These physicians will provide the clinical oversight to any new providers entering the program, as they will all rotate through Hartford Hospital catheterization labs. This will ensure quality standards are met and sustained, and clinical outcomes are tracked.

Page 104, Table D: Cardiac Projected Utilization by Inpatient/Outpatient

Backus Hospital - Projected			
Category	***FY16***	***FY17***	***FY18***
Inpatient	*113*	*112*	*112*
Outpatient	*50*	*53*	*57*
Total	***163***	***165***	***167***

The methodology utilized to create the projected PCI volume was done on a regional level, not on a zip-code specific analysis. This is due to the variability in zip-code level volume, and the inability to

create reliable trend patterns. Therefore, to estimate future demand for PCI among service area residents, 3d Health prepared market projections based on a set of utilization rates applied to the service area population. To estimate what the projected volume at Backus Hospital would be for inpatient and outpatient primary and elective PCI from the OHCA-defined service area, 3d Health compared volume from the Backus Angioplasty Region with OHCA's definition. See the Tables below, which is based on CHIME data from October 1 – June 30, 2015:

Town	*3d Health-Defined Service Area*	*OCHA-Defined Service Area*
Bozrah	*2*	
Brooklyn	*5*	
Canterbury	*2*	*2*
Chaplin	*1*	
Colchester	*7*	*7*
Columbia	*2*	
East Haddam	*9*	
Franklin	*3*	
Griswold-Lisbon	*10*	*10*
Hebron	*3*	
Killingly	*5*	
Lebanon	*6*	
Ledyard		*9*
Mansfield	*2*	
Montville		*12*
Norwich	*26*	*26*
Plainfield	*7*	
Plainville		*18*
Preston	*7*	*7*
Putnam	*2*	
Sprague	*3*	*3*
Sterling	*2*	
Thompson	*1*	
Voluntown	*2*	
Windham	*17*	
Woodstock	*1*	
Total	***125***	***94***

The OCHA-defined service area differs significantly from the Backus Angioplasty region. The towns of Ledyard, Plainville, and Montville are included in the OHCA service area, while it omits towns contiguous to Norwich as well in Northern Windham County. What the analysis illustrates, however, is that the OHCA defined service area captured about 75.2% of the Angioplasty Region volume. This, coupled with OHCA's calculation that this definition captured about 75% of Backus' inpatient discharges, leads the analysis to assume that 75.2% of the projected Backus volume illustrated on page 104 of the CON and on page 43 of the 3d Health Assessment (CON, Exhibit 8, Page 490) could originate from this service area. These numbers are reflected in the Table above.

5. Explain the decreases in the number of diagnostic catheterizations and transfers reflected on Figure 20 on page 62.

The decrease in the number of diagnostic catheterizations is multi-factorial. Backus had catheterization providers relocate to other jobs outside of the State or service area throughout the

previous three fiscal years. When these relocations occurred, the local cardiology practices had a shortage of catheterization providers. This physician shortage meant that patients requiring diagnostic catheterization services were referred to other facilities, outside of the Angioplasty Region, where the referring provider had professional relationships.

Recent physician recruitments (through Hartford HealthCare Medical Group as well as the private physician groups in the community) have resulted in an improvement in volumes at Backus from FY 2014 – FY 2015.

6. Given that Yale, Hartford and L+M are the PCI providers listed on page 46, as well as St. Francis, John Dempsey and Central CT shown in the table above also serve Backus' service area patients, explain:

a. Why the proposal is not an unnecessary duplication of existing health care services currently available;

These providers are all outside the defined Angioplasty Region, and none of them are located in the service area defined by OHCA, above, or in a contiguous town or zip code to this service area. Therefore, there is no duplication of services within the defined Angioplasty Region.

As illustrated previously, residents in this region are forced to travel far distances to receive this life-saving standard of care, and have a higher mortality because of it. Lawrence + Memorial, the closest provider of PCI services to the Region, is not treating most of the patients originating from the Angioplasty Region today. In FY 15, only 32 patients were treated from patients originating from this geography. 30 of the 32 patients live within 30 minutes of Backus Hospital. Additionally, 17 of the 26 towns within the Angioplasty Region had no PCI patients served by Lawrence + Memorial in FY 15. The majority of cases are leaving the community altogether, seeking care at The University of Massachusetts ("UMASS"), Yale, or Hartford Hospitals, all high volume providers.

b. How the proposal will not result in a shift in volumes from existing providers; and
c. How there will be no impact on existing provider.

The 3d Health Assessment (CON, Exhibit 8, Page 447) revealed that a majority of cases originating in the Angioplasty Region are being treated out of the area for Primary and Elective PCI to high-volume providers. In 2014, 48% of Primary cases were transferred to Hartford, and 11% of transfers went to Yale-New Haven Hospital ("YNHH") (3d Health Assessment, p. 22 (CON, Exhibit 8, Page 469). While Hartford captured the greatest share of Primary PCIs, YNHH captured the greatest share of Elective PCIs (3d Health Assessment, p. 23 (CON, Exhibit 8, Page 470)). YNHH is a full-service cardiac provider and like Hartford Hospital has one of the busiest cardiac catheterization laboratories in the State of Connecticut. The majority of the remaining Primary and Elective PCI market is split between UMASS, Lawrence + Memorial, and St. Francis Hospital. In FY 2012, 137 total cases went to UMASS, and in FY2014 22 cases from the Backus market went to Lawrence + Memorial, and 45 cases went to St. Francis (3d Health Assessment, p. 32 (CON, Exhibit 8, Page 479). John Dempsey and the Hospital of Central Connecticut are not treating patients from the Region due to the distance from the market. All of

these programs meet or exceed facility minimums each year, per the recommended guidelines, and the patient volume originating from the Backus market seeking care at these institutions is small enough to ensure that establishing a PCI program at Backus will not compromise the strength of the programs in existence at any of these providers. See the table below for more detailed information.

As stated in the response to question 4, above, multiple towns were excluded from the Backus Angioplasty Region as they are in closer proximity to Lawrence + Memorial; in a cardiac emergency such as the onset of a STEMI time is muscle. These patients are better served by seeking care at Lawrence + Memorial. Additionally, the town of Plainville is not within a close drive time to Backus, and Backus Hospital only received 2 inpatient discharges from Plainville in FY 2015. This town has been excluded from the analysis in the chart below.

This chart highlights the potential impact to other angioplasty providers as identified by OHCA. It assumes that all volume from the Angioplasty Region currently seeking care at Hartford Hospital would transfer to Backus, given that Backus would be the closest PCI provider to these communities. It also assumes that 36% (the overall Backus inpatient market share of the entire Angioplasty Region) of the volume currently cared for at other PCI providers would shift to Backus. This assumption is based on historical trends instead of use rates based on population size, disease burden, and demographics (a more reliable and accurate methodology for calculating potential volume). It therefore does not tie completely with the actual anticipated projected volume as shown on page 70 of the CON application and page 43 of the 3d Health Assessment (CON, Exhibit 8, Page 490), however it does come very close (only different by 6 cases).

Further, it does not back out the elective volume that would continue to seek care at Lawrence + Memorial based on patient choice and physician referral.

Ultimately, however, this analysis shows that although volume will shift from other institutions, ***it will not compromise*** *any of the existing programs in the State. It will, however, provide optimal patient access and bring a standard of care to a currently underserved market.*

Projected Angioplasty Region PCI Volume Shift to Backus

FY 2015 Data	Backus Angioplasty Region PCI Cases	Total Hospital PCI Cases	% of PCI Cases from the Backus Angioplasty Region	Backus Angioplasty Region IP Market Share	Projected PCI Volume Shift to Backus Hospital	Remaining Hospital PCI Volume
Hartford Hospital	135	1,099	12.3%	100%	135	964
John Dempsey Hospital	0	399	0.0%	36%	0	399
Lawrence & Memorial Hospital	32	216	14.8%		12	204
Saint Francis Hospital	53	784	6.7%		8	776
The Hospital of Central Connecticut	0	85	0.0%		0	85
UMass Memorial – University	137	~1,100 (OP Estimated)	12.5%		19	1,081
Yale-New Haven Hospital	138	1,575	8.8%		48	1,527

[1]UMass-University data from FY 2012; 33% of all elective estimated to be performed on an outpatient basis
[2]L&M data from OCHA filing
[3]Hartford data obtained directly
[4]YNNH, and St. Francis data per the CHA's Patient Census Report from October 2014 through September 2015

**Please note: The volumes reflected above are derived from the Angioplasty Region, as defined on page 4 of the 3d Health Assessment (CON, Exhibit 8, Page 451)*

7. Discuss and describe the existing referral base (physicians and physician practices, specifically the interventionalists) in the service area defined in the table above.

There is no referral base for Primary PCIs – these are emergency cases and are brought in through the EMS network, based on DPH guidelines and medical oversight. Additionally, Backus does not have a PCI program, so is not receiving referrals for elective procedures today.

Within the OHCA-definition of the market, there are three cardiology groups practicing at Backus. These practices include the Yale Medical Group, Norwich Cardiac Medicine, and Hartford HealthCare Medical Group. Two interventionalists currently have privileges at Backus to work in its diagnostic catheterization lab. In total, these practices employ 16 physicians.

Upon approval of the program, Hartford HealthCare Medical Group will recruit another interventionalist to work at Backus under the clinical oversight of Hartford Hospital. This interventionalist will also rotate through Hartford Hospital's catheterization lab to ensure adherence to clinical standards, and operator minimums are met and sustained.

Extending access to subspecialty experts across Hartford HealthCare is the mission for HHC's evolving Cardiovascular Institute. The Institute's care delivery model supports standardization of care, appropriate use of resources, and a collaborative team approach to ensure the patient receives comprehensive care within their community. Extending services to Backus under the Institute model supports the aforementioned goals and ensures quality is achieved through aligning providers with quality expectations under the direction of high volume operators. The program will be supported through the Institutes quality and leadership team, maintaining and growing services valuable to

patients within the HHC system. The practicing clinicians are all aligned with the Institute's strategic goals and objectives and support the extension of PCI services in a streamlined and effective manner.

Additionally, Backus Hospital has support from Day Kimball Hospital for establishment of the program. Day Kimball does not employ interventionalists, but does require a Connecticut option for patients requiring an Elective PCI. Day Kimball believes establishing a program at Backus will improve door-to-balloon times for patients originating from the northeast corner of the Angioplasty region.

8. Page 25 indicates physician alignment requirements have been met. Explain what the alignment is at Backus Hospital and its impact on the proposed services.

Hartford Hospital is a regional provider for cardiovascular services, and through the establishment of a Primary and Elective PCI program at Backus, will be able to provide consistent coverage for the program, standardize practice and ensure quality of care in accordance with Hartford Hospital standards. Hartford Hospital will have the ability to work collaboratively with both employed and independent providers in developing the program; the benefit of such an affiliation is to provide patients in the Backus Angioplasty Region with access not only to PCI services, but to expertise in subspecialty areas, surgical expertise from Hartford Hospital in a market that has no providers of open heart surgical services, and an ability to access, and participate in, an established quality program to standardize practice and monitor key core measures and outcomes.

Backus and Hartford Hospital have support from physician partners (as illustrated by letters previously submitted) to establish the program. Currently, these physicians are independent, tightly aligned, or employed by the Hartford HealthCare Medical Group. Physicians participating in the program will rotate through Hartford Hospital's catheterization lab, ensuring all clinical and volume standards are met or exceeded. Any new providers hired into the program will be incorporated into a medical group of high volume providers, given the requirements of the HHC Institute Care Delivery Model. These clinicians will benefit from the expertise and experience of the seasoned team practicing in the Hartford Hospital catheterization labs, and will be a part of the ongoing rotation to ensure regulatory standards and volume targets are achieved. This alignment will further Hartford HealthCare's journey towards achieving one registration, one health record, one standard of excellence, one bill, and one relationship.

9. Describe in detail the proposed on-call system with physicians at Hartford Hospital and Hartford Cardiac Laboratory, P.C. and Dr. John Michael Chua Chiaco to ensure continuous 24/7 coverage.

See response to question 10, below.

10. Provide a copy of the on-call schedule for the physicians that will provide coverage for the proposed program.

Until the program is approved by OHCA a detailed on-call system for the Backus program will not exist. Once approved, however, the on-call system will mirror that which currently exists at Hartford Hospital. A sample on-call schedule for the PCI program at Hartford Hospital is attached as ***Exhibit***

29 for illustrative purposes). All physicians participating in the program, however, will be part of a general call pool made up of high volume physicians. As stated to the answer to question 8, above, any new physicians hired as part of the program will practice at Hartford Hospital, ensuring seasoned provider oversight and adherence to standard quality guidelines.

11. In a table format, provide angioplasty volumes, separated by primary and elective procedures, for each of the physicians in the proposed program for the most recent full fiscal year, and indicate the year.

Fiscal Year 2015	*Primary*	*Elective*	*TOTAL*
Physician 1	*65*	*59*	*124*
Physician 2	*61*	*104*	*165*
Physician 3	*91*	*167*	*258*
Physician 4	*43*	*43*	*86*
Physician 5	*76*	*53*	*129*
Physician 6	*66*	*41*	*107*
Physician 7	*67*	*46*	*113*
*Physician 8^*	*Not available*		*173*
TOTAL HH	***469***	***513***	***1,155***

Data for physicians 1-7 obtained directly, provided by internal data analytics; Reflective of Hartford Hospital PCI volume only

^Physician 8 data obtained directly, reflects 6 months of data not included in original CON application; data not available by zip code

12. Table 6 on page 78 shows a projected 2% increase in PCIs from FY16 to FY18. Please elaborate on the assumptions used to arrive at the growth rate.

The projected Backus Hospital PCI volume shown in Table 6 on page 78 is calculated by applying Backus Hospital's historic market share and immigration rates to the projected service area volumes as shown on pages 42 and 43 of the 3d Health Assessment (CON, Exhibit 8, Pages 489-490). Since the typical Primary PCI patient presents at a hospital emergency department ("ED"), 3d Health applied Backus and Windham combined FY 2014 ED market share to the projections to estimate the potential for Primary PCI cases at Backus. Market share was calculated for each specific geographic region within the defined service area, based on 30 minute drive time from Backus. For those cases from towns within 30 minutes of Backus, 80% was applied to the total potential Primary PCI volume (the combined market share for Backus and Windham). For those cases from service area towns outside of 30 minutes away from Backus, 11% was applied to total potential volume Primary PCI volume (the combined market share for Backus and Windham). An immigration rate of 5.4% was applied, based on the historic emergency department experience (the combined immigration rate for Backus and Windham). In estimating Backus Hospital's Elective PCI volumes, "complex" Elective PCI cases (those with a history of previous cardiac event or intervention) were removed from the total potential Backus case volume, assuming that these patients would require care at a tertiary institution offering on-site cardiac surgical backup and would not receive their elective angioplasty at Backus. Backus Hospital inpatient market share for each town within the defined Backus service area (based on the 10, 10-30, and 30+ drive times) was applied to the remaining potential service area volume (75% of cases originating 10 minutes from Backus, 50% of

cases originating 10-30 minutes from Backus, and 25% of cases originating 30+ minutes from Backus). An immigration rate of 3.2% was applied, based on the historic Backus Hospital inpatient experience. The number of Elective PCI Lawrence + Memorial cases from patients originating from the Backus Service Area was projected based on historic OCHA data and removed from the potential Backus volume under the assumption that these cases would continue to be performed at Lawrence + Memorial. Thus, the 2% projected growth in Backus Hospital volume is a result of applying a constant market share to a growing number of service area cases.

13. On page 459, PCIs are defined to include ICD-9 CM procedure code 17.55 and NSTEMIs to include ICD-9-CM diagnoses codes 426.2 – 426.3. Explain each inclusion and provide a source/citation.

PCIs were defined to include ICD-9 CM procedure code 17.55 per the Connecticut Department of Public Health (http://www.ct.gov/dph/lib/dph/hems/chronic_dis/hospitaldata/cdi13web.pdf).

NSTEMIs were defined to include diagnosis codes 410.7x in any of the first ten positions. The use of diagnosis codes 426.2 and 426.3 were only to further classify patients as Left Bundle Branch Block if they had already been defined as an NSTEMI patient.

14. Revise and resubmit the payer mix table on page 79 as the rows appear to have shifted downward and are not correctly aligned. In addition, provide the assumptions used for the projected population mix.

Page 79, Table 7: Applicant's Current & Projected Payor Mix

Payer	*Current FY 2014*		*Projected*					
			*FY 2016***		*FY 2017***		*FY 2018***	
	Discharges	*%*	*Discharges*	*%*	*Discharges*	*%*	*Discharges*	*%*
Medicare			*109*	*50%*	*110*	*50%*	*113*	*50%*
*Medicaid**			*25*	*11%*	*25*	*11%*	*26*	*11%*
CHAMPUS & TriCare			*-*	*0%*	*-*	*0%*	*-*	*0%*
Other Government			*2*	*1%*	*2*	*1%*	*2*	*1%*
Total Government			***135***	***62%***	***136***	***62%***	***140***	***62%***
Commercial Insurers			*79*	*37%*	*80*	*37%*	*82*	*37%*
Uninsured			*2*	*1%*	*2*	*1%*	*2*	*1%*
Workers Compensation			*-*	*0%*	*-*	*0%*	*-*	*0%*
Total Non-Government			***81***	***38%***	***82***	***38%***	***85***	***38%***
Total Payer Mix			***216***	***100%***	***218***	***100%***	***225***	***100%***

****Volume reflects both IP & OP, incremental volume projections***

3d Health calculated a payor-weighted reimbursement by DRG based on the payor mix of all PCI patients originating the Backus service area.

15. Page 67 indicates a capital expenditure of $4.8 M for an additional cath lab, software and equipment update and allowances for ongoing capital needs. Page 62 shows a 32% decline in cardiac caths between 2012 and 2014. Explain the need for an additional cath lab.

STEMI patients requiring PCI experience the best clinical outcomes when the procedure is performed within 90 minutes from first medical contact. In order to achieve these results Backus must be able to have a procedure room ready to accept these patients at all times. During normal business hours of 7am-4pm the existing catheterization laboratory is utilized for diagnostic catheterizations and electrophysiology procedures such as pacemaker and ICD insertions. These procedures can range from 45 minutes to three hours. Waiting for an available room costs a STEMI patient heart muscle and does not result in optimal outcomes. A second room allows Backus to schedule diagnostic and electrophysiology patients in such a way that there will always be a room available within 30 minutes of a STEMI arrival to Backus. This will ensure Backus routinely meets the 90 minute door-to-balloon time recommendation from the 2014 AHA/ACC/SCAI STEMI guidelines.

Additionally, the second catheterization lab is investment in the total cardiovascular service line at Backus Hospital. As mentioned previously, electrophysiology procedures are performed in a catheterization lab. Adding a second room at Backus will allow that subservice line to grow, better meeting the demands of the community.

Finally, this second room, coupled with the establishment of PCI services at Backus, creates redundancy within the Hartford HealthCare system of care. Hartford Hospital's catheterization labs are at capacity, as demonstrated on page 35 of the 3d Health Assessment (CON, Exhibit 8, Page 482). The evolution of a Cardiovascular Institute at Hartford Health Care requires the System to leverage resources across the continuum of care. The addition of capacity (programmatic and physical plant) at Backus provides the care delivery system with the ability to manage complex, acute, and elective procedures across all Hartford HealthCare hospitals in a cost effective manner. In addition, 75% of the catheterization labs at Hartford Hospital have reached the end of useful life, requiring imaging upgrades in order to maintain quality and safety standards. With these labs being offline in 2016, having the ability to support access to care with a consistent team of physician experts, through the addition of a lab and program at Backus, will ensure timely care delivery and a consistent standard of care.

Establishing a program, and additional rooms, at Backus Hospital will allow for decompression of the Hartford lab in the case of planned or emergency maintenance or upgrades, or in times of high patient need.

16. Confirm the projection of 385 PCIs in year 5 in order to achieve operating gains.

3d Health reassessed the number of PCIs needed in year five to achieve operating gains and determined that the projection of 385 was off by four procedures. The confirmed number of PCIs needed in year five to achieve operating gains is 381.

This is based on a very conservative financial model that includes an annual inflation rate of 2.68%. If the annual inflation rate were set to zero, the number of PCIs needed in year five to achieve operating gains would be 277.

EXHIBIT 28

Summary Report

2015 Community Health Needs Assessment

Backus Hospital Service Area

Prepared for:
Backus Hospital

By:
Professional Research Consultants, Inc.
11326 P Street Omaha, NE 68136-2316
www.PRCCustomResearch.com

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NOTICE: This document and the information contained herein are embargoed until edited to include the hospital's selected priorities.

Professional Research Consultants, Inc.

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Summary Tables: Comparisons With Benchmark Data

The following tables provide an overview of indicators in the Backus Hospital Service Area. These data are grouped to correspond with the Focus Areas presented in Healthy People 2020.

Reading the Data Summary Tables

In the following charts, Backus Hospital Service Area results are shown in the larger, blue column.

The green columns [to the left of the BHSA column] provide comparisons among the two subareas, identifying differences for each as "better than" (☼), "worse than" (☁), or "similar to" (⛅) the opposing area.

The columns to the right of the service area column provide comparisons between local data and any available state and national findings, and Healthy People 2020 targets. Again, symbols indicate whether the Backus Hospital Service Area compares favorably (☼), unfavorably (☁), or comparably (⛅) to these external data.

Note that blank table cells signify that data are not available or are not reliable for that area and/or for that indicator.

Overall Health	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
% "Fair/Poor" Physical Health	⛅ 13.5	⛅ 13.4	13.5	⛅ 13.3	⛅ 15.3	
% Activity Limitations	⛅ 25.2	⛅ 18.9	22.0	☁ 17.5	⛅ 21.5	
	Note: In the green section, service areas are compared against one another. Throughout, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			☼ better	⛅ similar	☁ worse

Access to Health Services	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
% [Age 18-64] Lack Health Insurance	⛅ 6.7	⛅ 6.8	6.8	☼ 12.3	☼ 15.1	☁ 0.0
% [Insured] Went Without Coverage in Past Year	☁ 8.1	☼ 3.8	5.9		⛅ 8.1	
% Difficulty Accessing Healthcare in Past Year (Composite)	⛅ 39.0	⛅ 33.5	36.2		⛅ 39.9	
% Inconvenient Hrs Prevented Dr Visit in Past Year	⛅ 13.5	⛅ 16.3	14.9		⛅ 15.4	
% Cost Prevented Getting Prescription in Past Year	☁ 11.1	☼ 5.8	8.4		☼ 15.8	

Access to Health Services (continued)	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	SSA	BHSA	vs. CT	vs. US	vs. HP2020
% Cost Prevented Physician Visit in Past Year	11.4	5.9	8.6		18.2	
% Difficulty Getting Appointment in Past Year	15.1	14.1	14.6		17.0	
% Difficulty Finding Physician in Past Year	8.6	7.8	8.2		11.0	
% Transportation Hindered Dr Visit in Past Year	6.2	6.3	6.2		9.4	
% Skipped Prescription Doses to Save Costs	10.7	5.4	8.0		15.3	
% Difficulty Getting Child's Healthcare in Past Year	1.2	2.6	1.9		6.0	
Primary Care Doctors per 100,000			60.0	84.0	74.5	
% [Age 18+] Have a Specific Source of Ongoing Care	74.3	79.7	77.0		76.3	95.0
% [Age 18-64] Have a Specific Source of Ongoing Care	75.6	79.6	77.6		75.6	89.4
% [Age 65+] Have a Specific Source of Ongoing Care			76.5		80.0	100.0
% Have Had Routine Checkup in Past Year	75.7	78.2	77.0	71.8	65.0	
% Child Has Had Checkup in Past Year	95.5	96.3	95.9		84.1	
% Two or More ER Visits in Past Year	12.0	8.2	10.1		8.9	
% Rate Local Healthcare "Fair/Poor"	11.7	8.9	10.4		16.5	

Note: In the green section, service areas are compared against one another. Throughout, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Arthritis, Osteoporosis & Chronic Back Conditions	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	SSA	BHSA	vs. CT	vs. US	vs. HP2020
% Arthritis/Rheumatism	24.9	17.9	21.4	24.9	20.1	
% Osteoporosis	5.2	5.6	5.4		6.7	
% [50+] Arthritis/Rheumatism	41.3	35.1	38.2		37.3	
% [50+] Osteoporosis	10.2	11.1	10.6		13.5	5.3
% Sciatica/Chronic Back Pain	29.4	18.1	23.7		18.4	
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			better	similar	worse

Cancer	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	SSA	BHSA	vs. CT	vs. US	vs. HP2020
Cancer (Age-Adjusted Death Rate)			160.6	153.0	166.2	161.4
Lung Cancer (Age-Adjusted Death Rate)			40.9	38.7	44.7	45.5
Prostate Cancer (Age-Adjusted Death Rate)			15.7	18.2	19.8	21.8
Female Breast Cancer (Age-Adjusted Death Rate)			20.4	19.2	21.3	20.7
Colorectal Cancer (Age-Adjusted Death Rate)			13.7	12.1	14.9	14.5
Prostate Cancer Incidence per 100,000			122.6	152.4	142.3	
Female Breast Cancer Incidence per 100,000			133.1	136.6	122.7	
Lung Cancer Incidence per 100,000			69.5	64.8	64.9	

Cancer (continued)	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	**SSA**	**BHSA**	**vs. CT**	**vs. US**	**vs. HP2020**
Colorectal Cancer Incidence per 100,000			**41.0**	42.7	43.3	
Cervical Cancer Incidence per 100,000			**10.2**	6.2	7.8	
% Skin Cancer	6.9	4.1	**5.5**	5.8	6.7	
% Cancer (Other Than Skin)	6.6	5.1	**5.8**	7.5	6.1	
% [Women 50-74] Mammogram in Past 2 Years	87.9	88.0	**87.9**	81.5	83.6	81.1
% [Women 21-65] Pap Smear in Past 3 Years	85.0	88.7	**86.8**	80.1	83.9	93.0
% [Age 50+] Sigmoid/Colonoscopy Ever	86.0	82.3	**84.2**	74.5	75.2	
% [Age 50+] Blood Stool Test in Past 2 Years	28.3	31.0	**29.6**	16.4	36.9	
% [Age 50-75] Colorectal Cancer Screening	81.5	83.5	**82.5**		75.1	70.5
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			better	similar	worse

Chronic Kidney Disease	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	**SSA**	**BHSA**	**vs. CT**	**vs. US**	**vs. HP2020**
Kidney Disease (Age-Adjusted Death Rate)			**12.7**	12.5	13.2	
% Kidney Disease	1.8	3.2	**2.5**	2.1	3.0	
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			better	similar	worse

Diabetes	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
Diabetes Mellitus (Age-Adjusted Death Rate)			16.4	14.8	21.3	20.5
% Diabetes/High Blood Sugar	12.6	12.3	12.4	8.3	11.7	
% Borderline/Pre-Diabetes	8.3	6.3	7.3		5.1	
% [Non-Diabetes] Blood Sugar Tested in Past 3 Years	52.8	55.0	53.9		49.2	

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Dementias, Including Alzheimer's Disease	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
Alzheimer's Disease (Age-Adjusted Death Rate)			21.3	16.5	24.0	

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Family Planning	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
Births to Teens (Percent)			5.5	5.1	7.8	

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Hearing & Other Sensory or Communication Disorders	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
% Deafness/Trouble Hearing	9.8	11.1	10.4		10.3	

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Heart Disease & Stroke	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	SSA	BHSA	vs. CT	vs. US	vs. HP2020
Diseases of the Heart (Age-Adjusted Death Rate)			169.0	153.4	171.3	156.9
Stroke (Age-Adjusted Death Rate)			30.5	27.9	37.0	34.8
% Heart Disease (Heart Attack, Angina, Coronary Disease)	7.1	4.5	5.8		6.1	
% Heart Attack	5.5	2.4	4.0		3.9	
% Angina/Coronary Heart Disease	4.2	3.7	4.0		3.7	
% Stroke	2.1	2.7	2.4	2.3	3.9	
% Blood Pressure Checked in Past 2 Years	95.3	97.3	96.3		91.0	92.6
% Told Have High Blood Pressure (Ever)	39.5	39.5	39.5	31.3	34.1	26.9
% [HBP] Taking Action to Control High Blood Pressure	86.2	91.7	89.0		89.2	
% Cholesterol Checked in Past 5 Years	91.3	92.6	91.9	83.1	86.6	82.1
% Told Have High Cholesterol (Ever)	31.4	32.1	31.7	37.8	29.9	13.5
% [HBC] Taking Action to Control High Blood Cholesterol	88.3	85.8	87.0		81.4	
% 1+ Cardiovascular Risk Factor	86.1	90.3	88.2		82.3	

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

HIV	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
HIV Prevalence per 100,000			224.3	359.7	340.4	
% [Age 18-64] Ever Tested for HIV			45.2		50.6	
% [Age 18-44] HIV Test in the Past Year	17.3	23.1	20.2		19.3	

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Immunization & Infectious Diseases	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
% [Age 65+] Flu Vaccine in Past Year			68.2	63.6	57.5	70.0
% [High-Risk 18-64] Flu Vaccine in Past Year	51.7	59.7	55.6		45.9	70.0
% [Age 65+] Pneumonia Vaccine Ever			74.0	67.8	68.4	90.0
% [High-Risk 18-64] Pneumonia Vaccine Ever	35.4	42.7	38.9		41.9	60.0
% Have Completed Hepatitis B Vaccination Series	51.5	47.8	49.6		44.7	

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Injury & Violence Prevention	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	SSA	BHSA	vs. CT	vs. US	vs. HP2020
Unintentional Injury (Age-Adjusted Death Rate)			40.2	35.8	39.2	36.4
Motor Vehicle Crashes (Age-Adjusted Death Rate)			7.2	7.1	10.7	12.4
% "Always" Wear Seat Belt	90.8	92.0	91.4		84.8	92.0
% Child [Age 0-17] "Always" Uses Seat Belt/Car Seat	100.0	95.0	97.6		92.2	
% Child [Age 5-17] "Always" Wears Bicycle Helmet			67.3		48.7	
Firearm-Related Deaths (Age-Adjusted Death Rate)			5.6	5.5	10.4	9.3
% Firearm in Home	25.0	22.8	23.9		34.7	
% [Homes With Children] Firearm in Home	24.7	24.9	24.8		37.4	
% [Homes With Firearms] Weapon(s) Unlocked & Loaded			8.7		16.8	
Homicide (Age-Adjusted Death Rate)			2.4	3.8	5.3	5.5
Violent Crime per 100,000			341.4	280.6	395.5	
% Victim of Violent Crime in Past 5 Years	0.8	0.9	0.9		2.8	
% Victim of Domestic Violence (Ever)	14.1	10.1	12.1		15.0	
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			better	similar	worse

Maternal, Infant & Child Health	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
No Prenatal Care in First Trimester (Percent)			10.2	better 13.0		better 22.1
Low Birthweight Births (Percent)			7.6	similar 7.8	better 8.0	similar 7.8
Infant Death Rate			5.2	worse 4.9	better 6.0	better 6.0
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			better	similar	worse

Mental Health & Mental Disorders	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
% "Fair/Poor" Mental Health	similar 10.8	similar 8.8	9.8		similar 11.9	
% Diagnosed Depression	similar 19.1	similar 20.4	19.7		similar 20.4	
% Symptoms of Chronic Depression (2+ Years)	similar 28.5	similar 28.6	28.6		similar 30.4	
Suicide (Age-Adjusted Death Rate)			11.8	worse 9.5	better 12.5	worse 10.2
% Have Ever Sought Help for Mental Health	similar 30.2	similar 27.1	28.6		better 23.7	
% [Those With Diagnosed Depression] Seeking Help			83.7		similar 76.6	
% Member of HH Sought Help for Mental Health/Past Year	similar 24.6	similar 18.7	21.6			
% Typical Day Is "Extremely/Very" Stressful	similar 10.4	similar 11.9	11.1		similar 11.9	

Mental Health & Mental Disorders (continued)	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	SSA		vs. CT	vs. US	vs. HP2020
% [Children <18] Child Has "Fair/Poor" Mental Health	2.1	7.0	4.5			
% [Children <18] Couldn't Get Mental Help for Child in Past Year	0.6	1.1	0.8			

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Nutrition & Weight Status	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	SSA		vs. CT	vs. US	vs. HP2020
% Eat 5+ Servings of Fruit or Vegetables per Day	36.9	30.7	33.8		39.5	
% "Very/Somewhat" Difficult to Buy Fresh Produce	26.3	22.7	24.4		24.4	
Population With Low Food Access (Percent)			29.3	29.8	23.6	
% Medical Advice on Nutrition in Past Year	43.8	45.2	44.5		39.2	
% Healthy Weight (BMI 18.5-24.9)	31.6	25.8	28.6	35.6	34.4	33.9
% Overweight (BMI 25+)	67.2	71.8	69.5	62.6	63.1	
% Obese (BMI 30+)	32.0	32.8	32.4	25.0	29.0	30.5
% [Overweights] Perceive Self "About the Right Weight"	38.1	36.7	37.4		22.1	
% Medical Advice on Weight in Past Year	28.0	35.8	31.9		23.7	
% [Overweights] Counseled About Weight in Past Year	36.0	44.3	40.4		31.8	
% [Obese Adults] Counseled About Weight in Past Year	52.4	57.4	55.0		48.3	

Nutrition & Weight Status (continued)	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	**SSA**	**BHSA**	**vs. CT**	**vs. US**	**vs. HP2020**
% [Overweights] Trying to Lose Weight Both Diet/Exercise	39.4	35.7	**37.5**		39.5	
% Child [Age 5-17] Healthy Weight			**57.9**		56.7	
% Children [Age 5-17] Overweight (85th Percentile)			**34.1**		31.5	
% Children [Age 5-17] Obese (95th Percentile)			**21.2**		14.8	14.5
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.				better	similar	worse

Oral Health	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	**SSA**	**BHSA**	**vs. CT**	**vs. US**	**vs. HP2020**
% [Age 18+] Dental Visit in Past Year	75.3	77.6	**76.5**	76.1	65.9	49.0
% Child [Age 2-17] Dental Visit in Past Year	89.9	92.1	**91.0**		81.5	49.0
% Have Dental Insurance	79.1	80.4	**79.8**		65.6	
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.				better	similar	worse

Physical Activity	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	**SSA**	**BHSA**	**vs. CT**	**vs. US**	**vs. HP2020**
% No Leisure-Time Physical Activity	29.8	27.2	**28.5**	24.9	20.7	32.6
% Meeting Physical Activity Guidelines	44.6	42.6	**43.6**		50.3	
% Moderate Physical Activity	28.1	26.5	**27.3**		30.6	

Physical Activity (continued)	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	**SSA**	**BHSA**	**vs. CT**	**vs. US**	**vs. HP2020**
% Vigorous Physical Activity	33.5	34.3	**33.9**		38.0	
Recreation/Fitness Facilities per 100,000			**10.5**	13.2	9.4	
% Medical Advice on Physical Activity in Past Year	50.5	57.5	**54.0**		44.0	
% Child [Age 2-17] Physically Active 1+ Hours per Day	53.4	40.9	**47.3**		48.6	

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Respiratory Diseases (continued)	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	**SSA**	**BHSA**	**vs. CT**	**vs. US**	**vs. HP2020**
CLRD (Age-Adjusted Death Rate)			**43.2**	30.9	42.0	
Pneumonia/Influenza (Age-Adjusted Death Rate)			**14.0**	12.9	15.3	
% COPD (Lung Disease)	12.9	13.9	**13.4**	5.9	8.6	
% Adults Asthma (Ever Diagnosed)	22.1	19.2	**20.6**		16.4	
% [Adult] Currently Has Asthma	14.1	10.8	**12.4**	9.8	9.4	
% Child [Age 0-17] Asthma (Ever Diagnosed)	11.2	4.1	**7.6**		12.5	
% [Child 0-17] Currently Has Asthma	7.4	4.1	**5.8**		7.1	

Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.

better similar worse

Sexually Transmitted Diseases	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
Gonorrhea Incidence per 100,000			29.6	57.4	107.5	
Chlamydia Incidence per 100,000			244.1	364.9	456.7	
% [Unmarried 18-64] 3+ Sexual Partners in Past Year	6.9	7.8	7.4		11.7	
% [Unmarried 18-64] Using Condoms	34.8	26.1	30.3		33.6	
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			better	similar	worse

Substance Abuse	PSA vs. SSA: PSA	PSA vs. SSA: SSA	BHSA	BHSA vs. Benchmarks: vs. CT	BHSA vs. Benchmarks: vs. US	BHSA vs. Benchmarks: vs. HP2020
Cirrhosis/Liver Disease (Age-Adjusted Death Rate)			8.8	7.6	9.9	8.2
% Current Drinker	62.2	63.8	63.0	62.6	56.5	
% Chronic Drinker (Average 2+ Drinks/Day)	11.7	11.6	11.6		5.2	
% Binge Drinker (Single Occasion - 5+ Drinks Men, 4+ Women)	19.0	19.9	19.4		19.5	24.4
% Excessive Drinker (Heavy or Binge Drinking)	24.7	23.0	23.8		23.2	25.4
% Drinking & Driving in Past Month	4.1	2.0	3.1		5.0	
Drug-Induced Deaths (Age-Adjusted Death Rate)			17.6	13.5	14.1	11.3
% Illicit Drug Use in Past Month	4.4	0.6	2.5		4.0	7.1

Substance Abuse (continued)	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	**SSA**	**BHSA**	**vs. CT**	**vs. US**	**vs. HP2020**
% Ever Sought Help for Alcohol or Drug Problem	2.7	2.1	**2.4**		4.9	
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			better	similar	worse

Tobacco Use	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	**SSA**	**BHSA**	**vs. CT**	**vs. US**	**vs. HP2020**
% Current Smoker	19.3	18.6	**18.9**	15.5	14.9	12.0
% Someone Smokes at Home	13.4	12.1	**12.7**		12.7	
% [Non-Smokers] Someone Smokes in the Home	5.3	3.7	**4.5**		6.3	
% [Household With Children] Someone Smokes in the Home	11.9	9.2	**10.6**		9.7	
% [Smokers] Received Advice to Quit Smoking			**69.1**		67.8	
% [Smokers] Have Quit Smoking 1+ Days in Past Year			**54.0**		55.9	80.0
% Smoke Cigars	5.4	5.0	**5.2**		4.1	0.2
% Use Smokeless Tobacco	4.1	3.0	**3.5**		4.0	0.3
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			better	similar	worse

Vision	PSA vs. SSA		BHSA	BHSA vs. Benchmarks		
	PSA	SSA	BHSA	vs. CT	vs. US	vs. HP2020
% Blindness/Trouble Seeing	6.0	10.6	8.3		8.5	
% Eye Exam in Past 2 Years	67.4	64.6	66.0		56.8	
	Note: In the green section, service areas are compared against one another. Throughout these tables, a blank or empty cell indicates that data are not available for this indicator or that sample sizes are too small to provide meaningful results.			better	similar	worse

EXHIBIT 29

Nov 2015 (Eastern Time)

Sun	Mon	Tue	Wed	Thu	Fri	Sat
1 CALL FJK PRO IRS PRO TA	2 CALL DBF NIV JAH OFFICE CLINIC AR PRO TA	3 CALL AR NIV FJK PRO TA	4 BROWN STONE AR CALL JAH NIV JAH OFF DBF PRO TA	5 CALL RGM NIV AR OFF DBF PRO TA	6 CALL TAL NIV IRS	7 CALL TAL NIV FJK
8 CALL TAL	9 CALL FJK NIV DBF OFF RGM OFFICE CLINIC TAL	10 CALL DBF NIV TAL	11 CALL AR NEW BRITAIN TA NIV FJK	12 CALL RGM NIV JAH	13 CALL IRS NIV AR	14 CALL IRS NIV NIV
15 CALL IRS	16 CALL JAH NIV TAL OFFICE CLINIC IRS	17 CALL TAL NIV DBF	18 CALL FJK NIV IRS	19 CALL DBF NIV AR	20 CALL RGM EAST HARTFORD TA NIV FJK OFF IRS	21 CALL RGM NIV NIV
22 CALL RGM	23 CALL AR NIV JAH OFFICE CLINIC TA	24 CALL TAL NIV FJK OFF AR	25 CALL IRS ENFIELD/BLOOMFIEL NIV DBF OFF AR OFF FJK	26 CALL JAH	27 CALL JAH NIV IRS OFF AR OFF DBF OFF TA	28 CALL JAH NIV AR OFF TAL
29 CALL JAH	30 CALL FJK NIV AR	1 CALL RGM NIV TAL	2 BROWN STONE AR CALL TAL NIV IRS	3 CALL AR NIV DBF	4 CALL DBF NIV JAH OFF FJK	5 CALL DBF NIV TAL

Greer, Leslie

From: Armah, Olga
Sent: Monday, January 04, 2016 9:54 AM
To: Teitelbaum, Claudia S.; User, OHCA; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: Anthony, Robert J.; Janette.Edwards@hhchealth.org; Mercier, Carlene M.
Subject: RE: OHCA Docket 15-32031 Hartford Healthcare Backus Completeness Response 12-30-2015.pdf

Good morning Ms. Teitelbaum, this is to acknowledge receipt of the response.

Thanks.

Olga

Olga Armah
CT Department of Public Health
Office of Health Care Access (OHCA)
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

From: Teitelbaum, Claudia S. [mailto:CTeitelbaum@brownrudnick.com]
Sent: Wednesday, December 30, 2015 2:58 PM
To: User, OHCA; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: Anthony, Robert J.; Janette.Edwards@hhchealth.org; Mercier, Carlene M.
Subject: OHCA Docket 15-32031 Hartford Healthcare Backus Completeness Response 12-30-2015.pdf

-----Original Message-----
From: Teitelbaum, Claudia S.
Sent: Wednesday, December 30, 2015 2:52 PM
To: Teitelbaum, Claudia S.
Subject: Emailing: OHCA Docket 15-32031 Hartford Healthcare Backus Completness Response 12-30-2015.pdf

Your message is ready to be sent with the following file or link attachments:

OHCA Docket 15-32031 Hartford Healthcare Backus Completness Response 12-30-2015.pdf

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

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Greer, Leslie

From: Mercier, Carlene M. <CMercier@brownrudnick.com>
Sent: Monday, January 11, 2016 1:21 PM
To: User, OHCA; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: Anthony, Robert J.; Janette.Edwards@hhchealth.org
Subject: Docket No. 15-32031 - Add'l Letter of Support
Attachments: Hartford Heathcare_Backus - NECCA Letter of Support.PDF

Good Afternoon,

Please find attached for filing a cover letter and additional letter of support in the Hartford Healthcare Backus docket (No. 15-32031). This filing is being submitted electronically. Please let me know if you require a hard copy.

Best Regards,
Carlene Mercier

BROWNRUDNICK

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

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****

ROBERT J. ANTHONY, ESQ.

direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com

http://www.brownrudnick.com

BROWNRUDNICK

185 Asylum
Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

January 11, 2016

VIA E-MAIL
(ohca@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON – Supplemental Letter of Support

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital, attached please find one additional Letter of Support (from NorthEastern Connecticut Cardiology Associates, PC) for the Applicants' Certificate of Need Application to establish and operate a Primary and Elective Angioplasty Program at Backus Hospital.

Please do not hesitate to contact me if you have any questions.

Very truly yours,

BROWN RUDNICK LLP

By: _____
Robert J. Anthony

Enclosure

62279812 v1-WorkSiteUS-032836/0001

brownrudnick.com

NECCA

William M. Bradbury, MD, FACC *
Lisa T. Canter, MD, FACC *
Mary Frisella, MD, FACC *

*Assistant Professor
UMASS-Memorial Medical Center

37 Kennedy Drive
Suite A
Putnam, CT 06260
Tel: (860) 963-7519
Fax: (860) 963-0668

NorthEastern Connecticut Cardiology Associates, PC

David A. Whitehead
President
The William W. Backus Hospital
326 Washington Street
Norwich, Connecticut, 06360

Dear Mr. Whitehead,

Please accept this letter of support for the development of a Primary and Elective Percutaneous Cardiac Intervention (PCI) program at The William W. Backus Hospital.

A program of this kind is sorely needed in the northern New London and Windham counties, enabling Eastern Connecticut residents to have timely access to PCI. Many residents of this region are currently unable to access a PCI-capable facility within a 30-minute drive time, or within their local communities. This lack of access is a barrier to receiving what is considered to be the standard of care for a life-limiting heart condition.

As a local provider, I am convinced of the need to have this level of care available in our community – our families, friends and neighbors should not be at a disadvantage when it comes to their health, just because of where they live. Having the clinical and technological infrastructure available at Backus, coupled with its strong relationship with Hartford Hospital, will result in optimal care for cardiac patients in need of PCI.

Please accept this letter of support – Backus should be commended for its commitment to offering Percutaneous Cardiac Intervention, close to home for patients.

Sincerely,

William Bradbury MD, FACC

Lisa Canter MD, FACC

Mary Frisella MB, FACC

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

March 15, 2016

RECEIVED
MAR 17 2016
Office of
HEALTHCARE ACCESS

Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Hearing Officer Hansted,

My name is Greg Allard and I am the Vice President of American Ambulance Service, Inc. (AASI) located in Norwich, Connecticut. American serves not only Norwich (with a population of over 40,000); we serve 22 communities in Eastern Connecticut including the Mashantucket Pequot Tribal Nation. In addition to all of our emergency responsibilities, we provide non-emergency or routine ambulance and wheelchair transportation. We work closely with all of our community hospitals and skilled nursing and rehab facilities.

Support for a PCI Program at Backus

As the major EMS provider in the defined Backus Hospital Angioplasty Region, AASI fully supports the CON application to provide Primary and Elective PCI at Backus. The reason for our support is two-fold. Most importantly, we believe having such a program is in the best interest of all of the residents in the community we serve and our patients are always our number one priority. Secondly, it will create efficiencies within our system that have the potential to improve our availability to respond to emergency and non-emergency requests and this is due to the fact that our ambulances will remain in our primary service area longer.

Some STEMI patients can be identified in the field via an EKG performed in the out of hospital arena, however this can only occur if a Paramedic is on-board, either at the time of patient pick up or through an "intercept" en route to the hospital. In the defined Angioplasty Region three EMS providers have Advanced Life Support (ALS) abilities. In total, these EMS providers can staff 17 Paramedic vehicles, on average; there are 14 available ALS vehicles during the day, and 7 during the night.

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

Throughout the region there are many volunteer-based ambulance services that are Basic Life Support (BLS) capable and are not qualified to determine if a patient is experiencing a STEMI when picked up in the field. Thus, the potential exists for patients with unidentified STEMIs to arrive at Backus Hospital in need of Primary PCI if a Paramedic is not available.

Patients receiving diagnostic catheterizations that require Elective PCI also require transport via EMS to PCI-equipped facilities. Currently there is only one of those facilities in Eastern Connecticut and there are at least a dozen in the western half of Connecticut. Therefore, residents living in the Angioplasty Region must travel, by ambulance, significant distances for this life saving procedure.
Studies have proven that time is of the essence when dealing with STEMI patients in order to ensure the best possible health outcomes. So both Primary and Elective PCI can necessitate transport via EMS to a PCI-capable facility. As any commuter can tell you, travel times are highly dependent on weather conditions, traffic patterns and road work/construction as well as accidents. So the transfer times between facilities can vary greatly.

Additionally, on page 1449 of the Backus/Hartford Hospital Completeness Responses there is very valuable data provided by the American Heart Association's Mission: LifeLine that shows the Backus Hospital Angioplasty Region has: an average 75 minute transfer time for acute coronary intervention in New London County which has the third-highest mortality rate and, more importantly, it also includes Windham County (which has no access to a PCI capable provider in Connecticut) and it has the highest mortality rate in the State. A PCI program in Backus Hospital would therefore improve the timeliness of accessing critical, life-saving procedures.

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

Conclusion

For the reasons stated above, we at American Ambulance Service, Inc. urge the Office of Health Care Access to approve the William W. Backus Hospitals' request for PCI services.

Respectfully,

Gregory B. Allard, Vice President

Dedicated, Professional People Committed to Excellence, Caring for You.

Irene Cardinal
11 Prentice Street
Taftville, CT 06380

March 16, 2016

To whom it may concern:

My name is Irene Cardinal. I'm 55 years old and live in Taftville, Connecticut.

In the early morning of February 4 of this year I came to the Backus Hospital Emergency Department after experiencing a fever and elevated heart rate. While I had been diagnosed with an irregular heart beat in the past and do have slight high blood pressure from time to time, I have no other preexisting conditions that would have led me to believe that I was having a serious problem with my heart; I'm not a drinker or a smoker and I don't have diabetes. But in hindsight, I think the signs were all there.

After two blood tests came back negative, the cardiologist on-call—Dr. Amr Atef—ordered a stress test for me later that morning after my heart rate was normalized and I was admitted to the hospital. When the third blood test came back positive, (right before I got on the treadmill actually), Dr. Atef cancelled the stress test, ordered an echocardiogram and discussed the importance of an angiogram with me. He sent me to rest, eat, started some heart medications and scheduled the angiogram for the next morning. The angiogram done at Backus Hospital showed I had two blockages—one at 95 percent. I was to be transferred immediately to Hartford Hospital for angioplasty.

This all happened so quickly and my head was spinning. When I entered the hospital the day before, I thought at worst I'd be prescribed medicine for my racing heart. Now, I was being sent to Hartford Hospital for what could be a lifesaving procedure.

To make matters worse for me and my family, Connecticut was in the middle of a winter storm as nearly a foot of snow was falling across parts of the state. The ambulance crew that transported me was amazing but the trip through the storm was harrowing at best. The roads were a disaster, some stretches were unplowed, and we got stuck behind an accident for more than 20 minutes. I could hear the slush and snow crunching under the vehicle as we navigated the shoulder to drive past the crash. The 40 mile trip took more than two hours.

As you can imagine, the situation was also quite stressful for my husband. Not only was his wife having an unexpected medical emergency, but now, because of the storm, he couldn't make it to the hospital to be there for me during my procedure.

My procedure at Hartford Hospital was a success. I'm currently undergoing follow up care to determine what should be or needs to be done for the second lesser blockage. There's been no talk of having to go back to Hartford for any more procedures and I am hoping/praying none will

Live to Barbara

be necessary. My care at both Backus and Hartford Hospital was and continues to be exemplary. However, having to be transported for care during a snowstorm made a stressful event even more stressful for me and my family. I wouldn't want another person to have to go through that. Having angioplasty available at Backus Hospital would mean community members could rest easier knowing that lifesaving cardiac care is available close to home if and when they need it.

Sincerely,

Irene Cardinal

Irene Cardinal

Greer, Leslie

From: Armah, Olga
Sent: Friday, January 29, 2016 3:41 PM
To: Janette.Edwards@hhchealth.org
Cc: User, OHCA; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Carney, Brian
Subject: 15-32031 CON - Backus PCI Program - Application Deemed Complete
Attachments: 15-32031-CON Notification of Application Deemed Complete.docx

Dear Ms. Edwards:

Please note that OHCA has deemed complete the above noted CON application. See the attached.

Sincerely,

Olga Armah, M. Phil
Associate Research Analyst
Office of Health Care Access
CT Department of Public Health
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134

Phone: 860 418 7070
Fax: 860 418 7053
mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Acting Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

January 29, 2016 Via Email Only

Janette Edwards
Regional Director, Planning & Business Development
The William W. Backus Hospital
326 Washington Street
Norwich, CT 06360

RE: Certificate of Need Application Docket Number: 15-32031-CON
Establishment of a Percutaneous Coronary Intervention (PCI) program at William W. Backus Hospital
Notification Deeming the CON Application Complete

Dear Ms. Edwards:

This letter is to inform you that, pursuant to Section 19a-639a (d) of the Connecticut General Statutes, the Office of Health Care Access has deemed the above-referenced application complete as of January 29, 2016.

If you have any questions regarding this matter, please feel free to contact me at (860) 418-7070 or Jessica Schaeffer-Helmecki at (860) 509-8075.

Sincerely,

Olga Armah
Associate Research Analyst

Phone: (860) 509-8000 • Fax: (860) 509-7184 • VP: (860) 899-1611
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

Greer, Leslie

From: Greer, Leslie
Sent: Wednesday, February 10, 2016 4:32 PM
To: 'janette.Edwards@hhchealth.org'
Cc: Armah, Olga; Carney, Brian; Schaeffer-Helmecki, Jessica; Fernandes, David
Subject: The William W. Backus Hospital Hearing Notice
Attachments: 32031 Hearing Notice.pdf

Tracking:

Recipient	Delivery	Read
'janette.Edwards@hhchealth.org'		
Armah, Olga	Delivered: 2/10/2016 4:33 PM	Read: 2/11/2016 8:02 AM
Carney, Brian	Delivered: 2/10/2016 4:33 PM	Read: 2/11/2016 7:34 AM
Schaeffer-Helmecki, Jessica	Delivered: 2/10/2016 4:33 PM	
Fernandes, David	Delivered: 2/10/2016 4:33 PM	Read: 2/11/2016 8:28 AM

Ms. Edwards,
Attached is the hearing notice for The William W. Backus Hospital hearing scheduled on March 23, 2016 @ 9:30 a.m. A hard copy will be mailed to you.

Leslie M. Greer
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS#13HCA, Hartford, CT 06134
Phone: (860) 418-7013 Fax: (860) 418-7053
Website: www.ct.gov/ohca

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Acting Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

February 10, 2016

Janette Edwards
Regional Director, Planning & Business Development
The William W. Backus Hospital
326 Washington Street
Norwich, CT 06360

RE: Certificate of Need Application, Docket Number 15-32031-CON
The William W. Backus Hospital
Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

Dear Ms. Edwards,

With the receipt of the completed Certificate of Need ("CON") application information submitted by The William W. Backus Hospital ("Applicant") on January 29, 2016, the Office of Health Care Access ("OHCA") has initiated its review of the CON application identified above.

Pursuant to General Statutes § 19a-639a (f), OHCA may hold a hearing with respect to any Certificate of Need application.

This hearing notice is being issued pursuant to General Statutes § 19a-639a (f)

Applicant:	The William W. Backus Hospital
Docket Number:	15-32031-CON
Proposal:	Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

Keeping Connecticut Healthy
DPH
Connecticut Department of Public Health

Phone: (860) 509-8000 • Fax: (860) 509-7184 • VP: (860) 899-1611
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

Notice is hereby given of a public hearing to be held in this matter to commence on:

Date: March 23, 2016

Time: 9:30 a.m.

Place: Department of Public Health, Office of Health Care Access
410 Capitol Avenue, 3rd Floor Hearing Room
Hartford, CT 06134

The Applicant is designated as party in this proceeding. Enclosed for your information is a copy of the hearing notice for the public hearing that will be published in the *Norwich Bulletin* pursuant to General Statutes § 19a-639a (f).

Sincerely,

Kimberly R. Martone
Director of Operations

Enclosure

cc: Henry Salton, Esq., Office of the Attorney General
Antony Casagrande, Department of Public Health
Kevin Hansted, Department of Public Health
Wendy Furniss, Department of Public Health
William Gerrish, Department of Public Health
Jill Kentfield, Department of Public Health
Chris Stan, Department of Public Health
DeVaughn Ward, Department of Public Health
Marielle Daniels, Connecticut Hospital Association

KRM:OA:BC:JSH: DF:lmg

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Acting Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Office of Health Care Access

February 10, 2016 P.O. #54772

Norwich Bulletin
66 Franklin Street
Norwich, CT 06360

Gentlemen/Ladies:

Please make an insertion of the attached copy, in a single column space, set solid under legal notices, in the issue of your newspaper by no later than **Thursday, February 11, 2016**. Please provide the following **within 30 days** of publication:

- Proof of publication (copy of legal ad. acceptable) showing published date along with the invoice.

If there are any questions regarding this legal notice, please contact Kaila Riggott at (860) 418-7001.

KINDLY RENDER BILL IN DUPLICATE ATTACHED TO THE TEAR SHEET.

Sincerely,

Kimberly R. Martone
Director of Operations

Attachment
cc: Danielle Pare, DPH
Marielle Daniels, Connecticut Hospital Association

KRM:OA:BC:JSH:DF:lmg

Keeping Connecticut Healthy
DPH
Connecticut Department of Public Health

Phone: (860) 509-8000 • Fax: (860) 509-7184 • VP: (860) 899-1611
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

PLEASE INSERT THE FOLLOWING:

Office of Health Care Access Public Hearing

Statute Reference:	19a-638
Applicant:	The William W. Backus Hospital
Town:	Norwich
Docket Number:	15-32031-CON
Proposal:	Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital
Date:	March 23, 2016
Time:	9:30 a.m.
Place:	Department of Public Health, Office of Health Care Access 410 Capitol Avenue, 3rd Floor Hearing Room Hartford, CT 06134

Any person who wishes to request status in the above listed public hearing may file a written petition no later than March 18, 2016 (5 calendar days before the date of the hearing) pursuant to the Regulations of Connecticut State Agencies §§ 19a-9-26 and 19a-9-27. If the request for status is granted, such person shall be designated as a Party, an Intervenor or an Informal Participant in the above proceeding. Please check OHCA's website at **www.ct.gov/ohca** for more information or call OHCA directly at (860) 418-7001. If you require aid or accommodation to participate fully and fairly in this hearing, please phone (860) 418-7001.

From:	ADS
To:	Greer, Leslie
Subject:	Re: Hearing Notice DN: 15-32031-CON
Date:	Wednesday, February 10, 2016 11:03:23 AM

Good day!

Thanks so much for your ad submission.
We will be in touch shortly and look forward to serving you.

Don't forget to ask for ideas to expand your diversity coverage.

PLEASE NOTE: New Department of Labor guidelines allow web based advertising when hiring foreign nationals. To provide required documentation Graystone will retrieve & archive verification for the 1st and 30th days of posting for $115.00/web site. If required, notify Graystone when ad placement is approved.

If you have any questions or concerns, please don't hesitate to contact us at the number below.

We sincerely appreciate your business.

Thank you,
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2710 North Avenue
Bridgeport, CT 06604
Phone: 800-544-0005
Fax: 203-549-0061

E-mail new ad requests to: ads@graystoneadv.com
http://www.graystoneadv.com/

From: "Greer, Leslie" <Leslie.Greer@ct.gov>
Date: Wednesday, February 10, 2016 at 10:45 AM
To: Ads Desk <ads@graystoneadv.com>
Subject: Hearing Notice DN: 15-32031-CON

To Whom it May Concern,
Please run the attached hearing notice in the Norwich Bulletin on 1/11/16. For billing purposes, please refer to P.O. 54772. In addition, please forward me a copy of the "proof of publication" when it becomes available.

Thank you,

Leslie M. Greer
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS#13HCA, Hartford, CT 06134
Phone: (860) 418-7013 Fax: (860) 418-7053

Greer, Leslie

From: Robert Taylor <RTaylor@graystoneadv.com>
Sent: Thursday, February 11, 2016 3:53 PM
To: Greer, Leslie
Subject: FW: Hearing Notice DN: 15-32031-CON
Attachments: 15-32031np Norwich Bulletin.docx

Good afternoon,

This notice was published today. We will bill you $287.83 and send proof of publication when it becomes available.

Thanks,

Robert Taylor
Graystone Group Advertising
www.graystoneadv.com
2710 North Avenue, Suite 200
Bridgeport, CT 06604
Phone: 203-549-0060
Toll Free: 800-544-0005
Fax: 203-549-0061

From: ADS <ADS@graystoneadv.com>
Date: Wed, 10 Feb 2016 11:03:16 -0500
To: RTaylor <rtaylor@graystoneadv.com>
Subject: FW: Hearing Notice DN: 15-32031-CON

From: "Greer, Leslie" <Leslie.Greer@ct.gov>
Date: Wednesday, February 10, 2016 at 10:45 AM
To: Ads Desk <ads@graystoneadv.com>
Subject: Hearing Notice DN: 15-32031-CON

To Whom it May Concern,
Please run the attached hearing notice in the Norwich Bulletin on 1/11/16. For billing purposes, please refer to P.O. 54772. In addition, please forward me a copy of the “proof of publication” when it becomes available.

Thank you,

Leslie M. Greer
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS#13HCA, Hartford, CT 06134
Phone: (860) 418-7013 Fax: (860) 418-7053
Website: www.ct.gov/ohca

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Starts Here

Happy Grams

Happy 66th Anniversary
Al & Lucy Gualtieri
of Norwich

Notices

CT SCRAP: Will buy your scrap steel, copper, & aluminum, 33 Pequot Rd Uncs. 860-848-3366

Services

Starts Here

Services Offered

Notice
The state of Connecticut requires home improvement contractors to include their license number in all forms of advertising. To apply for an application for registration go to:
www.dcp.state.ct.us/licensing
or call
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or 800-842-2649

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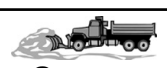

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STUMP, BRUSH: concrete disposal open Fri 8-5; Sat 8-12 33 Pequot Rd Uncasville CT. 860-848-3366

Stuff

Starts Here

Pets

BULLMASTIFF: Two 8WK old Female Puppies 4 sale. Live in NC, will be in CT Valentine's weekend. AKC and DNA certs, $1500 flexible. Call 919-604-5880

Antiques & Collectibles

CASH PAID: For Antiques, guitars, Silver, Gold, Old Toys Musical Instr uments, Trains, Military items, watches, paintings, anything old, 1 item or entire estate. call 860-707-9350

Household Goods

MATTRESS: Tax Season Mattress and Furniture BLOW OUT!!! Brand name mattresses 40-80% less than retail. All sizes and styles available. Queen sets as low as $150. 4 Piece Bedroom Sets Starting at $250 !!! Call 860-916-5040

Outdoor Recreation

BCFYL BASEBALL TRYOUTS: 11/12 yo Tue 2/9 @ 6 pm @ Sayles School Baltic. Residents of Sprague, Franklin, Canterbury, Lebanon, & Lisbon. RSVP Joe Genest 860-334-9448

Heating Supplies

SEASONED FIREWOOD:
cut, split & delivered
$190 a Cord
860-373-4377
860-639-7375

Heating Supplies

SEASONED FIREWOOD: Cut, split, & delivered 860-931-4516

Wanted To Buy

$CASH PAID$: Vintage Electronics Guitars, Amps, Pro & Vac Tube Audio, All Radios; Ham Equip., CB's, 860-707-9350

CT SCRAP: Will buy your scrap steel, copper, & aluminum, 33 Pequot Rd Uncs. 860-848-3366

Homes

Starts Here

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Several apartments to choose from!
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Call Today
860-886-0558 or 401-741-1046

JEWETT CITY: 3 br 1/2 duplex $980. incl.hook-up, hardwood floors, parking, Section 8 ok 860-591-6003, 860-861-4348

UNCASVILLE: 1 BR 1st floor, heat incl. handicap accessible, stove, fridge, walk-in closet, off st. parking, & laundry $760. Call 860-445-7240 or 860-639-4412

For Sale Homes

A Publishers Notice
All Real Estate advertised in this newspaper is subject to the State and Federal Fair Housing Acts which makes it illegal to advertise any preference, limitation, or discrimination or any intention to make any such preference, limitation or discrimination based on race color, religion, sex, familial status, national origin, handicap, ancestry, marital status, age, lawful source of income and sexual orientation. This newspaper will not knowingly accept any advertising for real estate which is in violation of the law.

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Starts Here

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2002 CUBE VAN: 1 ton cutaway cube van w/ 220,856 miles. Full height cab access & translucent roof. Running on the road presently. Needs TLC. Asking $3,000 860-887-8617

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LEGAL NOTICE
TOWN OF PLAINFIELD

An agreement between the Plainfield Board of Education and Plainfield Association of School Administrators, effective July 1, 2016 – June 30, 2019, is on file in my office and is available for public viewing.

Dated at Plainfield Connecticut this 10th day of February, 2016.

Louisa R. TrakasPlainfield Town Clerk

NOTICE OF DECISION
GRISWOLD PLANNING & ZONING COMMISSION

At its meeting of February 8, 2016, the Griswold Planning and Zoning Commission approved a settlement agreement reached between the Plaintiffs, Valerie Grills and James Grills, and the Defendants, 822 Voluntown Road, LLC, et al, Docket No. KNL-CV-15-6024403-S, now pending in New London Superior Court. There will be a hearing before the New London Superior Court on this matter on Thursday February 18, 2016 at 10:00am.

Dated this 9th day of February 2016

Branse & Willis, LLC

CITY OF NORWICH
PUBLIC NOTICE

At the regular meeting of the Zoning Board of Appeals held February 9, 2016 the following actions were taken:

V#16-02 – Application of Ronald McGuire for property located at 387 Plain Hill Road in a Residential (R80) zoning district. In accordance with Sec. 1.1 40' side yard setback required request reduction to 26' for the construction of a 16' x 20 single-story addition. **APPROVED**

Files may be inspected at the Zoning Dept, 23 Union St, Norwich Monday-Friday between 8:30 a.m. and 4:30 p.m

Zoning Board of Appeals Chairman Marc Benjamin

Legals

CITY OF NORWICH
PUBLIC NOTICE

An application is pending to demolish a structure(s) located at 4 Park Center Road. For Additional Information, Contact: James K. Troeger, Building Official

LEGAL NOTICE
TOWN OF WOODSTOCK

At the February 9, 2016 Zoning Board of Appeals Public Hearing, the following application was approved: 16-01 Sean Murphy / Rondeau's Service Station, LLC, 612 Rte 169 - Certificate of Location for existing auto service and repair.

Chair Martin Nieski

Searching For A home?
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We have the tools and the resouces you need.
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Legals

LEGAL NOTICE
NOTICE OF DECISION
GRISWOLD PLANNING & ZONING COMMISSION

At its regular meeting of February 08, 2016, the Griswold Planning and Zoning Commission approved by unanimous vote the settlement agreement reached between the Plaintiffs, Valerie Grills and James Grills, and the Defendants, Griswold Planning and Zoning Commission, 822 Voluntown Road, LLC, et al, Docket No. KNL-CV-15-6024403-S, now pending in New London Superior Court.

Dated this 10th day of February 2016

Martin McKinney
Chairman

LEGAL NOTICE
Office of Health Care Access
Office of Health Care Access Public Hearing

Statute Reference:	19a-638
Applicant:	The William W. Backus Hospital
Town:	Norwich
Docket Number:	15-32031-CON
Proposal:	Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital
Date:	March 23, 2016
Time:	9:30 a.m.
Place:	Department of Public Health, Office of Health Care Access 410 Capitol Avenue, 3rd Floor Hearing Room Hartford, CT 06134

Any person who wishes to request status in the above listed public hearing may file a written petition no later than March 18, 2016 (5 calendar days before the date of the hearing) pursuant to the Regulations of Connecticut State Agencies §§ 19a-9-26 and 19a-9-27. If the request for status is granted, such person shall be designated as a Party, an Intervenor or an Informal Participant in the above proceeding. Please check OHCA's website at www.ct.gov/ohca for more information or call OHCA directly at (860) 418-7001. If you require aid or accommodation to participate fully and fairly in this hearing, please phone (860) 418-7001.

RETURN DATE: MARCH 15, 2016 : **SUPERIOR COURT**

WELLS FARGO BANK, N.A. : **J.D. WINDHAM**

VS. : **AT PUTNAM**

THE HEIRS, BENEFICIARIES, REPRESENTATIVES AND CREDITORS OF THE ESTATE OF ANN-MARIE KENYON, ET AL :**JANUARY 18, 2016**

ORDER OF NOTICE

NOTICE TO: **THE HEIRS, BENEFICIARIES, REPRESENTATIVES AND CREDITORS OF THE ESTATE OF ANN-MARIE KENYON**

The plaintiff has named **THE HEIRS, BENEFICIARIES, REPRESENTATIVES AND CREDITORS OF THE ESTATE OF ANN-MARIE KENYON** as parties defendant in the complaint which it is bringing to the above-named court seeking a foreclosure of its Mortgage upon premises known as 27 PLAZA STREET, BROOKLYN, CONNECTICUT 06234. This complaint is returnable to the Court on March 15, 2016 and will be pending therein after that date.

The plaintiff has represented to said court, by means of an Affidavit annexed to said complaint, that despite all reasonable efforts to ascertain such information, it has been unable to determine the identity and/or whereabouts of **THE HEIRS, BENEFICIARIES, REPRESENTATIVES AND CREDITORS OF THE ESTATE OF ANN-MARIE KENYON, except for SHAUN KENYON, DEBBIE KENYON, JEAN MAYO, KELLY FRENCH, TRACEY WISSING and BRYNN BLAIS.**

NOW THEREFORE, it is hereby Ordered that notice of the institution of this action be given to each such Defendant by some proper officer causing a true and attested copy of this Order to be published in The Bulletin, once a week for two successive weeks commencing on or before March 2, 2016 and that return of such service be made to the Court.

Olga Christina Kolat,
Admin Clerk
JUDICIAL DISTRICT OF WINDHAM

A True Copy
Attest: Barbara Coffey
Connecticut State Marshal
Indifferent Person

Fun and Games

HOROSCOPE

ARIES (March 21-April 19): Assess your situation and what you need to do to bring about positive changes. Someone from your past will give you false hope. Don't rely on others for help, but make sure to get jobs finished on time. Be good to yourself. 3 stars

TAURUS (April 20-May 20): What you do to help others will pay off. A reunion will lead to an interesting and unusual offer. Take time out for personal care. Presentation matters, so put in the effort needed to look the part. Romance is in the stars. 3 stars

GEMINI (May 21-June 20): Be careful when sharing your ideas or possessions. You will attract people who have ulterior motives and could try to take credit for your work. If you don't believe in your abilities, it will be difficult to convince others to support your plans. 4 stars

CANCER (June 21-July 22): You may not like change, but this is an ideal time to embrace something new and challenging. Let your intuition guide you in a direction that promises greater creativity and opportunity. Romance will result in new beginnings and greater security. 2 stars

LEO (July 23-Aug. 22): Take the plunge and travel to a destination that offers something special. New connections will lead to a greater understanding of how you can establish yourself in a position that suits your skills, talents and qualifications. 5 stars

VIRGO (Aug. 23-Sept. 22): Spend more time on yourself, your family or something you believe in. Don't take a financial risk or overspend on something questionable. An unusual situation will develop with someone you have to deal with every day. 3 stars

LIBRA (Sept. 23-Oct. 22): Concentrate on what you know and what you need to learn to improve your chances of advancement. Don't be discouraged by someone who is offering negative feedback about your plans. Be true to yourself. 3 stars

SCORPIO (Oct. 23-Nov. 21): Speak up, share your ideas and bring about changes that will help you improve your community, neighborhood or lifestyle. A short trip will lead to a new endeavor. A romantic adventure will initiate creative ideas. 3 stars

SAGITTARIUS (Nov. 22-Dec. 21): Run your ideas by someone you trust. An unforeseen problem will develop if you move too quickly or don't take the time to test your plans before you begin. Don't go overboard. Start small and build slowly. Don't make decisions based on emotions. 2 stars

CAPRICORN (Dec. 22-Jan. 19): You'll face turmoil if you let things bother you. You may not be able to control what others do or say, but you can avoid attracting gossip and interference. Make your time and money count by spending it wisely. 2 stars

AQUARIUS (Jan. 20-Feb. 18): Avoid aggressive situations that have the potential to lead to an argument. Work by yourself. Don't present what you have to offer until you are fully satisfied that you have done your best. Strive for perfection, quality and balance. 4 stars

PISCES (Feb. 19-March 20): Keep your financial information private. An important partnership must be handled tactfully if you want to keep yourself from being taken advantage of. Avoid unpredictable people and situations. 3 stars

JUMBLE

Unscramble these four Jumbles, one letter to each square, to form four ordinary words.

LAPNT

REHUS

BRIFDO

XILIER

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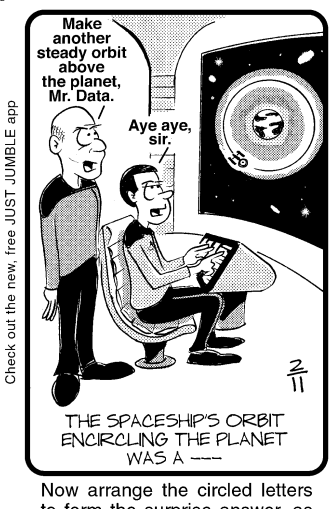
Check out the new, free JUST JUMBLE app

THAT SCRAMBLED WORD GAME
by David L. Hoyt and Jeff Knurek



Now arrange the circled letters to form the surprise answer, as suggested by the above cartoon.

Print your answer here: ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( )

(Answers tomorrow)

Yesterday's Jumbles: STUNT SENSE NOODLE LOCALE
Answer: When it came to places to build a home, the new subdivision had — LOTS AND LOTS

2-11 **CRYPTOQUOTE**

KJS CNBYU GJ EVNBT WK EVNBTMUZ, GJ EGSLK WK EGSLKMUZ, GJ YSU WK YSUUMUZ, GJ HJYT WK HJYTMUZ; MU DSEG GPN EBXN HBK, KJS CNBYU GJ CJON WK CJOMUZ. — RYBUQME LN EBCNE

Yesterday's Cryptoquote: ALL YOU NEED IS LOVE. BUT A LITTLE CHOCOLATE NOW AND THEN DOESN'T HURT. — CHARLES M. SCHULZ

Greer, Leslie

From: Armah, Olga
Sent: Wednesday, March 09, 2016 11:03 AM
To: Janette.Edwards@hhchealth.org
Cc: User, OHCA; Riggott, Kaila; Schaeffer-Helmecki, Jessica; Fernandes, David; Carney, Brian
Subject: Docket # 15-32031 CON: Request for Prefile Testimony & Issues
Attachments: 15-32031 Prefile Testimony Request.pdf

Dear Ms. Edwards,

Find attached a request for prefile testimony and issues related to the March 23, 2016 public hearing on the above referenced matter.

If you have any questions, please contact Jessica Schaefer-Helmecki at Jessica.Schaeffer-Helmecki@ct.gov or me.

Sincerely,

Olga

Olga Armah, M. Phil
Associate Research Analyst
Office of Health Care Access
CT Department of Public Health
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134

Phone: 860 418 7070
Fax: 860 418 7053
mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

March 9, 2016

Via Email Only

Janette Edwards
Regional Director, Planning & Business Development
The William W. Backus Hospital
326 Washington Street
Norwich, CT 06360

RE: Certificate of Need Application, Docket Number 15-32031
The William W. Backus/Hartford Hospital, Establishment of a Primary and Elective PCI

Dear Ms. Edwards,

The Office of Health Care Access ("OHCA") will hold a public hearing on the above docket number on March 23, 2016. The hearing is at 9:30 a.m. at the Department of Public Health, Office of Health Care Access, 410 Capitol Avenue, 3rd Floor Hearing Room in Hartford, CT 06134. Pursuant to the Regulations of Connecticut State Agencies § 19a-9-29(e), any party or other participant is required to prefile in written form all substantive, technical, or expert testimony that it proposes to offer at the hearing. OHCA requests that Middlesex Hospital ("Applicant") submit prefiled testimony by 4:00 p.m. on **March 16, 2016**.

All persons providing prefiled testimony must be present at the public hearing to adopt their written testimony under oath and must be available for cross-examination for the entire duration of the hearing. If you are unable to meet the specified time for filing the prefiled testimony you must request a time extension in writing, detailing the reasons for not being able to meet the specified deadline.

Additionally, please find attached OHCA's Issues. Please respond to the attached Issues in writing to OHCA by 4:00 p.m. on **March 16, 2016**.

Connecticut Department of Public Health

Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

Please contact Olga Armah or Jessica Schaeffer-Helmecki at (860) 418-7001 if you have any questions concerning this request.

Sincerely,

Kevin T. Hansted
Hearing Officer

Attachment

ISSUES

Office of Health Care Access Docket Number: 15-32031-CON

The William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI Program without Onsite Surgical Backup

The Applicants should be prepared to present and discuss supporting evidence on the following issues:

1. Clear public need for an elective PCI program at The William W. Backus Hospital.

2. Relevance of proposed "Backus Angioplasty Region" to elective PCI.

3. Ability of The William W. Backus Hospital to meet/maintain the ACCF/AHA/SCAI recommended minimum facility volume of 200 PCI procedures per year without a shift in volume from existing providers, including Hartford Hospital.

4. A proven gap in access to elective angioplasty unrelated to a shift in patient volume from existing providers.

5. The effect of a partnership between Day Kimball Hospital and UMass Memorial Medical Center on referrals from Day Kimball Hospital to The William W. Backus Hospital.

6. The effect that an elective PCI program at The William W. Backus Hospital would have on Lawrence + Memorial Hospital's overall PCI volumes.

7. According to the 2014 SCAI/ACC/AHA Expert Consensus Document "the addition of more PCI centers has not substantially improved access to PCI services for most patients." Please address this statement in the context of your proposal.

8. According to the 2014 SCAI/ACC/AHA Expert Consensus Document "multiple low-volume and partial-service PCI centers within a geographic area...increase costs for the overall health system and have not been shown to improve access." Please address this statement in the context of your proposal.

9. How it was determined that Ledyard and Montville patients would go to Lawrence + Memorial and not to The William W. Backus Hospital when inpatient discharge data indicates otherwise.

Provide a written response to the following as an attachment to the pre-file testimony, as these questions were not fully addressed in the application/completeness:

10. Provide the FY 2015 elective and primary PCI data on pages 465-466 and include Ledyard and Montville.

11. Data reported on pages 1444-1447 of the application do not match OHCA Hospital Reporting System Report 450 results. For example, OHCA Report 450 indicates the following statewide totals for the table on page 1446. Review and revise your response to completeness question #1, accordingly.

PCI	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	% Change FY09-14
Primary	2,844	3,408	3,522	2,998	2,775	3,276	15%
Elective	5,091	4,389	4,315	4,540	4,379	3,716	(27%)
Total	7,935	7,797	7,837	7,538	7,154	6,992	(12%)

Source: DPH Office of Health Care Access Hospital Reporting System Report 450

12. For the projections on page 1462, provide the data broken out by primary and elective rather than inpatient and outpatient PCIs for both OHCA defined primary service area and the proposed angioplasty region. Please note, replace Plainville with Plainfield in the OHCA defined-primary service area.

Greer, Leslie

Subject: FW: Docket Number 15-32031- The William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI program without Onsite Surgical Backup

Attachments: Notice of Appearance (3.16.16).pdf; Request for Intervenor status by L+M re Backus PCI CON (3.16.16).pdf

From: Kathleen Gedney [mailto:kgg@bvmlaw.com]
Sent: Wednesday, March 16, 2016 3:06 PM
To: Armah, Olga
Cc: Martone, Kim; Hansted, Kevin; Lazarus, Steven; Michele Volpe; Jennifer O'Donnell
Subject: Docket Number 15-32031- The William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI program without Onsite Surgical Backup

Ms. Armah:

Attached please find a Notice of Appearance of Attorney Michele Volpe on behalf of Lawrence + Memorial Hospital in the above captioned matter and a Petition for Intervenor Status by Lawrence + Memorial Hospital in the above captioned matter regarding the public hearing on March 23, 2016. Please confirm receipt of these attachments.

Additionally, could you please send us a copy of Backus's pre-filed testimony filed with OHCA in the above captioned matter as soon as it becomes available?

Thank you,

Kathleen Gedney-Tommaso
Attorney at Law
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, CT 06511
Tel: (203) 859-6238
Fax: (203) 777-5806
Email: kgg@bvmlaw.com

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DEPARTMENT OF PUBLIC HEALTH	:	
DIVISION OF OFFICE OF	:	
HEALTH CARE ACCESS	:	**DOCKET NO. 15-32031-CON**
	:	
IN RE: ESTABLISH AND OPERATE	:	
A PRIMARY AND ELECTIVE	:	
ANGIOPLASTY PROGRAM AT THE	:	
WILLIAM W. BACKUS HOSPITAL	:	**MARCH 16, 2016**

NOTICE OF APPEARANCE

In accordance with §19a-9-28 of the Conn. Agencies Reg., please enter the appearance of Michele Volpe, of Bershtein, Volpe & McKeon, P.C., on behalf of Lawrence + Memorial Hospital, Inc. in the above-captioned matter.

I will attend and participate in the hearing on March 23, 2016 on behalf of Lawrence + Memorial Hospital, Inc.

Respectfully Submitted,

LAWRENCE + MEMORIAL HOSPITAL, INC.

BY: _____

Michele M. Volpe, Juris No. 412124
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, Connecticut 06511
Tel. No. 20 3 777-5800
Fax No. 203 777-5806
mmv@bvmlaw.com
Its Attorney

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via United States mail, postage prepaid, and electronic mail, this 16th day of March, 2016 to the following:

Janette Edwards
Regional Director, Planning & Business Development
The William W. Backus Hospital
326 Washington Street
Norwich, Connecticut 06360
Janette.edwards@hhchealth.org

Robert Anthony
Attorney
Brown Rudnick LLP
185 Asylum Street
Hartford, Connecticut 06103
ranthony@brownrudnick.com

Michele M. Volpe
Bershtein, Volpe & McKeon P.C.

DEPARTMENT OF PUBLIC HEALTH	:	
DIVISION OF OFFICE OF	:	
HEALTH CARE ACCESS	:	**DOCKET NO. 15-32031-CON**
	:	
IN RE: ESTABLISH AND OPERATE	:	
A PRIMARY AND ELECTIVE	:	
ANGIOPLASTY PROGRAM AT THE	:	
WILLIAM W. BACKUS HOSPITAL	:	**MARCH 16, 2016**

PETITION OF LAWRENCE + MEMORIAL HOSPITAL, INC.
FOR INTERVENOR STATUS WITH FULL PROCEDURAL RIGHTS
INCLUDING RIGHT OF CROSS-EXAMINATION
AT MARCH 23, 2016 HEARING

Pursuant to Conn. Gen. Stat. §§4-166 *et seq.* and §19a-9-27 of the Regulations of Connecticut State Agencies, Lawrence + Memorial Hospital, Inc. ("L+M Hospital" or the "Petitioner") respectfully petitions the Department of Public Health division of Office of Health Care Access ("OHCA") for intervenor status in the above-referenced proceeding with full rights, including the right to inspect and copy records, receive a copy of any and all correspondence submitted to OHCA, present written and oral testimony, evidence and argument, and to cross-examine the Applicants, William W. Backus Hospital ("Backus") and Hartford Hospital ("Hartford Hospital") and any witnesses in the above captured matter.

I. Preliminary Statement

Petitioner is a not-for-profit 308-bed acute care community hospital located at 365 Montauk Avenue, New London, Connecticut. Pursuant to Docket Numbers 04-30297-CON and 12-31768-CON, L+M Hospital operates a primary and elective angioplasty program.

Petitioner will present evidence that (i) there is no public need for the Certificate of Need ("CON") application submitted by the Applicants for the establishment of a primary or elective angioplasty services; (ii) Backus has not satisfactorily identified the population to be served; (iii) Backus has failed to comply with policies and standards adopted by OHCA; (iv) Backus has failed to comply with well-established clinical guidelines; (v) Backus has failed to comply with the state-wide health care facilities and services plan; (vi) there is no lack of capacity of either primary or elective angioplasty services and the proposed services will result in duplicative services; (vii) the proposed services will have a negative effect on quality, accessibility and cost effectiveness of healthcare services in the community; and (iix) the proposed services are not financially feasible and will negatively impact the financial strength of the health care system in Connecticut.

II. Manner in Which L+M Hospital's Interest is Affected by the Proposal

A. L+M Hospital's interests are greatly affected by the proposal to establish primary or elective angioplasty services in L+M Hospital's service area. If OHCA were to approve Backus Hospital's primary and/or elective angioplasty services, such approval will have an adverse impact on L+M Hospital. Such adverse impact on L+M Hospital will include, among other concerns, a shift of required volume thereby decreasing utilization at L+M and impacting quality; as well as resulting in an adverse financial impact on L+M.

B. L+M Hospital is a health care facility as defined by Conn. Gen. Stat. 19a-630. L+M Hospital is a not-for-profit acute care community hospital that provides a variety of services including primary and elective angioplasty in the area. L+M Hospital

recently received CON approval for its primary and elective angioplasty program pursuant to Docket Numbers 04-30297-CON and 12-31768-CON, respectively. L+M Hospital's primary and elective angioplasty services are supported by a collaborative relationship with Yale-New Haven Hospital and Yale School of Medicine.

C. In the development and approval of L+M Hospital's elective angioplasty program, L+M Hospital evaluated the existing patient population and service area. L+M Hospital's volume projections were subject to OHCA scrutiny and the extensive oversight and review during the lengthy CON application and public hearing process. OHCA found that the addition of L+M Hospital's primary and elective angioplasty programs is beneficial to the state. Pursuant to Docket Number 12-31768-CON, L+M Hospital is subject to continuing direct OHCA oversight regarding its volume and is required to submit quarterly utilization reports and quality data. L+M Hospital is also subject to the OHCA directive that providers and facilities maintain certain utilization levels to ensure an appropriate level of experience.[1]

D. As Petitioner will demonstrate in the testimony and evidence provided, approval of primary or elective angioplasty services in L+M Hospital's region and as proposed by Applicant will significantly impact volume and utilization at L+M Hospital. As noted in Backus's application, Backus estimates it will draw volume away from L+M Hospitals' still fledging program. By approving Backus Hospital's application for duplicative services, volume will shift from L+M Hospital thereby resulting in a decrease of utilization at L+M resulting in a negative effect on volume and quality for an existing and approved primary and elective angioplasty program.

[1] *Statewide Health Plan* at p. 41.

E. It is well established that "[c]ompetition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interest of the community."[2] Approval of a primary or elective angioplasty services at Backus will have an adverse impact on L+M Hospital's primary and elective angioplasty program.

III. Manner and Extent to Which L+M Hospital Proposes to Participate

L+M Hospital will participate in this proceeding as follows:

A. L+M Hospital proposes to present documentary evidence, direct testimony and arguments at the public hearing. L+M Hospital will provide OHCA with information showing (i) the Applicant has not demonstrated public need in the CON application for the establishment of a primary or elective angioplasty services; (ii) Backus has not satisfactorily identified the population to be served; (iii) Backus has failed to comply with policies and standards adopted by OHCA; (iv) Backus has failed to comply with well-established clinical guidelines; (v) Backus has failed to comply with the state-wide health care facilities and services plan; (vi) there is excess capacity for both elective and primary PCI and the approval of either primary or elective or both services will result in duplicative services; (vii) the proposed services will have a negative effect on quality, accessibility and cost effectiveness of healthcare services in the community; and (iix) the proposed services are not financially feasible and will negatively impact the financial strength of the health care system in Connecticut.

B. L+M Hospital requests that it be granted permission to cross-examine representatives of Backus and Hartford Hospital (and any other parties, intervenors

[2] *Statewide Health Plan* at p. 39.

and/or informal participants) on issues, including but not limited to, the impact of this proposal on L+M Hospital, the lack of public need for this proposal and other issues related to the services that L+M Hospital has specific knowledge.

C. L+M Hospital requests that it be granted permission to inspect and copy any and all documents in the record of this matter and that it be copied on all future submissions and correspondence. L+M Hospital further requests that it be granted permission to participate in any formal or informal meetings or discussions involving the Applicants and OHCA staff.

IV. The Manner in which L+M Hospital's Participation Will Assist OHCA

A. As an existing provider of primary and elective angioplasty services in the area, L+M Hospital is in a unique position to provide OHCA with information not otherwise available to the agency. L+M can offer insight regarding the accessibility of primary and elective angioplasty currently in the service area and the impact of the proposal on existing providers.

B. L+M Hospital will provide the evidence summarized in this petition as well as related points at the public hearing through the pre-filed testimony from witnesses and consultants employed by and/or retained by L+M Hospital. As an existing provider of primary and elective angioplasty services, L+M Hospital will furnish assistance to OHCA and serve as a provider resource in resolving the issues in this contested case.

C. L+M Hospital's participation in the proceedings is in the interest of justice and will not impair the orderly conduct of these proceedings.

V. Summary of Anticipated Evidence

L+M Hospital opposes Backus' proposal to establish a primary and/or elective angioplasty services and will present evidence that Backus has not met its burden under Conn. Gen. Stat. 19a-639(a). The following is a summary of the evidence that L+M Hospital will offer at the public hearing.

A. Backus Fails to Establish there is Public Need

Petitioner will present evidence that there is no clear public need for the proposed primary or elective angioplasty services. L+M will provide data omitted from Backus's application which shows that primary and elective volumes are declining in Connecticut and that such data will negatively change Backus's utilization projections. Backus has not established a demand for primary or elective angioplasty in the service area as residents can choose to obtain primary and elective angioplasty from two (2) existing full-service providers within 40 miles (Hartford Hospital) and 56 miles (Yale-New Haven Hospital) and primary and elective angioplasty provider within 17 miles (L+M Hospital). As well as four (4) out of state hospitals with PCI programs that are closer for patients. Backus does not provide an appropriate needs analysis and improperly relies upon a contrived service area. As important, L+M Hospital will illustrate that its provision of both primary and elective angioplasty services already meet the need and access requirements for patients in the service area; and L+M has excess capacity to accommodate any future increase or additional demand of both primary and elective angioplasty services.

B. Backus's Proposed Services Are Duplicative

L+M Hospital will present evidence that its provision of primary and elective angioplasty services: (i) is presently operating with excess capacity; (ii) is satisfying the needs of the community; and (iii) can absorb any future needs of the community for both primary and elective angioplasty services. Further, L+M Hospital will present evidence that the addition of a primary and/or elective angioplasty services at Backus will result in an unnecessarily duplicative service and that Backus has not provided any evidence that existing programs are not meeting the needs of the community, any way it is defined.

L+M will also provide evidence that Backus has not adequately described the population to be served and that Backus's inclusion of patients outside its service area is not appropriate. The Applicant is using its own made up service area ("Angioplasty Region") and not any historical service area or recognized OHCA service area for Backus Hospital. This methodology is unreliable and speculative and Backus has offered no credible evidence that it will reach the speculative utilization it projects.

C. Backus Fails to Prove the Proposal Will Improve Quality and Accessibility

Evidence will be provided to demonstrate that the well-recognized literature specifically indicates and states that both the primary and elective angioplasty services being proposed by Backus do not meet established guidelines regarding when it is appropriate to implement additional primary and/or elective angioplasty services.[3] Operating primary and/or elective angioplasty services within 17 miles of each other is

[3] *ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions*, as updated.

not recommended under any established guidelines and will adversely impact quality. L+M Hospital will offer evidence that true door-to-balloon time in primary angioplasty cases will not improve for nearly all of the patients residing in the towns listed in "Angioplasty Region".

D. Backus Fails to Prove the Proposal is Financially Feasible

Backus' proposal to establish primary and elective angioplasty services is not financially feasible, even if only primary angioplasty services are provided. The Applicant itself states this will not be a profitable endeavor. Application, p. 65. The services will operate at a projected deficit and require a $4.8-million-dollar investment to upgrade the Backus facilities. Backus fails to address how this deficit and investment upgrade will be financially prudent when Connecticut hospitals are facing serious financial challenges in the current healthcare market. Further, the Applicant's financial projections are void of the impact of declining volumes for elective and primary angioplasty services across Connecticut. All of which do not result in sufficient evidence to support the projected volume and utilization.

Conclusion

L+M Hospital will demonstrate, through evidence, testimony, documentation and established industry standards, along with information presented in rebuttal and cross-examination, that Backus has failed to meet its burden to establish a clear public need for either primary or elective angioplasty services. The Application uses speculative and inaccurate utilization figures making it clear that an additional, duplicative primary and/or elective angioplasty service is not supported. For the foregoing reasons, L+M

Hospital respectfully requests Intervenor Status with full rights, including the right of cross-examination, pursuant to Section 19a-9-27 of the OHCA regulations.

THE APPLICANT
LAWRENCE + MEMORIAL HOSPITAL, INC.

BY: _____

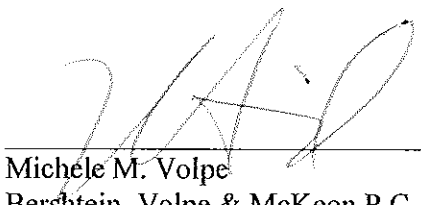
Michele Volpe, Juris No. 412124
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, Connecticut 06511
Tel. No. 20 3 777-5800
Fax No. 203 777-5806

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via United States mail, postage prepaid, and electronic mail, this 16th day of March 2016 to the following:

Janette Edwards
Regional Director, Planning & Business Development
The William W. Backus Hospital
326 Washington Street
Norwich, Connecticut 06360
Janette.edwards@hhchealth.org

Robert Anthony
Attorney
Brown Rudnick LLP
185 Asylum Street
Hartford, Connecticut 06103
ranthony@brownrudnick.com



Michele M. Volpe
Bershtein, Volpe & McKeon P.C.

Greer, Leslie

From: Armah, Olga
Sent: Thursday, March 17, 2016 8:17 AM
To: Kathleen Gedney
Cc: Martone, Kim; Hansted, Kevin; Lazarus, Steven; Michele Volpe; Jennifer O'Donnell; User, OHCA; Riggott, Kaila
Subject: RE: Docket Number 15-32031- The William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI program without Onsite Surgical Backup

Ms. Gedney-Tommaso:

This is to acknowledge receipt of your notice of appearance and intervenor status attachments.

Thanks.

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

From: Kathleen Gedney [mailto:kgg@bvmlaw.com]
Sent: Wednesday, March 16, 2016 3:06 PM
To: Armah, Olga
Cc: Martone, Kim; Hansted, Kevin; Lazarus, Steven; Michele Volpe; Jennifer O'Donnell
Subject: Docket Number 15-32031- The William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI program without Onsite Surgical Backup

Ms. Armah:

Attached please find a Notice of Appearance of Attorney Michele Volpe on behalf of Lawrence + Memorial Hospital in the above captioned matter and a Petition for Intervenor Status by Lawrence + Memorial Hospital in the above captioned matter regarding the public hearing on March 23, 2016. Please confirm receipt of these attachments.

Additionally, could you please send us a copy of Backus's pre-filed testimony filed with OHCA in the above captioned matter as soon as it becomes available?

Thank you,

Kathleen Gedney-Tommaso
Attorney at Law
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, CT 06511
Tel: (203) 859-6238
Fax: (203) 777-5806
Email: kgg@bvmlaw.com

Greer, Leslie

From: Mercier, Carlene M. <CMercier@brownrudnick.com>
Sent: Thursday, March 17, 2016 10:40 AM
To: User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: Cohen, Douglas A.; Anthony, Robert J.; Janette.Edwards@hhchealth.org
Subject: REVISED Docket No. 15-32031 / Responses to Pre-Hearing Questions & Pre-Filed Testimony
Attachments: REVISED HH Backus Pre-Hearing Responses & PFT.pdf; Backus - Pre-hearing Responses 3_16_16.DOCX

Good Morning,

Please note the Exhibits in the Pre-Hearing Responses were incorrectly numbered (page 1496, Exhibit 28 should have been 30 and Exhibit 29 should have been 31). Those two typos have been corrected in the attached documents and those are the only two changes that were made to the filing.

I apologize for any inconvenience this may cause.

Best Regards,
Carlene

BROWNRUDNICK

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

From: Mercier, Carlene M.
Sent: Wednesday, March 16, 2016 3:55 PM
To: 'ohca@ct.gov'; 'kevin.hansted@ct.gov'; 'jessica.schaeffer-helmecki@ct.gov'; 'olga.armah@ct.gov'; 'kaila.riggott@ct.gov'; 'david.fernandes@ct.gov'; 'kimberly.martone@po.state.ct.us'
Cc: Cohen, Douglas A.; Anthony, Robert J.; Janette.Edwards@hhchealth.org
Subject: Docket No. 15-32031 / Responses to Pre-Hearing Questions & Pre-Filed Testimony

Good Afternoon,

Please find attached the following on behalf of Hartford Hospital and The William W. Backus Hospital:

Cover Letter
Responses to Pre-Hearing Questions 10-12
Exhibit 30
Exhibit 31
Letter of Support from Greg Allard
Pre-File Testimony of David Whitehead
Pre-File Testimony of M. Shane Foreman

Pre-File Testimony of Bimal Patel
Pre-File Testimony of Francis J. Kiernan, M.D., F.A.C.C.
Pre-File Testimony of John A. Foley, M.D., F.A.C.P., F.A.C.C.
Pre-File Testimony of Mariane Carna, R.N., M.S.N.

Best Regards,
Carlene

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

****

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****

ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

BROWNRUDNICK
185 Asylum Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

March 16, 2016

VIA E-MAIL
(ohca@ct.gov; kevin.hansted@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON
Responses to Pre-Hearing Questions 10-12
Pre-Filed Testimony

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital, please find attached the following filings which are being submitted electronically, in PDF and Word formats (where applicable):

- **Responses to Pre-Hearing Questions**;
- **Exhibit 30** (Service Area Primary PCI by Town);
- **Exhibit 31** (Data Reconciliation Table);
- **Letter of Support from Greg Allard**, Vice President, American Ambulance ;
- **Pre-File Testimony of David Whitehead**, Senior Vice President & Chief Strategy and Transformation Officer, Hartford Healthcare (also past President & CEO, Backus Hospital);
- **Pre-File Testimony of M. Shane Foreman**, Founder & Chief Executive Officer, 3d Health;
- **Pre-File Testimony of Bimal Patel**, President, Backus Hospital & President, Windham Hospital & Senior Vice President, Hartford Healthcare;
- **Pre-File Testimony of Francis J. Kiernan, M.D., F.A.C.C.**, Interventional Cardiologist, Hartford Hospital & Director, Hartford Hospital Cardiac Lab & Director, Hartford Hospital Interventional Cardiology Fellowship;

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- **Pre-File Testimony of John A. Foley, M.D., F.A.C.P., F.A.C.C.**, Chief of Cardiology at Backus Hospital and Windham Hospital and Interim Medical Director of Specialty Care Services (East Region) at Hartford Healthcare and Director of Cardiovascular Services (East Region) for Hartford Healthcare.
- **Pre-File Testimony of Mariane Carna, R.N., M.S.N.**, Vice President of Cardiovascular Services at Hartford Healthcare.

Please note that Mr. Allard did not submit pre-filed testimony as he will not be available to testify on the morning of the hearing. Mr. Allard does plan to attend the afternoon session of the hearing and will be prepared to answer questions should they arise. Please do not hesitate to contact me if you have any questions.

Very truly yours,

BROWN RUDNICK LLP

By: _____
Robert J. Anthony

Enclosures

62428317 v1-WorksiteUS-032836/0002

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

IN RE:	**:**	**DOCKET NO. 15-32031-CON**
	:	
THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S CERTIFICATE OF NEED APPLICATION TO ESTABLISH A PRIMARY AND ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI) PROGRAM AT BACKUS HOSPITAL.	**:**	**March 16, 2016**

RESPONSES TO HEARING ISSUES 10-12

10. Provide the FY 2015 elective and primary PCI data on pages 465-466 and include Ledyard and Montville.

*See **Exhibit 30**, attached.*

11. Data reported on pages 1444-1447 of the application do not match OHCA Hospital Reporting System Report 450 results. For example, OHCA Report 450 indicates the following statewide totals for the table on page 1446. Review and revise your response to completeness question #1, accordingly.

PCI	FY2009	FY20	FY2011	FY2012	FY2013	FY2014	% Change FY09-14
Primary	2,844	3,408	3,522	2,998	2,775	3,276	15%
Elective	5,091	4,389	4,315	4,540	4,379	3,716	(27%)
Total	7,935	7,797	7,837	7,538	7,154	6,992	(12%)

Source: DPH Office of Health Care Access Hospital Reporting System Report 450

*See attached table (**Exhibit 31**) for detail and reconciliation.*

OHCA report 450 data was analyzed to determine Primary and Elective PCI historical trends by facility from 2009-2014 (the most current year of OHCA data available). The response to the Completeness Question #1, beginning on page 1445 considered programs at Bridgeport, John Dempsey, Hospital of Central Connecticut, Danbury, Greenwich, Hartford, L+M, Waterbury, St. Mary's, Norwalk, St. Francis, St. Vincent's, Stamford, and Yale, and did not account for New Milford Hospital, Connecticut Children's Medical Center ("CCMC"), or the Hospital of St. Raphael.

CCMC does not provide a traditional Primary and Elective PCI program, and these volumes are related to congenital conditions.

New Milford Hospital was also not included in the original analysis as data was only reported in FY 2009, with a total of 10 primary cases.

Finally, the Hospital of St. Raphael was omitted, as volume was not reported by St. Raphael in FY 2013-2014 (after acquisition by Yale New Haven Hospital).

Although three hospitals were not included in the original analysis, the response to the question remains accurate: data suggests that total PCI volumes in the State of Connecticut are not declining across the board. Even when including New Milford, CCMC, and St. Raphael's programs in the analysis, Primary PCI grew from FY2009-2014 by 18%.

While reported Elective PCI volume still declined (the initial analysis reported in response to completeness question #1 indicated a decline of 22% vs. 27% in the subsequent analysis which included the three facilities identified above) the reliability of the data remains questionable. Lawrence + Memorial reported no Elective volume in FY 13 or 14, despite receiving approval for an Elective program in February of 2013. St. Raphael reported no data in FY 2013-2014, however St. Raphael volume in FY 2009 impacted the analysis performed by OHCA, possibly exacerbating the true decline in volume (as St. Raphael's volume would be included in the denominator of the equation, but not in the numerator). Additionally, John Dempsey Hospital reported no Primary volume from FY 2009-2011, however reported Elective volumes for all years. Finally, New Milford Hospital reported 10 Primary cases in FY 2009 and no volume in following years.

These data integrity issues, in tandem with the wide swings in volume year over year, make it impossible to determine clear trends. The approach taken by 3d Health, and the creation of use rates to project need for future PCI interventions based on disease burden and demographic factors versus basing need in historic utilization creates a more accurate picture of need in a community, and for establishment of a program in Eastern Connecticut.

12. For the projections on page 1462, provide the data broken out by primary and elective rather than inpatient and outpatient PCIs for both OHCA defined primary service area and the proposed angioplasty region. Please note, replace Plainville with Plainfield in the OHCA defined-primary service area.

	Backus Angioplasty Region			OHCA-Defined Service Area		
Category	FY16	FY17	FY18	FY16	FY17	FY18
Primary	73	72	72	55	54	54
Elective	143	148	153	108	111	115
Total	**216**	**220**	**225**	**163**	**165**	**169**

EXHIBIT 30

Service Area Primary PCI by Town

Service Area Primary PCI by Town

Town / Town Part	FY09	FY10	FY11	FY12	FY13	FY14	FY15
Within 30 Minutes							
Norwich	18	20	15	17	19	14	17
Amston	2	2	1	-	1	4	3
Bozrah	-	3	2	1	2	1	1
Brooklyn	4	5	7	4	8	5	5
Canterbury	3	3	1	1	1	1	3
Chaplin	1	1	2	2	1	1	1
Colchester	9	7	11	12	1	2	7
Columbia	-	6	3	3	2	2	2
Franklin	1	1	-	-	1	1	3
Griswold-Lisbon	12	7	5	2	8	3	3
Killingly	11	8	8	9	11	9	10
Lebanon	1	3	3	3	-	5	2
Mansfield Center	2	6	-	4	3	3	1
Plainfield	7	5	9	12	8	9	7
Preston	1	1	2	2	2	1	1
Scotland	3	1	-	-	-	1	1
Sprague	-	1	2	2	1	-	1
Sterling	1	3	1	1	2	2	1
Voluntown	-	1	1	1	1	-	2
Windham	11	13	11	6	12	7	9
Subtotal	**87**	**97**	**84**	**82**	**84**	**71**	**80**
Outside 30 Minutes							
East Haddam	4	2	1	6	4	5	3
Hampton	-	-	1	3	2	2	2
Pomfret	2	1	1	1	2	1	1
Putnam	7	7	7	8	7	8	7
Thompson	1	1	1	1	1	1	1
Woodstock	1	2	1	1	2	1	1
Subtotal	**15**	**13**	**12**	**20**	**18**	**18**	**15**
Outside Service Area							
Ledyard	8	13	8	9	6	7	7
Montville	6	6	9	15	3	10	10
Subtotal	**14**	**19**	**17**	**24**	**9**	**17**	**17**
Total Service Area	**102**	**110**	**96**	**102**	**102**	**89**	**95**
Total	**116**	**129**	**113**	**126**	**111**	**106**	**112**

- Over the past seven years, there have been an average of 99 Primary PCI patients from the service area treated at Connecticut or Massachusetts hospitals.
- 84% of this volume originated from towns located within a 30 minute drive time to Backus.
- Larger clusters of Primary PCI cases are strongly correlated with larger population centers. However, incidence rates in general are low for this condition and year-to-year variation in volume by individual town is very common.

Service Area Inpatient Elective PCI by Town

Service Area Inpatient Elective PCI by Town

Town / Town Part	FY09	FY10	FY11	FY12	FY13	FY14	FY15
Within 30 Minutes							
Norwich	75	105	72	86	61	41	31
Amston	4	2	3	-	3	2	4
Bozrah	11	3	4	2	7	1	3
Brooklyn	3	8	11	9	10	6	13
Canterbury	2	7	3	8	9	1	3
Chaplin	2	1	2	2	3	3	-
Colchester	26	18	28	17	13	12	8
Columbia	7	11	5	5	8	3	1
Franklin	6	3	1	1	5	4	4
Griswold-Lisbon	39	29	47	34	29	17	18
Killingly	21	32	25	29	27	23	24
Lebanon	6	15	6	10	5	9	9
Mansfield Center	7	7	10	7	4	-	2
Plainfield	34	24	29	29	28	20	16
Preston	13	7	9	14	9	5	6
Scotland	2	1	4	-	2	1	-
Sprague	6	5	6	3	7	2	3
Sterling	6	2	2	4	5	5	5
Voluntown	8	8	5	5	3	3	2
Windham	37	36	25	26	21	17	19
Subtotal	**315**	**324**	**297**	**291**	**259**	**175**	**171**
Outside 30 Minutes							
East Haddam	12	13	7	8	9	6	10
Hampton	2	10	4	2	2	2	-
Pomfret	6	7	8	4	5	5	4
Putnam	19	20	19	22	18	19	19
Thompson	12	9	9	11	10	7	8
Woodstock	9	9	10	10	8	7	12
Subtotal	**60**	**68**	**57**	**57**	**52**	**46**	**53**
Outside Service Area							
Ledyard	19	22	19	10	20	9	10
Montville	32	46	31	28	34	21	15
Subtotal	**51**	**68**	**50**	**38**	**54**	**30**	**25**
Total Service Area	**375**	**392**	**354**	**348**	**311**	**221**	**224**
Total	**426**	**460**	**404**	**386**	**365**	**251**	**249**

- Similar to Primary PCI volumes, 82% of the service area Inpatient Elective PCI volume treated at Connecticut or Massachusetts hospitals over the past seven years originated from towns located within a 30 minute drive time to Backus.
- The number of Elective PCIs performed in an inpatient setting have been steadily decreasing since 2010.

EXHIBIT 31

FACILITY NAME	PRIMARY PCI							ELECTIVE PCI							TOTAL PCI						
	2009	2010	2011	2012	2013	2014	% Change	2009	2010	2011	2012	2013	2014	% Change	2009	2010	2011	2012	2013	2014	% Change
Bridgeport Hospital	200	182	192	176	174	169	(16%)	333	300	279	206	215	228	(32%)	533	482	471	382	389	397	(26%)
CT Children's Medical Center	4	-	-	1	5	3	(25%)	-	-	-	2	1	1	-	4	-	-	3	6	4	-
Danbury Hospital	83	100	107	132	98	97	17%	368	305	318	299	304	280	(24%)	451	405	425	431	402	377	(16%)
Greenwich Hospital	42	33	38	39	45	42	-	-	-	-	-	-	-	-	42	33	38	39	45	42	-
Hartford Hospital	1,027	1,230	1,247	427	436	406	(60%)	5	8	22	745	760	709	14080%	1,032	1,238	1,269	1,172	1,196	1,115	8%
John Dempsey Hospital	-	-	-	141	110	149	-	447	511	477	248	190	187	(58%)	447	511	477	389	300	336	(25%)
Lawrence+Memorial Hospital	77	81	70	91	108	102	32%	-	-	-	-	-	-	-	77	81	70	91	108	102	32%
New Milford Hospital	10	-	-	-	-	-	(100%)	-	-	-	-	-	-	-	10	-	-	-	-	-	(100%)
Norwalk Hospital	14	59	65	50	53	65	364%	-	-	-	-	-	-	-	14	59	65	50	53	65	364%
St. Francis Hospital and Medical Center	449	383	399	413	398	404	(10%)	795	678	569	541	544	455	(43%)	1,244	1,061	968	954	942	859	(31%)
St. Mary's Hospital	255	291	363	415	342	284	11%	-	-	-	-	-	-	-	255	291	363	415	342	284	11%
St. Vincent's Medical Center	132	448	227	271	307	567	330%	1,120	454	640	645	511	428	(62%)	1,252	902	867	916	818	995	(21%)
Stamford Hospital	42	55	60	79	110	123	193%	212	224	194	226	210	321	51%	254	279	254	305	320	444	75%
The Hospital of Central Connecticut	76	112	132	73	80	81	7%	-	-	-	-	-	-	-	76	112	132	73	80	81	7%
Yale-New Haven Hospital	9	10	158	271	359	627	6867%	1,271	1,347	1,305	1,237	1,470	929	(27%)	1,280	1,357	1,463	1,508	1,829	1,556	22%
Waterbury Hospital	156	122	166	149	150	157	1%	206	240	213	188	174	178	(14%)	362	362	379	337	324	335	(7%)
Hospital of Saint Raphael	268	302	298	270			(100%)	334	322	298	203			(100%)	602	624	596	473	-	-	(100%)
Total	**2,844**	**3,408**	**3,522**	**2,998**	**2,775**	**3,276**	15%	5,091	4,389	4,315	4,540	4,379	3,716	(27%)	**7,935**	**7,797**	**7,837**	**7,538**	**7,154**	**6,992**	(12%)

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

1503

March 15, 2016

Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Dear Commissioner Pino and OHCA Hearing Officer,

My name is Greg Allard and I am the Vice President of American Ambulance Service, Inc. (AASI) located in Norwich, Connecticut. American serves not only Norwich (with a population of over 40,000); we serve 22 communities in Eastern Connecticut including the Mashantucket Pequot Tribal Nation. In addition to all of our emergency responsibilities, we provide non-emergency or routine ambulance and wheelchair transportation. We work closely with all of our community hospitals and skilled nursing and rehab facilities.

Support for a PCI Program at Backus

As the major EMS provider in the defined Backus Hospital Angioplasty Region, AASI fully supports the CON application to provide Primary and Elective PCI at Backus. The reason for our support is two-fold. Most importantly, we believe having such a program is in the best interest of all of the residents in the community we serve and our patients are always our number one priority. Secondly, it will create efficiencies within our system that have the potential to improve our availability to respond to emergency and non-emergency requests and this is due to the fact that our ambulances will remain in our primary service area longer.

Some STEMI patients can be identified in the field via an EKG performed in the out of hospital arena, however this can only occur if a Paramedic is on-board, either at the time of patient pick up or through an "intercept" en route to the hospital. In the defined Angioplasty Region three EMS providers have Advanced Life Support (ALS) abilities. In total, these EMS providers can staff 17 Paramedic vehicles, on average; there are 14 available ALS vehicles during the day, and 7 during the night.

AMERICAN
AMBULANCE
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ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
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1504

Throughout the region there are many volunteer-based ambulance services that are Basic Life Support (BLS) capable and are not qualified to determine if a patient is experiencing a STEMI when picked up in the field. Thus, the potential exists for patients with unidentified STEMIs to arrive at Backus Hospital in need of Primary PCI if a Paramedic is not available.

Patients receiving diagnostic catheterizations that require Elective PCI also require transport via EMS to PCI-equipped facilities. Currently there is only one of those facilities in Eastern Connecticut and there are at least a dozen in the western half of Connecticut. Therefore, residents living in the Angioplasty Region must travel, by ambulance, significant distances for this life saving procedure.
Studies have proven that time is of the essence when dealing with STEMI patients in order to ensure the best possible health outcomes. So both Primary and Elective PCI can necessitate transport via EMS to a PCI-capable facility. As any commuter can tell you, travel times are highly dependent on weather conditions, traffic patterns and road work/construction as well as accidents. So the transfer times between facilities can vary greatly.

Additionally, on page 1449 of the Backus/Hartford Hospital Completeness Responses there is very valuable data provided by the American Heart Association's Mission: LifeLine that shows the Backus Hospital Angioplasty Region has: an average 75 minute transfer time for acute coronary intervention in New London County which has the third-highest mortality rate and, more importantly, it also includes Windham County (which has no access to a PCI capable provider in Connecticut) and it has the highest mortality rate in the State. A PCI program in Backus Hospital would therefore improve the timeliness of accessing critical, life-saving procedures.

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
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Conclusion

For the reasons stated above, we at American Ambulance Service, Inc. urge the Office of Health Care Access to approve the William W. Backus Hospitals' request for PCI services.

Respectfully,

Gregory B. Allard, Vice President

Dedicated, Professional People Committed to Excellence, Caring for You.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

IN RE	:	**Docket No. 15-32031-CON**
CERTIFICATE OF NEED APPLICATION TO ESTABLISH AND	:	
OPERATE A PRIMARY AND ELECTIVE ANGIOPLASTY	:	
PROGRAM AT THE WILLIAM W. BACKUS HOSPITAL IN	:	
NORWICH, CONNECTICUT	:	**MARCH 16, 2016**
	:	

PRE-FILED TESTIMONY OF
DAVID A. WHITEHEAD

Introduction

Good morning Commissioner Pino, Hearing Officer Hansted, and Office of Health Care Access staff. My name is David Whitehead and I am the Senior Vice President and Chief Strategy and Transformation Officer at Hartford Healthcare. I am also the past President and CEO of Backus Hospital and as such have been involved with this proposal from its inception. Given this history, I have the unique opportunity to convey the critical need for a Primary and Elective Percutaneous Coronary Intervention ("PCI") program in Norwich not only from a grass roots, local perspective but also from a global Hartford Healthcare vantage point. Today an inequitable distribution of crucial life-saving PCI services exists in our State. These services are a standard of care all individuals deserve access to, within the 30 minute transport time specified in the Office of Emergency Management Services ("OEMS") guideline issued in 2012, and yet no programs exist within a reasonable drive time for more than 230,000 residents of eastern Connecticut. Approval of this proposal, and establishment of this service at Backus Hospital, will respond to an identified community need by bringing quality interventional cardiac services through our partnership with Hartford Hospital to the communities served by Backus. This program will ultimately strengthen the entire healthcare network within the region.

Overview

This proposal requests approval for The William W. Backus Hospital ("Backus") and Hartford Hospital ("Hartford") to establish a Primary and Elective Percutaneous Coronary Intervention program at Backus Hospital (the "Program"). PCI procedures are performed in a cardiac catheterization lab, and are non-surgical procedures used to treat patients suffering from both acute and chronic cardiac conditions. Primary PCI, performed emergently, treats ST-Elevated Myocardial Infarctions ("STEMI"), a form of heart attack. In the case of these emergency situations a PCI must be performed in the shortest timeframe

possible, as any delay in care correlates to increased heart tissue death, and increases the chance of mortality or other undesirable clinical outcomes.

Elective PCI, or non-emergent PCI, is the standard for treating patients with symptoms of recurrent myocardial ischemia ("Unstable Angina" or "UA") and/or high risk findings on a non-invasive stress test. Elective PCI is often a scheduled procedure following extensive cardiac testing and/or a post-cardiac event (such as a Non ST-Elevated Myocardial Infarction) to relieve chest pain and related symptoms and, in many patients, prevent more serious heart conditions. Patients who undergo an Elective PCI have risk factors which show that if a PCI to correct the blockages causing the ischemia is not performed, the patient would be more likely to have a fatal myocardial infarction in the future. Unlike primary PCI, this procedure is scheduled, but ideally takes place within 24-48 hours of decision to treat. This effectively reduces the risk of future cardiac events. Once these patients have their coronary intervention, their reoccurring symptoms are alleviated and they are able to return to their baseline health.

Hartford Healthcare is dedicated to providing patients with an exceptional, coordinated care experience and a single, high standard of practice. A hallmark of Hartford Healthcare is to strengthen access to care that meets identified community needs by enhancing local healthcare delivery capabilities whenever possible. The establishment of a Primary and Elective PCI program within this region is supported by this strategy, and furthers the mission of Hartford HealthCare to improve the health and healing of the people and communities it serves.

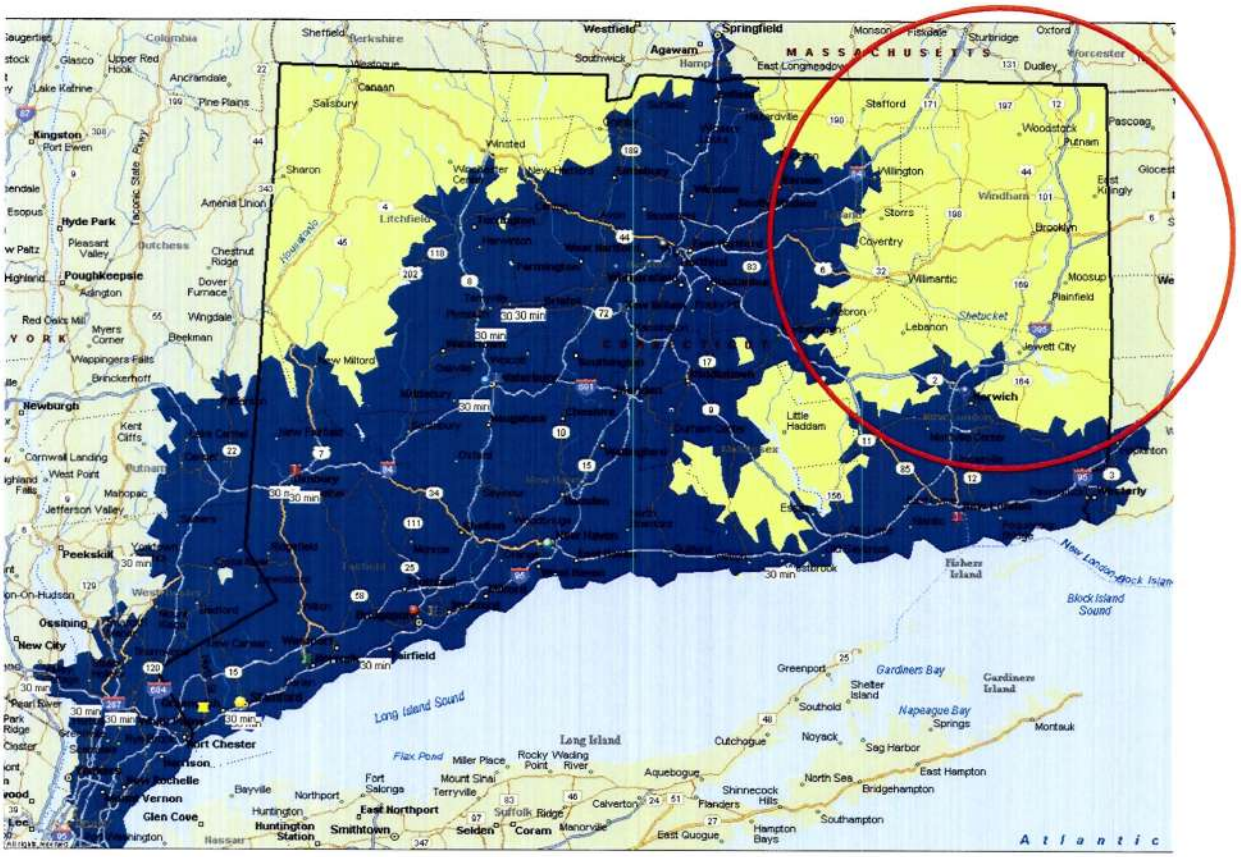
ACCESS TO PCI

While analyzing Primary and Elective PCI services, Backus defined an Angioplasty Service Region to more accurately represent the provision of care in eastern Connecticut. Instead of using the traditional, hospital-centric Primary and Secondary Service Areas, the Angioplasty Region was defined through the analysis of zip code level data. This revealed a large geography where services are currently unavailable, and thus an unmet need to a well-documented clinical standard of care. This analysis further demonstrated that residents of the Angioplasty Region (the definition of which will be discussed further by 3d Health) are receiving PCI procedures at a lower rate than the rest of the State or Nation, and yet are suffering from myocardial infarctions at a higher rate than the State and Nation. Specifically, the rate of Primary PCI interventions for residents living in the Angioplasty Region is 18% below the statewide level and 8% below the national level (CON, Exhibit 8, Page 451). The rate of Elective PCI interventions for this same population is 19% below the statewide level and 41% below the national level (3d Health Assessment, page 17 (CON, Exhibit 8, Page 464). These figures are especially disturbing given the demographics of the Angioplasty Region. More than 45% of this population is over the age of 45, compared to 41% nationally. This region also suffers disproportionately from high rates of obesity, diabetes and smoking - all factors resulting in projected increases in the need for, and utilization of, cardiovascular services in this region. Social determinants of health, such as low socioeconomic status, high rates of underinsured and uninsured, and high a population-to-physician ratio, perpetuate the disease burden in this area. The Angioplasty Region also includes 3 towns designated as 'Health Professional Shortage Areas' and 11 towns designated as 'Medically Underserved Areas,' further compounding existing challenges to accessing care.

The lack of readily available PCI services in the Angioplasty Region places a burden on families and caregivers of patients who are transported to, or seek treatment from, hospitals far from home. Duplicative out-of-pocket costs associated with multiple hospital admissions and duplicative procedures, lost time at work, childcare fees and travel expenses are an economic burden to the residents of this region. Less quantifiable but equally important is the effect of stress on the family separated by illness and geography, as well as the impact on future care coordination and management of the patient's heart condition.

While it may be true that there is sufficient access to PCI services in many parts of the State, this is not the case for residents living in the defined Angioplasty Region. In eastern Connecticut only a small number of towns, those along the southeastern CT shoreline, have sufficient access to a PCI provider. Approximately 230,000 residents in the towns surrounding and to the north of Norwich do not have access to a PCI provider within a 30 minute drive time today. These residents must travel significant distances to receive this standard of care. In response to the Completeness Questions (page 1448) a table was provided detailing drive time estimates to the closest PCI facility for communities centrally located within the Angioplasty Region. The drive times are absolute minimums, calculated in the best of conditions, and range from 36 minutes to 57 minutes, well beyond the 30 minute transport time specified in the Office of Emergency Management Services ("OEMS") guideline issued in 2012. Drive time is important; in the case of an emergency time is muscle, so the less time elapsed from the onset of symptoms until the beginning of treatment, the greater the patient's chances of minimizing permanent damage to heart muscle.

As indicated by the map below, a saturation of programs exist along the shoreline and within the central region of the State. The blue shading on the map represents the 30 minute drive time from each PCI capable facility in the State of Connecticut. The Northeast corner of the State, a geography mirroring the defined Angioplasty Region, has virtually no shading, and thus no access to PCI services within a 30 minute drive time. This analysis is further supported by the American Heart Association's Mission Lifeline analysis of drive time and access to PCI capable facilities, with the same gaping hole indicated on their map (also included below). The Mission Lifeline data indicates this geography as suffering from the highest mortality rates associated with Acute Myocardial Infarction and the greatest transport challenges. According to Mission Lifeline, Windham County's age adjusted mortality in individuals 35 years of age or older is greater than 34.3-47.4 deaths per hundred thousand. This is the worst in the State, while New Haven and Fairfield Counties (where the region is virtually saturated with access to programs) has the lowest age adjusted mortality rate, with 29.1-29.4 deaths per hundred thousand. This data validates Hartford HealthCare's stance that access to PCI services must be improved in order to affect cardiac mortality rates.


Westfield
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Monson
Fiskdale
Sturbridge
Oxford
Dudley
Worcester
Sheffield
Berkshire
Canaan
Salisbury
Winsted
Sharon
Litchfield
Stafford
Woodstock
Putnam
Pascoag
Willington
Windham
Storrs
Coventry
Brooklyn
Willimantic
Moosup
Plainfield
Sterling
Lebanon
Jewett City
Norwich
Little Haddam
Old Saybrook
Westbrook
Harbor Island
New London
Block Island
Block Island Sound
Long Island Sound
Long Island
Gardiners Bay
Napeague Bay
Greenport
Shelter Island
Gardiners Island
Southold
Cutchogue
Noyack
Sag Harbor
Springs
Montauk
East Hampton
Bridgehampton
Southampton
Hampton Bays
North Sea
Shinnecock Hills
Aquebogue
East Quogue
Flanders
Calverton
Miller Place
Rocky Point
Wading River
Flax Pond
Mount Sinai
Terryville
Fort Salonga
East Northport
Northport
Huntington
Huntington Station
Smithtown
Selden
Coram
Manorville
Suffolk Ridge
Bayville
Glen Cove
Vernon
Rochelle
Port Chester
Ossining
New City
Peekskill
Cornwall Landing
West Point
Jefferson Valley
Mahopac
Kent Cliffs
Newburgh
Brinckerhoff
Wappingers Falls
Beekman
Wingdale
Red Oaks Mill
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Pleasant Valley
Hyde Park
Poughkeepsie
Adlington
Dover Furnace
Chestnut Ridge
Amenia Union
Esopus
Kingston
Port Ewen
Lake Katrine
Columbia
Upper Red Hook
Glasco
Ancramdale
Pine Plains
Scenic State Pkwy
Housatonic
Shetucket
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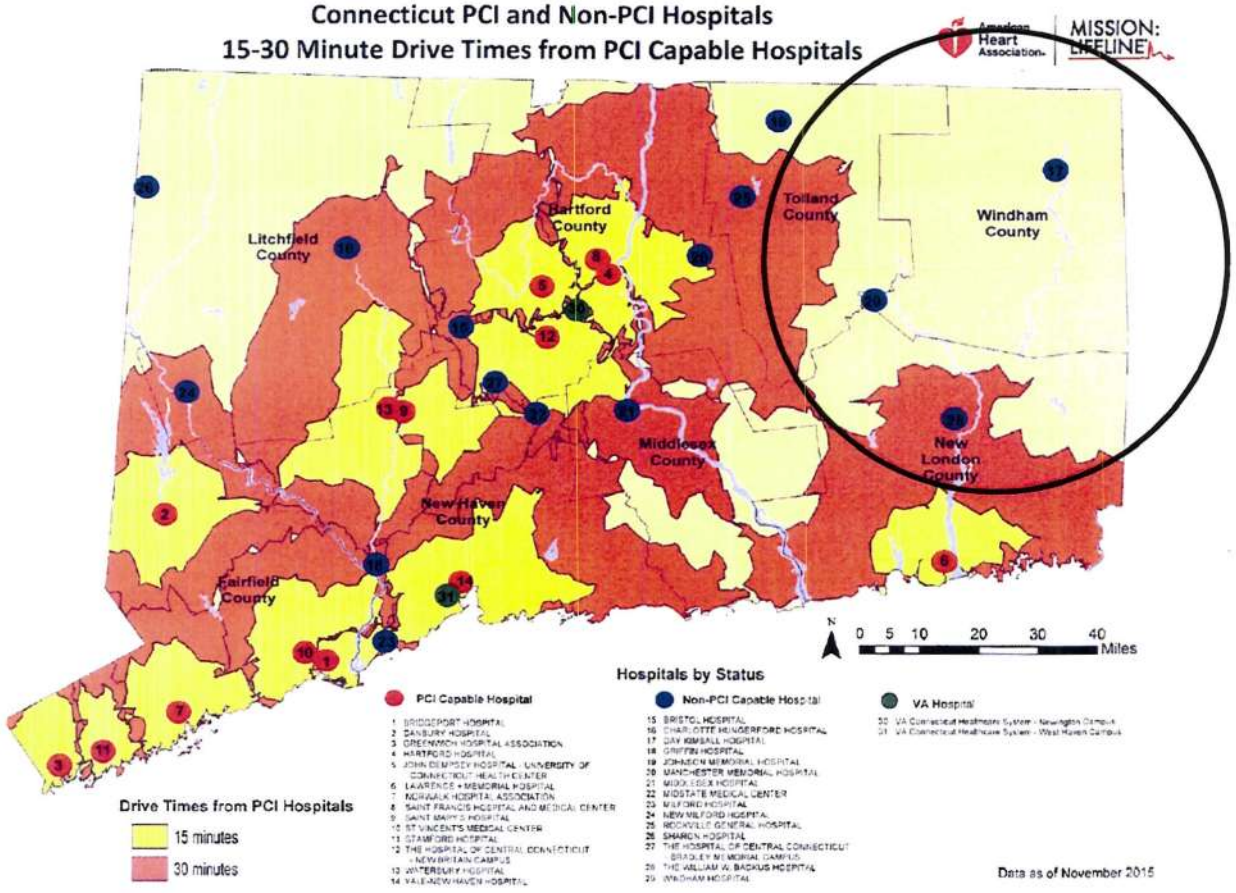
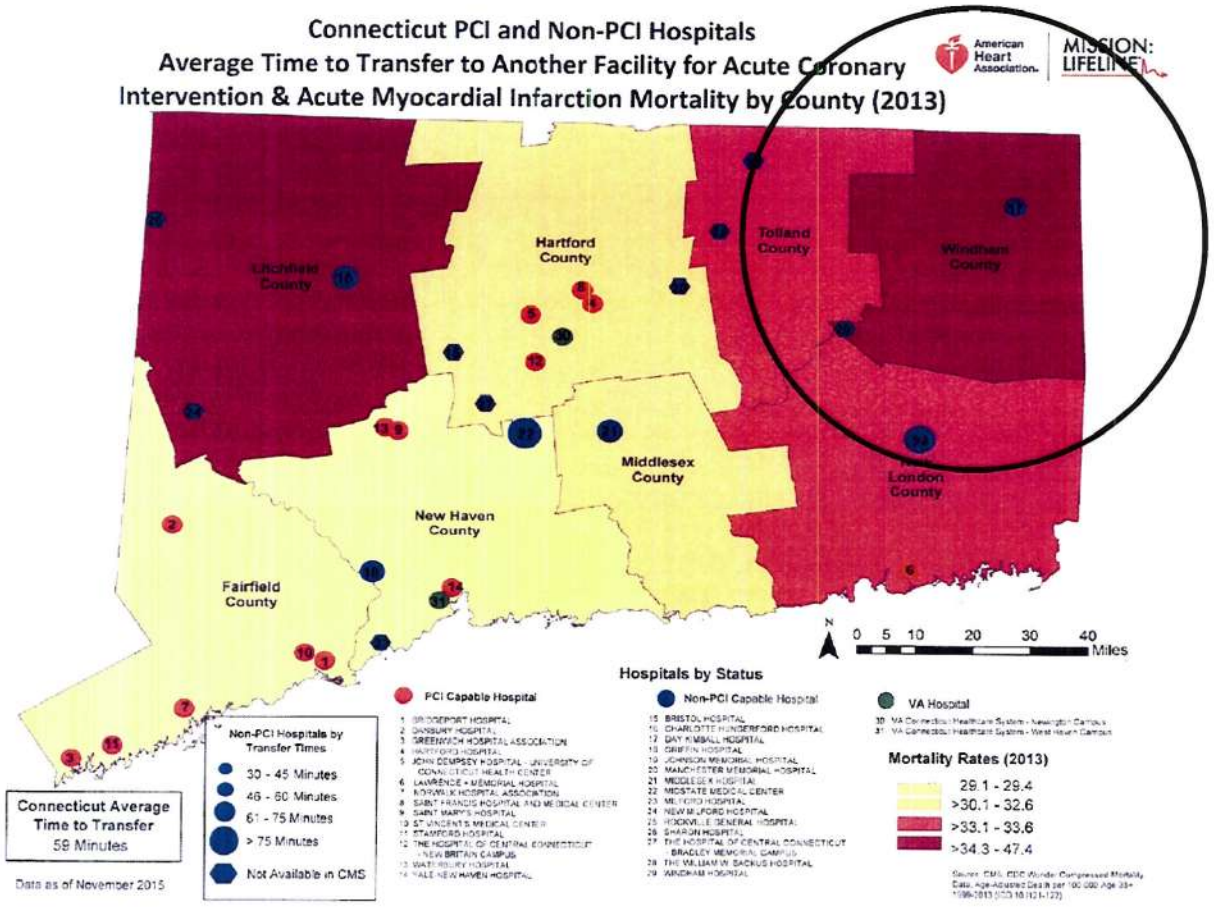

Connecticut PCI and Non-PCI Hospitals
15-30 Minute Drive Times from PCI Capable Hospitals
American Heart Association.
MISSION: LIFELINE
Litchfield County
Hartford County
Tolland County
Windham County
Middlesex County
New London County
New Haven County
Fairfield County
N
0 5 10 20 30 40
Miles
Drive Times from PCI Hospitals
15 minutes
30 minutes
Hospitals by Status
PCI Capable Hospital
1 BRIDGEPORT HOSPITAL
2 DANBURY HOSPITAL
3 GREENWICH HOSPITAL ASSOCIATION
4 HARTFORD HOSPITAL
5 JOHN DEMPSEY HOSPITAL - UNIVERSITY OF CONNECTICUT HEALTH CENTER
6 LAWRENCE + MEMORIAL HOSPITAL
7 NORWALK HOSPITAL ASSOCIATION
8 SAINT FRANCIS HOSPITAL AND MEDICAL CENTER
9 SAINT MARY'S HOSPITAL
10 ST VINCENTS MEDICAL CENTER
11 STAMFORD HOSPITAL
12 THE HOSPITAL OF CENTRAL CONNECTICUT - NEW BRITAIN CAMPUS
13 WATERBURY HOSPITAL
14 YALE-NEW HAVEN HOSPITAL
Non-PCI Capable Hospital
15 BRISTOL HOSPITAL
16 CHARLOTTE HUNGERFORD HOSPITAL
17 DAY KIMBALL HOSPITAL
18 GRIFFIN HOSPITAL
19 JOHNSON MEMORIAL HOSPITAL
20 MANCHESTER MEMORIAL HOSPITAL
21 MIDDLESEX HOSPITAL
22 MIDSTATE MEDICAL CENTER
23 MILFORD HOSPITAL
24 NEW MILFORD HOSPITAL
25 ROCKVILLE GENERAL HOSPITAL
26 SHARON HOSPITAL
27 THE HOSPITAL OF CENTRAL CONNECTICUT - BRADLEY MEMORIAL CAMPUS
28 THE WILLIAM W. BACKUS HOSPITAL
29 WINDHAM HOSPITAL
VA Hospital
30 VA Connecticut Healthcare System - Newington Campus
31 VA Connecticut Healthcare System - West Haven Campus
Data as of November 2015



Upon approval of this CON application, 118,000 residents in Eastern Connecticut (51% of the Angioplasty Region) will gain access to a facility offering PCI within a 30 minute drive time, and an additional 67,000 residents will have improved access within 10 minutes. Backus will become the closest PCI facility for an additional 28,000 residents in the Northeast portion of the state, and will become the closest Connecticut provider to 18,000 residents. This is significant, as residents of the far Northeast corner must seek these services out of state today.

This is not the first investment Backus Hospital has made in this region. In 2012 Backus established a full service, 24/7 satellite Emergency Department within the town of Plainfield for similar reasons. A need was revealed through careful market analysis, and a sound strategy to meet those needs was developed, and approved by OHCA on 12/3/2010, (Docket Number 09-31503-CON). The Backus Plainfield Emergency Care Center has fulfilled its mission and is providing emergency care to tens of thousands of individuals each year. Backus is further investing in the region through the development of a Center for Specialty Care. This center will house a full-time cardiology practice, among other specialty services, to enhance the access to primary and preventive care within the region. These investments support the population health model of care delivery that is being developed by Hartford HealthCare; however, like all public health and preventive health efforts, this approach will take many years to change the incidence of disease. Therefore, establishing a PCI program at Backus is necessary to treat the

population today, by providing individuals within the defined Angioplasty Region access to a life-saving clinical standard of care.

If this Application is approved, residents living in this geographically isolated and rural region will finally gain equitable access to a standard of care for the treatment of a leading cause of death. Therefore, I strongly urge you to approve this CON application and I thank you for your time today.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

IN RE	:	**Docket No. 15-32031-CON**
CERTIFICATE OF NEED APPLICATION TO ESTABLISH AND	:	
OPERATE A PRIMARY AND ELECTIVE ANGIOPLASTY	:	
PROGRAM AT THE WILLIAM W. BACKUS HOSPITAL IN	:	
NORWICH, CONNECTICUT	:	**MARCH 16, 2016**
	:	

PRE-FILED TESTIMONY OF
M. SHANE FOREMAN

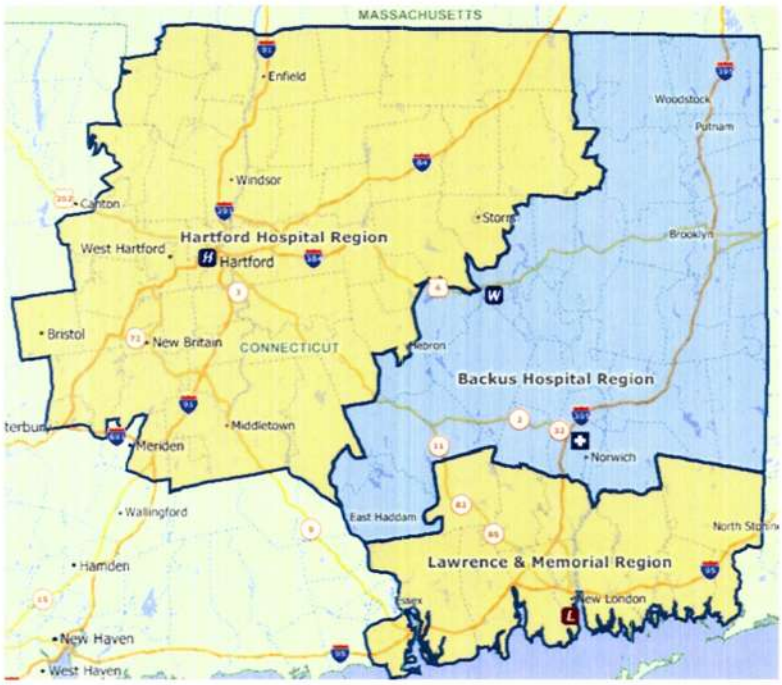
Introduction

Good morning Commissioner Pino and Office of Health Care Access ("OHCA") staff. My name is Shane Foreman and I am the Founder and CEO of 3d Health. Thank you for taking the time today to let me tell you about the clear public need for a Primary and Elective PCI program ("Program") located at The William W. Back Hospital ("Backus" or "Backus Hospital) and the set of analytics that we completed to come to this conclusion. Having completed a detailed market assessment, it is clear to me that a "hole" exists in northeast Connecticut where patients either do not have ready access to PCI services or are forced to leave the state for care.

The William W. Backus Hospital Region

In order to define the service area or "Region" that Backus Hospital would serve for PCI services, we relied on the State of Connecticut Department of Public Health guideline for transporting patients with prehospital-diagnosed ST Elevation Myocardial Infarction (STEMI). Under this guideline, STEMI patients with a transport time of under 30 minutes should be taken directly to a hospital with Primary PCI capabilities. As such, we used the 30-minute drive time as the standard for defining each Hospital's region.

In evaluating the potential for Backus to offer a Percutaneous Coronary Intervention ("PCI") program at the Hospital, 3d Health completed an in-depth drive time analysis for all of the towns in Eastern Connecticut. Each ZIP code was assigned to the closest potential Connecticut PCI facility, including Hartford Hospital, Backus Hospital, and Lawrence & Memorial Hospital. The resulting "Backus Hospital Region" is the defined service area for all of our analyses (please see the map below) and includes just over 230,000 patients.

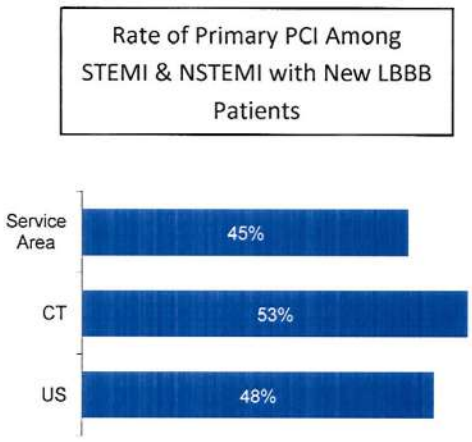


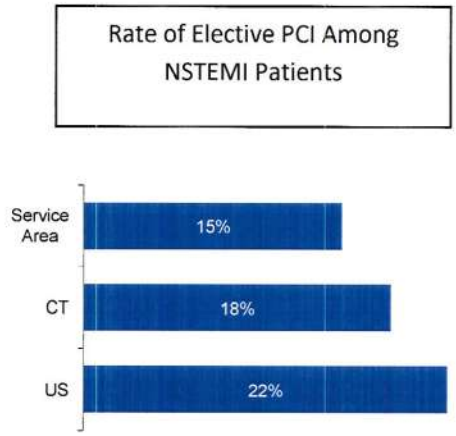
Based on the 30-minute drive time, there is a clear public need for PCI services within the Backus Hospital Region. Out of approximately 230,000 patients, 63% or 146,000 do not have access to a PCI facility within 30 minutes. Additionally, 18,000 patients are forced to leave the State in order to access PCI services within 30 minutes. The remaining 66,000 service area patients live within 10 minutes of Backus Hospital.

Incidence of Disease vs. Preferred Treatment

Overall, acute myocardial infarction ("MI") in the Backus Hospital Region has been increasing, up by over 12.6% since 2009 according to CHIME data. Based on CHIME data per 100,000 patients, the STEMI portion of the total acute MI volume in the service area is higher than the Connecticut average, 31% vs. 26% in the State. Based on CHIME Data per 100,000 patients and the latest data from the National Center for Health Statistics, the incidence of STEMI per 100,000 patients is also significantly higher in the Backus Hospital Region (104.3) than in both the state (83.0) and nation (81.9).

Yet, the rate of Primary PCI as an intervention for patients within the Backus Hospital Region is about 18% below the statewide level and 8% below the national level (chart on the left below). The Elective PCI rate of intervention for patients within the Backus Hospital Region is also well below state and national levels at 19% and 41% less, respectively (chart on the right below).





Current & Projected Volumes

According to CHIME and Massachusetts data, the volume of Primary PCI within the Backus Region has been relatively flat, with minor fluctuations on a year to year basis – from 8% up to 13% down in any given year. Similarly, the NSTEMI Elective PCI volume within the Region is flat, with year over year fluctuations – from 21% up to 14% down.

The large change within the market is a shift from Non-AMI Elective PCI being treated on an inpatient basis to the outpatient setting. From FY09 through FY14, Non-AMI Elective PCI volume from the Backus Region declined from 254 to 106 cases. At the same time, the Outpatient Elective PCI volume from this same Region rose from 33 to 204 cases, based on the percentage of total PCI cases that took place in an outpatient setting from the Coronary Angioplasty Patient Census Reports from the Connecticut Hospital Association.

To estimate future demand for PCI among Backus Hospital Region patients, 3d Health prepared market projections based on a set of utilization rates applied to the service area population. These utilization rates were calculated by age and gender using PCI volume originating across the state of Connecticut from FY 2009 through FY 2014. These rates also include an estimate for Connecticut patients treated at Massachusetts hospitals based on FY 2012 data. In modeling future inpatient Primary and Elective PCI volumes originating from the service area, 3d Health assumed no change in the underlying calculated utilization rates.

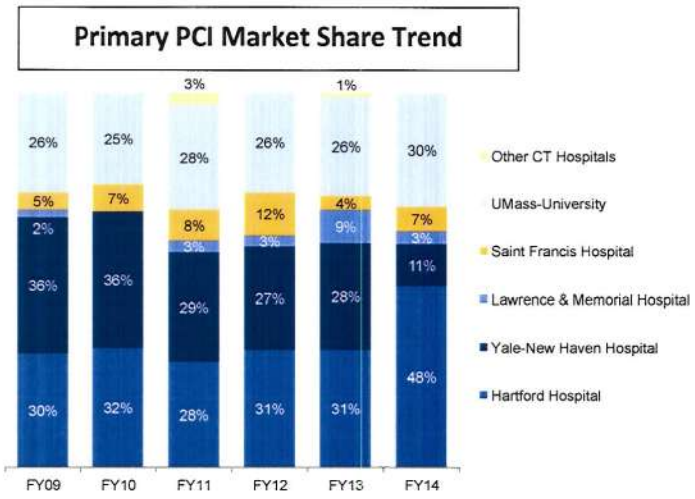
The net result of applying the CHIME-based utilization rates to the projected Backus Hospital Region is that the Primary PCI market volume grows from an estimated 104 cases in FY09 to 120 cases in FY20. The largest projected market change is in Elective PCI, with volumes growing from 408 cases in FY09 to 514 in FY20, driven by the increase in outpatient discussed above.

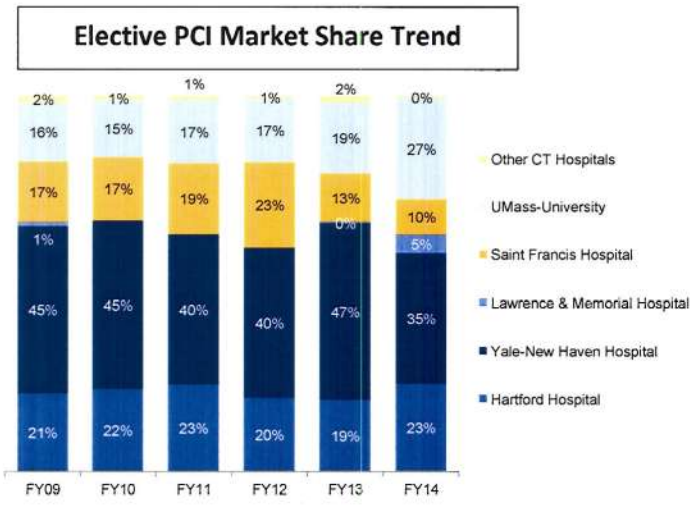
In projecting the potential PCI volume at Backus Hospital, 3d Health considered historic ED market share at both Backus Hospital and Windham Hospital, variation in ED market share based on proximity to each Hospital, ED in-migration rates, and we removed the complex Elective PCI cases from the analysis.

The resulting projected Primary PCI volume at Backus Hospital ranges from 79 cases in Year 1 to 82 cases by Year 5. The projected Elective PCI cases at Backus range from 151 in Year 1 to 167 in Year 5. The net result of the projected Primary and Elective PCI cases is a program that will complete between 216 and 233 PCI cases per year.

Impact on Other Facilities

As of FY14, almost 50% of the Primary PCI volume from the Backus Hospital Region is being treated at Hartford Hospital. Yale-New Haven Hospital treats 11% of these patients, followed by Saint Francis Hospital at 7% and Lawrence & Memorial Hospital at 3%. Virtually all of the remaining volume leaves the state for treatment. John Dempsey Hospital and The Hospital of Central Connecticut did not treat any Primary PCI Patients from the Backus Region in FY14.





For FY14, almost 25% of the Elective PCI volume from the Backus Hospital Region is being treated at Hartford Hospital. Patients from this Region opting to seek treatment at Yale-New Haven Hospital has trended downward by 10 points since FY09. Saint Francis Hospital treats 10% of these patients and

Lawrence & Memorial Hospital treats 5%. Virtually all of the remaining volume leaves the state for treatment.

In order to quantify the potential total impact of establishing the PCI Program at Backus Hospital on other providers, we utilized Backus Hospital's current inpatient market share of 36% from the Hospital Region and assumed 100% of the Hartford Hospital volume would move to Backus. Of the 216 projected Total PCI cases at Backus Hospital in Year 1, we anticipate 138 of the cases from Hartford Hospital, 54 cases from Yale-New Haven Hospital, 16 cases from Saint Francis Hospital, 8 cases from Lawrence & Memorial Hospital.

Conclusion

The proposed addition of PCI Services at Backus Hospital provides an exciting opportunity for 230,000 patients in Eastern Connecticut – the ability to receive PCI Services at a rate similar to the state and national levels, dramatically reduce the travel time for such services, limit the number of patients that must leave the state for care, and all without having a major impact on the existing facilities outside of the Hartford HealthCare family.

62426714

M. SHANE FOREMAN

POSITION

Founder and CEO, 3d Health, Inc.

EDUCATION

B.S., Accounting; Louisiana College, 1989

M.S.A., Health Services Administration, Central Michigan University, 1995

PROFESSIONAL AND BUSINESS HISTORY

3d Health, Inc., Chicago, Illinois; Founder and CEO, 2002

Navigant (formerly Tiber Group), Chicago, Illinois; Director, 1997

HCA (formerly Columbia/HCA), Lafayette, Louisiana; Regional Director, 1995

PhyServ, Lafayette, Louisiana; Vice President of Business Development, 1995

CHRISTUS Health (formerly Sisters of Charity), Alexandria, Louisiana; Chief Financial Officer, 1992

SUMMARY OF PROFESSIONAL AND BUSINESS EXPERIENCE

Hospital-Physician Joint Ventures

The Stark III final regulations published in September 2007 has reduced the number of relationship structures available to hospitals and physicians interested in partnering. Shane works closely with internal and/or external counsel to identify the structural options available at the outset of a project. 3d Health also has well established relationships with nationally recognized counsel that our clients are free to utilize.

Shane works with clients to identify, test, and confirm market opportunities and to negotiate and structure mutually beneficial relationships centered on capturing incremental patient volume and resulting market share.

Imaging Strategy

Developing an imaging strategy calls for a thorough understanding of the market, competition, and referring physician base. It also requires the ability to gauge any imaging opportunity in terms of capital expenditure and required return.

Shane works with hospitals, health systems, and physician groups on a wide range of strategic imaging services including market analysis, feasibility testing, referring physician requirements, cannibalization impact analyses, capacity analyses, reimbursement modeling, pro forma development, business planning, deal structuring, and new venture development.

Medical Staff Development Planning

A truly valuable Medical Staff Development Plan should provide a real-world assessment that helps identify both market opportunities and the right mix of physicians for a client organization. 3d Health combines senior management insight, medical staff perspective, best-of-industry data,

and a proprietary prioritization framework, to establish a strategic Medical Staff Development Plan.

Shane has extensive experience completing high impact and actionable Medical Staff Development Plans. He helps clients understand the physician resources required to achieve their market share and strategic objectives and has proven experience presenting results to executive teams, board members, and physician leaders.

Outpatient Strategy
A coordinated outpatient strategy not only requires a thorough understanding of a client's market, competition, and referring physician base, but it also calls for a detailed plan on how to best service a large volume of patients with high customer service demands – and to do it better than the competition.

Shane works with hospitals and health systems develop a comprehensive outpatient strategy that focuses on driving incremental market share, volume, and revenue while shoring up existing business.

Outsourced Analytics
3d Health has a demonstrated ability to identify the right analysis to quickly and effectively answer strategic questions facing client organizations. Shane helps clients outsource a portion of the business development and planning function and delivers the right analysis, perspective, and recommendations within aggressive time frames.

Physician Alignment Strategy
Shane has a long history of assisting hospitals in successfully developing and implementing physician alignment strategies. Whether the best strategy is physician employment, a joint venture, group practice development, development of call coverage arrangements, or a mutual focus on quality initiatives, Shane and 3d Health can help.

PROFESSIONAL AND BUSINESS AFFILIATIONS

Member, American College of Healthcare Executives

Member, Chicago Health Executives Forum

Member, Society for Healthcare Strategy and Market Development

Member, Association of Staff Physician Recruiters

Member, Healthcare Financial Management Association

SELECTED INTERVIEWS, PRESENTATIONS, AND PUBLICATIONS

"State of the State in Outpatient Imaging," RBMA Mid-Winter Board Meeting, January 2010.

"State of the State in Medical Staff Development," Carolinas Healthcare Public Relations & Marketing Society, Society for Healthcare Strategy & Market Development, November 2009.

"State of the State in Outpatient Imaging," California Radiological Society, October 2009.

"Cost of Care: Medical Imaging a Growth Industry, but Some Say Unneeded Scans Increase Expenses," M. Shane Foreman interviewed by Ryan McNeill in The Dallas Morning News, September 2009.

"Market Conditions Test Economics of Diagnostic Imaging Services," Jon Geise and M. Shane Foreman, Diagnostic Imaging, July 2009

"The Impact of the Recession on Physician Recruitment," M. Shane Foreman and Ron Flower, Journal of the Association of Staff Physician Recruiters, Summer 2009

"The Future of Hospital-Based Imaging," M. Shane Foreman, ImagingBiz.com, April 2009

"Expert Reveals What Providers Should Look for in Outpatient Imaging," SmartBrief, March 2009.

"Outpatient Imaging: Key Trends in a Tumultuous Market," interviewed by Kate Madden Yee at AuntMinnie.com, March 2009.

"State of the State in Outpatient Imaging," RBMA Imaging Center Conference, March 2009.

Forward to "Diagnostic Imaging Industry Outlook 2009: Market Trends & Analysis, January 2009.

"Crystal Ball Gazing: What Does the Future Hold for Diagnostic Imaging," Washington G-2 Reports' Diagnostic Imaging Institute 2008, October 2008.

"Outpatient Imaging: The Next Five Years," AHRA Fall 2008 Advanced Program, October 2008.

"Outpatient Imaging Health Predicted Strong through 2013," interviewed by Cynthia Keen at AuntMinnie.com, August 2008.

"Do Market Opportunities Remain in Outpatient Imaging?," co-authored with Rich Paulk in Radiology Business Journal, July 2008.

"Outpatient Imaging – The Next Five Years," AHRA Annual Meeting and Exposition, July 2008.

"Outpatient Imaging: The Next Five Years," Outpatient Outlook 2008, February 2008.

"Market Forces at Play in Hospital-Physician Partnering," Illinois Staff Physician Recruiters, November 2007.

"The Next Big Thing: The Future of Freestanding Radiation Therapy," co-authored with Jon Geise in ADVANCE for Imaging & Radiation Oncology, November 2007.

"The State of the State in Outpatient Imaging," RBMA Imaging Center Conference, November 2007.

"State of the State in Imaging," AHRA Annual Meeting and Exposition, July 2007.

"How the Market Influences and Creates Opportunities for Physician-Hospital Affiliation," American Medical Association, June 2007.

"State of the State in Imaging," Kutak Rock Imaging Conference, May 2007.

"Hospital-Physician Partnering Options Around Outpatient Neuroscience Services," World Research Group, February 2007.

"Developing Diagnostic Imaging Centers of Excellence within Not-For-Profit Health Systems," World Research Group, January 2007.

"Market Forces at Play in Hospital & Physician Partnering," Chicago Health Executives Forum, January 2007.

"Call Pay: Issues and Alternatives," QHR Regional Conference, September 2006.

"Tapping the Potential Synergy of Radiology, Pathology," interviewed by Karen Lusky in CAP Today, September 2006.

"Solutions for a Healthy Bottom Line: Improving Business and Clinical Operation," interviewed by Kathy Dix, Kris Ellis, and Jennifer Schraag in Today's SurgiCenter, June 2006.

"Solutions for a Healthy Bottom Line," SURGIstrategies, May 2006.

"Physician Strategy: Beyond Community Need," Illinois Staff Physician Recruiters, April 2006.

"The State of the State in Imaging," AHRA Annual Meeting and Exposition, August 2005.

"Building an Imaging Center: Laying the Foundation," co-authored with Jon Geise and Mary Reed in Radiology Management, July/August 2005.

"Are Radiologists Running the Show?," interviewed by Philip Betbeze in HealthLeaders Magazine, May 2005.

"MRI: An Automatic Return on Investment?," co-authored with Jon Geise in ADVANCE for Imaging and Oncology Administrators, April 2005.

"Secondary Considerations: Pre-owned Imaging and Radiation Therapy Equipment," co-authored with Jon Geise in ADVANCE for Imaging and Oncology Administrators, August 2004.

"The Battle Over Imaging Heats Up," AHRA Annual Meeting and Exposition, August 2004.

"Game On: Creating Competitive Advantages," co-authored with Patty Riskind, July/August 2004.

"Physician Compensation Issues in AMCs vs. Private Practice," Association of Academic Health Centers, August 2004.

"5-Minute Consult," M. Shane Foreman interviewed by Michelle Rogers in HealthLeaders, August 2001.

"Revisiting the Customer Service Model," M. Shane Foreman and Trent Green, COR Healthcare Market Strategist, August 2001.

"Consumer Focus Can Spur Group Practice Turnaround," co-authored with Andrew Draper in Healthcare Financial Management, June 2001.

"Strategic Physician Practice Positioning in a Highly Competitive Market," The Alliance for Healthcare Strategy and Marketing, March 2001.

"Optimizing Physician Practices Through Benchmarking," Acadiana Computer Systems Annual Meeting, November 2000.

"Medical Group Employment Decisions are Three-Fold," M. Shane Foreman and Neal Peyser, Managed Healthcare, August 2000.

"Moving Beyond the Historical Approach to Physician Partnerships," Catholic Health Association, June 2000.

"Optimizing Employed Medical Groups," VHA Pennsylvania Audio Conference, June 2000.

"Innovative Strategies to Recruit and Retain Physicians: Focused on Mid-Sized and Rural Markets," ACHE Rural Audio Conference Series, January 2000.

"Disintegration: How Employed Doctors Are Landing on Their Feet," interviewed by Martha Collins in Family Practice Management, November/December 1999.

"Primary Care Strategy: Toward a Sustainable Partnership with Primary Care," Health Care Advisory Board National Membership Meeting, 1999.

"Stopping the Bleed: Reversing Losses on Owned Practices," M. Shane Foreman and the Health Care Advisory Board for a Health Care Advisory Board publication, 1999.

"Developing a Health System-Based Physician Compensation Program," Health Care Consortium CPE Symposium, August 1999.

"A Practical Guide to Benchmarking Employed Medical Groups," White Paper No. 007 Tiber Group, 1998.

"Up and Coming Carve-Outs," M. Shane Foreman and Stuart Friedman, Health Systems Review, December 1997.

62428456

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

IN RE	:	**Docket No. 15-32031-CON**
CERTIFICATE OF NEED APPLICATION TO ESTABLISH AND	:	
OPERATE A PRIMARY AND ELECTIVE ANGIOPLASTY	:	
PROGRAM AT THE WILLIAM W. BACKUS HOSPITAL IN	:	
NORWICH, CONNECTICUT	:	**MARCH 16, 2016**
	:	

PRE-FILED TESTIMONY OF
BIMAL PATEL

Introduction

Good morning Commissioner Pino, Hearing Officer Hansted and Office of Health Care Access ("OHCA") staff. My name is Bimal Patel and I am the President of Backus Hospital and Windham Hospital and a Senior Vice President at Hartford Healthcare. Thank you for taking the time today to let me tell you about the overwhelming community support for a Primary and Elective PCI program ("Program") located at Backus Hospital has as well as the minimal impact this Program will have on existing providers.

Community Support

The need for Backus to establish a Primary and Elective PCI program is an integral part of its cardiac service line continuum, one that will improve the accessibility of cardiac services offered to the community. Backus has a commitment to the health and wellbeing of the community that goes beyond the walls of the Hospital. Backus has an active Community Health Education Department, which provides hundreds of low or no cost community programs and activities on an annual basis. Many of the programs sponsored by the Hospital relate to cardiovascular health.

There is tremendous support in the Angioplasty Region for Backus proposal to develop a PCI program. Backus reached out to the community, including fire department chiefs, ambulance personnel, physicians and municipal leaders, through phone calls, emails and face to face meetings to educate them about our proposed PCI Program. The feedback has been overwhelmingly positive and universally supportive. These stakeholders understand that there is a lack of adequate access to PCI services in the region and they can speak to the practical realities of this situation for area residents in need of care. We received letters of support from area fire departments, municipal leaders, physicians, and EMS personnel, all of which are included as part of our CON application.

Importantly, Robert Smanik, President of Day Kimball Hospital also provided a letter of support for our Program. Mr. Smanik indicated that Backus is increasingly looked to for its specialty services in our area and cited the improvement of patient safety with the reduction of travel times being a key factor motivating their support.

A PCI program at Backus will fill a void that exists in the eastern region of Connecticut and will improve the quality and accessibility of health care for these residents, who now must travel significant, unreasonable and unsafe distances, or be transported by LIFE STAR or EMS, for PCI services.

EMS Support

Notably, one of the biggest supporters of this Program is the EMS community. The EMS community understands that time is critical in these emergency cardiac situations and that patients would be better served obtaining life-saving procedures without lengthy travel times. In addition, when transport is needed from Backus to an out of market PCI facility, that emergency vehicle is tied up and unable to assist with other emergency situations.

Impact on Existing Providers

Backus' goal in obtaining Primary and Elective PCI is to provide a critical, life-saving procedure to the community it serves. The residents of this part of Connecticut deserve the same standard of care with regard to cardiac services that residents west of the Connecticut River enjoy. As Dr. Foley previously discussed, Backus has the capacity and physician support to establish a Primary and Elective PCI program. Currently the residents of Eastern Connecticut primarily travel to four Connecticut hospitals for PCI procedures. These facilities include Hartford Hospital, Yale New Haven Hospital, Lawrence and Memorial Hospital and Saint Francis Hospital, **none** of which are within a 30 minute drive time of the Angioplasty Region. No program currently providing PCI procedures will be compromised due to a shift of volume that would result of a Backus's Program. Each program will be able to maintain volume levels more than sufficient to meet the American College of Cardiology/American Heart Association's minimum standards. Specifically, Lawrence and Memorial Hospital ("L+M"), which serves a different market, only performed 22 primary and elective PCI procedures in FY2014 on patients from the Angioplasty Region. Additionally, self reported data filed by L+M with OHCA shows that in FY2015 17 of the 26 towns in the defined Angioplasty Region had no PCI patients served by L+M. The majority of cases are leaving the community altogether, seeking care at other high volume locations. On page 1467 of the Completeness Responses, a chart was provided detailing the PCI volume expected to shift to Backus (12.3% for Hartford, 14.8% for Lawrence & Memorial and 6.7% for Saint Francis) and the number of remaining PCI volume at each institution (964 for Hartford Hospital, 204 for Lawrence and Memorial and 776 for Saint Francis). This analysis clearly demonstrates that although volume will shift from other institutions, it will not compromise any of the existing programs in the State. Each hospital will be able to meet and maintain the ACCF/AHA/SCAI recommended minimum facility volume of 200 PCI procedures per year. It will, however, provide optimal patient access and bring a standard of care to a currently underserved market.

Commissioner, Hearing Officer Hansted, and OHCA staff, thank you for the opportunity to discuss with you this life saving program. I believe strongly that our community, our hospital and our providers are ready and willing to support this program. I am, of course, available to answer any questions that you may have.

62423879

Bimal Patel

Senior Vice President
Operational Integration

Hartford Healthcare

Organizational Description:

Hartford Healthcare: Operating company holding 6 hospitals, Physicians organization, Senior Services, Clinical Ancillary services, over $2.5B Net Revenue, 1600 acute care beds, 600 long-term care beds, and 16000+ FTEs

Hartford Hospital: Level 1 Trauma center - 867 Beds Acute Care Teaching Hospital, 5400 FTEs, $1.2 B net revenue

Mid-State Medical Center
Hospitals of Central Connecticut
Backus Hospital
Windham Hospital
Post-Acute Services: Senior care, Home care, Rehab services
Behavioral Health Services: Institute of Living, Natchaug Hospital and Rushford Hospital
Hartford Healthcare Medical Group

My Personal Purpose

Build a vibrant culture, develop leaders and help them find their best by using visionary, balanced and practical approach to deliver better quality of healthcare at affordable price point with un-matched service excellence and highest integrity.

Experiences

President, East Region and SVP HHC
Backus and Windham Hospitals **January 2016- Present**

Executive and leadership responsibility of the East Region of HHC including Backus and Windham hospitals, Plainfield emergency and ambulatory center, various outpatient clinics and urgent care centers, Backus physician organization and Conn Care network.

HHC responsibilities include Real Estate, Master planning and Contraction projects for the system.

Harford Healthcare, SVP Operational Integration **Dec 2014- Dec 2015**
Regional VP of Operations **August2013- Nov 2014**
Hartford Hospital, VP of Operations and Support **Feb 2009 – July 2013**

Responsibilities include operational integration reporting to EVP-COO of HHC System, I lead administration and management of major healthcare system initiatives such as Hospitals integration, System consolidation for efficiency and cost benefit, Spin-off key

service line to leverage capital, HHC 2020- infrastructure master plan and HHC Thrive-cost reduction.

Hartford Healthcare Thrive – cost reduction strategy, executive project leadership and Lean methodology:

- Responsible for the system Operating Margin goal via Balance Scorecard
- Reduced $195M in three years via partnership with Huron Healthcare Consulting largely focused on administrative services
- On target with additional $165M in one year improvement over $2.4B cost structure via administrative and clinical transformation work
- Productivity and efficiency infrastructure deployment to help achieve 25th percentile benchmark of these resources which resulted in over 500 FTEs reduction.
- HHC real estate portfolio
- HHC Lab Strategy deployment
- HHC Radiology Strategy leader
- Key administrative leader for all physicians driven clinical councils across HHC

Lead Healthcare System via following teams:

- Clinical and support integration of hospital operations – VP OPs
- Managing outsourcing and selling of clinical and support services for the system – M&A
- Develop Bone and Joint Institute in partnership with Orthopedic Physician Group(s).
- Build key strategic partnership with GE, Stanley, Siemens, CVS, Commercial labs - Strategy
- Develop retail healthcare via pharmacy, 340b, specialty and long-term care- Growth
- Help building HHC command center - Operations

Capital budget experiences and responsibilities:

- HHC2020 and routine Capital deployment annually at $ 100M
- $250M Strategic capital which included parking facility, ED expansion, and planning for Special Surgical Hospital for Ortho-Neuro-Spine.
- Facilities Master plan and support system growth initiatives
- Public utility company funds to improve power plant and fuel cell deployment

Key operational integration, leverage supply chain, engagement of physician leaders across the system and partner with nursing to horizontally integrate and deploy plan to improve efficiency, safety and quality.

Physicians and Nursing leadership experiences over ten years:

- Administrative member of Medical Executive Committee
- Clinical Chiefs council member
- Administrative leader for the Departments of Cardiology, Neurology, Radiation Oncology, Nephrology, Pulmonary, Pathology and Radiology.
- Management of service line leadership agreements

- Hospital Quality board and Safety Council
- Clinical nursing leadership in clinical ancillary and procedural areas
- Leadership of cardiac, vascular and endo-vascular platform
- Lead EPIC - EMR physician advisory committee and executive sponsor for EPIC rollout, bedside bar code, pharmacy systems, nursing and respiratory documentation

Board and non-profit community experiences:

- Member of Board Quality Committee
- Board of Governors for the hospital
- Connecticut Health Council member, a consortium of payers, providers, educators, suppliers, manufacturers, and consultants.
- Achieve Hartford Board member: Hartford Public Schools
- SINA (Southside institution of neighborhood alliance of hospitals and Trinity College) board member: community board for revitalization of neighborhood

Fund Development experiences:

- Meet and educate donors in and outside hospital
- Chair various fund raising committees
- Black and Red events raised $1M on annual basis
- Golf committee chair annual $400k raised
- Hospital Auxiliary Executive: annually raise and give $1.5M to hospital
- Open personal home for awareness and fund development

Community and Government experiences:

- Meet local leaders, Neighborhood Revitalization Zones, historical commission
- Interact with Mayor and administrative leadership of city including Planning & Zoning
- Interact with local senators and house representatives to build support and nurture relationship to promote organizational interests
- Attend political support functions as appropriate
- Emerging as a key executive for community connection

Achieved Objectives

- Hospital patient satisfaction has improved by 40 percentile points in 3 years after establishing Patient Experience Officer in a cost neutral method.

- Established productivity model for the hospital and system including position review committee structure and shift management tool.

- Became part of a team lead Hartford Hospital from $8M loss to gain of $53M over 4 years period from 2008 to 2012.

- Improve cost structure by $195M in first three years for the hospital and system while working towards a goal of new $165M over current year.

- Improved the food service program to ensure it is providing the highest level of quality, while minimizing costs. Patient Satisfaction scores went up by 70%.
- Prioritize and manage the various capital projects approximately $350 million over past five years including $150M Bone and Joint Institute
- Built CESI (center for education, simulation and innovation) and obtained grant of $15M from the state
- Wrote and received NIH grant of $3.5M construction for expanding neuro-psych research

Robert Packer Hospital – Guthrie Health System **March 2006 – Jan 2009**
Administrative Director Professional and Support Services
230 Beds Acute Care Teaching Hospital
Level II Trauma Center

Professional and Support Services responsibility included the administration and management of both clinical and support service functions for the Robert Packer Hospital. **Clinical areas** of responsibility included Cardiology, Oncology, Nephrology, Neurology, Radiology, Pathology and Critical care via oversight of Cardiac Cath lab, EP lab, Radiology, Neurology, Sleep services, Dialysis, Radiation Oncology, Respiratory Services and Pharmacy. Support services included Engineering and facilities, Environmental services, Biomedical Engineering, Laundry and Food Services, Patient Transport, Switch-board and Security.

Key achievements during three years were as follows.

- Solucient Top 100 hospital for 2 of the 3 years
- Top 100 Cardiovascular hospital for all 3 years
- Profitable operation with operating margin of 8-10 % annually for 3 years
- Employee satisfaction changed to top quintile
- Lead value analysis as a chair of the committee for the Guthrie Health System for two years with savings of 2 plus million each year above budget
- Help flatten the administrative structure with reorganization
- Stabilized the for-profit division of hospital during crisis
- Executive sponsor and successful implementation for the EPIC ® bed-side bar-coding, nursing documentation, e-MAR and pharmacy systems.

Robert Packer Hospital – Guthrie Health System **June 2004 – Feb 2006**
Administrative Director Pharmacy Services
230 Beds Acute Care Teaching Hospital
Level II Trauma Center
200 Beds long term care facility

Pharmacy services chief for both acute care hospital and long-term care. Total employees 40 with drug budget of 20 million.

Key achievements during two years period were as follows.

- Merge the long term care pharmacy in to retail operation during Medicare Part D and made profitable as well as compliant to regulations
- Renegotiated system contract with pharmaceutical venders and generated additional savings of $1.5 – 2 million annually for two year
- Stabilized the CPOE system which was failing due to pharmacy interface
- Cleaned CDM and revenue cycle processes
- Changed service orientation of pharmacy

Good Samaritan Hospital – GHS **December 1999 – May 2004**
Supervisor Pharmacy and Home Infusion Services
200 Beds Acute Care Teaching Hospital
35 Beds TCU, Rehab and Oncology Services

Pharmacy services supervisor of two sites. Delivered care to variety of services including acute care hospital, long-term care, rehab in-patients, home infusion and oncology outpatient infusion services.

Key achievements during four year period were as follows.

- Expanded home infusion services
- Rebuilt oncology service model
- Cleaned up inventory with 16 inventory turns and process improvements in contract compliance
- Service excellence superior status of pharmacy from customer base of nursing and patients

<u>For Profit Experiences as follows:</u>

Owen Healthcare- Cardinal Health **July 1996-December 1999**
Clinical Staff Pharmacist
On-call Special projects for north-east

During this time period, I worked at various North-East US hospitals for different reasons including start ups, close outs, staffing needs, administrative needs, regulation preparedness, information technology roll-out and program set ups.

Owen Healthcare- Cardinal Health **January 1995 - June 1996**
Director in Training
Management Fellowship

One and half years of both corporate and local hands on experience as well as curriculum based formal fellowship training with Owen Healthcare. A national hospital pharmacy management company with 300 plus hospital pharmacies in forty plus states. During this

period learned various aspects of pharmacy services including financials, clinical, IT and technical, managements and contracts, regulatory and P&T.

Owen Healthcare- Cardinal Health **March 1993 – December 1994**
Staff Pharmacist

During this period I functioned as a staff pharmacist for acute care hospital working directly with nursing, physicians and other clinical services. This experience helped build the quintessential base needed for future growth and development.

Education

BS in Pharmacy, LMCP, India 1990
Management Fellowship, Owen Healthcare, 1995
Certified in Long Term Care, Penn State University, 2003
Masters in Health Administration, Penn State University, 2004

References upon request from current and past work will be available.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

IN RE	:	**Docket No. 15-32031-CON**
CERTIFICATE OF NEED APPLICATION TO ESTABLISH AND	:	
OPERATE A PRIMARY AND ELECTIVE ANGIOPLASTY	:	
PROGRAM AT THE WILLIAM W. BACKUS HOSPITAL IN	:	
NORWICH, CONNECTICUT	:	**MARCH 16, 2016**
	:	

PRE-FILED TESTIMONY OF
FRANCIS J. KIERNAN, M.D., F.A.C.C.

Introduction

Good morning Commissioner Pino, Hearing Officer Hansted, and Office of Health Care Access staff. My name is Francis J. Kiernan and I am an Interventional Cardiologist at Hartford Hospital and Director of the Hartford Hospital Cardiac Lab and Interventional Cardiology Fellowship. Upon CON approval, I will oversee the Primary and Elective PCI program at Backus Hospital and oversee the relationship with Hartford Hospital.

Hartford Hospital is a regional provider for cardiovascular services, and through the establishment of a Primary and Elective PCI program at Backus, will be able to provide consistent coverage for the program, standardize practice and ensure quality of care in accordance with Hartford Hospital standards. Hartford Hospital will have the ability to work collaboratively with both employed and independent providers in developing the program. The benefit of such an affiliation is to provide patients in the Backus Angioplasty Region with access not only to PCI services, but to expertise in subspecialty areas, surgical expertise from Hartford Hospital in a market that has no providers of open heart surgical services, and an ability to access, and participate in, an established quality program to standardize practice and monitor key core measures and outcomes.

Standard of Care

Today, percutaneous coronary intervention ("PCI") is, and has long been recognized as the national standard of care for the treatment of acute myocardial infarction. Elective or urgent PCI is an important tool for the management of patients with coronary artery disease. All residents in Eastern Connecticut and residents in the Angioplasty Region, not just those in the greater New London area, deserve the same medical standard of care and access to the same level and quality of services. Data clearly

demonstrates that currently residents of the Angioplasty Region are receiving this standard of care (Primary and Elective PCI) at a lower rate than the rest of the State and Nation.

Connecticut's Department of Public Health guidelines highlight the relationship of time with clinical outcomes in the case of patients requiring a PCI for acute myocardial infarction or STEMI (which should be administered as soon as possible after the onset of symptoms). These regulations set a standard of care for STEMI patients, who, when identified in the field, should be transported to the closest PCI-capable facility, if there is one within a 30 minute drive time of the patient. For patients in the Angioplasty Region, all PCI-capable facilities are more than 30 minutes away.

Door-to-Balloon Time

The ACC/AHA STEMI Guidelines provide that "door-to-balloon" time ("DTB") – which is measured from when a patient presents at the Emergency Department at a PCI capable center to inflation of the balloon that opens the occluded artery – should not exceed 90 minutes. DTB times are often adversely impacted when a patient presents with a STEMI at a hospital without an angioplasty program. The process of evaluating patients in a community hospital and then transporting them to a PCI equipped hospital inevitably entails delays (such as delays associated receiving the patient and arranging for their transfer), and those delays result in preventable damage to heart muscle. Studies demonstrate that time is one of the most important factors in saving heart muscle during a cardiac emergency. The less time elapsed from the onset of symptoms until the beginning of treatment, the greater the patient's chances of minimizing permanent damage to heart muscle.

For Backus, current DTB times for patients transferred to PCI-capable facilities do not consistently meet the AHA/ACC STEMI Guidelines' optimal 90 minute time. An analysis of 105 Acute Myocardial Infarction patients who presented at Backus between FY 2011-May of FY 2015 indicated that the median DTB time for patients transferred to either Yale or Hartford Hospital was 134 minutes, with only **10%** (11 cases) treated within the recommended 90 minute DTB time (3d Health Assessment, p. 26). Thirty percent (30%) of patients transferred exceeded the 90-minute DTB recommendation by an hour. Overall, 59% of DTB times were between 90 and 150 minutes, (3d Health Assessment, p. 27). Importantly, transport time accounts for **over half** of the DTB minutes associated with transfers from Backus to YNHH and Hartford Hospital.

Door-in-Door-Out

Door-In-Door-Out ("DIDO") is the length of time from presentation at the community (non-PCI equipped) Emergency Department to transport to a Primary PCI equipped hospital. DIDO plays a major role in overall DTB time. DIDO should be limited to 30 minutes. From FY 2011 to May 2015, the median DIDO for the 285 STEMI patients who presented to Backus was 73 minutes (3d Health Assessment, p. 28). Only **11%** of cases met the recommended DIDO time of 30 minutes. Backus has worked to minimize DIDO delays through multiple strategies in the Emergency Department, which are detailed in the CON (see page 50-52). Backus, however, has reached the limits of its ability to lower DIDO times for patients who must be transferred to another facility for Primary PCI. Further decrease will be difficult due to factors beyond Backus's control, including activation and arrival of EMS transportation, which

adds substantial time to the total DIDO for STEMI patients arriving at the Backus Emergency Department. (3d Health Assessment, p. 29).

Delays associated with diversion and transport increase the total ischemic time (the amount of time from symptom onset to treatment), which also must be managed in order to ensure the highest quality clinical outcomes. In the case of a Primary PCI, time is muscle, and so a shorter transport time will likely reduce necrosis and ultimately improve patient outcomes. In the case of Elective PCI patients, time is still of the essence. Elective procedures can be time-sensitive and urgent procedures. The timing guidelines are not applicable to Elective PCI patients, but the elimination of a 30 minute drive time will improve ease of access to this care and ease the burdens on family members who will have to travel to the referral center.

Hartford Hospital

Hartford Hospital is one of the Region's leading providers of comprehensive cardiac services and it will provide the necessary training, oversight, and tertiary backup to ensure a high quality, efficient, and seamless PCI services at Backus. Hartford Hospital's Henry Low Heart Center is a full service cardiac provider, offering an array of comprehensive services and sophisticated techniques in a setting of highly personalized care. Hartford Hospital has a history of extraordinary quality outcomes. The National Cardiovascular Data Registry ("NCDR") report for the four quarters ending in Q3 2015, Hartford performed 1,174 PCIs. Of these, no patient required emergency CABG. These are phenomenal results, which illustrate the expertise and high quality of care delivered by Hartford Hospital physicians, as well as the safety and efficacy of delivering PCI services.

Both Hartford Hospital and Backus Hospital are members of Hartford Healthcare. Approval of the CON application will allow Backus to establish an interventional cardiac program through leveraging the existing expertise and experience at Backus in related fields and the expertise and experience of its tertiary/quaternary care partner, Hartford Hospital. The same high quality outcomes are anticipated at Backus, as the same physicians will be providing care, and will be held to the same standards as Hartford Hospital.

The Applicants plan to staff the Backus PCI lab 24/7, 365 days a year with on-call personnel available during the off hours. There will be an Interventional Cardiologist performing all PCI procedures with two RNs and two Radiologic Technologists in the room during each procedure. Backus also has emergency transfer agreements already in place with Hartford Hospital. Backus has also developed an on-call system to allow patients to have PCI performed within 90 minutes of the first medical contact (details can be found on page 30 of the CON).

The physicians participating in the Backus PCI program will be an extension of the Hartford Hospital interventional physician team. All physicians covering the Backus program will work under my oversight. The group providing PCI services at Hartford Hospital, Hartford Cardiac Laboratory, P.C., currently employs 7 physicians and has committed to provide clinical and administrative support to the Backus PCI program. Additionally, a private physician, Dr. John Michael Chua Chiaco, has committed to provide PCI coverage at Backus (CV attached as Exhibit 7 to the CON and Letter of Support attached as

Exhibit 11 to the CON). Dr. Chua Chiaco currently practices at Backus, and is located in Norwich, Connecticut. Efforts to recruit a new physician will begin once we have CON approval. The new physician will partner with Hartford Cardiac Laboratory, P.C. to provide coverage to Backus. This newly recruited physician will also rotate through the Hartford Hospital cardiac catheterization lab.

These physicians all provide coverage, or will provide coverage (in the case of any newly recruited physicians), at other hospitals, and will continue to do so after the Backus program is established. The rotation through programs at high-volume PCI centers ensures the physicians providing coverage at Backus will meet all operator minimums (as specified by the ACC/AHA guidelines and the State Health Plan), and are highly technically skilled. Furthermore, these physicians will be required to abide by pre-determined quality standards. This strong connection with Hartford Hospital's program and physician leadership will ensure the services provided at Backus are of the highest quality and produce strong clinical outcomes.

Establishing a Primary and Elective PCI program at Backus will upgrade all aspects of the hospital by providing higher levels of training and creating an elevated attention to detail that permeates the whole hospital. Importantly, Hartford Hospital will also benefit with the approval of this PCI program. A capacity analysis for Hartford Hospital's cardiac catheterization labs was conducted to understand whether there would be a benefit to Hartford if PCI volume was served locally at a Backus program, rather than transferred. The analysis indicated that during FY2014 Hartford Hospital was operating at approximately 92% of capacity (3d Health Assessment, p. 35). Thus, Hartford Hospital is at nearly full capacity within its existing infrastructure. The addition of a Backus program would therefore not only improve the DTB times for patients presenting locally, but would also help to ease some capacity constraints currently occurring at Hartford Hospital, as individuals currently requiring PCI who are traveling to Hartford for care would be able to receive the same care locally. This reduces the volume of patients treated at Hartford, without eroding the Hartford Hospital PCI program, and increases the Hartford Hospital's capacity without actually increasing the number of catheterization labs at Hartford Hospital.

Conclusion

Currently, the Door-In-Door-Out and Door-to-Balloon times for patients in the Angioplasty Region are outside acceptable windows. A PCI program at Backus will allow residents of the Angioplasty Region to obtain the care they require within the ACC/AHA STEMI Guidelines optimal timeframes. Timely access to PCI saves lives and improves health, and the people in that part of the State deserve the same standard of care and services that most all other Connecticut residents enjoy. The geographic "dual standard of care" that exists today in Connecticut should not be allowed to continue. Thank you for your time today.

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	:	

PRE-FILED TESTIMONY OF
JOHN A. FOLEY, M.D., F.A.C.P., F.A.C.C.

Introduction

Good morning Commissioner Pino and Office of Health Care Access staff. My name is John Foley and I am the Chief of Cardiology at Backus Hospital and Windham Hospital as well as the Interim Medical Director of Specialty Care Services; East Region and Director of Cardiovascular Services; East Region for Hartford Healthcare. I will be speaking today about the services currently offered by Backus as well as Backus offering Primary and Elective PCI.

Overview

Backus is an acute care general hospital in Norwich licensed for 233 beds/bassinets that offers a full range of inpatient and outpatient medical services to Eastern Connecticut including Diagnostic Cardiac Catheterizations. Backus is continually evaluating the need for new programs that will enhance timely access to life-saving services for the residents of eastern Connecticut. To that end, Backus and Hartford have submitted this CON application to expand the cardiac catheterization services offered at Backus to include an interventional cardiac program to perform Primary and Elective PCI. Although there is abundant need for PCI services in the Angioplasty Region (as defined by, and further explained by, 3d Health) where the patients are older, have more cardiac risk factors and are of a lower socio-economic status, there is not sufficient access to PCI services.

Over the last four years, Backus has made necessary investments to enhance the cardiovascular services it offers to the residents of eastern Connecticut including upgrading its cardiac catheterization lab equipment and integrating its new system into the Hospital-wide informatics system. In addition to the catheterization lab upgrades, the Cardiology Service Line started a Vascular Steering Committee, Chest Pain Observation Unit, Heart Failure Program, and is currently expanding the existing Peripheral Vascular program. The continued development and expansion of a Heart Failure Program is a specific strategic priority at Backus, with a focus on infusion services and education.

Backus has also set in motion the steps to provide Primary and Elective PCI service to the Angioplasty Region including performing extensive market analysis, aligning physicians, completing transfer agreements and determining the physical plant requirements. In addition, Backus plans to build an additional catheterization lab suite and will also create a back-up catheterization lab in the current Backus interventional radiology suite.

Primary & Elective PCI

Primary PCI is used to treat emergency situations and is the most effective way to treat the most common form of heart attack known as a ST-Segment Elevation Myocardial Infarction ("STEMI"), as well as new or presumed new onset Left Branch Bundle Blockage ("LBBB"). As previously mentioned by Mr. Whitehead, despite the demographics of the region (older with a higher prevalence of key risk factors for coronary heart disease) the rate for Primary PCI intervention is well below the State and National levels.

One way for a patient to access Primary PCI services is to be picked up by EMS and identified in the field as STEMI patient then transported to the closest PCI-capable facility (if there is one within a 30 minute drive time). Patients also present at the Backus Emergency Department with STEMI/LBBB and are typically transferred more than 40-50 miles to hospitals with PCI programs. Virtually all of these patients could be cared for at Backus if Backus offered PCI services. The delays associated with that transfer result in many patients not receiving Primary PCI within 90 minutes of presentation at an Emergency Department, as recommended by the ACC/AHA and as the standard of care dictates (Dr. Kiernan will discuss this further). Delays associated with diversion and transport also increase the total ischemic time (the amount of time from symptom onset to treatment), which also must be managed in order to ensure the highest quality clinical outcomes.

Elective PCI is the standard for treating Acute Coronary Syndrome (Non ST-Elevation Myocardial Infarction, "NSTEMI") in people with intermediate to high risk factors. Elective PCI is also the standard for treating patients with symptoms of recurrent myocardial ischemia ("Unstable Angina" or "UA") and/or high risk findings on a non-invasive stress test.

Over the last four years Backus transferred an average of 70 patients each year who, while receiving a diagnostic catheterization, were identified as requiring an Elective PCI. These patients are transferred from Backus to a PCI capable facility via EMS and endure duplicative services. These patients undergo a repeat catheterization to clear the blockages found in the initial procedure which often this requires another groin or radial puncture to the patient. This increases the risk of infection to the patient, and other arterial complications, as many times patients are transported with a sheath in place. It also duplicates the patient's exposure to radiation and sedation, as a repeat procedure must now take place.

These duplicative services not only compromise the quality of care received and the clinical outcomes, but they increase the cost of care. The logistics of traveling to a different hospital far away from your home can be challenging for many of the residents in the Angioplasty Region. Windham and

Northeastern Connecticut have some of the lowest numbers of motor vehicle registrations and rely more heavily on limited public transportation services, medical cab services, and taxi cabs for transportation. These transportation services, although widely used, are limited in scope and operation and may prove to be a financial hardship. When individuals without their own vehicle must leave their home communities for medical care the travel arrangements and time can be onerous and costly. The difficulty in securing reliable transportation impacts an individual's decision to seek care, and makes it difficult for an individual to receive regularly scheduled cardiac rehab or follow up after a procedure. Therefore, traveling such distances increases the burden on family members who must meet their loved one in an unfamiliar facility and city in an already stressful situation. Further, it is an impediment to patients receiving the proper follow up care.

Most importantly, transferring patients for PCI leads to a worsened patient experience. This is especially the case with Elective PCI. Individuals requiring Elective PCI are very sick people, many with co-morbid conditions. Many of these patients have been subjected to a long series of tests and procedures and gone through multiple visits with their doctor and have developed a level of trust and familiarity that provides an immeasurable amount of comfort to them and their families. Their doctors understand their history and current medical needs and are in the best position to make the decision about the most appropriate next steps in the patient's care plan. When patients are transferred to a different hospital for Primary or Elective PCI, this necessary information is not always communicated effectively and the patient is forced to interact with a completely new set of healthcare professionals. The investment in a PCI program at Backus Hospital will greatly improve the patient experience by lessening the anxiety associated with being transferred to a new hospital. It will also improve patient outcomes and treatment plans, as their local cardiologist, who knows the patient best, will be performing the procedure and providing the necessary follow up after the procedure is completed.

Referrals

There is no referral base for Primary PCIs – these are emergency cases and are brought in through the EMS network, based on DPH guidelines and medical oversight. At times EMS transports patients to Backus because it is the closest facility for an unidentified STEMI, there is not a PCI capable provider within 30 minutes for an identified STEMI, or because a patient requests a transport to Backus. These referral patterns are not expected to change if the proposal is approved. What will change is Backus' ability to provide timely access to PCI services to area residents rather than transferring them to facilities in New Haven or Hartford.

Elective PCI cases are subject to patient and physician selection, as well as those patients identified as requiring an Elective PCI while undergoing a diagnostic catherization at Backus. Within the Angioplasty Region there are three cardiology groups practicing at Backus. These practices include the Yale Medical Group, Norwich Cardiac Medicine, and Hartford HealthCare Medical Group. Two interventionalists currently have privileges at Backus to work in its diagnostic catheterization lab. In total, these practices employ 16 physicians. Upon approval of the program, Hartford HealthCare Medical Group will recruit other Interventionalists to work at Backus under the clinical oversight of Dr. Francis Kiernan, the lead Interventionalist practicing at Hartford Hospital. The Interventionalists participating in coverage at

Backus will also rotate through Hartford Hospital's catheterization lab to ensure adherence to clinical standards, and operator minimums are met and sustained.

The Applicants are not aware of an existing partnership between Day Kimball and UMass Memorial Medical Center and therefore are not in a position to speculate how any such partnership would effect referrals from Day Kimball to Backus.

Conclusion

I look forward to the day that I no longer have to look into the face of a patient or family member who is frightened by the prospect of traveling a long distance to be cared for by doctors and nurses they don't know. In the fifteen years I have lived and practiced in the Norwich area, I have witnessed OCHA's willingness to adapt their rules in order to benefit patients and their families. The need for safe, timely, and expert Primary and Elective PCI in the Angioplasty Region of Connecticut has been firmly established. I wholeheartedly support this CON application as a way to advance valuable, necessary care and access to patients in the Angioplasty Region.

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	:	

PRE-FILED TESTIMONY OF
MARIANE CARNA, RN, MSN

Introduction

Good morning Commissioner Pino, Hearing Officer Hansted, and Office of Health Care Access ("OHCA") staff. My name is Mariane Carna and I am the Vice President of Cardiovascular Services at Hartford HealthCare. I would like to focus today on the importance of providing the patients we serve with timely access to care, by our world class interdisciplinary experts within the field of cardiovascular medicine. Hartford HealthCare has embarked on a vision to establish a Heart and Vascular Institute with the primary focus of coordinating care across the continuum. This includes, but is not limited to, complex procedures such as Primary and Elective angioplasty. Patients will benefit from an interdisciplinary approach to care under an integrated care delivery system. This model supports our network affiliate's scope of practice and includes practitioners dedicated to the Institute's goals and objectives. These goals and objectives are aligned with standards of care and best practices across the country. The development of the Heart and Vascular Institute in our East Region is differentiated by offering an extension of the expertise provided by our tertiary care center at Hartford Hospital. The overall goal of providing this service supports the HHC vision of creating a single standard of care in a consistent manner, monitored by a quality control team nationally recognized for expertise in cardiovascular interventions.

Institute Oversight

Hartford Hospital offers an array of comprehensive services and complex procedures in a setting of highly personalized care. Backus will leverage Hartford Hospital's expertise and experience in creating its PCI program, as well as Hartford Hospital's many centers of excellence contiguous with general cardiology, heart failure, and electrophysiology. This will support a comprehensive approach to managing patients with cardiovascular disease requiring intervention. This holistic approach treats the patient comprehensively, and ensures ongoing follow up and care management.

The Interventional team at Hartford Hospital will provide the necessary training, oversight, and backup to ensure a high quality, efficient, and seamless Interventional service at Backus. In addition, the

training requirements and clinical protocols will be the same at both hospitals, managed under the direction of the Institute's physician led quality team. Hartford HealthCare is currently deploying Epic throughout the System. By 2017 all Hartford HealthCare affiliates will be on Epic, which will create availability of clinical information across the healthcare system. Community providers will have the option of joining the Epic platform through Hartford HealthCare's "Community Connect" program, which will allow providers and practices associated with Hartford HealthCare access to the Epic products that are linked to the inpatient and ancillary systems of Hartford HealthCare. This results in delivering the patient and provider a unified patient record within a true community health record. Key benefits of Hartford HealthCare's partnership with Epic are better coordination of patient care, avoidance of duplicative testing and procedures, as well as the ability to measure quality and ultimately manage cost.

Conclusion

A PCI program at Backus Hospital will support the mission and vision of our Hartford HealthCare Heart & Vascular Institute by creating access to care close to home, under the direction of leading experts in the field of cardiovascular medicine. We have recruited world renowned leaders in cardiac surgery, cardiology, and vascular surgery that have elevated the program to regional and national status. The tertiary care center at Hartford Hospital has published academically over 100 studies in endovascular procedures and has been a pioneer in this field. Hartford HealthCare is working to reduce the cost of care to patients having to receive multiple procedures, and to ensure coordinated and streamlined care. For these reasons, I ask you to approval the CON Application and I thank you for your time today.

62426645

Greer, Leslie

From: Armah, Olga
Sent: Thursday, March 17, 2016 10:48 AM
To: Kathleen Gedney; Michele Volpe; Jennifer O'Donnell
Cc: User, OHCA; Martone, Kim; Hansted, Kevin; Riggott, Kaila; Schaeffer-Helmecki, Jessica; Fernandes, David; Carney, Brian
Subject: FW: REVISED Docket No. 15-32031 / Responses to Pre-Hearing Questions & Pre-Filed Testimony
Attachments: REVISED HH Backus Pre-Hearing Responses & PFT.pdf; Backus - Pre-hearing Responses 3_16_16.DOCX

FYI

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

From: Mercier, Carlene M. [mailto:CMercier@brownrudnick.com]
Sent: Thursday, March 17, 2016 10:40 AM
To: User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: Cohen, Douglas A.; Anthony, Robert J.; Janette.Edwards@hhchealth.org
Subject: REVISED Docket No. 15-32031 / Responses to Pre-Hearing Questions & Pre-Filed Testimony

Good Morning,

Please note the Exhibits in the Pre-Hearing Responses were incorrectly numbered (page 1496, Exhibit 28 should have been 30 and Exhibit 29 should have been 31). Those two typos have been corrected in the attached documents and those are the only two changes that were made to the filing.

I apologize for any inconvenience this may cause.

Best Regards,
Carlene

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538

F: 860.509.6501
www.brownrudnick.com

From: Mercier, Carlene M.
Sent: Wednesday, March 16, 2016 3:55 PM
To: 'ohca@ct.gov'; 'kevin.hansted@ct.gov'; 'jessica.schaeffer-helmecki@ct.gov'; 'olga.armah@ct.gov'; 'kaila.riggott@ct.gov'; 'david.fernandes@ct.gov'; 'kimberly.martone@po.state.ct.us'
Cc: Cohen, Douglas A.; Anthony, Robert J.; Janette.Edwards@hhchealth.org
Subject: Docket No. 15-32031 / Responses to Pre-Hearing Questions & Pre-Filed Testimony

Good Afternoon,

Please find attached the following on behalf of Hartford Hospital and The William W. Backus Hospital:

Cover Letter
Responses to Pre-Hearing Questions 10-12
Exhibit 30
Exhibit 31
Letter of Support from Greg Allard
Pre-File Testimony of David Whitehead
Pre-File Testimony of M. Shane Foreman
Pre-File Testimony of Bimal Patel
Pre-File Testimony of Francis J. Kiernan, M.D., F.A.C.C.
Pre-File Testimony of John A. Foley, M.D., F.A.C.P., F.A.C.C.
Pre-File Testimony of Mariane Carna, R.N., M.S.N.

Best Regards,
Carlene

BROWNRUDNICK

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

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****

Greer, Leslie

From: Armah, Olga
Sent: Thursday, March 17, 2016 2:30 PM
To: Kathleen Gedney; Jennifer O'Donnell; Michele Volpe; ranthony@brownrudnick.com; janette.edwards@hhchealth.org
Cc: User, OHCA; Hansted, Kevin; Martone, Kim; Riggott, Kaila; Schaeffer-Helmecki, Jessica; Fernandes, David; Carney, Brian
Subject: RE: William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI program without Onsite Surgical Backup
Attachments: 15-32031- Ruling re Intervenor Status.pdf

Dear Ms. Gedney-Tommaso:

Please see attached ruling on intervenor status.

Thanks.

Olga

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

From: Kathleen Gedney [mailto:kgg@bvmlaw.com]
Sent: Wednesday, March 16, 2016 6:02 PM
To: janette.edwards@hhchealth.org; ranthony@brownrudnick.com
Cc: Armah, Olga; Michele Volpe; Jennifer O'Donnell
Subject: William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI program without Onsite Surgical Backup

In accordance with Conn. Agencies Reg. 19a-9-27(a), attached please find a Notice of Appearance of Attorney Michele Volpe on behalf of Lawrence + Memorial Hospital in the above captioned matter and a Petition for Intervenor Status by Lawrence + Memorial Hospital in the above captioned matter regarding the public hearing on March 23, 2016. A hard copy is also being sent to your address.

Regards,

Kathleen Gedney-Tommaso
Attorney at Law
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, CT 06511
Tel: (203) 859-6238
Fax: (203) 777-5806

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Office of Health Care Access

IN THE MATTER OF:

A Certificate of Need Application by
The William W. Backus Hospital
Notice to Petitioner re: Request for Status

Docket Number: 15-32031-CON

**RULING ON A PETITION FILED BY
LAWRENCE + MEMORIAL HOSPITAL, INC.
TO BE DESIGNATED AS AN INTERVENOR**

By petition dated March 16, 2016, Lawrence + Memorial Hospital, Inc. ("Petitioner") requested Intervenor status in the public hearing to be held by the Department of Public Health ("DPH") Office of Health Care Access ("OHCA") regarding the Certificate of Need ("CON") application of The William W. Backus Hospital ("Applicant") filed under Docket Number: 15-32031-CON.

Pursuant to Connecticut General Statutes § 4-177a, the Petitioner is hereby designated as an Intervenor with full rights of cross-examination at the hearing scheduled for March 23, 2016 at 410 Capitol Avenue, Hartford, Connecticut. As an Intervenor with full rights of cross-examination, the Petitioner may participate as indicated below.

The Petitioner is granted the right to inspect and copy records on file with OHCA related to the CON filed under Docket Number 15-32031-CON and shall be copied on all pleadings, correspondence and filings submitted from this point forward by the Applicant until the issuance of a final decision by OHCA. As an Intervenor with full rights of cross-examination, the Petitioner may be cross-examined by the Applicant and the Petitioner has the right to cross-examine the Applicant. The Petitioner shall file its pre-file testimony by the close of business on March 18, 2016.

OHCA will make any additional rulings as to the extent of the hearing participation rights of the Petitioner throughout the hearing in the interest of justice and to promote the orderly conduct of the proceedings.

3/17/16
Date

Kevin T. Hansted
Hearing Officer

Connecticut Department of Public Health

Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

Greer, Leslie

From: User, OHCA
Subject: FW: OHCA Docket Number 15-32031 - The William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI program without Onsite Surgical Backup
Attachments: L+M Pre-Filed Testimony re OHCA Docket No. 15-32031.pdf

From: Kathleen Gedney [mailto:kgg@bvmlaw.com]
Sent: Friday, March 18, 2016 2:51 PM
To: Hansted, Kevin
Cc: Armah, Olga; Martone, Kim; Lazarus, Steven; Michele Volpe; Jennifer O'Donnell
Subject: OHCA Docket Number 15-32031 - The William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI program without Onsite Surgical Backup

Good Afternoon Mr. Hansted:

In accordance with your letter dated March 17, 2016 regarding the above captioned matter, attached please find Lawrence + Memorial Hospital, Inc.'s pre-filed testimony on behalf of Bruce Cummings, Dr. Daniel Rissi, Dr. Brian Cambi and Seth Van Essendelft. Please confirm receipt of this attachment.

Please do not hesitate to contact Michele Volpe (203-777-5802) or I (203-859-6238) with any questions.

Regards,

Kathleen Gedney-Tommaso
Attorney at Law
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, CT 06511
Tel: (203) 859-6238
Fax: (203) 777-5806
Email: kgg@bvmlaw.com

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Greer, Leslie

From: Armah, Olga
Sent: Friday, March 18, 2016 3:50 PM
To: janette.edwards@hhchealth.org; ranthony@brownrudnick.com; CMercier@brownrudnick.com
Cc: User, OHCA
Subject: FW: OHCA Docket Number 15-32031 - The William W. Backus Hospital and Hartford Hospital - Establishment of a Primary and Elective PCI program without Onsite Surgical Backup
Attachments: L+M Pre-Filed Testimony re OHCA Docket No. 15-32031.pdf

Attached is a copy of L+M's prefiled testimony for the Wednesday, March 23 hearing.

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

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Please do not hesitate to contact Michele Volpe (203-777-5802) or I (203-859-6238) with any questions.

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Kathleen Gedney-Tommaso
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105 Court Street, 3rd Floor
New Haven, CT 06511
Tel: (203) 859-6238
Fax: (203) 777-5806
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DEPARTMENT OF PUBLIC HEALTH	:	
DIVISION OF OFFICE OF	:	
HEALTH CARE ACCESS	:	**DOCKET NO. 15-32031-CON**
	:	
IN RE: ESTABLISH AND OPERATE	:	
A PRIMARY AND ELECTIVE	:	
ANGIOPLASTY PROGRAM AT THE	:	
WILLIAM W. BACKUS HOSPITAL	:	**MARCH 18, 2016**

PRE-FILE TESTIMONY OF BRUCE CUMMINGS

Good Morning. My name is Bruce Cummings and I am the Chief Executive Officer and President of Lawrence + Memorial Hospital, Inc. ("L+M Hospital" or "L+M"). I am here today to speak in opposition of the William W. Backus Hospital (the "Applicant" or "Backus") Certificate of Need ("CON") application (the "Application") to provide primary and elective angioplasty without onsite cardiothoracic surgical backup.

L+M Hospital has been serving the region for over 100 years and has a staff in excess of 2,400 professional, technical and support personnel in nearly every medical specialty. Our mission is to improve the health of our region. In 2008, L+M began offering – and continues to this day to further develop and refine -- a strong quality primary and elective regional angioplasty program to serve patients and to offer a level of care in our service area that meets or exceeds national standards. As with all L+M's services, our angioplasty program is focused on providing innovative, high quality care to the community and we will make every effort to continue to do so. In collaboration with Yale School of Medicine and the Yale New Haven Heart and Vascular Center, L+M has helped lead the way in Connecticut for angioplasty performed at a community hospital.

I am here today to encourage OHCA to deny Backus Hospital's Application. L+M has spent a great deal of time analyzing Backus Hospital's Application and its potential harmful

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impact on our angioplasty program. Attached is L+M's work product outlining all of the deficiencies in Backus Hospital's proposed program ("Attachment A"). Detailed in the attachment is Backus Hospital's failure to meet the CON requirements that OHCA has spent years studying and outlining for purposes of determining whether and when complex clinical services, especially primary and elective angioplasty services, are appropriate to offer at a hospital. Backus's proposed angioplasty services will not be in the best interest of patients, Backus or any other hospital in Connecticut. Backus has not demonstrated a clear public need for the proposal in either the made up "Angioplasty Region" or the traditional OHCA-defined service area. The angioplasty services proposed by Backus are duplicative of L+M's existing angioplasty program and will have an adverse impact on L+M's program. As important, Backus proposal is not financially feasible. Based on all of these factors, it is impossible for OHCA to approve Backus Hospital's Application.

Thank you for providing me the opportunity to speak today in opposition of Backus Hospital's Application. Dr. Brian Cambi will speak in detail regarding the clinical deficiencies in the Application, Seth Van Essendfelt will discuss the financial failure of the Application, and Dr. Daniel Rissi will speak to the administrative and operations short comings in the Application. I encourage OHCA to deny the Application.

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Attachment A
Summary of L+M's Position

Backus's Failure to Meet CON Requirements regarding establishing Primary and Elective Angioplasty Services

OHCA considers 12 factors when reviewing a Certificate of Need application. These 12 factors are derived from statutory criteria at Conn. Gen. Stat. 19a-639 (a) which states "In any deliberations involving a certificate of need application filed pursuant to section 19a-638, as amended by this act, the office shall take into consideration and make written findings concerning each of the following guidelines and principles:"

(1) Whether the proposed project is consistent with any applicable policies and standards adopted in regulations by the Department of Public Health;[1]

- Backus's application is inconsistent with the professional guidelines OHCA has utilized including in evaluating implementation of PCI services, namely the American College of Cardiology, the American Heart Association and the Advisory Council for Cardiothoracic Surgery.[2] These Guidelines address both primary and elective programs.
    - 2014 ACCF/AHA/SCAI Guidelines **strongly advise against** the development of PCI facilities within a 30-minute emergency transfer time to an established facility. L+M is within 30 minutes of Backus.
    - 2014 ACCF/AHA/SCAI Guidelines state that "multiple low-volume and partial service PCI centers within a geographic area… increased costs for the overall health system and have not been shown to improve access."[3] As applied to a primary PCI-only program or a primary and elective program at Backus, an additional low-volume provider will not improve access.
    - ACCF/AHA/SCAI Guidelines state that "the addition of more PCI centers has not substantially improved access to PCI services for most patients."[4] Approval of primary or elective PCI services at Backus will not improve access for any patients.
    - ACCF/AHA/SCAI state primary PCI is only reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished. Backus has not shown appropriate planning.

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[1] C.G.S. 19a-639(a)(1).
[2] Connecticut Department of Public Health Office of Health Care Access, *Statewide Health Care Facilities and Services Plan,* at p. 41 (October 2012; supplemented 2014) (hereinafter referred to as "Statewide Health Plan"). http://www.ct.gov/dph/lib/dph/state_health_planning/dphplans/ohca_statewide_facilities_services_plan_2012.pdf; http://www.ct.gov/dph/lib/dph/ohca/publications/2014/final_2014__facilities_plan_-_2_24_15.pdf
[3] Dehmer GJ, et al. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. Catheterization and Cardiovascular Interventions 2014; 84:169-187 at 180.
[4] 2014 SCAI/ACC/AHA Update at 177.

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- 2013 ACCF/AHA Guideline for Management of STEMI: "In the absence of contraindications, fibrinolytic therapy should be administered to patients with STEMI at non-PCI-capable hospitals when the anticipated FMC-to-device time at a PCI-capable hospital exceeds 120 minutes because of unavoidable delays (Class I, Level of Evidence B)." Backus did not administer any such therapy confirming that Backus is confident that appropriate transfers can be made.
- ACCF/AHA/SCAI Guidelines conclude that facilities performing under 200 cases are associated with worse outcomes. If Backus introduced angioplasty services, L+M will be performing less cases. Further, Backus does not meet the required case volume in its predictions for the OHCA-defined service area.[5]

- The ACCF/AHA/SCAI Guidelines state "the development of PCI facilities within a 30-min transfer time to an established facility is therefore strongly discouraged."
  - L+M's established primary and elective angioplasty program is a mere twenty-one (21) minutes away from Backus Hospital and is clearly within the recommended thirty (30) minute transfer time.
- The ACCF/AHA/SCAI Guidelines also provide that "primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished" (emphasis added).
  - Backus has not demonstrated appropriate planning including failing to provide an appropriate call coverage proposal.
- Backus's Application is also inconsistent with DPH's report entitled "Hospital Transfers of Emergency Coronary Angioplasty Patients for Elective Surgery or Open Heart Surgery: October 1, 2013 to September 30, 2014"[6]
  - The report states "[t]here is no evidence of unmet need for the provision of PCI in the system; however, there is indication of excess capacity."[7]
  - The report emphasizes declining volumes across the state.[8]
- Backus's Application is also inconsistent with DPH's report entitled "Connecticut EMS Vehicle Equipment List."[9]

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[5] Application at 1462.

[6] Connecticut Department of Public Health, *Hospital Transfers of Emergency Coronary Angioplasty Patients for Elective Surgery or Open Heart Surgery: October 1, 2013 to September 30, 2014* (January 15, 2015) (hereinafter referred to as "Hospital Transfers"). http://www.ct.gov/dph/lib/dph/ohca/misc/pa_13-208_sec._69_cardiac_transfers_report_final.pdf

[7] *Hospital Transfers* at 8.

[8] *Hospital Transfers* at 8.

[9] Connecticut Department of Public Health, *Connecticut EMS Vehicle Equipment List*, February 10, 2014. Backus improperly relies upon Connecticut EMS STEMI Guidelines put forth by the CT DPH on January 23, 2012. Since 2012, the CT DPH, recognizing the importance of early detection of STEMI patients in field, has expanded the EMT scope of practice to include 12-lead EKG acquisition and transmission in a directive put forth on December 30, 2014. This is a clear indication that the Connecticut Department of Public Health's focus is not on additional PCI sites, but appropriately diagnosing patients with STEMI in the field, pre-hospital, so they can be rapidly treated at the most appropriate location.

- Early detection of STEMI patients in the field should be a priority, not a new primary PCI program.
- Resources allocated to diagnosing patients by EMS in the field is more cost effective than adding another PCI program.

- OHCA has extensively reviewed the implementation of primary and elective PCI programs in Connecticut and Backus's Application does meet the standards.
  - In Docket No. 12-31768, L+M submitted numerous agreements, policies and protocols (e.g. patient selection guidelines, joint quality assurance review process, transfer protocol, surgical backup policy, etc.)
  - Demonstration of clear public need.
  - Evidence demonstrating the services would contribute positively to the quality of health care delivery in the region.

(2) The relationship of the proposed project to the state-wide health care facilities and services plan;

- The Backus proposal is inconsistent with the Statewide Health Care Facilities and Services Plan.
  - The Plan states that "[c]ompetition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interest of the community."[10] The proposed services:
    - Compete with L+M;
    - Compete with Hartford Hospital;
    - Compete with St. Francis; and
    - Compete with four (4) out of state hospitals.

    Therefore, the proposed services are not in the best interest of the community.

  - Backus Hospital is currently not performing primary PCI and is not likely to achieve the requisite number of cases listed in the Plan. Applicant has only transferred an average of 70 cardiac catheterization patients per year that were identified as requiring elective PCI.[11]

(3) Whether there is a clear public need for the health care facility or services proposed by the applicant;

- Backus has not demonstrated clear public. L+M has excess capacity.
- OHCA itself through extensive research and reports state: "[t]here is no evidence of unmet need for the provision of PCI in the system; however there is indication of excess capacity."[12]

[10] *Statewide Health Plan* at p. 39.
[11] *Application* at p. 17.
[12] *Hospital Transfers* at p. 8.

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- The hospitals listed on p. 46 of the Application that are currently serving the Angioplasty Region are sufficiently addressing the current need.
- L+M maintains a viable angioplasty program in the same geographic area and has no backlog and can accept additional volume.
- L+M's established primary and elective angioplasty program is a mere twenty-one (21) minutes from Backus.
- OHCA's completeness questions acknowledge to the Applicant that angioplasty volumes are trending downward nationally and state-wide.[13]
- The State's health care community is combating heart disease through other initiatives:
    - better control of high blood pressure and high cholesterol,
    - a decline in smoking,
    - improvements in treatments, medication and quality of care[14]
    - the use of statin drugs
    - Backus does not address the use of increased efforts to combat heart disease through methods other than primary and elective PCI.
- Introduction of duplicative angioplasty services at Backus will significantly impact volume and utilization at L+M.
    - L+M is only 17.1 miles away from Backus. 25% of the Angioplasty Region **primary** PCI patients are served at L+M Hospital resulting in a drastic impact to L+M's existing PCI program.[15]
    - Hartford Hospital is 40 miles away from Backus, yet Backus is transferring primary PCI patients to a facility that is double the drive time (Hartford Hospital) further taxing Hartford Hospital's cath lab.[16] L+M has excess capacity to accommodate additional PCI volume. Were Backus to transfer primary PCI patients to L+M instead of Hartford Hospital, L+M could assist in alleviating Hartford Hospital's capacity issues.

[13] "National PCI procedure volume peaked in 2006 and has since dropped 30% because of factors such as increased emphasis on the use of other treatment modalities that include drug eluting stents and medical therapy, improved primary and secondary prevention efforts and reduced incidents of STEMI. Similar to the nation, statewide PIC volumes have been declining over the last seven years (Figure 1). The total number of PIC procedures in Connecticut dropped 20% from 8,966 to 7,154 between FY 2007 and FY 2013."[13] *Hospital Transfers* at p. 8.

[14] "Generally, both primary and elective PCI volumes are declining in the nation and in Connecticut because of increased emphasis on other treatment modalities." *Hospital Transfers* at p. 10.

[15] *Application* at 46.

[16] *Application* at 1536.

(4) Whether the applicant has satisfactorily demonstrated how the proposal will impact the financial strength of the health care system in the state or that the proposal is financially feasible for the applicant;

- Impacting Financial Strength:
  - Hospitals are currently facing serious financial challenges in the current healthcare market.
    - Offering an unnecessary program that is duplicative of existing providers in the service area and that will operate at a large deficit is not appropriate.
    - Drawing patients from other hospitals that adequately meet the primary and elective angioplasty needs of the service area will result in losses for other hospitals already serving the population.
    - This will contribute to a decrease in the overall financial stability of Connecticut's health care delivery system.
    - Staffing angioplasty services and ensuring call coverage and readiness make it a very expensive program to operation. Having excess capacity is not cost effective for a proposed provider or an existing provider of angioplasty services.
- Project is Financially Feasible for the Applicant:
  - The Applicant has stated the services are not financially viable.[17] The program will operate at a projected deficit that will increase every year.[18]
  - The project will require a $4.8-million-dollar investment to upgrade the Backus facilities.[19] Backus is proposing to invest nearly $5 million dollars of scarce capital resources into an unnecessary program that is duplicative of existing providers in the service area and that will continuously operate at a larger deficit each year with no prospective break-even point.
  - Applicant's financial projections are not in line with declining volumes across the state.[20]
  - Applicant submitted insufficient evidence to support the projected volume and utilization.

[17] *Application* at p. 65.
[18] *Application* at p. 1409 (Financial Forms). Deficits are $355,363 in 2016, $457,817 in 2017, $559,701 in 2018 and $705,757 in 2019.
[19] *Application* at p. 67.
[20] *Hospital Transfers* at p. 8.

(5) Whether the applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region, including, but not limited to, (A) provision of or any change in the access to services for Medicaid recipients and indigent persons;

- Quality:
    - OHCA recommends that providers and facilities maintain certain utilization levels to ensure providers maintain an appropriate level of experience.[21] Due to the estimated low volume, the proposal will not ensure providers and facilities are properly trained and thus will not improve quality.
    - Full service hospitals that offer open heart surgery need to maintain certain volumes to maintain proficiency. A decrease in volume could result in a decrease in proficiency in other programs, leading to an overall decrease in quality cardiac care in the state.
    - Expert consensus guidelines strongly recommend providing 24/7 on-call PCI capability stating that primary PCI should not be performed at facilities unless it is provided on a 24/7 basis. Backus has not supplied the requested call-coverage schedule to support the guidelines.
- Accessibility:
    - ACCF/AHA/SCAI Guidelines state that "the addition of more PCI centers has not substantially improved access to PCI services for most patients."[22] Approval of primary or elective PCI services at Backus will not improve access for any patients.
    - The Applicant will not improve accessibility of health care delivery. Door to Balloon timing is generally equivalent to that of L+M and other hospitals with PCI capability. The Applicant will not improve accessibility of health care delivery based on improved Door to Balloon time.
        - Offering PCI service at Backus does not result in all patients from the Angioplasty Region receiving PCI services at Backus. Many ambulances bypass certain primary PCI sites for unknown reasons such as referral patterns. Thus, the Door to Balloon time analysis by the Applicant cannot be relied upon.[23]
        - There is no true improvement in time from first medical contact for the proposed program. Whether a patient lives 10 minutes away from Backus or 30, a key rate limiting factor is the time for cath lab team activation and cath lab set-up, which will take 50 minutes to accomplish. Thus access of door to balloon time or lab arrival to device time is not significantly improved for a large majority of the patients living in the made up "Backus Angioplasty Region" due to this team/lab "prep" time.

[21] *Statewide Health Plan* at p. 41.
[22] 2014 SCAI/ACC/AHA Update at 177.
[23] *Application* at p. 34-38.

- Backus's own inadequate response are problematic and do not support a finding of public need. Backus's DIDO time is seventy-three (73) minutes, forty- three (43) minutes over the recommended thirty (30) minute DIDO timeframe. Backus's DIDO time is much worse then other similarly situated hospitals.

- Cost Effectiveness:
  - Duplicate services are not cost-effective. See response to #5.

(6) The applicant's past and proposed provision of health care services to relevant patient populations and payer mix, including, but not limited to, access to services by Medicaid recipients and indigent persons;

- The patient population already has access to these services and there is no public need.
- Backus utilizes a methodology for defining the service area and population that are inconsistent with established OHCA criteria and standards.
- Backus has mischaracterized the regional needs of the "Angioplasty Region" based on age, income, health and other characteristics compared to State and national averages.[24]

(7) Whether the applicant has satisfactorily identified the population to be served by the proposed project and satisfactorily demonstrated that the identified population has a need for the proposed services;

- The Applicant has not satisfactorily identified the population. The Applicant is using its own made up defined service area ("Angioplasty Region") and not the Hospital's historical service area or a recognized OHCA service area.[25] This made up "Angioplasty Region" is irrelevant to both the proposed primary and elective services. Backus's relies upon a consultant, 3d Health, Inc. ("3d"), to derive a contrived service area rather than rely on its own historical patient draw.
  - Backus is anticipating drawing patients outside of its service area. Some of these towns send patients are closer to out of state providers (Worcester, MA). This also creates insufficient evidence to support the projected volumes to support need.
- There is already an existing provider of primary and elective PCI in the service area, L+M, that overlaps with Backus service area. This also creates insufficient evidence to support the projected volumes to support need.
- L+M only realizes a 54% retention rate for patients with STEMI in the market – Backus's projections of 80% are unreasonable.
- The anticipated Angioplasty Region does not account for patients who may want to have elective PCI at a different hospital (for example, Yale or Hartford because they have open heart surgery backup). By the Applicant's own admission, 58% of its Angioplasty Region patients travel to Hartford Hospital or Yale to receive elective PCI.[26]

[24] *Application* at p. 43; 44; 454; 456.
[25] *Application* at p. 37.
[26] *Application* at p. 45.

(8) The utilization of existing health care facilities and health care services in the service area of the applicant;

- Existing health care facilities are satisfactorily meeting the needs of the Backus service area any way the services area is defined, whether pursuant to the OHCA defined service area or the "Angioplasty Region."
    - 11.3% of the Angioplasty Region patients are served at L+M Hospital.[27]
- Backus has not listed any incidents of patient harm based on having to transfer patients to other hospitals.

(9) Whether the applicant has satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities;

- Backus's proposed patient population draws patients that are being serviced by existing, OHCA-approved PCI providers (e.g. Hartford Hospital, St. Francis, Yale, L+M) as well as four (4) out of state facilities. Approving PCI services at Backus will result in duplicative services. Additional programs will dilute professional and institutional competencies.
- Applicant fails to acknowledge that volumes are declining for the services being proposed. Backus instead offers bogus information that angioplasty utilization in the "Angioplasty Region" will increase.[28] OHCA directly inquires of Backus to "explain the reasoning for the 24% growth in PCI's (page 69), given declining state and national PCI trends."[29] Backus cannot meet volume requirements without siphoning volume from other existing programs.
- A Connecticut specific decline in volume as documented in the report entitled "Hospital Transfers of Emergency Coronary Angioplasty Patients for Elective Surgery or Open Heart Surgery: October 1, 2013 to September 30, 2014" and prepared by OHCA.
    - The report emphasizes declining volumes across the state.
- Coronary heart disease prevalence has been stable or declining in recent years. According to the CDC, heart disease prevalence declined among US adults from an average of 11.8% in 2001 to 10.9% in 2013. New England adults have a lower rate of heart disease than US adults overall. This rate is similarly stable or declining.
- In addition, the CDC found that the prevalence of heart attacks among US adults declined from 3.5% in 2001 to 3.0% in 2013. The prevalence of heart attacks among New England adults was similarly found to be 3.0% in 2013.[30] See Table attached.
- National angioplasty (PCI) rates are the lowest they have been since 1996, and continue to trend downward. According to the Society for Cardiovascular Angiography and

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[27] *Application* at p. 46.
[28] *Application* at p. 69; 1444.
[29] Completeness Question 1 (October 30, 2015).
[30] Center for Disease Control ("CDC") Health Data Interactive, 1993-2013, NHIS, Chronic Conditions, ages 18+. Available at http://205.207.175.93/DHI/Tableviewer/tableview/aspx.

Intervention, the American College of Cardiology Foundation, and the American Heart Association in their 2014 Expert Consensus Document, "...the annual volume of PCI procedures peaked in 2006 and has since declined by over 30%."[31] The report cites several contributing factors to the decline:

- Education in restenosis, attributable to drug-eluting stents;
- Rise of medical therapy to treat stable coronary artery disease;
- Growth in primary and secondary prevention efforts;
- Reduction of the incidence of ST-segment elevation myocardial infarction (STEMI); and
- Development and application of appropriate use criteria for implementation of PCI services.

(10) Whether an applicant, who has failed to provide or reduced access to services by Medicaid recipients or indigent persons, has demonstrated good cause for doing so, which shall not be demonstrated solely on the basis of differences in reimbursement rates between Medicaid and other health care payers;

- Not applicable.

(11) Whether the applicant has satisfactorily demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the geographic region; and

- L+M will be dramatically impacted and harmed by the introduction of duplicative services.
  - Proposed PCI services must demonstrate a low likelihood of causing the annual primary or elective PCI volume to fall below the minimum standard at an existing PCI facility. Backus's proposal does not demonstrate that it will not impact existing providers. Backus' proposal will be duplicative to L+M's existing primary and elective angioplasty program and will hinder L+M's ability to provide high quality cost efficient services. Backus will siphon volume from L+M's program.
- L+M will have a negative financial impact as a result of the proposed program.

(12) Whether the applicant has satisfactorily demonstrated that any consolidation resulting from the proposal will not adversely affect health care costs or accessibility to care.

- Backus has stated this will not be a profitable endeavor and Backus Hospital may pass costs onto patients.
- "Cardiac expert's guidelines recommend that to maintain competency, physicians must perform PCI procedures at high volume institutions; this has an impact on PCI referral

[31] Laslatt LJ, Alagona P, Clark BA, et al. The worldwide environment of cardiovascular disease: Prevalence, diagnosis, therapy, and policy issues. J Am Coll Cardiol 2012; 60:S1-49.

patterns"[32] because providers feel pressure to keep certain institutional volumes up. This type of result could adversely drive up health care costs for payors and patients. The introduction of an additional, unnecessary elective and primary angioplasty program into the service area could result in undermining the quality of care at each hospital in the service area.

Backus has not demonstrated a clear public need for primary or elective angioplasty services. Accepted medical literature highlights that there is no need for primary or elective PCI services because they do not improve access for patients. Backus will not reach the recommended volume for a primary and elective program nor will it have the volume for a primary program alone. Backus has not followed impatient data to establish its service area, but has rather contrived its own immaterial service area. There is no gap in access to primary or elective angioplasty services for patients in Backus's Angioplasty Region or Backus's OHCA-defined service area.

For all of the foregoing reasons, the Backus Application should be denied. Based on the statewide decline at all Connecticut providers of angioplasty, the speculative projected new cases, and the fact that there are existing providers currently providing primary and elective angioplasty services in the proposed service area and these providers have the capacity to fulfill the primary and elective angioplasty needs of the community, OHCA should find that there is access to primary and elective angioplasty services for residents within Backus's service area, and further, Backus fails to demonstrate and provide evidence of a clear public need for this proposal. Based on the lack of sufficient evidence demonstrating that the Applicant's proposed project fulfills a clear public need for primary or elective angioplasty, OHCA should conclude that the financial projections and volumes upon which these services are based are not reasonable nor achievable, and that the project is not financially feasible. We respectfully request that the Backus Application be denied.

[32] *Hospital Transfers* at p. 9.

Curriculum Vitae

Bruce D. Cummings, FACHE
901 Pequot Avenue
New London, Connecticut 06320
Home email: thompsonlake@hotmail.com
Home phone: 860-447-9518

Present Position

Lawrence + Memorial Healthcare – New London, CT
President and Chief Executive Officer 2005 – Present

Key accomplishments:
- Led acquisition of Westerly Hospital (Westerly, RI) in 2013
- John D. Thompson Award and Community Service Award from the Connecticut Hospital Association
- L+M named one of the state's 20 best places to work by Connecticut Magazine

Previous Positions

Olean General Hospital – Olean, New York
President and Chief Executive Officer 2002 – 2005

Blue Hill Memorial Hospital – Blue Hill, Maine
Chief Executive Officer 1990 – 2002

Mid-Maine Medical Center – Waterville, Maine
Vice President, Strategic Planning, Marketing and Corporate Development 1985 – 1990
Director of Ambulatory Care 1980 – 1985

City of Danbury – Danbury, Connecticut
Director of Health 1978 – 1980

Education

M.P.H - Yale University School of Medicine, Department of Epidemiology and Public Health 1977

B.A. - Colby College 1973

Professional Affiliations and Associations

American College of Healthcare Executives (Fellow)
Connecticut Hospital Association, Board of Directors, Chair (2014-2016)
Visiting Nurse Association of Southeastern Connecticut, Director
American Hospital Association, Regional (New England) Policy Board, Delegate
Sea Research Foundation, Board of Directors

DEPARTMENT OF PUBLIC HEALTH	:	
DIVISION OF OFFICE OF	:	
HEALTH CARE ACCESS	:	**DOCKET NO. 15-32031-CON**
	:	
IN RE: ESTABLISH AND OPERATE	:	
A PRIMARY AND ELECTIVE	:	
ANGIOPLASTY PROGRAM AT THE	:	
WILLIAM W. BACKUS HOSPITAL	:	**MARCH 18, 2016**

PRE-FILE TESTIMONY OF BRIAN CAMBI, M.D.

Good Morning. My name is Dr. Brian Cambi and I am the Medical Director of the Lawrence + Memorial Hospital, Inc. ("L+M Hospital" or "L+M") Heart and Vascular Center in affiliation with Yale-New Haven Hospital ("YNHH"). I am here today to speak in opposition of the William W. Backus Hospital (the "Applicant" or "Backus") Certificate of Need ("CON") application (the "Application") to provide primary and elective angioplasty without onsite cardiothoracic surgical backup.

My professional background is described in the Curriculum Vitae attached as Exhibit A to my testimony. Briefly, I am a graduate of SUNY Buffalo School of Medicine and completed my postgraduate and fellowship training in cardiology and interventional cardiology at YNHH. I am board certified in Cardiology and Interventional Cardiology, as well as Nuclear Cardiology and Echocardiography.

Since 2008, I have served as the Medical Director of the L+M primary angioplasty program, and now currently hold the position of Medical Director of the L+M Heart and Vascular Center. I reside in East Lyme, CT and 80% of my time is spent clinically or administratively supporting L+M Hospital. One day per week, or 20% of my time, I spend at YNHH completing complex angioplasty procedures. My remarks today address the clinical and

quality aspects of Backus's Application. Specifically that there is (i) no clear public need, (ii) L+M Hospital is equipped to serve the patients of the geographic region safely and without concern including via transfer from Backus to L+M , (iii) Backus's proposal is inconsistent with guidelines adopted by OHCA for primary and elective angioplasty programs, (iv) that the addition of another angioplasty program in the geographic area will negatively affect the current care provided to patients, and (v) adding new angioplasty services to the geographic area will provide no improvement in quality, rather it may lead to a decline in quality.

I. No Clear Public Need Has Been Established Based on Clinical Factors

L+M Hospital currently offers an existing primary and elective angioplasty program that meets the needs of the service area as defined by OHCA and has the clinical capacity to accept additional patients. Patients benefit from the existing experience of the L+M Hospital angioplasty providers and supporting clinical staff (e.g., CCU and telemetry nurses).

A. L+M Hospital Already Maintains a Viable Program in the Same Geographic Area

L+M Hospital has a well-established angioplasty program that provides both primary and elective angioplasty to patients in the geographic area described as the Backus Hospital's "Angioplasty Region." Since the establishment of L+M Hospital's primary angioplasty program in 2008 and the elective program in 2013, L+M Hospital has performed over 700 primary angioplasties and over 280 elective interventional procedures. L+M Hospital's clinical affiliation with YNHH remains strong.

In my career to date, I have performed over 1,000 angioplasty cases with a high success rate and low complication rate. I am also a Yale School of Medicine ("YSM") clinician and faculty member, as are and all interventional cardiologists that cover L+M Hospital's angioplasty

program. Communication and emergent transport between L+M Hospital and YNHH, when needed, has been seamless. Additionally, L+M Hospital has thoughtfully and methodically invested in the equipment and personnel to ensure a sustainable and reliable program to the patients in eastern Connecticut. Such investments include recent and upcoming upgrades to each of L+M Hospital's two catheterization laboratories to ensure state-of-the-art equipment, as well as completing a quarterly CME-qualifying lecture series designed to educate L+M Hospital staff (e.g., physicians, nurses, technicians, and sonographers) through presentation of latest national standards for clinical guidelines and L+M-specific medical case review.

B. L+M Hospital has Capacity for Additional Volume

L+M Hospital has sufficient clinical capacity for additional volume. L+M Hospital has no backlog and has the staff and resources to provide additional angioplasty services. As noted previously, L+M has two catheterization suites to accommodate patients. L+M's established primary and elective angioplasty program is a mere twenty-one (21) minutes away from Backus and has angioplasty resources and staff available consistent with national standards ACCF/AHA/SCAI Guidelines[1]. The Applicant wholly ignores this fact and offers immaterial evidence about patient origin distance from L+M Hospital to distract from the fact that L+M Hospital is a qualifying transfer location for Backus.

C. Patients are Better Served Being Transported to L+M

Clinical outcomes are not affected when patients are transported within the appropriate timeframe. L+M Hospital is the closest PCI-capable hospital to Backus. For STEMI patients presenting at Backus directly, Backus has ample time to transfer patients to L+M for immediate

[1] *"ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention; a Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiograph and Interventions,"* as updated and amended (the "ACCF/AHA/SCAI Guidelines").

PCI within the recommended timeframe of 120 minutes per the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. According to such guidelines, "immediate transfer to a PCI-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI who initially arrive at or are transported to a non-PCI-capable hospital, with an FMC-to-device time system goal of 120 minutes or less." Backus cites its long door-in-door-out ("DIDO") time and inter-facility transfer times as a factor in being unable to meet this standard. However, despite being the closest PCI-capable provider, to date, only a limited number of STEMI transfers from the Backus ED are received at L+M. Since 2010, there were a total of three (3) transfers from Backus Hospital to L+M for emergent angioplasty. Of those three (3) cases, two (2) were only transferred to L+M because there was a large snowstorm at the time in January of 2015. To Backus's credit, they transferred these patients to L+M because it was in the patients' best interest because L+M is the closest PCI-capable hospital.

Were Backus to reduce its DIDO times and transfer patients to L+M, STEMI patients presenting first at Backus are well-positioned to receive their device at L+M within recommended timeframes. According to L+M's latest ACC-NCDR quality report, in the last rolling four (4) quarters ending 2015Q3, L+M's "median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)" was 89 minutes. These transfers were from Westerly Hospital (Westerly, RI) to L+M, with a travel time of twenty-seven (27) minutes. Given the previously mentioned travel time of 21 minutes between Backus and L+M, it is highly probable that transferred STEMI patients will receive immediate PCI well within the stated 120 minute threshold, and potentially even under 90 minutes were Backus to send primary angioplasty cases to L+M versus alternate and further facilities.

Backus continues to misquote and misuse the AHA/ACC STEMI Guidelines as it relates to 90 minutes versus 120 minute DTB time.[2] For non-PCI capable facilities, the time to device is 120 minutes, not the 90 minutes Backus continues to quote. The 90 minute DTB time in the Guidelines is recommended for PCI-capable facilities.

L+M should be the receiving PCI-capable facility for STEMI patients presenting at the Backus ED as travel times are minimal, and L+M has demonstrated its ability to not only meet, but far exceed clinical recommendations for time to device for transferred patients.

D. No Clinical Benefit to Backus Obtaining Primary PCI

Even if Backus were to have a primary PCI program, patients in the "Angioplasty Region" will not receive a faster time to device.

Backus's proposal relies heavily on travel or drive time analyses, suggesting that a primary PCI program at Backus will improve time-to-device for patients in the "Angioplasty Region." This contention is misguided, and can be disproved by the very data and information provided by Backus in its CON application. Backus states that when activated from the field, the "Cath Lab Team Activation" and "Cath Lab Setup" time will take approximately 50 minutes to complete.[3] Thus, even if EMS's transfer time to Backus is short, patients cannot undergo PCI at any time prior to the 50-minute time period elapsing. In every scenario for Backus, 50 minutes is the very minimum time it takes before the procedure can even occur. Similar to Backus, existing PCI providers all receive field/EMS activation prior to the patient's arrival. As existing providers are all located less than 45 minutes from the towns in the "Angioplasty Region," the transfer time to the receiving hospital is occurring concurrently to the "cath lab readiness."

[2] Application at 48;1534.
[3] Application at 477.

As shown in the table below, 42% of the population in the "Angioplasty Region" is located within a thirty (30) minute drive time of an existing PCI provider and 85% are within a thirty-five (35) minute drive time of an existing PCI provider.

Travel time to Nearest PCI facility for Towns in Angioplasty Region (in-state or out-of-state facilities)				
	≤ 30 minutes	31-35 minutes	36-40 minutes	41-45 minutes
Number of Towns	11	11	2	2
Town Names	Bozrah Colchester Columbia Franklin Hebron Lisbon Norwich Preston Putnam Sprague Thompson	Canterbury East Haddam Griswold Killingly Lebanon Plainfield Pomfret Sterling Voluntown Windham Woodstock	Brooklyn Mansfield	Chaplin Hampton
Total Population	107,110	109,858	34,362	4,211
% of Angio Region	41.9%	43.0%	13.4%	1.6%

Thus, even patients in the most remote locations of the "Angioplasty Region" will arrive at a PCI facility within 45 minutes, 5 minutes prior to the cath lab readiness being complete. And for a large majority of the "Angioplasty Region," transfer to a PCI-capable hospital will occur in less than 35 minutes. There is no marked improvement in time-to-device were Backus to have a primary PCI program because of the time-to-activate and setup the cath lab. This 50-minute duration negates any clinical benefit of a reduced transfer time.

E. Backus Includes Improper Procedures in its Calculations for Public Need

Additionally, Backus includes ICD-9 procedure code 17.55 (transluminal coronary atherectomy) in its analysis and projections of PCI volume. Although indeed a PCI procedure, the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site

Surgical Backup[4] very clearly states that, "rotational or other atherectomy devices…should not be performed in facilities without on-site surgery." Performing these procedures at Backus, a facility without onsite cardiothoracic surgery backup, runs counter to the latest clinical guidelines and will put patients at risk if performed. Thus, Backus's inclusion of the procedure attributed to ICD-9 code 17.55 is not appropriate in justifying public need for a PCI program and projections of volume for this procedure should not be included and in fact are not suitable for facilities without onsite surgery per the most recent clinical guidelines.

F. Backus Fails to Acknowledge Availability of Air Ambulance Transfer

Further, there are ample air ambulance services available in the area. Backus has a LIFE STAR helicopter stationed at its campus. Backus is the only hospital in Windham or New London counties to have an on-site air ambulance and a trauma center. LIFE STAR operates 24 hours a day, seven days a week. Backus states on its website that "[e]mergent transfers can occur in less than an hour via LIFE STAR, which is stationed at Backus."[5] Pursuant to a Hartford Healthcare publication, the travel time between Norwich and Hartford is only 17 minutes.[6]Pursuant to Hartford Hospital data, 25% of LIFE STAR transfers are for cardiac cases.[7] This shows there is already a heavy reliance on LIFE STAR to improve the travel time for cardiac patients to a hospital with full open heart services.

Backus has not included any travel time statistics in its Application regarding the use of the LIFE STAR helicopter. For patients who are already travelling more than 30 minutes to Backus (e.g. East Haddam, Hampton, Pomfret, Putnam, Thompson, Woodstock[8]), the total time

[4] Dehmer GJ, et al. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. J Am Coll Cardiol 2014; 63:2624-41.
[5] https://backushospital.org/our-services/cardiology/ (accessed March 7, 2016).
[6] https://backushospital.org/wp-content/uploads/2015/06/06-26-15-HT_FINAL.pdf (accessed March 7, 2016).
[7] http://www.harthosp.org/lifestar/FAQs/default.aspx (accessed March 7, 2016).
[8] Application at 36.

to balloon may be decreased by using LIFE STAR. However, Backus does not include these advantages of LIFE STAR in its Application. Without these statistics, Backus has not accurately identified the most effective transfer for certain patients or their respective transfer times. Backus has also failed to acknowledge other hospital campuses that have the capability to accept LIFE STAR transfers, including L+M Hospital. Without Backus including the use of LIFE STAR in its analysis, Backus has failed to appropriately analyze transfer time requirements.

II. Backus's Proposal is Inconsistent with Guidelines Adopted by OHCA

The Applicant's arguments are inconsistent with benchmarks and standards adopted by OHCA through its adoption of the ACCF/AHA/SCAI Guidelines. Such standards are developed by clinical experts in the field and serve as the guiding resource for determining the appropriateness of implementation of these programs. Backus's proposal invokes many problems cited by the ACCF/AHA/SCAI Guidelines including the development of duplicative services and inappropriate planning.

A. The Proposal is not Consistent with Transfer Time Guidelines

The proposal is inconsistent with 2014 ACCF/AHA/SCAI Guidelines that strongly advise against the development of PCI facilities within a 30-minute emergency transfer time to an established facility stating specifically that "if the transfer time is ≤30 minutes, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital...*The development of PCI facilities within a 30-min transfer time to an established facility is therefore strongly discouraged*" (emphasis added).[9] L+M's established primary and elective angioplasty program is a mere twenty-one (21) minutes away from Backus

[9] Dehmer GJ, et al. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. J Am Coll Cardiol 2014; 63:2624-41.

and is clearly within the recommended thirty (30) minute transfer time. Thus Backus's proposal undoubtedly contradicts the latest recommendations from SCAI/ACC/AHA, a recommendation put forth to stem the proliferation of PCI programs where such implementation will have an adverse impact on the volume of existing established providers and quality of care.

B. The Proposal is Not Consistent with Planning Guidelines

The ACCF/AHA/SCAI Guidelines also provide that "primary PCI is reasonable in hospitals without on-site cardiac surgery, *provided that appropriate planning for program development has been accomplished*" (emphasis added). In the same report, elective PCI in hospitals without onsite cardiothoracic surgical backup was elevated from Class III to Class IIb (Level of Evidence: B), with the same stipulation regarding appropriate planning. These 2011 recommendations were reiterated in the ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures Guidelines. Backus's proposal does not comply with either the 2011 or the 2013 recommendations as Backus has failed to demonstrate appropriate planning for its proposed PCI program.

Backus has not provided OHCA, even upon OHCA's request, with the "proposed on-call system to ensure continuous 24/7 coverage" and the "on-call schedule for the physicians that will provide coverage" for the primary PCI program.[10] Instead, Backus stated "until the program is approved by OHCA a detailed on-call system for the Backus program will not exist."[11] In lieu of a call coverage proposal, Backus provided OHCA with the on-call schedule for Hartford Hospital. It should be noted that in L+M Hospital's CON application in 2004 to establish a primary PCI program, L+M provided a call schedule to OHCA, and detailed the physicians involved, and coverage time for local cardiologists versus those from YSM. The lack of a

[10] Application at 1467.
[11] *Id.*

Backus call coverage schedule suggests significant planning deficiencies, those the ACCF/AHA/SCAI has warned against for facilities attempting to initiate PCI programs.

Personnel recommendations outlined in the 2011 and reiterated in the 2014 ACCF/AHA/SCAI expert consensus reports state that PCI programs without onsite cardiothoracic surgical backup include "experienced nursing and technical laboratory staff with training in interventional laboratories." Backus's assertion that "radiology technical staff experience [in interventional radiology lab] with peripheral angioplasty and stenting will complement a Primary and Elective PCI program" is not valid.[12] Although technically similar, vascular angioplasty and stenting procedures and experience in the IR lab does not translate seamlessly into competence for coronary angioplasty and stenting procedures. In addition to the clear anatomical differences, the circumstances surrounding an emergent coronary event and associated patient monitoring (e.g., heart rhythm, blood pressure) are not factors in vascular procedural work that is largely elective and non-emergent. Thus to equate interventional vascular lab experience with coronary cath lab experience is misguided. Aptitude in coronary procedures, particularly for patients with STEMI, is "learned" through formal training and real-world experience. As noted in their CON application, Backus has not cared for a STEMI victim onsite in years. All patients have been transferred and no fibinolytic therapy dispensed. For this reason, Backus's ancillary staff such as cardiac nurses, intensive care nurses, echo techinicians, etc. are not accustomed to treating these patients or providing routine post-care. Backus has not adequately outlined a plan to educate staff on caring for these complex patients.

In my opinion, practice staffing for primary or elective PCI procedures at a community hospital like L+M or Backus is two nurses and one tech. Backus's proposed staffing model

[12] Application at 21.

includes two techs and one nurse which may impact the quality of care provided as an improper level of clinical providers will be available.[13] Backus's personnel recommendations and lack of call coverage plan suggest program planning to-date is lacking and inappropriate. Backus also fails to designate a director to coordinate and operate the program. As such, Backus does not conform to best practice, nor does it comply with ACCF/AHA/SCAI guidelines.

C. The Proposal is Not Consistent With Treatment Guidelines

Additionally, for patients with STEMI, it is commonly accepted that the preferred treatment is PCI versus medical or fibinolytic therapy for most patients. However, use of fibrinolytic therapy (or thrombolytics) is the recommended treatment protocol for patients presenting at non-PCI-capable hospitals under certain circumstances. According to the 2013 ACCF/AHA Guideline for Management of STEMI: "In the absence of contraindications, fibrinolytic therapy should be administered to patients with STEMI at non-PCI-capable hospitals when the anticipated FMC-to-device time at a PCI-capable hospital exceeds 120 minutes because of unavoidable delays (Class I, Level of Evidence B)."[14] Backus's proposal states there were zero (0) doses of fibrinolytic therapy or thrombolytic medication dispensed in FY 2014 to patients presenting with STEMI (Backus CON, Page 104). As a non-PCI-capable hospital, failure to use fibrinolytic therapy or thrombolytic medication on any patient suggests Backus and its health care providers were confident patients could be transferred to PCI-capable hospitals and receive their device procedures within the recommended timeframe of 120 minutes noted above. If such treatment decisions were made, it does not follow that it is clinically necessary that Backus provide primary angioplasty services.

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[13] *Application* at 84.

[14] O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013;61(4):e78-e140. doi:10.1016/j.jacc.2012.11.019.

D. The Proposal is Not Consistent with Volume Requirements

In 2013, clinical guidelines from the ACCF/AHA/SCAI concluded there is a volume-quality relationship at institutions performing less than 200 PCIs annually. The report states: "An institutional volume threshold <200 PCIs annually appears to be consistently associated with worse outcomes, but above this level, there is no relationship between even higher annual volumes and improved outcomes. Accordingly, the writing committee recommends a minimum institutional volume threshold of 200 PCIs per year."[15] The 2014 SCAI/ACC/AHA Expert Consensus Document on Percutaneous Coronary Intervention Without On-Site Surgical Backup referenced earlier reaffirmed these recommendations for institutional volume, as did the CT DPH Hospital Transfer Report referenced earlier.[16] Although these recent clinical guidelines have now documented proof of the volume-quality relationship, published guidelines before 2013 stressed the importance of maintaining 200 cases. With this understanding, L+M has strived to complete 200 cases minimally between its primary and elective PCI program even before the 2013 and 2014 guidelines were produced.

In FY 2015, L+M performed 216 total coronary interventional cases.[17] As represented in Backus's application, in FY 2015 alone, 32 PCI cases at L+M originated from patients who reside within Backus's "Angioplasty Region."[18] Backus also represents that 51 PCI cases (28 primary PCI and 23 elective PCI cases) at L+M originated from patients who resided within Backus's OHCA-defined service area, representing a 23.6% portion of L+M's total PCI volume.[19] Loss of this volume to Backus will reduce L+M's volume to well below the 200

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[15] *Id.*
[16] Dehmer GJ, et al. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. J Am Coll Cardiol 2014; 63:2624-41.
[17] During 2015, 184 cases were angioplasty procedures and 32 cases were diagnostic interventions (e.g., FFR and IVUS).
[18] Application at 1464.
[19] Application at 1458.

threshold. L+M is striving to meet clinical guideline volume requirements and is improving each year. If L+M were to fall well below the threshold, quality indicators at L+M may be impacted.

In addition, per the Agreed Settlement with OHCA signed in 2013, OHCA has been monitoring the L+M program closely. L+M is required on a quarterly basis to submit volume by patient town, as well as its quality dashboard tracked and produced by the ACC-NCDR. L+M is just barely three (3) years into full operation of its elective program, and is not even half way through OHCA's monitoring timeline of seven (7) years. It is the expectation of OHCA per the Agreed Settlement that L+M perform a quantity of procedures higher than those recommended by the ACC, thus because L+M is likely to fall well below the minimum threshold with Backus's program in place, approval of Backus's CON by OHCA will lead to the inability of L+M to meet the requirements of the Agreed Settlement between OHCA and L+M.

E. Backus Improperly Relies on Obsolete Guidance

Backus improperly relies upon Connecticut EMS STEMI Guidelines put forth by the CT DPH on January 23, 2012. Since 2012, the CT DPH, recognizing the importance of early detection of STEMI patients in field, has expanded the EMT scope of practice to include 12-lead EKG acquisition and transmission in a directive put forth on December 30, 2014. This is a clear indication that the Connecticut Department of Public Health's focus is not on additional PCI sites, but appropriately diagnosing patients with STEMI in the field, pre-hospital, so they can be rapidly treated at the most appropriate location. Similarly, initiatives like the American Heart Association's Mission Lifeline have focused on collaboration among PCI-receiving hospitals, PCI-referring hospitals, and EMS to ensure STEMI patients receive care in a timely fashion. As stated in the literature, "since 2000, there has been a substantial decline in the incidence of

STEMI and there is now greater emphasis on developing systems of care for STEMI patients as promoted in the Mission Lifeline initiative."[20]

III. The Proposal Will Result in Unnecessary Duplication of Existing Services Which Can Negatively Affect the Current Care Provided to Patients

Approving this proposal will add an identical service to the same geographic and may negatively affect the current care provided to patients.

A. Applicant Fails to Acknowledge that Volume is Declining

The Applicant fails to acknowledge that utilization is not expected to rise in the Angioplasty Region and instead offers inaccurate information that angioplasty utilization in the "Angioplasty Region" will increase. The Applicant fails to recognize that the health care community is combating heart disease through preventative methods including better control of high blood pressure and high cholesterol and smoking cessation, and fails to address the improvements in treatments, medication and quality of care.[21] The use of statin drugs and other non-interventional treatments will contribute to continuing declines of primary and elective angioplasty volumes. These factors are not minor – they represent significant changes in the provision of cardiac care that have directly impacted the amount of angioplasty procedures nationwide and in Connecticut. By failing to address the use of increased efforts to combat heart disease through methods other than primary and elective angioplasty, Backus has failed to properly and clearly identify the needs of the proposed service area.

[20] Dehmer GJ, et al. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. J Am Coll Cardiol 2014; 63:2624-41.
[21] "Generally, both primary and elective PCI volumes are declining in the nation and in Connecticut because of increased emphasis on other treatment modalities." *Hospital Transfers* at p. 10.

B. The Service Area is Already Appropriately Served

The service proposed by the Applicant is duplicative because patients in the "Angioplasty Region" are already being adequately served. Backus is not the closest or similarly close provider to seven (7) towns in the Angioplasty Region (Hebron, Killingly, Montville, Pomfret, Putnam, Thompson, and Woodstock). See Attachment B and Attachment C. Pomfret, Putnam, Thompson, and Woodstock are all closer to UMass Memorial Medical Center (UMass) located in Worcester, Massachusetts. Nine (9) other towns in the Angioplasty Region are already within 30 minutes travel time of an existing PCI provider (towns include Bozrah, Colchester, Columbia, Franklin, Hebron, Lisbon, Norwich, Preston, and Sprague). Patients' needs in these above towns are already being met. Two (2) towns not included in the "Angioplasty Region," but part of Backus's primary service area as defined by OHCA, are already within 30 minutes of an existing primary PCI provider (towns include Ledyard and Montville). Patients' needs in these two towns are already being met. The other 13 towns in the self-defined "Angioplasty Region" are within 31-45 minute drive time of an existing PCI provider (towns include Brooklyn, Canterbury, Chaplin, East Haddam, Griswold, Hampton, Killingly, Lebanon, Mansfield, Plainfield, Sterling, Voluntown, and Windham). Patients' needs for elective or primary angioplasty in every one of these towns are already being met.

IV. The Addition of Another Angioplasty Program in The Geographic Area Will Negatively Affect the Current Care Provided to Patients

The addition of any angioplasty services in the same service area of L+M Hospital's existing primary and elective program will provide no improvement in quality. Rather, it may lead to a decline in quality as evidenced by national standards. Further, angioplasty providers

may be pressured to improperly refer patients to low-volume centers which may lead to bad quality outcomes.

A. L+M Hospital Meets the Angioplasty Needs of the Service Area and Will Be Negatively Impacted if an Additional Service is Introduced

L+M Hospital's existing primary and elective angioplasty program meets the needs of all patients of Backus Hospital as it is within the recommended transfer time. Patients are better served at existing facilities as there is no benefit to competing programs within the same geographical region. The addition of a program well within a thirty (30) minute transfer time from Backus Hospital is redundant and against the directives of the established ACCF/AHA/SCAI Guidelines adopted by OHCA and by the cardiology community as a whole. Backus's proposed primary and elective angioplasty program will be in direct competition with "another PCI program in the same geographic area" (L+M Hospital). This is against OHCA's guidelines on the development of new angioplasty programs and is not consistent with the Statewide Health Plan nor is it "in the best interest of the community."[22] As such, competition with L+M's program is not in the best interest of the community. Backus incorrectly states it will not affect existing programs even though L+M Hospital is in Backus's geographic area and serves a large portion of angioplasty patients from Backus's service area. It is highly unlikely that Backus may reach its projected utilization figures based on everything that has been presented in the Application and as outlined in OHCA's careful questions. Backus may be offering a disservice to the residents of this state by directing scarce resources to a program that,

[22] *Statewide Health Plan* at 39.

because it will not meet the minimum utilization required of facilities, will offer more harm than benefit. Adding this proposed program at Backus will compromise patient care.

B. Introduction of Additional Duplicative Services Will Undermine the Quality of Care

Existing health care facilities, including L+M Hospital, are satisfactorily meeting the needs of the Backus service area. An additional angioplasty program is unnecessary. The introduction of another duplicative elective and primary angioplasty program in this region will result in undermining the quality of care at each hospital that offers the same services. Cardiac physicians in Connecticut perform angioplasties at various locations – to add an additional location for these providers without a clear benefit to the public is harmful to patients. Specifically, "[c]ardiac experts guidelines recommend that to maintain competency, physicians must perform PCI procedures at high volume institutions; this has an impact on PCI referral patterns"[23] Although Backus states proposed participating providers are high-volume, seasoned PCI providers,[24] Backus contradicts itself by stating it will be recruiting additional providers, whose credentials are unknown, and also fails to incorporate that a physician recently out of fellowship will be included in the rotation.[25] "[I]t is unwise for a newly trained interventional cardiologist to start a new PCI program."[26]

C. Additional Programs Will Dilute Professional and Institutional Competencies

Competencies are achieved and maintained at L+M solely through the primary and elective programs, and are greatly enhanced through the increased number of cases now completed at L+M. Likewise, other departments and clinical areas that "touch" the patient also

[23] *Hospital Transfers* at 9.
[24] Application at 1462.
[25] Application at 105.
[26] *ACCF/AHA/SCAI Guidelines*, 2014 update at 183.

benefit by increased volume including the inpatient units and staff who house post-procedure patients after either an primary or elective case. Backus's program will not improve quality of health care delivery in the region, but will in fact be harmful to L+M's program by reducing volume and the experience attained by all providers of care.

V. Conclusion

In conclusion, Backus's proposal is not clinically appropriate and should be denied because (i) no clear public need has been established as L+M Hospital is equipped to serve the patients of the geographic region safely and without concern including via transfer from Backus to L+M Hospital; (ii) Backus's proposal is inconsistent with guidelines adopted by OHCA; (iii) the Applicant's proposal does not meet national standards established for primary or elective angioplasty programs; (iv) the addition of another angioplasty program in the geographic area will negatively affect the current care provided to patients; and (v) adding new angioplasty services to the service area will not result in improved quality, rather it may lead to a decline in quality. This application should be denied as it does not meet the same parameters as other angioplasty CONs in Connecticut.

Thank you for this opportunity to speak today. I welcome any questions.

Attachment A

CV

CURRICULUM VITAE

Date of Revision: 2/1/16

Name: Brian C. Cambi M.D. FACC FSCAI

Education:

B.S.	The College of William and Mary (Biology) 1995 - Magna Cum Laude
M.D.	SUNY at Buffalo School of Medicine and Biomedical Science 1999 - Summa Cum Laude

Career/Academic Appointments:

1999-02	Intern and Resident, Internal Medicine, Yale-New Haven Hospital, New Haven, CT
2002-03	Chief Resident, Internal Medicine, Yale-New Haven Hospital, New Haven, CT
2003-06	Cardiology Fellow, Yale University School of Medicine, New Haven, CT
2006-07	Interventional Cardiology Fellow, Yale University School of Medicine, New Haven, CT
2007-08	Clinical Instructor, Dept. of Internal Medicine, Section of Cardiology, Yale University School of Medicine, New Haven, CT
2008-present	Assistant Professor, Dept. of Internal Medicine, Section of Cardiology, Yale University School of Medicine, New Haven, CT

Administrative Positions:

2008-2012	Director, Yale primary angioplasty program at L+M Hospital, Yale University School of Medicine, New Haven, CT
2013-present	Medical Director, Yale New Haven Heart and Vascular Center at Lawrence and Memorial Hospital

Board Certification:

American Board of Internal Medicine, Cardiovascular disease 2006
American Society of Echocardiography, Echocardiography 2006
American Society of Nuclear Cardiology, Nuclear Cardiology 2006
American Board of Internal Medicine, Interventional Cardiology 2007

Professional Honors & Recognition:

International/National/Regional

1999: Summa Cum Laude, Doctor of Medicine, SUNY at Buffalo School of Medicine
1999: The John Watson Award in Medicine
1999: Association of Pathology Chairs Award
1998: Alpha Omega Alpha Honor Medical Society
1997: James Gibson Anatomical Honor Society
1995: Phi Sigma National Honor Society
1995: Magna Cum Laude, Bachelor of Science, The College of William and Mary

Professional Organizations:

American College of Cardiology
2008-present Member, Fellow

Society for Cardiovascular Angiography and Interventions
2008-present Member, Fellow

Attachment B

Travel or Drive Time to Select Hospitals by Town (in minutes)

Source: Google Maps, 2016.

Note: all hospitals listed except Backus Hospital can perform primary and elective PCI

	Backus Hospital	**Hartford Hospital**	**St. Francis Hospital**	**L+M Hospital**	**Rhode Island Hospital**	**Miriam Hospital**	**Umass Medical center**	**Kent County Hospital**
Town	Norwich	Hartford	Hartford	New London	Providence	Providence	Worcester	Warwick
State	CT	CT	CT	CT	RI	RI	MA	RI
Bozrah	5	35	34	23	56	59	56	50
Brooklyn	26	51	51	43	40	44	39	42
Canterbury	18	53	52	35	43	47	44	45
Chaplin	29	42	42	46	54	58	51	56
Colchester	15	28	28	34	65	69	66	60
Columbia	22	30	29	39	65	68	62	67
East Haddam	27	35	35	40	77	81	78	71
Franklin	9	42	42	26	59	63	60	54
Griswold	16	53	52	33	45	50	50	38
Hampton	27	45	45	45	48	51	47	50
Hebron	24	26	25	42	71	75	67	69
Killingly	31	64	64	48	35	39	38	37
Lebanon	13	38	38	33	63	67	64	58
Ledyard	15	52	52	18	53	58	63	46
Lisbon	8	45	45	25	52	55	52	44
Mansfield	31	37	36	48	64	68	54	66
Montville	13	44	44	17	60	65	64	52
Norwich	5	44	44	25	54	59	59	46
Plainfield	17	53	53	34	40	44	41	41
Pomfret	37	50	50	54	46	49	34	48
Preston	11	50	50	30	51	58	57	43
Putnam	31	60	60	48	41	45	26	43
Sprague	12	47	46	30	56	60	57	50
Sterling	23	60	60	40	39	42	44	34
Thompson	35	62	61	52	45	49	24	47
Voluntown	19	56	56	36	39	43	53	31
Windham	18	40	39	35	56	60	57	58
Woodstock	39	52	51	56	49	53	34	51

Attachment C

Distance to Select Hospitals by Town (in miles)

Source: Google Maps, 2016.

Note: all hospitals listed except Backus Hospital can perform primary and elective PCI

	Backus Hospital	**Hartford Hospital**	**St. Francis Hospital**	**L+M Hospital**	**Rhode Island Hospital**	**Miriam Hospital**	**Umass Medical center**	**Kent County Hospital**
Town	Norwich	Hartford	Hartford	New London	Providence	Providence	Worcester	Warwick
State	CT	CT	CT	CT	RI	RI	MA	RI
Bozrah	4.9	34.8	35.7	19.3	53.2	54.8	63.6	45.8
Brooklyn	22.5	44.1	44.9	36.7	31.6	33.2	40.5	34.6
Canterbury	16.0	43.5	44.2	30.2	35.8	37.4	46.3	34.1
Chaplin	20.8	35.4	36.2	35.1	43.7	45.4	47.5	46.8
Colchester	14.1	25.6	26.5	21.3	62.3	64.0	72.8	55.0
Columbia	16.7	24.2	25.0	31.1	53.0	54.6	57.9	56.0
East Haddam	24.2	27.4	28.2	35.8	72.5	74.1	82.9	65.1
Franklin	6.6	40.5	41.4	20.9	54.8	56.4	65.3	47.5
Griswold	13.2	49.3	50.1	27.4	40.5	44.4	52.1	32.3
Hampton	18.5	38.3	39.0	35.9	37.5	39.1	46.5	40.5
Hebron	21.6	21.9	22.8	27.7	57.7	59.3	65.7	62.5
Killingly	30.1	51.2	52.0	44.3	26.0	27.6	36.4	29.1
Lebanon	9.9	31.6	32.4	24.3	58.2	59.8	68.6	50.8
Ledyard	8.9	50.6	51.5	11.7	54.5	58.4	63.5	46.3
Lisbon	8.1	44.1	45.0	22.3	45.0	46.3	55.1	36.8
Mansfield	21.5	26.7	27.5	35.8	49.8	51.4	47.7	52.9
Montville	11.3	38.9	39.8	11.0	63.2	67.1	69.8	55.0
Norwich	1.6	41.0	41.9	16.5	48.2	52.1	59.7	40.0
Plainfield	16.7	52.8	53.6	30.9	34.1	35.8	44.6	31.3
Pomfret	36.1	42.7	43.5	50.3	34.3	35.9	31.4	37.3
Preston	5.8	45.3	46.2	20.7	45.8	49.7	59.2	37.6
Putnam	35.1	48.7	49.5	49.3	29.7	31.4	28.4	32.8
Sprague	6.9	43.7	44.6	24.3	49.4	51.0	59.9	42.1
Sterling	22.9	58.9	59.8	37.1	29.4	31.1	45.5	26.1
Thompson	39.2	53.2	54.0	53.4	37.4	39.0	24.5	40.5
Voluntown	15.8	51.8	52.7	30.0	35.8	39.7	54.7	27.6
Windham	13.5	33.3	34.1	27.9	46.0	47.6	56.4	44.3
Woodstock	39.0	46.8	47.6	53.2	37.2	38.8	31.2	40.3

DEPARTMENT OF PUBLIC HEALTH	:	
DIVISION OF OFFICE OF	:	
HEALTH CARE ACCESS	:	**DOCKET NO. 15-32031-CON**
	:	
IN RE: ESTABLISH AND OPERATE	:	
A PRIMARY AND ELECTIVE	:	
ANGIOPLASTY PROGRAM AT THE	:	
WILLIAM W. BACKUS HOSPITAL	:	**MARCH 18, 2016**

PRE-FILE TESTIMONY OF DANIEL RISSI, M.D.

Good Morning. My name is Dr. Daniel Rissi and I am the Vice President and Chief Medical and Clinical Operations Officer at Lawrence + Memorial Hospital, Inc. ("L+M Hospital" or "L+M"). I am here today to speak in opposition of the William W. Backus Hospital (the "Applicant" or "Backus") Certificate of Need ("CON") application (the "Application") to provide primary and elective angioplasty without onsite cardiothoracic surgical backup.

L+M Hospital is a not-for-profit 308-bed acute care community hospital located at 365 Montauk Avenue, New London, Connecticut which is 17.1 miles from Backus. L+M Hospital is an existing provider of primary and elective angioplasty services pursuant to Office of Health Care Access ("OHCA") CON Docket Numbers 04-30297-CON and 12-31768-CON. As an existing provider of primary and elective angioplasty in the service area, L+M Hospital's interests are greatly affected by Backus's proposal to establish another primary and elective angioplasty in the area. All of the data and literature clearly demonstrates a decline in angioplasty utilization, ample available capacity in the service area and other factors that lead to a determination of no clear public need for the Applicant to provide primary or elective angioplasty; all of which will absolutely result in duplicative services. Further, the Applicant has

not satisfactorily identified the population to be served and has failed to define and identify the service area or support the utilization data.

Professional Background

My professional background is described in the Curriculum Vitae attached as Exhibit A. In my role as Vice President and Chief Medical and Clinical Operations Officer, I oversee medical affairs and operations, but have also managed the strategy and planning functions at L+M. Prior to joining L+M, I served as Interim President and Chief Executive Officer for Olean General Hospital in New York. My residency training was in Family Medicine at Eastern Maine Medical Center, and I completed my medical degree at Johns Hopkins University School of Medicine.

I. No Clear Public Need Has Been Established

The Applicant's has failed to establish a clear public need for either primary or elective angioplasty in its proposed service area. The Applicant:

- does not adequately address declining PCI volume;
- relies upon improper data for its volume prediction;
- fails to acknowledge that providers are combating heart disease through other non-invasive methods;
- fails to acknowledge historical discharge data does not support public need;
- mischaracterizes the existing and available PCI services; and
- fails to address its own response times.

A. The Applicant does not Adequately Address Declining PCI Volume

The Applicant improperly calculates utilization growth in providing volume projections in future years despite clear, undeniable research that national and statewide angioplasty volumes

are declining. In its Application, Backus states it expects a substantive 24% growth in angioplasty services.[1] OHCA itself has acknowledged the nationwide decline and elaborated on the decline in Connecticut: "National PCI procedure volume peaked in 2006 and has since dropped 30% because of factors such as increased emphasis on the use of other treatment modalities that include drug eluting stents and medical therapy, improved primary and secondary prevention efforts and reduced incidents of STEMI. Similar to the nation, statewide PCI volumes have been declining over the last seven years. The total number of PCI procedures in Connecticut dropped 20% from 8,966 to 7,154 between FY 2007 and FY 2013."[2] Backus's data filed in its initial CON application also demonstrates about a 10% decrease in Primary PCI services from 2009 to 2014.[3]

L+M Hospital is not alone in questioning Backus's proposed volume growth as OHCA itself questioned this in its completeness questions to Backus on October 30, 2015. Even with further OHCA inquiry, the Applicant still did not properly address the clear downward trend of PCI volume. Rather, Backus admits it does "not incorporate state or national trends" and goes on to state that "data suggests that total PCI volumes in the State of Connecticut are not declining across the board" and "total PCI trends remained fairly flat" and then stated that "PCI volumes in totality only declined 5% over six years."[4] These statements demonstrates Backus's utter failure to address clear and undeniable declining volumes and shows how Backus has erroneously presented arguments in spite of OHCA's records that clearly show volumes are declining

[1] Application at 69.
[2] Connecticut Department of Public Health, *Hospital Transfers of Emergency Coronary Angioplasty Patients for Elective Surgery or Open Heart Surgery: October 1, 2013 to September 30, 2014* at p. 8 (January 15, 2015) (hereinafter referred to as "Hospital Transfers"). http://www.ct.gov/dph/lib/dph/ohca/misc/pa_13-208_sec._69_cardiac_transfers_report_final.pdf
[3] Application at 465.
[4] Application at 1444;1445; and 1446.

statewide. Backus questions the legitimacy of OHCA's analysis. Backus's representations are also inconsistent from the Application to the completeness question responses. Initially, Backus states that angioplasty volumes are expected to increase by 24%, states angioplasty volume is flat and then states volume is declining. These points represent only some of the incorrect assumptions that are serious flaws in Backus's analysis that cannot be reconciled and must lead to a finding that Backus has not established a public need.

B. Backus Relies Upon Improper Data to Assess Public Need

Furthering Backus's failure to establish public need, the Applicant relies on the wrong data and improperly uses cardiac risk factors to develop the Applicant's proposed patient utilization figures instead of relying on historic angioplasty data from Backus's service area. The Applicant dramatically and extensively describes many cardiac risk factors at length for the population in its "Angioplasty Region" rather than address the fact that the historical data for the service area will not yield qualifying utilization results. The 2015 community needs assessments provided by Backus in its initial CON application filing and subsequent completeness questions responses do not suggest the region is sicker, unhealthier, has poorer social determinants of care, or has barriers to access that would warrant the addition of a PCI program at Backus.

As depicted in Attachment B, C, and D, in nearly every category for each market analyzed (Eastern Region, Backus Hospital Service Area, and Windham Hospital Service Area), the communities fare equal or better than both Connecticut and/or United States averages. The Applicant cites to the fact that the "Angioplasty Region" population has a high percentage of residents over the age of 45 (45%) when in fact, that percentage is the same as the State's average.[5] Moreover, according to Backus's sources, the percent of residents aged 65+ is less

[5] Application at 454.

than Connecticut's rate (15% versus 16%). Thus, the age breakdown of the Angioplasty Region does not translate into need for an additional PCI provider as Backus's application would suggest. The Applicant cites "low socioeconomic status" for residents of the Angioplasty Region, and high percentage of households with median income less than $50,000 as reasons for high prevalence for coronary heart disease. According to data from the Connecticut Economic Resource Center (CERC) provided in Attachment E, only two of the 28 towns in the Angioplasty Region or Backus PSA have median household incomes less than $50,000. Furthermore, increased prevalence of coronary heart disease, as noted in a recent publication from the Connecticut Department of Public Health, is tied to annual incomes less than $25,000. Adults with these household incomes "are significantly more likely to have had a stroke or coronary heart disease compared to adults with annual household incomes of $50,000-74,999 and $75,000 or more." Thus there is no correlation that can be made between the household income of the region and increased need for PCI services.

The STEMI data cited in the Application[6] is from six years ago - too old to be relied upon. Further, Backus relies heavily upon heart disease mortality, which is not a predictor of PCI need. Heart disease mortality rates are declining nationally, statewide, and regionally. Data provided in Backus's initial CON application shows mortality rates in eastern Connecticut have fallen significantly recently, outpacing declines in Connecticut and the United States overall as depicted below.

[6] Application at 463.

Heart Disease Mortality Rate Trends				
	2005-2007	2007-2009	2009-2011	2011-2013
Eastern CT	182.5	178.3	174.4	165.7
CT	173.7	168.9	158.7	153.4
US	200.7	185.8	177.6	171.3
Heart Disease Mortality Rate % Change between Time Periods				
	2005-2007	2007-2009	2009-2011	2011-2013
Eastern CT		-2.3%	-2.2%	-5.0%
CT		-2.8%	-6.0%	-3.3%
US		-7.4%	-4.4%	-3.5%

Source: Eastern Region Community Health Assessment, provided by Backus in its initial CON application

Higher mortality does not translate into a need for more PCI services, as heart disease encompasses a multitude of diagnoses (e.g., cardiomyopathy, myocarditis, atrial fibrillation and flutter, endocarditis, etc.), conditions that can and often should be treated with alternative therapies such as medications or surgical interventions.

C. *The Applicant Has Failed to Acknowledge that Providers are Combating Heart Disease through Other Methods*

The Applicant fails to acknowledge that the health care community is combating heart disease through preventative methods including better control of high blood pressure and high cholesterol and smoking cessation, and fails to address the improvements in treatments, medication and quality of care.[7] The use of statin drugs and other non-interventional treatments will contribute to continuing declines of primary and elective angioplasty volumes. Factors contributing to the decline also include a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, the increasing use of techniques such as fractional

[7] "Generally, both primary and elective PCI volumes are declining in the nation and in Connecticut because of increased emphasis on other treatment modalities." *Hospital Transfers* at 10.

flow reserve to better evaluate lesion severity and the development and application of appropriate use criteria. These factors are not minor – they represent significant changes in the provision of cardiac care that have directly impacted the amount of angioplasty procedures nationwide and statewide. By failing to addressing the use of increased efforts to combat heart disease through methods other than primary and elective angioplasty, Backus has failed to properly and clearly assess the needs of the proposed service area.

D. Backus has Mischaracterized the Availability of Existing Services

Backus has mischaracterized the readily available and existing angioplasty services. As declared by OHCA itself, "[t]here is no evidence of unmet need for the provision of PCI in the system; however, there is indication of excess capacity."[8] L+M Hospital offers care only 17.1 miles and twenty-one (21) minutes away from Backus. The distance from L+M to Backus is shorter than the previously denied Norwalk Hospital program, which was denied, in part, due to proximity to other providers. Moreover, L+M Hospital has no backlog and can accept additional volume. Currently, 11.3% of the Angioplasty Region patients are served at L+M Hospital resulting in a large impact to L+M Hospital's existing PCI program.[9] Backus admits that "some towns in the OHCA defined region are better served by other institutions, such as Lawrence + Memorial, Hospital of Central Connecticut, or John Dempsy, due to the proximity of the patient's origin to the PCI capable facility."[10] Backus states that in Fiscal Year 2015, L+M treated 32 patients from Backus's proposed Angioplasty Region;[11] 32 cases represents a huge percentage of patients for programs that need 200 cases a year to maintain quality.

[8] *Hospital Transfers* at 8.
[9] Application at 46.
[10] Application at 1461.
[11] Application at 1464.

E. Backus's Own Inadequate Responses Are Problematic and Do Not Support a Finding of Public Need

Backus also argues that patients in the Angioplasty Region are subject to door to balloon times that are too long and over the suggested limits and therefore there is need in the Angioplasty Region.[12] Backus's door-in-door-out time ("DIDO"), defined as the time between arrival at a non-PCI-capable facility to discharge/transfer to a PCI-capable facility,[13] is seventy-three (73) minutes, forty- three (43) minutes over the recommended thirty (30) minute DIDO timeframe.[14] Should Backus meet the thirty (30) minute DIDO time and transfer patients to L+M which is only twenty-one (21) minutes away, Backus patients will be in a much more favorable position than patients who are subject to Backus's current DIDO average of seventy-three (73) minutes. Although Backus claims to have exhausted all means to reduce DIDO further, data Backus provides suggests other non-PCI-capable hospitals have been able to fare better, including Middlesex Hospital, Charlotte Hungerford Hospital, Griffin Hospital, and Day Kimball.[15] A finding of public need for a PCI program at Backus is highly questionable given that Backus has failed to adequately improve DIDO response time, and is thus contributing largely to any delays in time to device for STEMI patients. In addition, Backus's prolonged DIDO times call into question the ability of Backus to operate a safe and effective PCI program.

F. Historical PCI Discharges Do Not Support a Finding of Public Need

Lastly, the historical PCI discharges in the area do not support the Application. CHIME data shows that Hartford Hospital only had a total of 50, 49 and 45 PCI patients from New

[12] Application at 49.
[13] Application at 26.
[14] Application at 475.
[15] Application at 1450.

London, Windham and Tolland counties respectively in 2014. It is highly unlikely Backus will draw all Hartford Hospital's patients from New London, Windham and Tolland counties. Even if Backus were to take all of Hartford Hospital's angioplasty patients from Backus's proposed service area, it will not reach the threshold of 200 cases.[16] The current PCI discharges do not support Backus meeting the required 200 case minimum. Further, Backus will not meet the minimum number required for primary angioplasty.

In sum, Backus has failed to establish public need. The Applicant fails to establish clear public need because the Applicant does not adequately address declining PCI volume; relies upon improper data for its utilization prediction; has failed to acknowledge that providers are combating heart disease through other non-invasive methods; has mischaracterized the existing and available PCI services; has failed to address its own inadequate response times; and the historical discharge data does not support public need.

II. No Satisfactory Identification of the Patient Population to be Served

The Applicant has not satisfactorily identified the population to be served. The Applicant has not properly identified the population to be served because the Applicant utilized a fabricated service area; Backus fails to provide proper evidence to support the use of towns outside its traditional OHCA-defined service area; Backus has failed to address how it will change referral patterns; and Backus improperly assumes that volume from other service areas will transfer to Backus.

[16] See, "Hartford Hospital Inpatient PCI Volume Analysis by County, FY 2014" CHIME data.

A. The Applicant Has Fabricated the Service Area

The Applicant is using its own fabricated term ("Angioplasty Region") that does not align with the Hospital's historical service area or a recognized OHCA service area.[17] In fact, the Angioplasty Region contains seventeen (17) towns that are not included in the recognized Backus service area. Backus excludes Ledyard and Montville from their analysis of volume, citing these towns are closer to L+M.[18] As noted in Attachment F and Attachment G, this is not true. Travel time from these towns to Backus is shorter than to L+M. Therefore, it is not beyond reason to include L+M volumes from these towns as "at-risk" with the program at Backus, given the proximity of the towns to Backus vs. L+M. Proper hospital strategic planning is dependent on historical patient populations, CHIME data and other resources collected and analyzed by OHCA and other public and private agencies.

Backus has not followed these accepted methods and is instead anticipating drawing patients outside of its service area – presumably to ensure that it meets the required patient utilization figures required in the medical literature on the development of angioplasty programs. Some of these towns may send patients to closer, out of state providers. Backus fails to include out of state PCI providers and acknowledges the same in the first few pages of its Application. Backus is not the closest provider to four (4) towns in the Angioplasty Region. Pomfret, Putnam, Thompson, and Woodstock are all closer to UMass Memorial Medical Center ("UMass") located in Worcester, Massachusetts. UMass is full-service cardiovascular provider with primary and elective angioplasty, as well as a cardiac surgery program. As noted in the Day

[17] Application at 37.
[18] Application at 1454.

Kimball Healthcare ("DKH") Community Health Needs Assessment Implementation Strategy from September 9, 2013, DKH "strengthened [its] relationship with UMass for STEMI transfers" and "met regularly with [their] UMass partners to review STEMI data." Clearly, a strong referral relationship exists between DKH and UMass for STEMI patients, and patients' needs in these four (4) towns are already being met. Nine (9) towns in the "Angioplasty Region" are already within 30 minutes' travel time of an existing primary PCI provider (towns include Bozrah, Colchester, Columbia, Franklin, Hebron, Lisbon, Norwich, Preston, and Sprague). Patients' needs in these 9 towns are already being met. Two (2) towns not included in the "Angioplasty Region," but part of Backus's primary service area per established discharge data, OHCA and CMS are already within 30 minutes of an existing primary PCI provider (towns include Ledyard and Montville). Patients' needs in these 2 towns are already being met. The other 13 towns in the "Angioplasty Region" are within 31-45 minute drive time of an existing PCI provider (towns include Brooklyn, Canterbury, Chaplin, East Haddam, Griswold, Hampton, Killingly, Lebanon, Mansfield, Plainfield, Sterling, Voluntown, and Windham). Patients' needs in these 13 towns are already being met. By creating a broad service area, Backus has utilized false and insufficient evidence to support the projected patient population to be served.

B. Backus Fails to Provide Proper Evidence to Support the Use Towns Outside Recognized State and National Criteria for a Defined Service Area

Backus's relies upon on a consultant, 3d Health, Inc. ("3d"), to derive a contrived service area rather than rely on its own historical patient draw or state or national criteria for a defined service area. 3d also fails to provide adequate supporting documentation – for example, there is no backup for the source of Outpatient Elective PCI Cases or Unmet Need/Other Outmigration in the 3d report. Further, Backus contends that low PCI procedure rates in the Angioplasty Region

are the result of under-utilization of PCI services. Research evaluating geographic variation in PCI use rates have suggested that lower rates are not due to under-utilization, rather "geographic regions with lower PCI rates have a higher proportion of PCIs performed for appropriate indications." Thus, the lower utilization rate can be attributed to appropriate use.

C. Backus Has Failed to Address How It Will Change Referral Patterns

Backus is also anticipating drawing PCI volume from the pool of patients who are sent to Hartford Hospital and L+M Hospital. Backus has not satisfactorily identified that these patients will be now served at Backus because Backus has not offered any evidence that it will be able to change traditional and consistent referral patterns of sending patients to L+M, an existing provider of primary and elective angioplasty in the service area or to Hartford Hospital, a high-volume angioplasty program with surgical backup.

There is a large cardiology group that serves the Angioplasty Region that is affiliated with Yale (Cardiology Associates, Norwich, CT) and Backus has offered no evidence that such group would change its referral patterns of sending its patients to established affiliated programs at Yale or L+M. Backus anticipates 48 cases would shift to Backus from Yale;[19] based on current referral patterns, the shift of almost 50 cases a year is unreasonable. The Application does not address any other referral relationships by physicians in the area that would refer patients to Backus over other hospitals currently serving the market. It is not appropriate to assume that a patient who meets the certain angioplasty criteria in the Angioplasty Region will receive angioplasty at all or will receive such services at Backus. Patients may receive other

[19] Application at 1446.

treatment or obtain primary angioplasty at other facilities due to ambulance patterns or proximity to other locations.

D. Backus Improperly Assumes that Volume from Other Service Areas Will Transfer to Backus

Backus has improperly relied upon the combined ED market share for Backus and Windham Hospital; relying on Windham Hospital data is far-reaching. Additionally, based on L+M's experience, it is unreasonable to assume that Backus will retain all the volume based on STEMI incidence alone. L+M only realizes a 54% retention rate for patients with STEMI in the market – Backus's projections of 80% are unreasonable. Further, patients may seek elective angioplasty at other locations due to proximity, familiarity, backup surgery option, provider recommendation, referral patterns, etc. The Applicant even notes that 58% of its "Angioplasty Region" patients travel to Hartford Hospital or Yale to receive elective angioplasty.[20] Thus the anticipated "Angioplasty Region" does not account for patients who may want to have elective angioplasty at a different hospital (for example, Yale because it has open heart surgery backup or L+M Hospital because it is closer).

Backus's elective PCI projections are overstated. On page 1459 of the Application, Backus provides data which shows of 234 diagnostic catheterizations completed at Backus, 21.36% or 50 cases were transferred for elective PCI. This is consistent with L+M's existence experience as demonstrated below in Column E:

[20] Application at 45.

	Column A	Column B	Column C	Column D	Column E	Column F
	Total Diagnostic Caths at L+M	Total Patients Requiring Elective PCI	Total Patients with Elective PCI at L+M	Total Patients Transferred for Elective PCI	% of Diagnostic Caths with Elective PCI	% of Diagnostic Caths with Elective PCI at L+M
FY 12	583	108	0	108	18.5%	0.0%
FY 13 below elective PCI approval on 2/4/13	197	35	0	35	17.8%	0.0%
FY 13 after elective PCI approval on 2/4/13	354	84	55	29	23.7%	15.5%
FY 14	677	145	99	46	21.4%	14.6%
FY 15	632	128	95	33	20.3%	15.0%

As stated above, clinical guidelines specify that for certain high-risk patients, elective PCI at facilities without onsite surgical backup is contraindicated due to the increased potential for a serious complication during the procedure. For this reason, as demonstrated in Column F, only a subset of candidates for elective PCI can have their procedure at L+M. The rest are transferred or referred to another facility with onsite surgery capabilities.

Since Backus's proposed angioplasty services are markedly similar to L+M's established program, it would seem reasonable to assume Backus will have a similar experience to L+M. As applied, based on Backus's diagnostic catheterization volume[21] Backus's elective PCI volume would only be 35 cases (234 cases x 15%). This figure is significantly lower than Backus's stated projection of 151 cases.[22]

Additionally, a rule-of-thumb is every three (3) diagnostic catheterization procedures result in one (1) elective PCI case. Further, although literature states that approximately 89% of

[21] Application at 1459.
[22] Application at 70.

elective PCI cases are appropriate for sites without onsite surgery,[23] using this methodology, Backus's elective PCI volume would equate to 69 cases. However, L+M's capture rate is 74%. This 74% capture rate would more accurately reflect what Backus should expect. Using the 74% capture rate, Backus's elective volume would only equate to 58 cases. Thus under these two alternate methodologies, Backus's elective PCI volume is still significantly less than the hospital has projected in its CON application.

Even without calling into question Backus's projected primary cases (which is addressed elsewhere in this pre-file testimony and by my colleagues), Backus would only complete 148 PCI procedures in the first year of operation using the best case methodology above for elective volume (or 69 cases). Thus, Backus's volume would be far below the 200 case minimum recommended in the clinical guidelines.

Although clinical guidelines state that angioplasty services offered at hospitals that perform under 200 cases may be acceptable, such approval is only if the hospital is located in a region underserved because of geography. The 2014 guidelines have clearly defined geographic isolation "not by distance but by the time required for emergent transport of a STEMI patient to another facility."[24] The guideline states geographic isolation is demonstrated if the travel time between facilities is >30 minutes. As mentioned several times in this pre-filed testimony and by my colleagues, the travel time between Backus and L+M is 21 minutes. This time is far below the 30-minute threshold. Therefore, Backus has not met the criteria for geographic isolation, and it is inappropriate for Backus to operate angioplasty services that would not have a minimum of

[23] Aversano, T., et al. Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery. N Engl J Med 2012; 366: 1792-1802.
[24] *ACCF/AHA/SCAI Guidelines*, 2014 update, Catheterization and Cardiovascular Interventions 84:169, 180 (2014).

200 cases per year. As indicated above, even without accounting for statewide and national PCI volume decline and other factors, Backus will not hit the 200 case threshold.

Without an appropriate analysis of patient retention, the proposed patient population to be served is not identified. Additionally, Backus cannot expect to re-direct all "Angioplasty Region" volume from Hartford Hospital. Elective PCI programs without onsite cardiothoracic surgical backup are prohibited from performing cases on high risk patients with or without high risk lesions. Thus, it is entirely inappropriate to assume all Hartford cases would shift to Backus as this would be in direct contradiction to all recent clinical guidelines remarking on appropriate use of elective PCI.

In sum, Backus fails to support the finding of the population to be served. The Applicant has not properly identified the population to be served because the Applicant utilized a fabricated service area; Backus fails to provide proper evidence to support the use towns outside its traditional OHCA-defined service area; Backus has failed to address how it will change referral patterns; and Backus improperly assumes that volume from other service areas will transfer to Backus.

III. The Project is not Consistent with Standards and Guidelines

One of the most critical factors in reviewing CON applications is how the proposal meets standards and guidelines established and/or adopted by OHCA. Any such standards and guidelines are utilized to ensure all potential patients in the state receive safe and efficient care. Applicant's arguments are inconsistent with benchmarks and standards adopted by OHCA

through its adoption of the peer-reviewed ACCF/AHA/SCAI Guidelines,[25] as amended.[26] Backus's proposal is inconsistent with the standards and guidelines because the proposal is not consistent with guidelines that discourage the establishment of duplicative services within a 30-minute transfer time; OHCA's guidelines do not support the development of directly competitive programs; and Backus improperly relies on obsolete guidance.

A. The Proposal is Not Consistent with Guidelines Which Discourage the Establishment of Duplicative Services within a 30 Minute Transfer Time

First, the proposal is not consistent with a major factor in the ACCF/AHA/SCAI Guidelines which states that "the development of PCI facilities within a 30-minute transfer time to an established facility is therefore strongly discouraged."[27] L+M's established primary and elective angioplasty program is a mere twenty-one (21) minutes away from Backus Hospital and is clearly within the recommended thirty (30) minute transfer time. The Applicant wholly ignores this factor and offers immaterial evidence about patient origin distance from L+M Hospital to distract from the fact that L+M Hospital is a qualifying transfer location for Backus. Patients are better served at existing facilities as there is no benefit to competing programs within the same geographical region. L+M Hospital's existing primary and elective angioplasty program meets the needs of all patients of Backus Hospital as it is within the recommended transfer time. The ACCF/AHA/SCAI Guidelines state that "[i]f the transfer time is ≤ 30 min, it

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[25] *"ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention; a Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiograph and Interventions,"* as updated and amended (the "ACCF/AHA/SCAI Guidelines").

[26] OHCA has endorsed the ACCF/AHA/SCAI Guidelines. Connecticut Department of Public Health Office of Health Care Access, *Statewide Health Care Facilities and Services Plan,* at p. 41 (October 2012; supplemented 2014) (hereinafter referred to as "Statewide Health Plan") http://www.ct.gov/dph/lib/dph/state_health_planning/dphplans/ohca_statewide_facilities_services_plan_2012.pdf; http://www.ct.gov/dph/lib/dph/ohca/publications/2014/final_2014__facilities_plan_-_2_24_15.pdf; *Hospital Transfers.*

[27] *ACCF/AHA/SCAI Guidelines*, 2014 update, Catheterization and Cardiovascular Interventions 84:169, 180 (2014).

is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital."[28] The addition of a program well within a thirty (30) minute transfer time from Backus Hospital would be redundant and would be directly against the directives of the established ACCF/AHA/SCAI Guidelines adopted by OHCA and by the cardiology community as a whole. More PCI sites have been shown to not improve access sufficiently to justify the expense, and the impact on alternative providers whose volume inevitably is negatively impacted by new sites siphoning volume in a declining PCI market.

B. OHCA's Guidelines Do Not Support the Development of Directly Competitive Programs

Second, Backus's proposed primary and elective angioplasty program will be in direct competition with "another PCI program in the same geographic area" (L+M Hospital), which is against OHCA's guidelines on the development of new angioplasty programs and, as OHCA continues to command, would "not be in the best interest of the community."[29] As such, competition with L+M Hospital is not in the best interest of the community. In direct contrast to OHCA's directive, Backus incorrectly states that the impact it will have is not significant and it will not adversely affect existing programs, even though L+M Hospital is in Backus's geographic area and serves a large portion of angioplasty patients from Backus's service area. In FY 2015, 32 PCI cases at L+M originated from patients who resided within Backus's "Angioplasty Region."[30] This represents a significant portion of L+M's total PCI volume for FY 2015. Backus also represents that 51 PCI cases at L+M originated from patients who resided within Backus's OHCA-defined service area.[31] Given the patient origin for L+M's existing volume, L+M is at-risk for a substantial volume reduction should Backus be granted approval to

[28] *ACCF/AHA/SCAI Guidelines*, 2014 update at 180.
[29] *Statewide Health Plan* at p. 39.
[30] Application at 1464.
[31] Application at 1458.

start a PCI program. This decline will reduce L+M volume to well below 200 cases, the minimum threshold recommended in the latest expert clinical guidelines.

In sum, Backus's proposal is inconsistent with standards and guidelines because the proposal is not consistent with guidelines that discourage the establishment of duplicative services within a 30-minute transfer time and OHCA's guidelines do not support the development of directly competitive programs.

IV. The Proposal is Unnecessary and Duplicative

Existing health care facilities including L+M Hospital are satisfactorily meeting the needs of the Backus service area and any additional angioplasty programs are unnecessary and duplicative. Backus's proposed patient population draws patients that are being serviced by existing, OHCA-approved PCI providers (e.g. Hartford Hospital, Yale, L+M Hospital). L+M has two catheterization labs, no backlog, and the capacity to accommodate and accept additional PCI volume. Backus has not fully acknowledged the presence of non-Connecticut providers, even when they are closest PCI-capable facility to Angioplasty Region residents. Duplicative services within the thirty (30) minute transfer, such as patients transferred from Backus to L+M Hospital, are unnecessary. Cardiac physicians in Connecticut perform angioplasties at various locations – to add an additional location for these providers without a clear benefit to the public is unnecessary and results in providers referring patients to certain hospitals to keep institutional volumes at certain levels. Specifically, "[c]ardiac experts guidelines recommend that to maintain competency, physicians must perform PCI procedures at high volume institutions; this has an impact on PCI referral patterns"[32] Approving this proposal will add an identical service to the

[32] *Hospital Transfers* at 9.

same geographic region in the state. Backus has not listed any incidents of patient harm based on having to transfer patients to other hospitals.

V. Conclusion

In conclusion, Backus's application for primary and elective angioplasty should be denied because Backus has failed to establish a public need; the Applicant has not has satisfactorily identified the population to be served by failing to accurately identify the service area and failing to estimate utilization data in a reasonable manner; the proposal is not consistent with standards and guidelines; and the proposal is unnecessary and duplicative. We ask that this application should be held to the high standards and scrutinized under the same light as other angioplasty CONs in recent years. In today's fragile hospital marketplace, hospitals must strategically plan to continue to first offer the basic and safety net services for communities and ensure the existence of the same.

Thank you for providing the opportunity to speak today. I am happy to answer any questions.

Attachment A
CV

Daniel Rissi, MD

365 Montauk Avenue
New London, CT 06320
(860) 442-0711

Professional Experience

Febuary 2008 to present; Lawrence & Memorial Healthcare; VP/Chief Medical & Clinical Operations Officer
June 2006 to February 2008; Lawrence and Memorial Hospital; Vice President and Chief Operating Officer
October 2005 to January 2006; Olean General Hospital; Interim President and Chief Executive Officer
January 2003 to June 2006; Olean General Hospital; Vice President for Medical Affairs
March 2002 to August 2002: Blue Hill Memorial Hospital; Interim Chief Executive Officer
1990 to 2002: Blue Hill Memorial Hospital; Medical Director (full time since 1998); Chief of Staff
1996 to 2002: Maine Network for Health; Medical Director (1998-2002)

Additional Professional Activities

2014 to present: CT Hospital Association Committee on Patient Care Quality
2010 to present: CT Medical Examining Board; physician member
2009 to present: Qualidigm; Board member
2003-2006: Olean General Hospital, Olean, New York; active medical staff
1980-2003: Blue Hill Memorial Hospital, Blue Hill, Maine; active medical staff
1980-2003: Eastern Maine Medical Center, Bangor, Maine; affiliate medical staff
1980-1994: Island Medical Center Doctors, Stonington, Maine; physician, managing partner

Education and Training

American Board of Family Medicine; certified 1980, recertified 1986,1992, 1998, 2004, 2013
Certificate of added Qualification in Geriatrics, AAFP; certified 1988; recertified 1998
Medical Review Officer; certified by AAMRO 2003
Aviation Medical Examiner (FAA); certified 1981, recertified 1986, 1991
State of Maine Medical Examiner; certified 1977
1977-1980 Eastern Maine Medical Center; Residency in Family Medicine
1973-1977 Johns Hopkins University School of Medicine; MD
1969-1973 Yale University; BA

Professional Memberships

American College of Physician Executives; member since 1996
American Academy of Family Physicians; member since 1980; Fellowship 1994
National Board of Medical Examiners; diplomate 1977

Attachment B
Eastern Region Community Needs Statistics
Source: Backus Initial CON.

		CT	US	Eastern Region
High Blood Pressure	% Told Have High Blood Pressure (Ever)*	31.1	34.1	35.7
High Blood Pressure	% Taking Action to Control High Blood Pressure	n/a	89.2	91.1
High Blood Pressure	% Blood Pressure Checkin in Past 2 Years	n/a	91.0	96.8
High Cholesterol	% Told Have High Cholesterol (Ever)*	37.8	29.9	32.4
High Cholesterol	% Taking Action to Control High Cholesterol	n/a	81.4	84.6
High Cholesterol	% Cholesterol Checked in Past 5 Years	83.1	86.6	93.4
Smoking	% of Population who are Current Smokers	15.5	14.9	16.6
Diabetes	Diabetes Age Adjusted Death Rate	14.4	21.3	15.8
Diabetes	% of Population with Diabetes/High Blood Sugar	8.1	11.7	11.0
Obesity	% of Overweight Population (BMI 25+)	62.6	63.1	66.2
Physical Inactivity	% of Population with No Physical Activity	24.9	30.4	27.0
Heart Disease	% Heart Disease	n/a	6.1	5.9
Heart Disease	% 1+ Cardiovascular Risk Factor	n/a	82.3	85.1
Heart Disease	% Heart Attack	n/a	3.9	n/a
Social Determinants	Population in Poverty	10.0	14.9	8.6
Social Determinants	Population Below 200% FPL	22.4	33.6	20.8
Social Determinants	No High School Diploma (Age 25+)	11.0	14.3	9.9
Social Determinants	Unemployment Rate (Age 16+)	5.7	8.4	5.8
Social Determinants	Linguistically Isolated Population	4.7	4.9	2.6
Overall Health	% Fair/Poor Physical Health	13.3	15.3	12.7
Access to Health Services	% (Age 18-64) Lack Health Insurance	12.3	15.1	7.1
Access to Health Services	% (Insured) Went Without Coverage in Past Year	n/a	8.1	5.8
Access to Health Services	% Difficulty Accessing Healthcare in Past Year	n/a	39.9	36.9
Access to Health Services	% Transportation Hindered Dr. Visit in Past Year	n/a	9.4	6.5

LEGEND	
	= better than CT or US average
	= similar to CT or US average
	= worse than CT or US average

Attachment C

Backus Hospital Service Area Community Needs Statistics

Source: Backus Initial CON and Completeness Responses.

		CT	US	Backus Hospital Service Area
High Blood Pressure	% Told Have High Blood Pressure (Ever)*	31.5	34.1	39.5
High Blood Pressure	% Taking Action to Control High Blood Pressure	n/a	89.2	89.0
High Blood Pressure	% Blood Pressure Checkin in Past 2 Years	n/a	91.0	96.3
High Cholesterol	% Told Have High Cholesterol (Ever)*	37.8	29.9	31.7
High Cholesterol	% Taking Action to Control High Cholesterol	n/a	81.4	87.0
High Cholesterol	% Cholesterol Checked in Past 5 Years	83.1	86.6	91.9
Smoking	% of Population who are Current Smokers	15.5	14.9	18.9
Diabetes	Diabetes Age Adjusted Death Rate	14.8	21.3	n/a
Diabetes	% of Population with Diabetes/High Blood Sugar	8.3	11.7	n/a
Obesity	% of Overweight Population (BMI 25+)	63.6	65.1	69.5
Physical Inactivity	% of Population with No Physical Activity	24.9	26.3	28.5
Heart Disease	% Heart Disease	n/a	6.1	5.8
Heart Disease	% 1+ Cardiovascular Risk Factor	n/a	82.3	88.2
Heart Disease	% Heart Attack	n/a	3.9	4.0
Social Determinants	Population in Poverty	10.0	14.9	9.2
Social Determinants	Population Below 200% FPL	22.4	33.6	22.5
Social Determinants	No High School Diploma (Age 25+)	11.0	14.3	10.9
Social Determinants	Unemployment Rate (Age 16+)	5.7	5.4	n/a
Social Determinants	Linguistically Isolated Population	4.7	4.9	3.3
Overall Health	% Fair/Poor Physical Health	13.3	15.3	13.5
Access to Health Services	% (Age 18-64) Lack Health Insurance	12.3	15.1	6.8
Access to Health Services	% (Insured) Went Without Coverage in Past Year	n/a	8.1	5.9
Access to Health Services	% Difficulty Accessing Healthcare in Past Year	n/a	39.9	36.2
Access to Health Services	% Transportation Hindered Dr. Visit in Past Year	n/a	9.4	6.2

LEGEND	
	= better than CT or US average
	= similar to CT or US average
	= worse than CT or US average

Attachment D

Windham Hospital Service Area Community Needs Statistics

Source: http://www.windhamhospital.org/File%20Library/Health%20and%20Community/PDFs/2015-PRC-CHNA-Report---Windham-Hospital--Hartford-HealthCare-.pdf (accessed October 15, 2015).

		CT	US	Windham Hospital Service Area
High Blood Pressure	% Told Have High Blood Pressure (Ever)*	31.3	34.1	28.9
High Blood Pressure	% Taking Action to Control High Blood Pressure	n/a	89.2	95.1
High Blood Pressure	% Blood Pressure Checkin in Past 2 Years	n/a	91.0	97.7
High Cholesterol	% Told Have High Cholesterol (Ever)*	37.8	29.9	28.2
High Cholesterol	% Taking Action to Control High Cholesterol	n/a	81.4	89.0
High Cholesterol	% Cholesterol Checked in Past 5 Years	83.1	86.6	94.5
Smoking	% of Population who are Current Smokers	15.5	14.9	14.7
Diabetes	Diabetes Age Adjusted Death Rate	14.8	21.3	n/a
Diabetes	% of Population with Diabetes/High Blood Sugar	8.3	11.7	n/a
Obesity	% of Overweight Population (BMI 25+)	62.6	63.1	64.9
Physical Inactivity	% of Population with No Physical Activity	24.9	20.7	21.0
Heart Disease	% Heart Disease	n/a	6.1	4.7
Heart Disease	% 1+ Cardiovascular Risk Factor	n/a	82.3	82.9
Heart Disease	% Heart Attack	n/a	3.9	2.7
Social Determinants	Population in Poverty	10.0	14.9	9.1
Social Determinants	Population Below 200% FPL	22.4	33.6	21.1
Social Determinants	No High School Diploma (Age 25+)	11.0	14.3	10.4
Social Determinants	Unemployment Rate (Age 16+)	7.8	7.4	5.7
Social Determinants	Linguistically Isolated Population	4.7	4.9	1.8
Overall Health	% Fair/Poor Physical Health	13.3	15.3	10.7
Access to Health Services	% (Age 18-64) Lack Health Insurance	12.3	15.1	8.2
Access to Health Services	% (Insured) Went Without Coverage in Past Year	n/a	8.1	3.9
Access to Health Services	% Difficulty Accessing Healthcare in Past Year	n/a	39.9	39.0
Access to Health Services	% Transportation Hindered Dr. Visit in Past Year	n/a	9.4	5.6

LEGEND
= better than CT or US average
= similar to CT or US average
= worse than CT or US average

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Attachment E
Median Household Income by Town
Source: CERC, 2014

	Backus PSA	Angioplasty Region	Median Household Income
Canterbury	X	X	$ 66,641
Colchester	X	X	$ 92,522
Griswold	X	X	$ 64,574
Ledyard	X		$ 88,057
Lisbon	X	X	$ 80,539
Montville	X		$ 67,262
Norwich	X	X	$ 51,304
Plainfield	X	X	$ 62,775
Preston	X	X	$ 76,296
Sprague	X	X	$ 67,415
Bozrah		X	$ 83,188
Brooklyn		X	$ 62,857
Chaplin		X	$ 75,333
Columbia		X	$ 92,973
East Haddam		X	$ 91,146
Franklin		X	$ 88,333
Hampton		X	$ 75,278
Hebron		X	$ 114,286
Killingly		X	$ 55,598
Lebanon		X	$ 81,120
Mansfield		X	$ 67,615
Pomfret		X	$ 82,661
Putnam		X	$ 46,440
Sterling		X	$ 67,794
Thompson		X	$ 63,385
Voluntown		X	$ 74,032
Windham		X	$ 41,007
Woodstock		X	$ 81,705

Attachment F

Travel or Drive Time to Select Hospitals by Town (in minutes)

Source: Google Maps, 2016.

Note: all hospitals listed except Backus Hospital can perform primary and elective PCI

	Backus Hospital	**Hartford Hospital**	**St. Francis Hospital**	**L+M Hospital**	**Rhode Island Hospital**	**Miriam Hospital**	**Umass Medical center**	**Kent County Hospital**
Town	Norwich	Hartford	Hartford	New London	Providence	Providence	Worcester	Warwick
State	CT	CT	CT	CT	RI	RI	MA	RI
Bozrah	5	35	34	23	56	59	56	50
Brooklyn	26	51	51	43	40	44	39	42
Canterbury	18	53	52	35	43	47	44	45
Chaplin	29	42	42	46	54	58	51	56
Colchester	15	28	28	34	65	69	66	60
Columbia	22	30	29	39	65	68	62	67
East Haddam	27	35	35	40	77	81	78	71
Franklin	9	42	42	26	59	63	60	54
Griswold	16	53	52	33	45	50	50	38
Hampton	27	45	45	45	48	51	47	50
Hebron	24	26	25	42	71	75	67	69
Killingly	31	64	64	48	35	39	38	37
Lebanon	13	38	38	33	63	67	64	58
Ledyard	15	52	52	18	53	58	63	46
Lisbon	8	45	45	25	52	55	52	44
Mansfield	31	37	36	48	64	68	54	66
Montville	13	44	44	17	60	65	64	52
Norwich	5	44	44	25	54	59	59	46
Plainfield	17	53	53	34	40	44	41	41
Pomfret	37	50	50	54	46	49	34	48
Preston	11	50	50	30	51	58	57	43
Putnam	31	60	60	48	41	45	26	43
Sprague	12	47	46	30	56	60	57	50
Sterling	23	60	60	40	39	42	44	34
Thompson	35	62	61	52	45	49	24	47
Voluntown	19	56	56	36	39	43	53	31
Windham	18	40	39	35	56	60	57	58
Woodstock	39	52	51	56	49	53	34	51

Attachment G:

Distance to Select Hospitals by Town (in miles)

Source: Google Maps, 2016.

Note: all hospitals listed except Backus Hospital can perform primary and elective PCI

	Backus Hospital	**Hartford Hospital**	**St. Francis Hospital**	**L+M Hospital**	**Rhode Island Hospital**	**Miriam Hospital**	**Umass Medical center**	**Kent County Hospital**
Town	Norwich	Hartford	Hartford	New London	Providence	Providence	Worcester	Warwick
State	CT	CT	CT	CT	RI	RI	MA	RI
Bozrah	4.9	34.8	35.7	19.3	53.2	54.8	63.6	45.8
Brooklyn	22.5	44.1	44.9	36.7	31.6	33.2	40.5	34.6
Canterbury	16.0	43.5	44.2	30.2	35.8	37.4	46.3	34.1
Chaplin	20.8	35.4	36.2	35.1	43.7	45.4	47.5	46.8
Colchester	14.1	25.6	26.5	21.3	62.3	64.0	72.8	55.0
Columbia	16.7	24.2	25.0	31.1	53.0	54.6	57.9	56.0
East Haddam	24.2	27.4	28.2	35.8	72.5	74.1	82.9	65.1
Franklin	6.6	40.5	41.4	20.9	54.8	56.4	65.3	47.5
Griswold	13.2	49.3	50.1	27.4	40.5	44.4	52.1	32.3
Hampton	18.5	38.3	39.0	35.9	37.5	39.1	46.5	40.5
Hebron	21.6	21.9	22.8	27.7	57.7	59.3	65.7	62.5
Killingly	30.1	51.2	52.0	44.3	26.0	27.6	36.4	29.1
Lebanon	9.9	31.6	32.4	24.3	58.2	59.8	68.6	50.8
Ledyard	8.9	50.6	51.5	11.7	54.5	58.4	63.5	46.3
Lisbon	8.1	44.1	45.0	22.3	45.0	46.3	55.1	36.8
Mansfield	21.5	26.7	27.5	35.8	49.8	51.4	47.7	52.9
Montville	11.3	38.9	39.8	11.0	63.2	67.1	69.8	55.0
Norwich	1.6	41.0	41.9	16.5	48.2	52.1	59.7	40.0
Plainfield	16.7	52.8	53.6	30.9	34.1	35.8	44.6	31.3
Pomfret	36.1	42.7	43.5	50.3	34.3	35.9	31.4	37.3
Preston	5.8	45.3	46.2	20.7	45.8	49.7	59.2	37.6
Putnam	35.1	48.7	49.5	49.3	29.7	31.4	28.4	32.8
Sprague	6.9	43.7	44.6	24.3	49.4	51.0	59.9	42.1
Sterling	22.9	58.9	59.8	37.1	29.4	31.1	45.5	26.1
Thompson	39.2	53.2	54.0	53.4	37.4	39.0	24.5	40.5
Voluntown	15.8	51.8	52.7	30.0	35.8	39.7	54.7	27.6
Windham	13.5	33.3	34.1	27.9	46.0	47.6	56.4	44.3
Woodstock	39.0	46.8	47.6	53.2	37.2	38.8	31.2	40.3

DEPARTMENT OF PUBLIC HEALTH	:	
DIVISION OF OFFICE OF	:	
HEALTH CARE ACCESS	:	**DOCKET NO. 15-32031-CON**
	:	
IN RE: ESTABLISH AND OPERATE	:	
A PRIMARY AND ELECTIVE	:	
ANGIOPLASTY PROGRAM AT THE	:	
WILLIAM W. BACKUS HOSPITAL	:	**MARCH 18, 2016**

PRE-FILE TESTIMONY OF SETH VAN ESSENDELFT

Good Morning. My name is Seth Van Essendelft and I am the Chief Financial Officer and Vice President of Support Services at Lawrence + Memorial Hospital, Inc. ("L+M Hospital" or "L+M"). I am here today to speak in opposition of the William W. Backus Hospital (the "Applicant" or "Backus") Certificate of Need ("CON") application (the "Application") to provide primary and elective angioplasty without onsite cardiothoracic surgical backup.

My testimony will address: (i) the adverse financial impact that the Applicant's proposed services will have on L+M, a newly-established program; (ii) the negative impact to the financial strength of the health care system in the state, (iii) that evidence suggests the services are not financially feasible for the Applicant, and (iv) that the proposed services will adversely affect health care costs and accessibility.

Professional Background

My professional background is described in the Curriculum Vitae attached as Exhibit A to my testimony. I am currently Chief Financial Officer and Vice President of Support Services of L+M Health Care where I oversee the financial and support operations at two acute care hospitals (L+M and Westerly Hospitals), and the Lawrence + Memorial Medical Group. Prior to joining L+M, I served in other similar financial and operational roles of progressing

responsibilities at two other health systems outside CT, and one of the national health insurance companies.

I. Negative Impact to L+M's Established Program

The Applicant's proposed services will have a negative impact on L+M's newly established program. In 2013, L+M received CON approval to establish elective angioplasty as an adjunct to its existing primary program. There were several important clinical and community reasons to add this service, and the reality to improve the financial performance of L+M's angioplasty program, and reduce the operating loss of the primary underlying program. L+M has dedicated precious financial resources and personnel to its angioplasty program. L+M's expenditure to staff the program 24/7/365 with highly trained interventional cardiologists is very costly, especially for community hospitals such as L+M where the market volume is not large compared to much larger metropolitan areas. L+M's yearly costs just to maintain 24/7/365 access is in excess of $1.5 million. In addition, L+M continues to invest in technologies and equipment to support the program, including two state-of-the-art cardiac catheterization labs at L+M hospital. The majority of these operational costs and all of the capital costs are fixed, and as such do not fluctuate with volume. With dwindling volumes statewide and nationally, the cost per case to provide PCI services is beyond the revenues generated. However, L+M provides such service at a loss, to meet community needs and improve access for this region. By adding elective PCI, and not substantially altering the fee to staff the program, L+M improved the financial position of its much needed PCI program.

Additionally, L+M has continued trying to grow its program by providing outreach to neighboring hospitals, including Backus Hospital, and Westerly Hospital in Rhode Island. In the Backus Application it was noted that Backus anticipates drawing patients from the L+M service

area. This will decrease L+M's volume and associated revenues which will have a negative impact on both the proficiency and financial viability. If approved, the Applicant's proposal will reduce both primary and elective PCI volume at L+M, thus leading to larger financial losses as L+M's fee to have 24/7/365 physician coverage of its program is consistent, regardless of volume. In FY 2015 alone, Backus states that 32 PCI cases at L+M originated from patients who reside within Backus's "Angioplasty Region."[1] This represents a significant portion of L+M's total PCI volume for FY 2015. Backus also represents that 51 PCI cases at L+M originated from patients who resided within Backus's OHCA-defined service area.[2] This represents a 23.6% portion of L+M's total PCI volume.[3] Any way it is looked at, a large percentage of L+M's patients derive from Backus's service area. Were Backus to siphon these cases from L+M, L+M will experience a significant incremental financial loss. The applicants, in their proposal, contend that L+M will see no volume reductions with the establishment of their PCI program. Given the patient origin for L+M's existing volume, this assumption seems highly unlikely and is not supported by existing data, with outcomes contrary to the assertion that will very likely place L+M's program at financial risk.

II. Negative Impact to the Financial Strength of the Health Care System

There will be a negative impact to the financial strength of Connecticut's health care system by the addition of duplicative and costly angioplasty services at Backus Hospital. This negative impact is shown by Backus's proposal being an improper use of its funds and the establishment of an unnecessary program, and the financial adverse impact to established programs at L+M and other hospitals.

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[1] Application at 1464.
[2] Application at 1458.
[3] *Id.*

It is no secret that Connecticut hospitals are facing serious financial challenges in the current healthcare market. The gap between costs and reimbursement and other financial concerns has placed a significant financial burden on Connecticut hospitals. These financial challenges are leading to further consolidation of the market to best utilize resources and capacity. More so now than ever, hospitals must carefully plan strategic investments or risk disrupting the fragile financial status of the hospital and the Connecticut health care environment. Without careful planning, the State's health care system is threatened.

The research and due diligence we have evaluated suggests that Backus has not adequately considered its provision of primary and/or elective angioplasty in light of these fundamental financial and quality concerns. Simply put, Backus is proposing to invest nearly $5 million dollars of scarce capital resources into a program that is duplicative of existing providers in the service area and that will continuously operate at a larger deficit each year with no prospective break-even point. Backus highlights the minimal savings from transportation costs but these proposed savings are overshadowed by the considerable annual loss accounted for in the operation of the proposed program. Backus also fails to address how it will adapt and support a full primary and elective angioplasty program in light of recent negative financial impacts, especially the increased hospital taxes and inadequate Medicaid reimbursement. By operating a duplicative program, which will operate at a loss, and attempting to extract patients away from existing providers at established angioplasty services in the service area, Backus negatively impacts the financial strength of the broader health care system.

Additionally, drawing patients from other hospitals that adequately meet the primary and elective angioplasty needs of the service area will result in negative impacts to those hospitals with existing programs, especially programs that are continuing to build volume in order to be

fully established. Primary and elective angioplasty are particularly expensive and laborious programs to operate due, in part, to the requirement to have trained cardiologists on call twenty-four (24) hours a day. Backus claims that the program will offer a critical service to its "Angioplasty Region" patients however Backus does not address how the program will negatively affect the state's current programs. As it is unlikely that Backus will reach its projected utilization figures based on other testimony offered, Backus is doing a disservice to the residents of this state by directing scarce resources to a program that, because it will not meet the minimum utilization required of facilities and will offer more harm than benefit, ultimately compromising patient care. Addition of a program to the service area will contribute to a decrease in the overall financial stability of the state's health care delivery system.

III. Project is Not Financially Feasible

By the Applicant's own admission, this proposal is not a profitable endeavor and specifically shows a decreasing deficit continuing from year to year. Backus will experience a significant financial loss in order to offer angioplasty services. The project will require an almost $5 million-dollar investment to upgrade the Backus facilities to be able to accept primary and elective angioplasty cases.[4] Based on the unprofitability of the proposal and the availability of duplicative angioplasty programs in the area, it is questionable why Backus is seeking approval of this project. Furthering the fact that the financial projections are not feasible, the Applicant's financial projections are based on inflated volumes that did not take into account declining angioplasty volumes and demand levels across the nation and the state.[5]

[4] *Application* at 67.
[5] *Hospital Transfers* at 8.

00069

IV. Project Will Adversely Impact Health Care Costs and Accessibility

The Applicant has outwardly stated this is not a profitable endeavor and that a large capital investment will be required to operate the program. The return on this capital investment may never be realized at Backus Hospital, which may require a different financial perspective and passing of costs onto patients and all healthcare stakeholders as resources become increasingly restrictive. It most certainly does not consider the implications to L+M as outlined earlier. Additionally, while our comments have focused on the operating costs of the hospital, we should be clear that there will be increasing costs and challenges in recruiting and retaining specialized staff and physicians to support duplicative programs without either resulting in sufficient volume to ensure sustainability. The introduction of an additional, unnecessary primary and/or elective angioplasty program into the service area will result in undermining the quality of PCI services at all hospitals in the service area. "Cardiac experts guidelines recommend that to maintain competency, physicians must perform PCI procedures at high volume institutions; this has an impact on PCI referral patterns"[6]. This type of result could prevent Backus from every truly developing a high quality program, while at the same time, place real risk on diluting the proficiency of the L+M program, which in both cases adversely drives up health care costs for payors and patients.

In addition, the 2014 SCAI/ACC/AHA Guidelines for PCI without onsite surgery state, "for the future, the focus must now shift to developing a rational plan for the distribution of PCI services. Small PCI programs with large fixed costs are inefficient and unnecessary if they do not improve access in areas of need." The guideline goes onto to state, "the writing group reaffirms the statement from the 2011 ACCF/AHA/SCAI PCI Guidelines that "desires for

[6] *Hospital Transfers* at 9.

personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate consideration for initiation of PCI programs without on-site cardiac surgery" and suggests new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations." For the first time, the 2014 guideline clearly defines geographic isolation as "not by distance but by the time required for emergency transport of a STEMI patient to another facility" and states "multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access. If the transfer time is $\leq$30 min, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital." Therefore, the guideline states "the development of PCI facilities within a 30-minute emergency transfer time to an established facility is therefore strongly discouraged." As has been stated, Backus is twenty-one (21) minutes away from L+M, thus the latest clinical guidelines strongly deter programs like Backus is suggesting from forming. Not only are there quality implications of multiple low volume centers, but the guideline cautions that "further declines in PCI volumes might necessitate the closure of PCI programs in the future." Although L+M has provided much needed PCI services to the region to meet the community need at a financial loss the institution for years, even greater financial losses due to less volume will be a great burden to L+M and may impact L+M's ability to invest in its PCI or other program development.

V. Conclusion

In conclusion, Backus's application for primary and elective angioplasty should be denied because the proposal (i) will have an adverse financial impact on L+M, a newly-established program; (ii) will negatively impact the financial strength of the health care system in

Connecticut, (iii) is not financially feasible for the Applicant, and (iv) will increase health care costs, threaten quality and accessibility. In today's fragile hospital marketplace, it is important now more than ever to allocate financial resources prudently in order to continue to provide the basic healthcare safety net services for communities.

Thank you for providing the opportunity to speak today. I am happy to answer any questions. My colleagues will discuss the administrative and clinical deficiencies of the Application.

Attachment A
CV

Curriculum Vitae

Seth Van Essendelft

152 Long Wharf Road
Mystic, Connecticut 06355
Cell (252) 320-2032
Email svanessendelft@lmhosp.org

PRESENT POSITION

Lawrence + Memorial Healthcare– New London, CT & Westerly, RI

Chief Financial Officer/ Vice President of Support Services	2014 – Present

PREVIOUS POSITIONS

Vidant Health– Greenville, NC

Vice President of Financial Services (Financial Officer), Vidant Medical Center	2011 – 2014
Vice President of Financial Operations (Financial Shared Services), Vidant Health	2009 – 2011

Doctors Hospital– Coral Gables, FL

Financial Officer/Controller	2006 – 2009

CIGNA Corporation –Various Locations

CIGNA Healthcare, Dental & Vision Subsidiary	
AVP, Director of Strategic Planning and Control, Plantation, FL	2005 – 2006
Financial Leadership Program, Hartford, CT	2000 – 2005
CIGNA Healthcare Division	
Director of Capital Planning	2003 – 2005
Assistant Director, PPO Product Controller	2001 – 2003
CIGNA Retirement and Investments Division	
Assistant Director, Consolidated Asset Financial Reporting	2000 – 2001

PREVIOUS MILITARY EXPERIENCE

United States Coast Guard –Various Locations 1991 – 2011

Senior Reserve Officer, Coast Guard Sector - Miami, FL	2005 – 2011
Command Center Operations Controller, First Coast Guard District – Boston, MA	2000 – 2005
Budget Officer, Pacific Area Command – Alameda, CA	1998 – 2000
Commanding Officer, Cutter Point Huron – Virginia Beach, VA	1994 – 1996
Department Head, Cutter Diligence – Wilmington, NC	1991 – 1994

EDUCATION

M.B.A

The College of William and Mary, Graduate School of Business – Williamsburg, VA 1997

B.S., Management

United States Coast Guard Academy – New London, CT 1991

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TABLE OF THE RECORD

APPLICANT: **The William W. Backus Hospital**

DOCKET NUMBER: **15-32031-CON**

PUBLIC HEARING: **March 23, 2016 at 9:30 a.m.**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room**
Hartford, Connecticut

EXHIBIT	DESCRIPTION
A	Letter from The William W. Backus Hospital (Applicant) dated September 30, 2015 enclosing the Certificate of Need (CON) application to Establish and Operate a Primary and Elecive Angioplasty Program under Docket Number 15-32031, received by OHCA on September 30, 2015. (1437 Pages)
B	Letters of support in the matter of the CON application filed under Docket Number 15-32031, received by OHCA on various dates. (3 pages)
C	OHCA's letter to the Applicants dated October 30, 2015, requesting Additional information and/or clarification in the matter of the CON application under Docket Number 15-32031.(7 Pages)
D	Designation letter dated December 16, 2015 of Hearing Officer in the matter of the CON application under Docket Number 15-32031. (1 page)
E	Applicant's responses to OHCA's letter of October 30, 2015 along with a revised Exhibit 24, dated December 30, 2015, in the matter of the CON application under Docket Number 15-32031, received by OHCA on December 30, 2015. (49 Pages)
F	Letters of support in the matter of the CON application filed under Docket Number 15-32031, received by OHCA on January 11, 2016. (2 pages)
G	OHCA's letter to the Applicant dated January 29, 2016 deeming the application complete in the matter of the CON application filed under Docket Number 15-32031. (1 page)

H	OHCA's request for legal notification in the *Norwich Bulletin* of OHCA's Notice to the Applicant of the public hearing scheduled for March 23, 2016, in the matter of the CON application under Docket Number 15-32031, dated February 10, 2016. (4 pages)
I	OHCA's letter to the Applicant dated March 9, 2016 requesting prefile testimony and enclosing issues in the matter of the CON application under Docket Number 15-32031. (4 pages)
J	Letter from Lawrence + Memorial to OHCA dated March 16, 2016 noticing the appearance of Bershtein, Volpe & McKeon, P. C. on Behalf of Lawrence + Memorial Hospital and Petition of Lawrence + Memorial Hospital, Inc.for Intervenor Status with full rights of cross-examination in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 16, 2016. (11 pages)
K	Letter from the Applicant to OHCA enclosing Prefile Testimony and responses to issues dated March 9, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 17, 2015. (48 pages)
L	OHCA's Ruling on the Petition of Lawrence + Memorial Hospital to be granted intervenor status in the matter of the CON application under Docket Number 15-32-31, dated March 17, 2016. (1 page)
M	Letter from the Intervenor to OHCA dated March 18, 2016 enclosing Prefile Testimony in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 18, 2016. (74 pages)

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TENTATIVE AGENDA

HEARING

Docket Number: 15-32031

The William W. Backus Hospital

Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

March 23, 2016 at 9:30 a.m.

I. **Convening of the Public Hearing**

II. **Applicant's Direct Testimony**

III. **Intervenor's Testimony**

IV. **Intervenor Cross-Examines Applicant**

V. **Applicant Cross-Examines Intervenor**

VI. **OHCA's Questions**

VII. **Closing Remarks**

XI. **Public Hearing Adjourned**

* * * COMMUNICATION RESULT REPORT (MAR. 22. 2016 10:06AM) * * *

FAX HEADER:

TRANSMITTED/STORED : MAR. 22. 2016 10:05AM FILE MODE	OPTION	ADDRESS	RESULT	PAGE
527 MEMORY TX		912037775806	OK	4/4

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: MICHELE VOLPE

FAX: 203 777-5806

AGENCY: BERSHTEIN, VOLPE AND MCKEON

FROM: OHCA

DATE: 3/22/16 **Time:**

NUMBER OF PAGES: 4
(including transmittal sheet

Comments:

Please see attached information regarding the hearing that is being held on March 23, 2016 for DN: 15-32031-CON

PLEASE PHONE Barbara K. Olejarz IF THERE ARE ANY TRANSMISSION PROBLEMS.

Phone: (860) 418-7001 ***Fax: (860) 418-7053***

410 Capitol Ave., MS#13HCA
P.O.Box 340308
Hartford, CT 06134

Olejarz, Barbara

From: Olejarz, Barbara
Sent: Tuesday, March 22, 2016 10:31 AM
To: 'janette.edwards@hhchealth.org'
Cc: Armah, Olga
Subject: Backus Hearing information
Attachments: 32031-3.pdf

Tracking:	**Recipient**	**Delivery**
	'janette.edwards@hhchealth.org'	
	Armah, Olga	Delivered: 3/22/2016 10:31 AM

3/22/16

Hi Janette,

Attached is the table of record and the tentative agenda for tomorrow's hearing.

Barbara K. Olejarz
Administrative Assistant to Kimberly Martone
Office of Health Care Access
Department of Public Health
Phone: (860) 418-7005
Email: Barbara.Olejarz@ct.gov

Greer, Leslie

From: Johnson, Kyle R. <KJohnson@brownrudnick.com>
Sent: Tuesday, March 22, 2016 6:00 PM
To: User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim; mmv@bvmlaw.com
Cc: Janette.Edwards@hhchealth.org; Anthony, Robert J.
Subject: Docket No. 15-32031-CON / Applicants' Motion in Limine
Attachments: Docket No. 15-32031-CON - Applicants_ Motion in Limine.pdf

Good Evening,

Please find attached the Applicants' Motion in Limine to be filed in this docket.

BROWNRUDNICK

Kyle Johnson
Energy, Utilities & Environment

Brown Rudnick LLP
City Place 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6570
F: 856.509.6685
M: 646-896-4581
Kjohnson@brownrudnick.com
www.brownrudnick.com

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ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

185 Asylum
Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

March 22, 2016

VIA E-MAIL
(ohca@ct.gov; kevin.hansted@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us; mmv@bvmlaw.com)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON - Motion in Limine

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital, enclosed for filing is The William W. Backus Hospital and Hartford Hospital's Motion in Limine to Preclude Use of Data Regarding Out-of-State Providers.

Very truly yours,

BROWN RUDNICK LLP

By: Robert J Anthony
Robert J. Anthony

Enclosure

62431323 v1-WorksiteUS-032836/0002

brownrudnick.com

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

DEPARTMENT OF PUBLIC HEALTH	:	
OFFICE OF HEALTH CARE ACCESS	:	**DOCKET NO. 15-32031-CON**
	:	
	:	
IN RE: THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S CERTIFICATE OF NEED APPLICATION TO ESTABLISH A PRIMARY AND ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM AT BACKUS HOSPITAL	:	**MARCH 22, 2016**

THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S MOTION IN LIMINE TO PRECLUDE USE OF DATA REGARDING OUT-OF-STATE PROVIDERS

Hartford Hospital and The William W. Backus Hospital ("Applicants"), by and through their undersigned counsel, hereby request that the Connecticut Department of Public Health ("DPH") Office of Health Care Access ("OHCA") issue a ruling precluding the consideration of out-of-state health care facilities to address the lack of Percutaneous Coronary Intervention ("PCI") providers in the Angioplasty Region in making a determination on the Applicants' Certificate of Need Application to Establish and Operate a PCI Program at The William W. Backus Hospital ("Backus") (the "CON Application").[1]

In its Pre-File Testimony, Intervenor Lawrence + Memorial Hospital, Inc. ("L+M") suggests that out-of-state PCI providers are an appropriate means to address the lack of access to PCI services for patients in the Angioplasty Region. *See Pre-Filed Testimony of L+M*, Pages

[1] Capitalized words not defined herein shall have the meaning set forth in Applicants' CON Application.

00005, 00009, 00010, 00019, 00046. This is wholly inappropriate and OHCA should act to exclude such testimony. Pursuant to OHCA's February 4, 2010 Declaratory Ruling (Docket No. 09-31433-DCR), OHCA is allowed to exclude volume data from out-of-state patients that are treated at a Connecticut health care facility in its evaluation of Certificate of Need ("CON") applications. It necessarily follows that OHCA should also exclude from consideration the use of out-of-state PCI facilities as a solution to the lack of PCI providers in the Angioplasty Region. For the reasons set forth below, OHCA should issue a ruling precluding the consideration of out-of-state PCI facilities to address the lack of PCI providers in the Angioplasty Region.

1. It is inappropriate to consider the availability of out-of-state PCI facilities in evaluating the need for PCI service in the Angioplasty Region because such facilities are not subject to OHCA approval, oversight, reporting obligations, or general OHCA quality control. OHCA does not have a say in the need for such facilities, nor does it have control over the quality of services being rendered by such facilities. Further, out-of-state PCI facilities are not subject to OHCA's rigorous oversight and reporting obligations. Moreover, OHCA has no control over whether said out-of-state PCI facilities will continue to operate and serve nearby patients, including Connecticut patients.

2. It is inappropriate to consider the availability of out-of-state PCI facilities in evaluating the need for PCI service in the Angioplasty Region as continuity of care suffers as a result of in-state patients being treating at out-of-state PCI facilities. Communication among specialists and between specialists and a patient's primary care physician is a key component to continuity of care. STEMI patients treated at out-of-state health care facilities that have Connecticut-based primary care physicians do not have the benefit of community-based relationships between the STEMI physician and the primary care physician that can foster easy

and free-flowing communication. Degradation of the level of communication between a treating and primary care physician can be extremely detrimental to a patient's continuity of care.

3. It is inappropriate to consider the availability of out-of-state PCI facilities in evaluating the need for PCI service in the Angioplasty Region due to challenges that arise in patients' ability to pay for health care costs via insurance. Due to the promulgation of the Patient Protection and Affordable Care Act ("ACA"), health insurance availability and coverage can vary greatly from patient to patient and from state to state. Connecticut patients being treated at out-of-state health care facilities could face long delays in reimbursement of health care costs, or, in some instances, may not be able to use health insurance at all.

4. It is inappropriate to consider the availability of out-of-state PCI facilities in evaluating the need for PCI service in the Angioplasty Region due to challenges that arise in the sharing of Electronic Medical Records ("EMR"). EMRs are an important tool in today's health care industry. EMRs are instrumental in patient continuity of care and in improving efficiency within the industry. The state of EMRs, however, is far from perfect and is certainly not uniform across the industry. Indeed, many health care providers utilize proprietary software unavailable to other health care providers. As a result, sharing of EMRs from practice to practice can be a challenging and time consuming practice. This is especially true when in-state patients are being treated at out-of-state facilities. A delay in transmitting EMRs to a primary care physician can be extremely detrimental to continuity of care.

For the foregoing reasons, the Applicants believe it is inappropriate to consider out-of-state health care facilities in evaluating the need for PCI service in the Angioplasty Region and Applicants hereby request that OHCA issue a ruling excluding the use of such testimony.

Respectfully submitted,

Hartford Hospital and
The William W. Backus Hospital

By: Robert J Anthony

Robert J. Anthony
Brown Rudnick LLP
CityPlace I, 185 Asylum Street
Hartford, CT 06103-3402
(860) 509-6517 (tel.)
(860) 509-6501 (fax)
ranthony@brownrudnick.com
Juris No. 403862
Its Attorney

CERTIFICATION

I hereby certify that true and correct copies of the above were served by electronic mail on this 22nd day of March, 2016, followed by first class mail, postage prepaid, to the following counsel of record:

Michele M. Volpe
Attorney for Lawrence + Memorial Hospital, Inc.
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, Connecticut 06511
mmv@bvmlaw.com

Robert J. Anthony
Brown Rudnick LLP

Greer, Leslie

From: Jennifer O'Donnell <jlo@bvmlaw.com>
Sent: Wednesday, March 23, 2016 9:03 AM
To: User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim; ranthony@brownrudnick.com
Cc: Michele Volpe; Kathleen Gedney
Subject: Docket No. 15-32031-CON- Intervenor's Opposition to Applicant's Motion In Limine
Attachments: Intervenor's Opposition to Applicant's Motion in Limine (Docket No 15-32....pdf

Please see attached letter and Intervenor's Opposition to the Applicant's Motion in Limine. Thank you.

Jennifer L. O'Donnell
Paralegal
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, Connecticut 06511-6957
Telephone: (203) 777-5800 (ext. 104)
Direct Line: (203) 777-5804
Facsimile: (203) 777-5806

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BERSHTEIN, VOLPE & McKEON P.C.
ATTORNEYS AT LAW
105 COURT STREET, THIRD FLOOR
NEW HAVEN, CONNECTICUT 06511
203-777-5800
Fax: 203-777-5806

Michele M. Volpe
Direct Dial (203) 777-6995

March 23, 2016

VIA EMAIL
(ohca@ct.gov; kevin.hansted@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@ct.gov; ranthony@brownrudnick.com

Ms. Kimberly Martone
Office of Healthcare Access
Department of Public Health
410 Capital Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON –Intervenor's Opposition to Applicant's Motion In Limine

Dear Ms. Martone:

On behalf of Lawrence + Memorial Hospital, Inc. (the "Intervenor"), enclosed please find the Intervenor's opposition to The William W. Backus and Hartford Hospital's motion in limine to preclude use of data regarding out-of-state providers.

Very Truly Yours,

Michele M. Volpe
Bershtein, Volpe & McKeon, P.C.

Enclosure

DEPARTMENT OF PUBLIC HEALTH	:	
OFFICE OF HEALTH CARE ACCESS	:	**DOCKET NO. 15-32031**
	:	
	:	
IN RE: THE WILLIAM W. BACKUS	:	
HOSPITAL AND HARTFORD	:	
HOSPITAL'S CERTIFICATE OF NEED	:	
APPLICATION TO ESTABLISH A	:	
PRIMARY AND ELECTIVE	:	
PERCUTANEOUS CORORNARY	:	
INTERVENTIONAL PROGRAM AT	:	
BACKUS HOSPITAL	:	**MARCH 23, 2016**

LAWRENCE + MEMORIAL HOSPITAL, INC.'S OPPOSITION TO THE APPLICANT'S MOTION IN LIMINE TO PRECLUDE USE OF THE DATA REGARDING OUT OF STATE PROVIDERS

Intervenor Lawrence + Memorial Hospital, Inc., ("L+M"), by and through its undersigned counsel, hereby opposes the motion in limine to preclude use of data regarding out-of-state providers submitted by The William W. Backus and Hartford Hospital's (collectively, the "Applicants") on March 22, 2016 ("Applicant's Motion"). The Applicant's have wrongly and inappropriately interpreted OHCA's position on the consideration of out of state providers in Certificate of Need ("CON") analysis. The Intervenor hereby requests that the Department of Public Health ("DPH") Office of Health Care Access ("OHCA") deny the Applicant's Motion and issue a decision that OHCA is permitted to use such data.

I. Applicant Wrongly And Inappropriately Interprets OHCA's Position On The Consideration Of Out Of State Providers In CON Analysis.

The Applicant wrongly and inappropriately interprets OHCA's position on the consideration of out of state providers in CON analysis. The declaratory ruling cited by the Applicant, Declaratory Ruling Docket Number 09-31433-DCR dated February 4, 2010 ("Declaratory Ruling") is strictly limited to the issue of the utilization of out-of-

state **patients** (emphasis added), not out-of-state providers. As stated by OHCA, the issue presented was limited to "whether sections 19a-634 and 19a-637 of the Connecticut General Statutes require or allow the Agency to exclude patients who live out of state, but are treated in a Connecticut health care facility, when evaluating the need for a particular health care service." Declaratory Ruling at 1. After careful analysis, OHCA concludes that "19a-634 and 19a-637 do not require OHCA to exclude patients who live out of state, but are treated at a Connecticut health care facility, from its evaluation of need for a particular health care service." Declaratory Ruling at 8.

At no point does OHCA consider or analyze the use of out of state providers in its Declaratory Ruling. The Declaratory Ruling does not require that OHCA must exclude out of state providers in all CON analysis, only the narrow issue of whether OHCA may use its discretion to exclude out of state providers based on a "review of all evidence submitted." Declaratory Ruling at 8. OHCA further states it will evaluate "each CON application based upon the evidence in each case." *Id.* The Declaratory Ruling is narrow in its scope of addressing only the use of out of state patients and it is inappropriate for the Applicant to draw conclusions on OHCA's behalf that its narrow Declaratory Ruling would lead to unrelated conclusion regarding out of state providers.

II. OHCA Has Discretion To Consider Out Of State Providers In CON Analysis

As there is no statute, regulation or ruling that disallows the use of out of state providers in CON analysis, OHCA may utilize its broad powers to determine public need, including the use of out of state providers in its analysis of CON applications. In fact, OHCA has considered out of state providers in previous CON decisions, including those related to angioplasty services. *See* CON Decision Docket No. 12-31748 Greenwich

Hospital and Yale-New Haven Hospital Establish and Operate an Elective Angioplasty Program Without Onsite Surgical Backup at Greenwich Hospital. ("Each of the existing providers of elective angioplasty is approximately 6 and 11 miles away from Greenwich Hospital. A letter from White Plains Hospital in Westchester County, NY, state that its elective angioplasty program presently has capacity to serve the needs of community and they are not aware of any backlog of cases in their service area." Docket No. 12-31748 at 13.)

Therefore, the Applicant's motion that OHCA exclude out of state provider data is contrary to OHCA's decision in previous angioplasty CON analysis.

III. OHCA Should Consider Out of State Providers in its Consideration of the Application at Issue

OHCA should consider the presence of out of state providers in determining the need for Primary or Elective PCI services in the Application at issue. As was determined in the aforementioned Greenwich CON, OHCA did consider the utilization of out of state providers by Connecticut residents. Therefore, OHCA should consider the presence of out of state providers, such as UMASS, in its analysis of public need in this Application. In fact, OHCA has already requested and considered out of state providers in this Application as evidenced by the questions presented to the Applicant requesting they address volume at UMASS. *See*, OHCA's Issues List to the Applicant, February 9, 2016, Issue #5. Additionally, the Applicant itself has also integrated data relating to UMASS at pages 1458 and 1464 of the Application.

OHCA should consider out of state providers in assessing need for health care services and whether Connecticut residents have access to needed services irrespective of

whether those services are provided by in or out of state provider. Out of state providers should not be excluded from OHCA's CON analysis. OHCA is rightly considering these out of state providers because concerns related to quality and overutilization transcend state bounds. The numerous quality concerns outlined in the SCAI/ACC/AHA Expert Consensus Document relating to decreased quality when there are multiple low-volume providers within close proximity are present whether or not the providers are located in contiguous states. OHCA should recognize that Connecticut residents are affected by decreased quality whether or not such low-volume providers are duplicative to in-state or out-of-state providers.

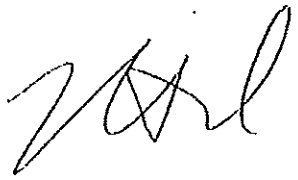
Lastly, the Applicant's arguments relating to insurance, community relationships and electronic medical records ("EMR") are misplaced. The issues of out of state health insurance coverage are not unique to patients in Connecticut or any resident living near a state border. However, coverage for an emergent service, such as primary angioplasty, is likely not an issue for patients with insurance coverage. Further, Medicare coverage is national. As for the Applicant's argument relating to communication between community based physicians and institutions, it is inaccurate to say that many community and institutional relationships do not transcend state bounds. The Intervenor's own health system operates hospitals in Connecticut and Rhode Island. Finally, EMR issues relating to compatibility are also not unique to Connecticut and non-Connecticut providers – providers in different health care systems within the same state or independent providers within the State also experience EMR compatibility issues.

For the foregoing reasons, the Intervenor hereby requests that OHCA deny the Applicant's motion in limine to preclude the use of data regarding out of state providers

and issue a ruling that OHCA is permitted to consider such data. OHCA is not limited by the Declaratory Ruling as the Declaratory Ruling is limited to the narrow issue of out of state ***patients not providers***. Further, OHCA has discretion to include out of state provider data and should consider such out of state provider data in its analysis and decision relating to the Application.

Respectfully Submitted,

Lawrence + Memorial Hospital, Inc.



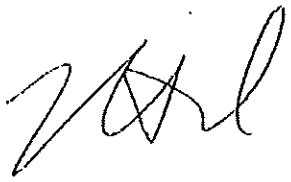
By: _____

Michele M. Volpe
Bershtein Volpe & McKeon, P.C.
105 Court Street, 3rd Floor
New Haven, Connecticut
203-777-5800 (phone)
203-777-5806 (fax)
mmv@bvmlaw.com
Juris No. 412124
Its Attorney

CERTIFICATION

I hereby certify that true and correct copies of the above were served by electronic mail on this 23rd day of March, 2016, followed by first class mail, postage prepaid, to the following counsel of record:

Robert J. Anthony
Brown Rudnick, LLP
CityPlace I, 185 Asylum Street
Hartford, Connecticut 06103-3402
ranthony@brownrudnick.com



Michele M. Volpe
Bershtein, Volpe & McKeon, P.C.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

IN RE	:	**Docket No. 15-32031-CON**
CERTIFICATE OF NEED APPLICATION TO ESTABLISH AND	:	
OPERATE A PRIMARY AND ELECTIVE ANGIOPLASTY	:	
PROGRAM AT THE WILLIAM W. BACKUS HOSPITAL IN	:	
NORWICH, CONNECTICUT	:	**MARCH 23, 2016**
	:	

APPEARANCE

An appearance by the following on behalf of The William W. Backus Hospital and Hartford Hospital is hereby requested in this docket.

Douglas A. Cohen, Esq.
Brown Rudnick LLP
CityPlace 1
185 Asylum Street
Hartford, CT 06103
Tel. 860-509-6511
Email: dcohen@brownrudnick.com

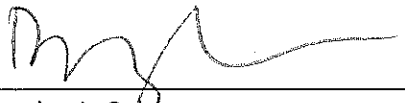
Respectfully Submitted,

Douglas A. Cohen, Esq.
Brown Rudnick LLP
CityPlace 1
185 Asylum Street
Hartford, CT 06103
Tel. 860-509-6511
Email: dcohen@brownrudnick.com

Certification

I hereby certify the foregoing Appearance was hand delivered to the following on March 23, 2016:

Michele M. Volpe, Esq.
Bershtein, Volpe & McKeon P.C.
105 Court Street
New Haven, CT



Douglas A. Cohen

Oral Testimony of Bruce Cummings

Hello my name is Bruce Cummings. I am the CEO and President of L+M Hospital.

I adopt my pre-filed testimony. I would like to say a few words to commence L+M's presentation and speak against the Application submitted by Backus.

While I have great respect for my colleagues at Backus and Hartford Hospitals, I believe the primary PCI program and the elective PCI program that the applicant proposes are duplicative and fundamentally flawed in their conception. Included in my pre-filed testimony is a detailed summary outlining all of the deficiencies and failure of Backus to meet the CON requirements.

L+M has been serving the region for over 100 years and staffs over 2,400 professional, technical and support personnel in nearly every medical specialty. Our mission is to improve the health of our region.

L+M is continuing to develop a strong primary and elective angioplasty program to serve patients and offer a level of care in the region that meets or exceeds national standards. In collaboration with Yale School of Medicine and the Yale New Haven Heart and Vascular Center, L+M has helped lead the way in Connecticut for angioplasty performed at a community hospital.

L+M has a successful record of performing emergency angioplasty for the past five years. At L+M, interventional cardiologists are on call 24/7 to provide the service, and they are always in close communication with paramedics and Emergency Department staff, and are ready for an emergency procedure even before the patient arrives at the hospital. Our primary and elective program is led by Medical Director, Dr. Brian Cambi, a Yale School of Medicine interventional cardiologist who maintains a permanent residence in our primary service area.

As with all L+M's services, our angioplasty program is focused on providing innovative, high quality care to the community and we will make every effort to continue to do so. However, OHCA approval of any portion of the Application before them will make it dangerously difficult for L+M's program to be viable.

I would like to introduce three individuals who will speak in more detail about the various deficiencies in Backus's application. First, Dr. Brian Cambi, the head of L+M's angioplasty program will speak to the clinical problems. Second, Dr. Daniel Rissi, chief medical officer at L+M will speak to the operational and administrative flaws in the Application. Last, Seth Van Essendelft, chief financial officer, will speak to the financial concerns in the Application.

Representatives from Lawrence & Memorial Hospital appreciate the opportunity to be here today to provide detailed information outlining the reasons why the Application before you should be denied.

Oral Testimony of Dr. Brian Cambi

Good morning, my name is Dr. Brian Cambi and I adopt my pre-file testimony.

I am an Interventional Cardiologist on faculty at Yale School of Medicine and am the Medical Director of the L+ M Heart and Vascular Center in affiliation with Yale New Haven Hospital's Heart and Vascular Center. I have been running L+M's primary angioplasty program for acute MI since 2008 and more recently in 2013 have begun overseeing its elective PCI program. I live in East Lyme Connecticut and spend greater than 80% of my time on campus at L+M. Our program is the only of its kind in the state putting me in a unique position to comment on all aspects of a community PCI program.

I am here today to speak against the application submitted by Backus Hospital. While I have great respect for my cardiology colleagues at Backus and Hartford Hospitals, I believe both primary and elective PCI services that the applicant proposes are unnecessary to meet the health care needs of our community and fundamentally flawed in their conception.

In the clearest of terms, Backus should be denied its proposed primary and elective PCI services as approval would run counter to the latest clinical guidelines regarding PCI programs without on-site surgery, and as importantly, the CT Department of Health's own published report regarding statewide PCI facilities.

We all know it is critical to restore normal blood flow to compromised heart muscle for patients suffering a sudden acute heart attack. There is a large body of literature that demonstrates primary percutaneous coronary intervention (PCI) is the ideal treatment strategy for such patients provided it can be delivered in a timely fashion. It is impractical, however, for PCI centers to be available within every 30-mile radius throughout our state or our country. In fact, the 2014 update on PCI without on-site surgical backup consensus statement from SCAI\ACC\AHA has gone so far as to say establishing PCI centers within 30 minutes of each other is ***highly advised against*** as redundant PCI centers only drive quality down by creating low-volume institutions and increase cost unnecessarily for the system. Even the CT DPH 2015 report on hospital transfers of emergency coronary angioplasty patients notes, "There is no indication of unmet need in Connecticut, while there appears to be excess capacity for PCIs."

The previously mentioned 2014 update on PCI guidelines statement goes on to recommend patients presenting to a non-PCI capable facility with STEMI be transferred to a PCI capable Center providing reperfusion or door-to-balloon-time can be delivered within 120 minutes. If this cannot be accomplished, then medical therapy with fibrinolysis remains the ideal recommended treatment strategy. It is my contention that we can easily adhere to these recommendations without beginning another program at Backus Hospital, as L+M is a mere 21 minutes from Backus Hospital. This is well within the guideline recommendation of <30min drive transfer time between non-pci and pci-capable facilities.

The applicant describes their difficulty achieving reperfusion times less than 120 minutes when transferring STEMI patients to a PCI capable facility such as Hartford Hospital or Yale New Haven Hospital. Backus cites long transfer times to PCI capable centers and persistent internal difficulties in improving their "door- in- door- out times" (DIDIO) despite extensive attempts to do so as key factors contributing to their non-adherence. However, Backus fails to mention that in the last 5 years Backus has only transferred 3 patients to L+M's PCI Program, which is the closest PCI program to Backus at a mere 21-minute drive time away. Transfers to Hartford Hospital and Yale New Haven Hospital are twice as long. Currently, L+M routinely receives STEMI transfers from another non-PCI capable hospital that is farther away than Backus at 27 minutes. Not only do we achieve guideline recommended reperfusion times of less than 120 minutes in these transferred STEMIs but the median door-to-balloon time in the last fiscal year for such patients was less than 90 minutes.

Even with the applicant's inability to improve its internal efficiency, if Backus had routinely chosen to avail itself of L+M's program, I believe patient care would have been substantially improved and guidelines would have been met. L+M has no backlog and has two dedicated cardiac catheterization labs as well as the staff and resources to accommodate additional patients. Even patients in areas north and east of Backus can receive optimal cardiac care without a program at Backus if clinical guidelines are adhered to. In its application Backus describes a timeline of 50 minutes from activation to cath lab readiness. None of the patients in their service area or newly defined "angioplasty region" are longer than a 50 minute ride from a PCI facility. Therefore, it is likely that reperfusion times would be similar or better if these patients were brought to the nearest facility either in this state or neighboring ones.

The Applicant's inability to comply with the national standard DIDO time of 30 minutes (Backus's average is greater than 70 minutes) also raises concerns for heart attack patients who develop complications during their PCI procedure, should the Applicant's proposal be approved. Backus's inability to transfer patients in a timely and efficient manner will negatively impact these critically ill patients receiving timely care at a tertiary facility.

Patients suffering from sudden heart attack are critically ill and have a high mortality rate. Ideal treatment necessitates a comprehensive team approach. Backus Hospital has not cared for STEMI patients in many years. Similarly, the vast majority of acute coronary syndrome patients (non-STEMIs) have been transferred from Backus's facility. This has left many of the supporting nurses, technologists, and other medical providers largely inexperienced in dealing with this unique patient population. Similarly, in the cardiac catheterization laboratory the experience of the supporting staff is critically important. While the cath lab nurses and interventional radiology technologists at Backus have much experience in performing percutaneous interventions in PERIPHERAL blood vessels the skill set required to care for heart attack victims is quite different. One must recognize that procedures are now occurring in the vessels that surround the patient's heart resulting in a unique set of hemodynamic consequences and potential complications. Patients are often unstable and even in cardiogenic shock compared with patients

receiving an angioplasty on a blood vessel in their leg. There are also devices unique to the treatment of heart attack victims like intra-aortic balloon pumps that are quite complex and require constant monitoring in the critical care unit after the procedure. These staffing requirements are outlined nicely in Table 4 of the SCAI/ACC/AHA 2014 Update on PCI without on-site surgical backup. The applicant fails to address any of these deficiencies and in my opinion would be creating an environment of inexperienced supporting providers that may lead to unnecessary complications.

Providing PCI in a community hospital is a very rewarding experience but can be very challenging and is quite different than providing the same service in a large tertiary environment. With nearly 10 years of experience behind me, I can tell you treating critically ill heart attack victims without any house staff, fellows, or supporting physicians can be daunting. One of the keys to our success was establishing my role to serve as Medical Director and dedicated physician champion, as the guidelines recommend, who lives and works in the community in which he provides care. This has led to extremely strong relationships in the work place and created an atmosphere of trust emblematic of any successful team. Members of the team know each other extremely well. They know their individual rolls as well as their colleague's practice habits including strengths and weaknesses. This kind of intimate understanding among team members cannot be overemphasized and is vital to successful patient care in critically ill STEMI patients. Without having a Medical Director of Backus' program on site, who lives and works in the community as I do, the applicant fails to recognize this critically important component to a successful program.

Much of my remarks thus far have addressed the applicant's failure to establish need for a primary PCI program. I would like to now speak for a moment about elective PCI. By its very name this service is not emergent in nature and can be planned. Unlike acute heart attack victims these patients are stable and many are outpatients. The applicant's suggestion that time is of the essence for this group of patients is misleading and not supported by any guideline recommendation. What is discussed in detail in the guidelines, however, is rigorous criteria for facilities to safely perform PCI on elective patients and rigorous criteria for the kinds of patients that are appropriate to receive this elective treatment at a PCI center without on-site cardiothoracic surgical backup. In all the studies that examined the safety and efficacy of performing elective PCI at off-site centers, each participating site had already established primary PCI centers with high quality outcomes and low complication rates. Backus hospital has no experience in providing PCI of any kind. The guidelines warn against inexperienced operators performing elective procedures at off-site centers. The two interventional cardiologists on staff at Backus Hospital completed their training less than one year ago. Their lifetime experience performing PCI is small. One such physician, Dr. Chua Chiaco, is named as playing a significant role in the coverage of their proposed program. Asking him to perform elective angioplasty in a novel elective PCI program, in a community hospital without on-site mentorship, is warned against in the guidelines and I believe a set up for failure.

People often ask me if I get apprehensive performing PCI in heart attack victims. My answer often surprises them. While I am confident performing both procedures, it is less stressful in the emergency setting **than** in an elective setting. In sudden heart attack victims, as a physician, you are trying to stabilize an unstable patient. You are trying to save a life that otherwise is likely to be lost. In elective PCI there is always the possibility of making a stable patient unstable. It is for this reason that patients must be selected carefully in the elective environment to minimize the chance of developing a complication. L+M follows the guidelines closely and focuses on selecting low risk patients with low risk lesions, the kind of patient pool described as "the best scenario for PCI without on-site surgery." Patients who are high-risk or have lesions that are high-risk continue to be treated more effectively and safely at a tertiary facility. The Applicant fails to recognize that a significant proportion of patients are inappropriate to have their elective procedure done at a community hospital without on-site bypass capability. This has led to an over-estimation of the number of cases that could be appropriately handled at their facility. It is quite concerning that Backus has stated repeatedly that 100% of the volume from their region currently migrating to Hartford hospital will shift to Backus. This will either be an unsafe situation for many patients or is an oversight in Backus's understanding of the patient-type most appropriate to receive care at their facility. In either case, OHCA should be highly concerned.

Furthermore, Backus makes a common mistake in assuming that all non-ST elevation MI patients will be suitable for PCI. The truth is many of these patients will not. Some will require bypass surgery. Many others have their heart attacks for reasons other than obstructive coronary artery disease. Some may have myopericarditis (an inflammation of the heart muscle), some may have a cardiomyopathy such as stress induced cardiomyopathy, some may have coronary dissection, some may have congestive heart failure, and others may have demand related infarcts from the stress of other critical medical illness or arrhythmias. The overwhelming majority of these cases will not require PCI but are more appropriately treated with medical therapy.

Lastly, guidelines have recommended trying to achieve a volume of 200 cases for all PCI programs in community hospital's without on-site cardiothoracic surgery. There is a clear correlation between quality and volume with optimal quality outcomes associated with case volumes greater 200. If Backus were to be granted a primary PCI program, or an elective PCI program or both, it will significantly lower case volume at L+M. The State will then have two programs with subpar volume and in all likelihood lower quality outcomes compared with a single robust program that currently operates at L+M with appropriate volumes, high quality outcomes, and low complication rates. All this will come at a significant financial cost on an already stressed healthcare system. I fail to see how any of this is good for our patients or the health care communities we serve.

In closing I would like to drive home the following point. If our overriding objective is to improve the cardiovascular care of the region and is unencumbered by financial gain and interest in expanding market share than there is indeed no unmet need for the citizens of this region in Connecticut. The solution is to simply start adhering to the most recent updated guidelines put

out by the SCAI/AHA/ACC and those of the Connecticut Department of Public Health. If Backus had done so, and been transferring their STEMI patients to the ***nearest*** PCI facility, at L+M, optimal reperfusion times would have undoubtedly been achieved and will continue to be achieved in these patients. If we are truly interested in continuing to improve care for our citizens with heart attack, rather than investing millions of dollars into unnecessary duplicative programs, we should invest in educating our patients about the warning signs of coronary artery disease. Furthermore, significant efforts and resources should be allocated to identify STEMI patients earlier in the field by streamlining 12-lead acquisition and transmission to a PCI Center to facilitate direct transfer to that program.

I will be happy to answer any questions at the end of L+M's presentation.

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Oral Testimony of Seth Van Essendelft

Good Morning. My name is Seth Van Essendelft.

I adopt my pre-filed testimony.

I am the Chief Financial Officer and Vice President of Support Services at Lawrence + Memorial Hospital. I oversee the financial and support operations for the L+M health system, including two acute care hospitals of L+M Hospital and Westerly Hospital, and the Lawrence + Memorial Medical Group.

Thank you for the opportunity speak against the Application submitted by Backus as the Applicant's proposed primary or elective PCI services will have a significant negative financial impact on L+M's developing program.

In 2013, L+M received CON approval to establish elective angioplasty in addition to its existing primary program. L+M has been developing this program and providing outreach to neighboring hospitals including Backus and Westerly Hospital in Rhode Island. L+M has invested significant financial resources and personnel in its angioplasty program, recruiting and retaining exceptional physician, nursing and other key staff to support this worthy program. These investments include staff, technology and equipment, including two state-of-the-art cardiac catheterization labs.

If approved, the Applicant's proposal will reduce both primary and elective PCI volume at L+M. This will lead to definitive and quantifiable financial losses and threaten the ongoing viability, quality and efficiency of the L+M program. Even approval of a primary program alone at Backus will have a significant adverse financial impact on L+M's developing program. Although Backus went through great lengths to contrive a segmented service area and articulate that there would be no negative implications to other existing programs, the facts do not support this assertion. For example, they carve out towns from the "Angioplasty Region" that are clearly within overlapping areas of L+M's and Backus' existing primary service areas. A credible review based on L+M patient origin data indicates that 25 to 30 percent of the existing L+M program volume is at risk if Backus' Application is approved and there is high probability that volume loss will be much greater for L+M. This risk is due to the existing overlapping service areas combined with the steerage leverage that Backus possess as part of the Hartford HealthCare System. At the low end of the range, L+M's incremental losses are expected to be in excess of $1 million given the significant fixed cost nature of the program and L+M investments already made.

While this negative financial impact will be felt acutely at L+M, it is not limited to our hospital. There will be a negative impact to the financial strength of Connecticut's health care system in general. Connecticut hospitals are facing serious financial challenges leading to consolidation and cutting of programs, even essential services and safety net programs. It is imperative that hospitals carefully plan strategic investments. In this case, Backus has proposed a very costly solution to an unneeded healthcare service. Rather than create a duplicative service, Backus as a sponsoring hospital could opt for a simple solution of leveraging existing technology already

deployed within the EMS system to more quickly and effectively identify and route appropriate patients directly to L+M. As evidenced in early commentary, cases from the L+M catchment area that should already be serviced by L+M's program are being subverted and transferred to Hartford Hospital. Despite being nearly double the transit time, Backus patients are being transferred to Hartford Hospital due in part to Backus's alignment within the broader Hartford Healthcare System.

If approved, primary PCI or elective PCI services at Backus will adversely impact health care costs, quality and sustainability. As my colleagues have addressed, the addition of duplicative and costly primary or elective angioplasty services at Backus Hospital is not carefully planned as Backus has not demonstrated public need or adequately identified the service area. As it is unlikely that Backus will reach its projected utilization figures without significant financial strain to L+M's developing program, Backus is doing a disservice to the residents of this state by directing scarce resources to a program that will offer more harm than benefit, all while weakening the existing quality and patient care of the previously approved program at L+M.

Based on the clear showing of unprofitability of the proposal, which appears aggressive in its assumptions, and the negative financial impacts to L+M, other angioplasty programs and the state as a whole, it is questionable why Backus is seeking approval of these services. I am confident that OHCA will consider the lack of financial viability in this proposal and deny both the primary and elective angioplasty requests.

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Oral Testimony of Daniel Rissi, M.D.:

Hello my name is Dr. Daniel Rissi and I adopt my pre-file testimony.

I am the Vice President and Chief Medical and Clinical Operations Officer at L+M. I oversee medical affairs and clinical operations, but I have also managed the strategy and planning functions at L+M.

I would like to address the administrative and operational flaws in Backus Hospital's CON application.

While my pre-file testimony, as well that of my colleagues, calls into question most of the rationale put forth by Backus' CON, I need to highlight some key deficiencies for OHCA's consideration.

If approved, Backus's application will have far reaching negative implications for L+M. Backus has not clearly defined the patient population to be served and, therefore, its volume projections are highly suspect. Backus has used a contrived service area which it calls the "Angioplasty Region." Clearly, with a target volume to achieve, the applicant has created a made up service area merely in an attempt to hit minimum thresholds established by national clinical experts. Backus fails to use the primary service area based on its own discharge data and as has been historically defined for purposes of OHCA. The "Angioplasty Region" is even more expansive than the market Backus's primary and secondary service areas based on its own community health needs assessment. The "Angioplasty Region" does not include certain towns in the southern region of its PSA, presumably to downplay the tremendous harmful impact that even approval of just Primary PCI will have on L+M's developing PCI program.

The most important point that should not be lost is that 95% of this Angioplasty Region is already within or nearly within the national guidelines for travel time. Specifically, one half of the towns in the Angioplasty Region are within 30 minutes of an existing PCI capable facility and nearly all of the other half are closer to another PCI facility than Backus or within a few minutes of another PCI capable facility.

Of equal importance, regardless of how the service area is defined, Backus has not demonstrated a clear public need for primary or elective PCI services. All data and research put forth by national experts and the CT DPH have shown PCI volume declining and have projected further declines in large part due to enhanced medical management, alternative therapies, and other preventative steps. Backus's 24% growth in angioplasty services over the next few years is a complete overstatement based on all available leading research, guidelines, and Connecticut data.

Backus paints a picture of the "Angioplasty Region" that is in contrast to the actual statistics of the composition of its residents. For example, despite Backus's claim, the "Angioplasty Region" is not older. The percent of residents aged 45+ is exactly the same as Connecticut's

average age. Moreover, according to Backus's sources, the percent of residents 65+ in the Angioplasty Region is less than Connecticut's rate – 15% vs. 16%. So clearly there is a disconnect between Backus's assertions regarding the region and the statistical data of the area. The Applicant also suggests the "Angioplasty Region" has a "low socioeconomic status" and high percentage of households with median incomes less than $50,000 which translates into high prevalence for coronary heart disease. This is untrue. According to data from the Connecticut Economic Resource Center (CERC), only 2 of the 28 towns in the Angioplasty Region or in Backus's primary service area, have median incomes of less than $50,000. Backus is incorrect in its assessment of the income levels of its contrived market, and also incorrect in its use of the data. As noted in the April 2015 CT DPH report titled "Burden of Cardiovascular Diseases in Connecticut," increased prevalence of coronary heart disease is tied to annual incomes of less than $25,000, not the $50,000 Backus references. So clearly there is no correlation that can be made between the household income of the region and increased need for PCI services.

Also, according to the Eastern Region Community Health Assessment provided by Backus in its CON application, the Eastern Connecticut region actually maintains the fastest ***decreasing*** heart disease mortality rate in the State, despite the claim by Backus that this area is completely underserved. Additionally, Backus states to OHCA that high blood pressure, diabetes and high cholesterol are high in the area, but fails to openly share that patients in the market have similar or better statistical rates for these conditions compared to the State or to the Nation, and that residents in the "Angioplasty Region" are managing their condition by taking action to control these issues. A close look at the data provided in the Backus CON for the Eastern Region, which L+M has analyzed and provided in pre-file documentation, clearly shows these comparisons.

National guidelines are ***advising against*** the very program Backus is proposing, and the CT DPH has stated there is no unmet need for PCI in the state. Multiple PCI centers that are duplicative have been shown to degrade quality by creating low-volume centers. Research has emphasized the logical placement of PCI centers, and a more regional approach to STEMI care. National studies support a focus on pre hospital care and rapid transfer from non-PCI facilities to PCI-capable facilities. The CT DPH's October 2015 report on angioplasty patients confirms this by stating very clearly "that because of declining PCI volumes there should be greater focus on ***system*** level of care for STEMI patients," not more PCI centers. Initiatives like Connecticut's Mission Lifeline have supported such approaches. Although frequently referenced in Backus's arguments, the OEMS 2012 guideline does not take into consideration the very recent and best expert opinion regarding PCI services. While the OEMS 2012 guideline has improved care for many patients by ensuring timely access to PCI for STEMI patients, it is inappropriate to use this one document as the basis for another PCI center in Connecticut, with all the new research, guidelines, and expert opinion that indicate Backus's program is duplicative and not in the best interest of patients.

Backus's proposal is not consistent with national or Connecticut standards and guidelines. Backus does not abide by the established ACCF/AHA/SCAI Guidelines adopted by OHCA,

which discourage the establishment of duplicative services within a 30-minute transfer time. Further, the same guidelines do not support the development of a directly competitive program. These Guidelines specifically state that competitive programs are not in the best interest of the community. It is undeniable that angioplasty services at Backus will directly compete with L+M's establishing primary or elective angioplasty program. Backus has estimated that 51 angioplasty cases were from the Backus OHCA-defined service area- this will be a significant loss to L+M.

Backus's application does not meet the requirements for establishing primary or elective angioplasty services on any level and therefore should be denied.

S:\doc\11 5451-5500\115491 L & M Hosp re OHCA\Docs\Opposition to Backus PCI CON\Scripts (Oral Testimony)\Script for Daniel Rissi - Final v2 (3.22.16).docx

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TABLE OF THE RECORD

APPLICANT: **The William W. Backus Hospital**

DOCKET NUMBER: **15-32031-CON**

PUBLIC HEARING: **March 23, 2016 at 9:30 a.m.**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room**
Hartford, Connecticut

EXHIBIT	DESCRIPTION
A	Letter from The William W. Backus Hospital (Applicant) dated September 30, 2015 enclosing the Certificate of Need (CON) application to Establish and Operate a Primary and Elecive Angioplasty Program under Docket Number 15-32031, received by OHCA on September 30, 2015. (1437 Pages)
B	Letters of support in the matter of the CON application filed under Docket Number 15-32031, received by OHCA on various dates. (3 pages)
C	OHCA's letter to the Applicants dated October 30, 2015, requesting Additional information and/or clarification in the matter of the CON application under Docket Number 15-32031.(7 Pages)
D	Designation letter dated December 16, 2015 of Hearing Officer in the matter of the CON application under Docket Number 15-32031. (1 page)
E	Applicant's responses to OHCA's letter of October 30, 2015 along with a revised Exhibit 24, dated December 30, 2015, in the matter of the CON application under Docket Number 15-32031, received by OHCA on December 30, 2015. (49 Pages)
F	Letters of support in the matter of the CON application filed under Docket Number 15-32031, received by OHCA on January 11, 2016. (2 pages)
G	OHCA's letter to the Applicant dated January 29, 2016 deeming the application complete in the matter of the CON application filed under Docket Number 15-32031. (1 page)

H	OHCA's request for legal notification in the *Norwich Bulletin* of OHCA's Notice to the Applicant of the public hearing scheduled for March 23, 2016, in the matter of the CON application under Docket Number 15-32031, dated February 10, 2016. (4 pages)
I	OHCA's letter to the Applicant dated March 9, 2016 requesting prefile testimony and enclosing issues in the matter of the CON application under Docket Number 15-32031. (4 pages)
J	Letter from Lawrence + Memorial to OHCA dated March 16, 2016 noticing the appearance of Bershtein, Volpe & McKeon, P. C. on Behalf of Lawrence + Memorial Hospital and Petition of Lawrence + Memorial Hospital, Inc.for Intervenor Status with full rights of cross-examination in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 16, 2016. (11 pages)
K	Letter from the Applicant to OHCA enclosing Prefile Testimony and responses to issues dated March 9, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 17, 2015. (48 pages)
L	OHCA's Ruling on the Petition of Lawrence + Memorial Hospital to be granted intervenor status in the matter of the CON application under Docket Number 15-32-31, dated March 17, 2016. (1 page)
M	Letter from the Intervenor to OHCA dated March 18, 2016 enclosing Prefile Testimony in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 18, 2016. (74 pages)

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

AGENDA

HEARING

Docket Number: 15-32031

The William W. Backus Hospital

Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

March 23, 2016 at 9:30 a.m.

I. **Convening of the Public Hearing**

II. **Applicant's Direct Testimony**

III. **Intervenor's Testimony**

IV. **Intervenor Cross-Examines Applicant**

V. **Applicant Cross-Examines Intervenor**

VI. **OHCA's Questions**

VII. **Closing Remarks**

XI. **Public Hearing Adjourned**

OHCA HEARINGS - EXHIBIT AND LATE FILE FORM

Applicants: The William W. Backus Hospital

DN: 15-32031-CON

Hearing Date: March 23, 2016

Time: 9:30 a.m.

Proposal: Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

OHCA Exhibit #	Description
1	
2	
3	
4	
5	

Applicant Exhibit #	Description
p	Notice of appearance.
Q	Oral Testimony of Bruce Cummings.
4	
5	

Intervenor Exhibit #	Description
1	
2	
3	
4	
5	
6	
7	

Informal Exhibit #	Description
1	
2	
3	
4	
5	
6	
7	

Applicant Late File #	Description	Due Date	Rec'd
1	Zip codes from center of town along with towns within the agioplasti region to the nearest PCI facility regardless if the provider is in the state. Due April 1st.	April 1, 2016	
2			
3			
4			
5			
6			

Intervenor Late File #	Description	Due Date	Rec'd
1			
2			
3			
4			
5			
6			

Notes:

PUBLIC HEARING
INTERVENOR
SIGN UP SHEET

March 23, 2016
9:30 a.m.

Docket Number: 15-32031-CON
The William W. Backus Hospital
Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

PRINT NAME	Phone	Fax	Representing Organization
Michele Volpe	203-772580		BVM for L+M
Shvaddha Patel	860 442 0711		L+M
Brian C. Cambi	860912-1514		L+M
Seth Van Essendelft	2523202032		L+M
Daniel Rissi	860 442 0711		L+M

The William W. Backus Hospital

PRINT NAME	Phone	Fax	Representing Organization
Nader Bahadory	860-836-5318		Hartford Healthcare
Barbara Durdy	860-972-4231		Hartford Healthcare

PUBLIC HEARING
APPLICANT
SIGN UP SHEET

March 23, 2016
9:30 a.m.

Docket Number: 15-32031-CON
The William W. Backus Hospital
Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

PRINT NAME	Phone	Fax	Representing Organization
Stuart Markwith, MD	860-545-2349		Hartford Hospital
Kathleen Tommaro	203-859-6238		BVM for LHM
Rebecca Durham	860-857-1058		Backus Hospital HHC
M. Shane Foreman	704-248-7652		3D Health
Paul Sweet	860-230-3001	860 230-3003	Town of Plainfield CT

PRINT NAME	Phone	Fax	Representing Organization
BIMAL PATEL	860-462-2961		Backus Hospital
Sohu Foley	860-861-0611		Backus
Fran Kiernan	8609722975		HH
Marianne Canna	203 885 2104		HHC
DAN LOSER	860-823-2[illegible]		HHC
Dyke Whitehead	8602674185		HHC
Doug Cohen	860 509 6511		BR for BH
Bob Anthony	860 536 6517		BR for BH
Bruce Logan[illegible]	860-442-0711		LHM Hospital
Janette Edwards	860-263-4168		HH/WWBH
[illegible]	860 972 0700		HHC
Deberey Hinchey	860 334-1965		City of Norwich - Mayor

PUBLIC HEARING
GENERAL PUBLIC
SIGN UP SHEET

March 23, 2016
9:30 a.m.

Docket Number: 15-32031-CON
The William W. Backus Hospital
Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

PRINT NAME	Phone	Fax	Representing Organization
PAUL THOMPSON	860 972 1793	860 545 2802	HARTFORD HEALTHCARE
Kyle Mcclaine	860 460 5229	800 892 8744	Hartford Healthcare.
Matt McKennan	203 907 9858		Yale New Haven Health
Amy Zilis	815-751-0884		Jeffers Cashard

Greer, Leslie

From: Armah, Olga
Sent: Thursday, March 31, 2016 3:01 PM
To: Johnson, Kyle R.; Janette.Edwards@hhchealth.org; Anthony, Robert J.; Michele Volpe
Cc: User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Fernandes, David; Carney, Brian; Martone, Kim; mmv@bvmlaw.com; Kathleen Gedney; Jennifer O'Donnell
Subject: RE: Docket No. 15-32031-CON / Applicants' Motion in Limine
Attachments: 15-32031 -Ruling on motion in limine.pdf

Good afternoon,

Please find attached OHCA's ruling on Docket No. 15-32031-CON Applicants' Motion in Limine.

Thanks.

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

From: Johnson, Kyle R. [mailto:KJohnson@brownrudnick.com]
Sent: Tuesday, March 22, 2016 6:00 PM
To: User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim; mmv@bvmlaw.com
Cc: Janette.Edwards@hhchealth.org; Anthony, Robert J.
Subject: Docket No. 15-32031-CON / Applicants' Motion in Limine

Good Evening,

Please find attached the Applicants' Motion in Limine to be filed in this docket.

Kyle Johnson
Energy, Utilities & Environment

Brown Rudnick LLP
City Place 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6570
F: 856.509.6685
M: 646-896-4581
Kjohnson@brownrudnick.com
www.brownrudnick.com

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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Office of Health Care Access

IN THE MATTER OF:

A Certificate of Need Application by
The William W. Backus Hospital and
Hartford Hospital

Docket Number: 15-32031-CON

RULING ON MOTION IN LIMINE FILED BY THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL AND OPPOSITION THERETO FILED BY LAWRENCE + MEMORIAL HOSPITAL, INC.

On March 22, 2016 The William W. Backus Hospital and Hartford Hospital (collectively referred to herein as the "Applicants") filed a motion in limine to preclude use of data regarding out-of-state PCI providers. On March 23, 2016 Lawrence + Memorial Hospital, Inc. ("Intervenor") filed an opposition to the Applicants' motion.

After careful consideration of the Applicants' motion and the Intervenor's objection, the Office of Health Care Access hereby orders the following:

The Applicants' motion is hereby DENIED;

The Intervenor's objection is hereby SUSTAINED.

3/31/16
Date

Kevin T. Hansted
Hearing Officer

Keeping Connecticut Healthy
DPH
Connecticut Department of Public Health

Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

Greer, Leslie

From: Mercier, Carlene M. <CMercier@brownrudnick.com>
Sent: Friday, April 01, 2016 3:16 PM
To: User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim; mmv@bvmlaw.com
Cc: Cohen, Douglas A.; Anthony, Robert J.; Janette.Edwards@hhchealth.org
Subject: Docket No. 15-32031-CON Late File
Attachments: Hartford HealthCare _ Backus Late File 4-1-16.PDF; Hartford HealthCare _ Backus - Late File 4-1-16.DOCX

Good Afternoon,

Please find attached the Applicants' Late File in this matter.

Best Regards,
Carlene

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

****

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****

ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

BROWNRUDNICK
185 Asylum Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

April 1, 2016

VIA E-MAIL
(ohca@ct.gov; kevin.hansted@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us; mmv@bvmlaw.com)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON – Late File

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital (the "Applicants"), enclosed for filing is the information requested of the Applicants during the first part of the Public Hearing (March 23, 2016) on this docket.

Very truly yours,

BROWN RUDNICK LLP

By: Robert J. Anthony/ar
Robert J. Anthony

Enclosure

62440087 v1-WorkSiteUS-032836/0002

brownrudnick.com

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

DEPARTMENT OF PUBLIC HEALTH	:	
OFFICE OF HEALTH CARE ACCESS	:	**DOCKET NO. 15-32031-CON**
	:	
	:	
IN RE: THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S CERTIFICATE OF NEED APPLICATION TO ESTABLISH A PRIMARY AND ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM AT BACKUS HOSPITAL	:	**April 1, 2016**

THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S LATE FILE INFORMATION

At the March 23, 2016 public hearing in this docket, The William W. Backus Hospital and Hartford Hospital (the "Applicants") were asked to provide the number of zip codes within the Angioplasty Region that currently have access within a 30 minute drive time to a PCI capable facility including out-of-state providers.

Applicants' Response:

There are 38 zip codes within the Angioplasty Region, which aggregate to 26 towns. Table 1 below identifies the 2015 population for each zip code, the current closest PCI-capable facility and the subsequent distance (in miles) and drive time (in minutes) to the PCI-capable facility.

Analysis of Table 1 clearly demonstrates the following 7 key points:

1. 71,189 (31%) individuals currently have access to a PCI-capable facility within 30 minutes, while **160,230 (69%) residents of the Angioplasty Region do not**. Importantly, included within the 71,189 individuals who currently have 30 minute access to a PCI-capable facility are 18,035 residents who must travel out-of-state for care to meet this standard.
2. 9 of the 38 zip codes (24% of zip codes within the Angioplasty Region) currently have access to a PCI-capable facility within a 30 minute drive. These zip codes are highlighted in yellow in Table 1. However, **76% of the Angioplasty Region zip codes do not have access within 30 minutes** as the standard of care dictates.
    - 9 of the zip codes aggregate to 6 towns: Lebanon, North Franklin, Thompson, Bozrah, Norwich, and Putnam. As indicated above, these 9 zip codes represent 31% of the total 231,419 Angioplasty Region population.
    - **3 of the 9 zip codes mentioned in the previous bullet must leave the state to seek care within 30 minutes** (North Grosvenordale, Thompson, and Putnam). These 3 zip codes represent 25% of the 71,189 individuals with 30-minute access today, or 18,035 residents.
3. 14 of the 38 zip codes (37% of the zip codes) have an **out of state provider** as the closest PCI facility.
    - 11 of the 14 zip codes that have an out of state provider as the closest PCI provider are **also outside the 30 minute optimal drive time** (Brooklyn, Danielson, Dayville, East Killingly, Pomfret Center, Quinebaug, Woodstock &

Woodstock Valley, Moosup, Sterling, and Voluntown). **These zip codes represent 51,722 or 22.3% of the entire Angioplasty Region.**

- As discussed above, the remaining 3 of the 14 zip codes (North Grosvenordale, Thompson and Putnam) are within 30 minutes to a PCI capable provider but must travel out of state to seek services. These zip codes represent approximately 8% of the population of the Angioplasty Region.

4. Lawrence + Memorial Hospital ("L+M") is the closest provider to 16 zip codes within this region today, however **only 6 of these 16 zip codes have access to L+M within 30 minutes. The remaining 10 zip codes must travel more than 30 minutes to L+M for care**.

   - Backus would be the closest provider to all 16 of these zip codes.
   - If Backus receives approval to establish PCI services, the drive time for the 6 zip codes (53,154 residents) within 30 minutes of L+M today would be significantly improved to a drive time between 2-15 minutes. The drive time for the remaining 10 zip codes **(49,325 residents) would be improved from greater than 30 minutes to a 12-30 minute drive time**. The establishment of this service at Backus will optimize the current standard of care for more than 102,000 residents of the Angioplasty Region.

5. **Backus Hospital is closer to all of the 38 zip codes, or 231,419 residents, than L+M.** The proximity of these zip codes to Backus will improve quality and outcomes, and will provide the residents of this Region with the same standard of care enjoyed by residents of the L+M region today.

6. If Backus Hospital were to start PCI services, it would be the closest provider to 23 of the 26 towns or 88% of the towns within the Angioplasty Region, **equating to 92% of the population of the Angioplasty Region.**

   - Putnam, Thompson and Woodstock are closer to out of state providers.

Table 1

			Nearest PCI Capable Facility					Backus Hospital		Lawrence and Memorial Hospital	
ZIP Code	City	2015 Population	Nearest PCI Capable Facility	Nearest Facility State	Distance (miles)	Drive-Time (minutes)	Within 30 Minutes?	Distance (miles)	Drive-Time (minutes)	Distance (miles)	Drive-Time (minutes)
06226	Willimantic	20,209	Hartford Hospital	CT	29.6	41	No	15.4	23	29.7	42
06231	Amston	4,271	Hartford Hospital	CT	27.3	34	No	19.2	23	27.5	43
06234	Brooklyn	8,156	St. Vincent Hospital	MA	40.3	41	No	22.4	29	36.6	48
06235	Chaplin	2,099	Hartford Hospital	CT	35.8	46	No	20.9	31	35.3	50
06237	Columbia	5,320	Hartford Hospital	CT	25.8	35	No	18.3	26	32.6	45
06239	Danielson	11,641	St. Vincent Hospital	MA	36.1	34	No	25.8	25	40.1	44
06241	Dayville	6,505	St. Vincent Hospital	MA	31.4	34	No	32.6	34	46.8	52
06243	East Killingly	218	Landmark Medical Center	RI	23.8	35	No	33.0	34	47.2	52
06247	Hampton	2,660	Lawrence and Memorial Hospital	CT	33.6	43	No	18.2	28	33.6	43
06249	Lebanon	7,138	Lawrence and Memorial Hospital	CT	23.2	30	Yes	10.4	15	23.2	30
06250	Mansfield Center	4,713	Hartford Hospital	CT	31.1	44	No	21.1	33	35.4	52
06254	North Franklin	1,969	Lawrence and Memorial Hospital	CT	21.5	30	Yes	7.0	11	21.5	30
06255	North Grosvenordale	4,842	St. Vincent Hospital	MA	24.6	25	Yes	39.7	38	53.9	57
06256	North Windham	2,263	Hartford Hospital	CT	32.9	42	No	17.7	27	32.1	46
06259	Pomfret Center	4,544	St. Vincent Hospital	MA	31.3	38	No	35.0	37	43.3	56
06260	Putnam	9,385	St. Vincent Hospital	MA	28.1	28	Yes	35.1	33	49.3	51
06262	Quinebaug	416	St. Vincent Hospital	CT	20.9	31	No	44.3	46	58.5	64
06264	Scotland	157	Lawrence and Memorial Hospital	CT	29.9	40	No	12.5	21	29.9	40
06266	South Windham	398	Lawrence and Memorial Hospital	CT	25.9	35	No	11.5	17	25.9	35
06277	Thompson	3,808	St. Vincent Hospital	CT	24.2	24	Yes	39.5	37	53.7	55
06280	Windham	3,326	Lawrence and Memorial Hospital	CT	28.2	39	No	13.7	20	28.2	39
06281	Woodstock	7,049	St. Vincent Hospital	MA	25.3	37	No	43.8	49	52.0	68
06282	Woodstock Valley	1,179	St. Vincent Hospital	MA	33.0	41	No	31.5	44	45.8	63
06330	Baltic	3,462	Lawrence and Memorial Hospital	CT	24.3	32	No	6.9	14	24.3	32
06331	Canterbury	5,033	Lawrence and Memorial Hospital	CT	28.0	38	No	11.4	21	28.0	38
06334	Bozrah	2,839	Lawrence and Memorial Hospital	CT	20.2	27	Yes	5.9	8	20.2	27
06336	Gilman	72	Lawrence and Memorial Hospital	CT	21.5	29	Yes	7.2	11	21.5	29
06351	Jewett City	16,272	Lawrence and Memorial Hospital	CT	25.1	35	No	13.2	17	25.1	35
06354	Moosup	6,410	Kent Hospital	RI	24.4	41	No	22.2	25	36.4	44
06360	Norwich	38,207	Lawrence and Memorial Hospital	CT	17.7	23	Yes	0.7	2	17.7	23
06365	Preston	4,708	Lawrence and Memorial Hospital	CT	19.1	31	No	5.8	12	19.1	31
06374	Plainfield	8,320	Lawrence and Memorial Hospital	CT	30.5	34	No	16.3	16	30.5	34
06377	Sterling	3,081	Kent Hospital	RI	23.1	39	No	24.6	27	38.8	46
06380	Taftville	2,929	Lawrence and Memorial Hospital	CT	19.6	28	Yes	2.7	6	19.6	28
06384	Voluntown	2,523	Kent Hospital	RI	27.7	32	No	17.4	22	31.2	40
06415	Colchester	17,063	Hartford Hospital	CT	30.0	32	No	16.8	17	25.1	36
06423	East Haddam	4,989	Lawrence and Memorial Hospital	CT	22.8	39	No	22.5	30	22.8	39
06469	Moodus	3,245	Hartford Hospital	CT	31.4	36	No	22.3	24	30.6	43

Source: Google Maps, 2016; Study conducted between 6pm and 7:30pm Eastern

© 3d Health, Inc.

Respectfully submitted,

Hartford Hospital and
The William W. Backus Hospital

By: Robert J. Anthony /cm

Robert J. Anthony
Brown Rudnick LLP
CityPlace I, 185 Asylum Street
Hartford, CT 06103-3402
(860) 509-6517 (tel.)
(860) 509-6501 (fax)
ranthony@brownrudnick.com
Juris No. 403862
Its Attorney

CERTIFICATION

I hereby certify that true and correct copies of the above were served by electronic mail on this 1st day of April, 2016, followed by first class mail, postage prepaid, to the following counsel of record:

Michele M. Volpe
Attorney for Lawrence + Memorial Hospital, Inc.
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, Connecticut 06511
mmv@bvmlaw.com

Robert J. Anthony /ay

Robert J. Anthony
Brown Rudnick LLP

62440153 v1-WorkSiteUS-032836/0002

Greer, Leslie

From: Armah, Olga
Sent: Wednesday, April 06, 2016 3:44 PM
To: Johnson, Kyle R.; Janette.Edwards@hhchealth.org; Anthony, Robert J.; Michele Volpe
Cc: User, OHCA; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Fernandes, David; mmv@bvmlaw.com; Kathleen Gedney; Jennifer O'Donnell
Subject: Docket No. 15-32031-CON - 3/23 Hearing Transcript
Attachments: 32031 Hearing Transcripts.pdf

Please find attached the 3/23 hearing transcript for Docket No. 15-32031-CON.

Thanks.

Olga

Olga Armah, M. Phil
Associate Research Analyst
Office of Health Care Access
CT Department of Public Health
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134

Phone: 860 418 7070
Fax: 860 418 7053
mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

OFFICE OF HEALTH CARE ACCESS

THE WILLIAM W. BACKUS HOSPITAL

ESTABLISHMENT OF A PRIMARY AND ELECTIVE PCI PROGRAM AT THE WILLIAM W. BACKUS HOSPITAL

DOCKET NO. 15-32031

MARCH 23, 2016

9:52 A.M.

DEPARTMENT OF PUBLIC HEALTH
410 CAPITOL AVENUE
HARTFORD, CONNECTICUT

POST REPORTING SERVICE
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. . .Verbatim proceedings of a hearing before the State of Connecticut, Department of Public Health, Office of Health Care Access, in the matter of The William W. Backus Hospital, Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital, held at the Department of Public Health, 410 Capitol Avenue, Hartford, Connecticut, on March 23, 2016 at 9:52 a.m. . . .

HEARING OFFICER KEVIN HANSTED: Good morning, everyone. This hearing before the Office of Health Care Access, identified by Docket No. 15-32031, is being held on March 23, 2016 to consider The William Backus Hospital's application for the establishment of a primary and elective PCI program at The William Backus Hospital.

This public hearing is being held pursuant to Connecticut General Statutes, Section 19a-639a, and will be conducted as a contested case, in accordance with the provisions of Chapter 54 of the Connecticut General Statutes.

My name is Kevin Hansted, and I have been

designated to serve as the Hearing Officer for this matter.

The staff members assigned to assist me in this case are Kaila Riggott, Jessica Schaeffer-Helmecki, Olga Armah, Brian Carney and David Fernandes. The hearing is being recorded by Post Reporting Services.

In making its decision, OHCA will consider and make written findings concerning the principles and guidelines set forth in Section 19a-639 of the Connecticut General Statutes.

The Applicant, William W. Backus Hospital, has been designated as a party in this proceeding. Lawrence & Memorial Hospital has requested Intervenor status and has been designated as an Intervenor with full rights in this proceeding.

At this time, I will ask staff to read into the record those documents already appearing in OHCA's Table of the Record in this case.

All documents have been identified in the Table of the Record for reference purposes. Jessica?

MS. JESSICA SCHAEFFER-HELMECKI: My name is Jessica Schaeffer-Helmecki, and, on behalf of OHCA, I'd like to request Exhibits A through O be entered into the record.

HEARING OFFICER HANSTED: Are there any objections to any of the exhibits?

MR. DOUGLAS COHEN: I have. Is O on the sheet that you passed out this morning?

MS. MICHELLE VOLPE: Yes.

HEARING OFFICER HANSTED: Yes.

MR. COHEN: Okay. I also have an additional document for the record, which is a letter from a patient, Irene Cardinal(phonetic), so if I could pass that around now?

HEARING OFFICER HANSTED: Sure.

MR. COHEN: I have copies for everyone.

HEARING OFFICER HANSTED: Okay.

MS. VOLPE: Will Ms. Cardinal be here to --

MR. COHEN: No. This is not a -- she's not part of testimony. It's just a letter of support.

HEARING OFFICER HANSTED: Just a letter of support. Okay and did you want to enter that as an exhibit?

MR. COHEN: No. Just a letter of support in the record.

HEARING OFFICER HANSTED: Attorney Volpe, do you have any objection?

MS. VOLPE: I don't have any objection, no.

HEARING OFFICER HANSTED: Okay, thank you. That will be entered into the record, but not an exhibit.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: You're welcome. Attorney Volpe, do you have any objections to any of the exhibits in the record?

MS. VOLPE: No. We're good with adding N and O and discussing it at the next break.

HEARING OFFICER HANSTED: Okay.

MS. VOLPE: Thank you.

HEARING OFFICER HANSTED: Thank you. And, at this time, would all the individuals, who are going to testify, even if you're not sure you're going to testify, please stand, raise your right hand and be sworn in by the court reporter?

(Whereupon, the parties were duly sworn in.)

HEARING OFFICER HANSTED: And just a reminder for those folks, who were just sworn in. When you testify today, just please state your full name for the record before you testify for purposes of the court reporter. I appreciate that.

And, first, let me just tell everyone. I know this is a small room. There's a lot of people in here. It's going to get hot, even though you may not be hot yet. Feel free to take off your jackets if you need to. If you want to step out just to cool off. If anybody needs a break, just let me know. I'm happy to do so.

We're going to change up what we usually do. There was a motion in limine filed by the Applicant in this matter and, also, an objection thereto, filed by the Intervenor.

I have not made rulings on either of those, and, so, what we'll do this morning is we'll hear presentations from both the Applicant and the Intervenor.

After that, any individuals from the public, who would like to give comment or public officials, may do so at that time.

Then we will take a short break, so everyone could review the motion in limine, as well as the objection, and, after that break, we'll come back and hear argument on the motion and the objection. Is that okay with everyone?

MS. VOLPE: That's acceptable to us.

MR. COHEN: No objection.

HEARING OFFICER HANSTED: No objection? Okay. Okay, so, we'll proceed in that manner, and, the Applicant, you may proceed at this time with your initial presentation.

MR. COHEN: Okay. As an initial matter, some administrative issues. The first, we have two demonstrative exhibits. These are in the application or the completeness questions. They're identical to what's in there.

We don't need to have these identified as exhibits, but they're just demonstrative exhibits for our witnesses. They're identical to what's already in the record, so I just wanted to point that out to you.

HEARING OFFICER HANSTED: Okay. Before you proceed, Attorney Volpe, are you okay with that?

MS. VOLPE: I don't have an objection to those, but to the extent they're going to be referred to, if you could provide the page reference in the application to us now? We can't see that from here.

MR. COHEN: This one is completeness response, page 1450. It's entitled Connecticut PCI and non-PCI hospitals average time to transfer to another facility for an acute coronary intervention, and this is completeness response, page 1448, and there's no title.

It's just a map of 30-minute drive times map, and, again, that's in the completeness questions.

HEARING OFFICER HANSTED: Thank you, counsel.

MS. VOLPE: I just have one question on the map.

HEARING OFFICER HANSTED: Sure.

MS. VOLPE: Is there a source for that? What's the primary source?

MR. COHEN: Yeah. It's 3d Health, and you can Cross-Examine him on that when he gets to testify on it.

HEARING OFFICER HANSTED: Is the source cited in the application?

MR. COHEN: I believe it is.

MS. VOLPE: Yeah, I didn't note it. That's why we asked. I don't know that it's on the page, or, if it is, the print was so fine it wasn't readable by my old eyes.

MR. COHEN: And then the last administrative matter is that one of our witnesses won't be here until the afternoon, Greg Allard. He's submitted a letter, submitted some support for the application. He is a non-Backus employee involved in EMS.

MS. VOLPE: And all I would ask, then, it's a letter of support. Is it going to be considered part of the Table of Record?

HEARING OFFICER HANSTED: That was going to be my question, one of two. Is he a formal witness, and will he testify and be subject to Cross?

MR. COHEN: He will be subject to Cross. He's not going to be presenting anything. He didn't prepare pre-filed testimony, will not be presenting, but we would like him sworn, and if there are questions related to EMS, as he's an expert on those issues, he can testify to them.

HEARING OFFICER HANSTED: And did you say the letter was already submitted?

MS. VOLPE: It's been submitted.

HEARING OFFICER HANSTED: It's been submitted, okay.

MR. COHEN: Yeah.

HEARING OFFICER HANSTED: Okay.

MR. COHEN: Exactly.

MS. VOLPE: So I guess my objection would be, in the event he doesn't show up and available for Cross, I mean we don't know, you know, how short or long the proceeding would go, I'd like to suggest that it not

be part of the Table of Record and it be offered as a letter of support.

HEARING OFFICER HANSTED: Absolutely. If he doesn't show up and, therefore, he's not subject to Cross, I'll accept the letter as a public comment, but not as an exhibit.

MR. COHEN: Sure. Okay.

HEARING OFFICER HANSTED: Okay, you may proceed if there are no other administrative matters.

MR. COHEN: No other administrative matters. Thank you.

HEARING OFFICER HANSTED: Okay.

MR. COHEN: With that, first, I want to thank you for your attention and for this hearing. We're going to be presenting here on behalf of Backus and Hartford Hospital application for primary and elective angioplasty, without on-site backup.

Ten years ago, if we had this application, it would have been extremely contentious, because angioplasty, without on-site surgical backup, was new, and I think Connecticut and OHCA should be commended for its actions over the last 10 or 12 years in providing these kinds of, allowing these kinds of services to be provided at a community hospital.

So, pure and simple, this application is for providing a lifesaving service to an isolated and underserved population in what people refer to as the quiet corner of Connecticut.

While other areas of the state may be saturated or over-saturated with these lifesaving angioplasty services, that population in our angioplasty region east of the Connecticut River is not over-saturated, and our witnesses will talk about that today.

We have a compelling case for the need for these services, and that need will not impact in any significant manner the L & M program. This is not a shift of patients from L & M to Backus. That's very important for you to consider.

Our witnesses will outline in our testimony today the exhaustive efforts and study that we've made in putting this application together, in addressing each and every question that OHCA has raised, and we're prepared to discuss our responses today.

Importantly, this is not an isolated freestanding program, like some others, but is a part of Hartford HealthCare's Cardiovascular Institute.

Our interventionalists are high-volume providers, with excellent outcomes and a lot of

experience. Our staff is well-experienced and trained, and, together, they'll bring this excellence, diligence, procedures and attention to detail to this program.

Our population is sicker than the rest of the state, and, as we'll show, the rates of angioplasty are much lower in our angioplasty region than in the rest of the state.

Why? And that's a question that you, as OHCA, have to answer today. We will answer that question and provide a solution to this different standard of care for this population.

With that, I give you David Whitehead, who is the Senior V.P., Chief Strategy and Transformation Officer.

HEARING OFFICER HANSTED: Mr. Whitehead, I'm going to take all witnesses up here, just to make it clear who is speaking as a witness.

MR. DAVID WHITEHEAD: Oh, sure. Well, good morning.

HEARING OFFICER HANSTED: Good morning.

MR. WHITEHEAD: And thank you for your time. My name is David Whitehead. I am the Chief Strategy and Transformation Officer for Hartford HealthCare, and I would like to adopt my pre-filed

testimony.

HEARING OFFICER HANSTED: Thank you.

MR. WHITEHEAD: I'm going to introduce some key themes, and then, as you have seen a number of my colleagues, will come forward and elaborate on their testimony.

I'm not going to read my testimony, and I've coached them to do the same in this process, because I know that you've taken the time to look at it already.

The real issue here is access to an area currently served by Backus. That includes three towns designated as health professional shortage areas and 11 towns designated as medically underserved areas.

It is also an area high risk for coronary artery disease, due to the high level of risk factors prevalent in this region's population.

There is a high rate of obesity, diabetes and smoking, all factors resulting in projected increases and the need for and utilization of cardiovascular services in this region.

Social determinants of health, such as low socioeconomic status, high rates of underinsured and uninsured, and a high population to physician ratio perpetuate the disease burden in this area.

Limited access to PCI services contribute to the current rates of emergency PCI and elective PCI interventions for residents in this rural part of the state being significantly below state and national levels.

As OHCA is aware, this is not the first investment in this region by Backus or Hartford HealthCare. In 2012, Backus established a full service, 24/7 satellite emergency care center in the Town of Plainfield.

The center of this isolated medically underserved geographic region, a need was revealed through careful market analysis. A sound strategy to meet community need was developed and approved by OHCA on December 3, 2010 under Docket No. 09-31503.

The methodology used in that application to identify a gaping hole of emergency services in an emergency service region is the same methodology used to define the angioplasty region.

I would ask for your approval of this application, based on the clear public need that’s been demonstrated in this application, but, more importantly, for the 230,000 residents, who reside in this isolated, undisturbed geographic region, so that they can have

improved access for this lifesaving care. That will conclude my testimony.

HEARING OFFICER HANSTED: Thank you, Mr. Whitehead.

MR. WHITEHEAD: And, with that, I would like to introduce Mariane Carna, who is executive lead for the Hartford HealthCare Heart and Vascular Institute.

HEARING OFFICER HANSTED: Good morning.

MS. MARIANE CARNA: Good morning. My name is Mariane Carna, and I adopt my pre-filed testimony.

HEARING OFFICER HANSTED: Thank you.

MS. CARNA: Thank you for your time and attention this morning. It’s an honor to be here.

My role with Hartford HealthCare is the Vice President of the Heart and Vascular Institute. I encourage the team to recognize that, although we are looking at primary and elective angioplasty, that this is part of a continuum of care that we are looking to build with multidisciplinary teams across our organization.

My role has been, I’ve been there for five months now, is to leverage the current resources that we have at our tertiary care center, so looking at Backus as our region this will be an extension of expertise that we currently have at our main medical center with high

volume operators under the Institute's guidance and direction.

We have developed a co-management model, so I have physician experts that are at my right leading the Institute under the direction of a quality infrastructure that will also be served as managing the direction of the Backus program in the east, so this is not, in our minds, a new program, but an extension of a current service area that we have.

You'll be hearing from our experts in our clinical community, Dr. John Foley and Dr. Paul Thompson, who are our physician leads in that area.

In addition to the elective in the PAMI(phonetic) program, we're also looking to build other services throughout the continuum as primary cardiology, vascular surgery, electrophysiology, so that patients will have access to the full spectrum of services that we offer at Hartford HealthCare.

So I appreciate your time and attention this morning. I look to introduce Bimal, who is our President of the East Region.

HEARING OFFICER HANSTED: Good morning.

MR. BIMAL PATEL: Good morning. My name is Bimal Patel. I'm the President of the East Region,

Senior Vice President, Hartford HealthCare. I adopt the pre-filed testimony.

HEARING OFFICER HANSTED: Thank you.

MR. PATEL: As the President of the East Region, I sleep and I wake up looking at the map, more than 200,000 people living, which is 6,000 rooms like this, distributed over that large geography, and think about what we for the care and what we do for the access.

It is not about just one hospital. It's not just about a small region or small town. It's about East Region of Hartford HealthCare, and I'm responsible for the care that we render and provide, not just within cardiovascular, but across the other service lines, as well.

So the epicenter for our care that we render in East Region is not Norwich. It's beyond that. It's above that. And I think the circle that you see kind of describes that we have that responsibility as Hartford HealthCare.

We have two hospitals in our service area, Windham Hospital and Backus Hospital, and we have Plainfield Emergency Center, and we continue to develop a variety of different access points that are ambulatory in nature and taking the care of patient needs.

The importance of today, we can talk about economics, case mix index base cost for care for discharge. We talk about profitability of our organization versus other organizations. Hands down, we've beaten all those (coughing), but I'm not here to talk about that.

We have experts through the case on clinical bases and on economic bases, etcetera. This is beyond economics. It is about providing access and it's providing care to the community.

It's a clear public need. Submitted information clearly states that, that compared to Connecticut overall, Hartford HealthCare's East Region and Hartford HealthCare's Backus, in particular, has poor numbers, in terms of healthcare outcomes.

Our population we serve is not impacted equally. They are disadvantaged, and I'm here to represent those 200,000 people today in front of you, as your authority to have access to care and my authority or my responsibility to provide the care. I think we've got to really look at this in the mirror and say how can I go back to 200,000 people and tell them that we can't have the same outcome for access to care with the rest of the Connecticut population?

So I humbly support and put these efforts in front of you this morning, as the leader of Eastern Connecticut Healthcare, that you would grant us an access that what we've asked here.

And, with that note, let me introduce our leader for Chief in East Region's Cardiology, Dr. John Foley.

HEARING OFFICER HANSTED: Thank you.

MR. PATEL: Thank you.

HEARING OFFICER HANSTED: Good morning.

DR. FOLEY: Good morning. Excuse me. I have a little bit of a cold.

HEARING OFFICER HANSTED: That's fine.

DR. FOLEY: I won't touch the microphone, nor breathe on anybody.

HEARING OFFICER HANSTED: 'Tis the season.

DR. FOLEY: My name is John Foley. I'm currently the Director of the Cardiovascular Service Line for the Hartford Medical Group and Chief of Cardiology at Backus and Windham Hospital.

I really appreciate you spending your time today meeting with us.

I have filed testimony previously and would like to adopt that for the record.

HEARING OFFICER HANSTED: Thank you.

DR. FOLEY: I'm going to reference notes, so it keeps me on track. I hope I'm a better doctor than presenter at hearings.

My role, should we be successful in getting the cath lab, will be to work with Dr. Kiernan and members of the Hartford Hospital angioplasty team to implement any of the strategic and operational goals that we need to get this program started.

We are not, and you've heard this before and it will be a theme, we're not in a vacuum. We are working really as an extension of Hartford Hospital, but when I think about my patients, the people that I take care of, and it's been mentioned earlier, compared to the general people in Connecticut, the population group they're sicker.

They have more hypertension, higher rates of smoking, higher rates of diabetes, obesity, inactivity, and, overall, the mortality is worse than the rest of the state.

It's been said that the rates of angioplasty have decreased, and, certainly, in some areas of the country, perhaps even the state, that's true, but if you look at the Hartford Hospital volumes over the

last two years, we've seen increases in the number of procedures performed, so, from the Hartford HealthCare perspective, we don't see that lack of volume.

When you consider the angioplasty region, though, and you compare the fact that they're sicker and yet their rates for angioplasty and PCI services are a lot lower, 18 percent compared to statewide for primary PCI and eight percent lower than national, when you look for elective, it's worse, 19 percent compared to the state and 40 percent compared to national.

So, you know, if the patients are sicker, the obvious question is why are they getting fewer PCIs, and I think there's one word, and it's access, which is really the mission for us today.

Why are their rates lower? Well Hartford HealthCare is doing more than just putting forward a CON for a cath lab to improve access.

If you look in the Windham community, and you'll see the maps, a very sick population group and very needy, in terms of what they need from services. We are increasing the footprint for cardiology in Windham by increasing office space.

The urgent center at Plainfield has been talked about. The volumes that were originally predicted

in that application have been more than doubled, so I think that that's been a huge success and has shown that Plainfield is an important area for care.

As such, in June, we're going to be opening our newest cardiology office in a building adjacent to the Plainfield walk-in, and we'll have a very busy cardiology presence there.

And finally, in June, the one and only cardiology practice that currently is in Putnam, there are three cardiologists that will be joining the Hartford medical group, and they'll be part of my practice, again, working within the region, so those physicians will be referring, and their patients will be taken care of.

Looking at the map of Windham County, with a very high mortality and a low rate of access and the map showing that the northeast corner of Connecticut is outside of a drive time clearly to any PCI hospital within 30 minutes, so those are the patients that we're really talking about, it might be 25 or 30 minutes from a small fringe or region in Norwich to Lawrence & Memorial Hospital, but we're talking about the person at the Woodstock Fair, who has a heart attack, and they will do far better stopping at Backus with emergency services than continue on to any other PCI hospital.

And saying that a patient can then just go out-of-state to another hospital, whether it's Rhode Island, or Massachusetts, or whether they can go to another PCI-capable hospital, loses sight of some critical issues; long drive times to visit their loved one.

I have patients, who don't even have automobiles. Our rate of automobile ownership in our catchment area is far lower than other areas of the state. They can't even get someplace to pick up their loved ones.

Care is fragmented. There are problems with insurance. There are excess costs to the systems and families, and, frequently, when they're in those institutions, they're referred to other physicians, which then they have to follow-up with, and, so, we have failed in access to care for the angioplasty, but then they've repeatedly gone back out of network to great distances for further follow-up care.

When you look, especially in the case of a routine angioplasty that develops from a cath, so the elective PCI cases, I've taken a detailed history and physical, I know the patient well, I know their family, I've probably taken care of most of them, the decision,

once I see a lesion, as to what is best to treat that patient, is best made by the person, who knows them well and not necessarily on the fly in an angioplasty suite many, many miles away.

When a patient gets a catheterization at Backus and requires transfer, it brings up all the issues that I've talked about, but there are a few others.

Again, excess cost to the patient and system, the risk of vascular, excuse me, complications and bleeding, and repeat arterial puncture, which, again, leads to more cost and more risk to the patient.

I will say it again. A cardiac cath is best done by qualified doctors, who know the patient and who can make the best decision locally.

I first came to Connecticut in 1999. I trained at UMass Medical Center, so I'm familiar with UMass. I do cardiac catheterization. At that point, I had to bring my patients to Lawrence & Memorial to do catheterizations. We did not have a program and they did.

At that time, you know, it was an inconvenience to the patients. There were extra costs, communication issues, and, quite frankly, the patients did not like to travel. It was difficult for them, and

many opted not to go.

Soon, Backus applied to OHCA and was granted privileges for diagnostic catheterizations, and I think our record will show that it's been a safe and effectively-run program over the years.

OHCA was presented with a CON request by Lawrence & Memorial for elective angioplasty. Their physician lead operator at the time, who, by the way, has recently left Lawrence & Memorial and has joined our cardiology practice in Norwich, was anything but a high-volume operator, and, yet, that program was successful, and the outcomes were good, and they later went on to do elective PCI.

I think OHCA was out in front. There were some areas of the country that had done it, not a lot, but OHCA saw the merits of elective PCI in a hospital, who did emergency plasty.

So the experiment has been done, you've already seen it, and it's worked. We have a sicker population group, who I've hopefully shown that or will show that, and these patients will be cared for in what will be an extension of the cardiac cath lab at Hartford Hospital. We bring to the table all of their expertise and many years of experience, including their high volume

case mix.

I'll conclude by saying that I have frequently been at the bedside or in an exam room talking to patients, talking to them about a transfer to a hospital further away for elective catheterization, and watched tears break out, because they had no idea how they were going to get there, or get home, or how they're going to visit their loved ones.

I remember vividly an 85-year-old man, who was in tears that it would be the first time away from his wife for a night in 60 years.

I think we can do better than this. This is an application submitted after years of thought and careful deliberation. We need OHCA's support to build a PCI program for those patients, who continue to go without.

I thank you very much for your time, and I look forward to answering any questions later. I'd like to introduce Dr. Paul Thompson, who is the Chief of Cardiology at Hartford Hospital.

HEARING OFFICER HANSTED: Thank you, Doctor.

DR. PAUL THOMPSON: My name is Paul Thompson. I'm the Chief of Cardiology at Hartford

Hospital, and I'm also the Medical Director of the Hartford HealthCare Heart and Vascular Institute, and where I'd like to go is just take a few minutes to show you why we think that this program is an integrated and integral part of our overall Heart and Vascular Institute.

So a little bit about me. I've been at Hartford Hospital for 19 years, I've been Chief of Cardiology at Hartford Hospital for the past 10 years, and, over that period of time, we've grown from five employed full-time physicians to where we have 21, and, so, our emphasis has been on growing the program and making it quality.

Over the last year, we had 139 full length publications, so we've tried to make a clinically-excellent, as well as a nationally-recognized program.

It's turned out to be an excellent program. Last year, we were eight points away from being one of the top 50 cardiovascular programs by U.S. News and World Report, and the crowned jewel of that program is actually our interventional cardiology program, which is directed by Fran Kiernan, who sits here.

These are nine geographic full-time cardiologists, who essentially do nothing, but

interventional cardiology at Hartford Hospital. They started our angioplasty program in 1982. They have done about 30,000 procedures since that time and have kept the volume that we do at about 2,000 cases per year since 2009, so a fairly steady volume of that.

They've also had a lot of experience in starting programs. For example, they helped Backus get their original diagnostic cath program. They helped Middlesex get their diagnostic cath program. Helped UConn start their full angioplasty program and, also, helped the Hospital of Central Connecticut start their primary angioplasty program.

They've also started our TAVR Program, our Mitral Valve Clip Program. My point is that they have a lot of experience in starting programs and doing them well.

I want to make the point that the Backus program is considered by us an extension of the program. It will be staffed, directed by these Hartford Hospital-based geographic full-time interventional cardiologists.

Now just a quick word about the Heart and Vascular Institute. Our goal is to integrate cardiovascular care throughout the region that we serve, so it's not just an angioplasty program, but we already

have electrophysiologists, who are working at Backus Hospital, so the point is to provide excellent cardiovascular care throughout that region.

We'd like to achieve a bunch of number ones. Number one is we'd like to have number one quality, but we'd also like to have one primary care cardiologist, one medical record, one bill for the patient, an integrated care program.

Why? Because integrated care is the best care you can provide. So, again, the point is we do not want Backus, this angioplasty program, to be viewed as a standalone program. It's integrated and integral to our overall plan for the Cardiovascular Institute.

So why primary angioplasty? Look, it's common knowledge that for a myocardial infarction, time equals cardiac muscle. Sure, there are benchmarks, in terms of 90 minutes or 120 minutes, but I think every one of us knows that the quicker you can get an artery open, the better off you are, and if you look at the maps and if you look at the material presented by others, Backus is closer, angioplasty would be quicker.

Especially, quicker is better if you can assure quality, and that's our point. This is going to be an extension of the Hartford Hospital Interventional

Program.

Why the elective angioplasty or the procedures? That's because we want to make an integrated, not fragmented, care model; one primary care cardiologist, one medical record, so the idea of transferring people in and out is fragmented care, and we don't think that's the best care that we can provide.

John has presented the issue about the positive impact on families, but our overall goal is to improve the quality of cardiovascular care that we provide in that area.

So I'm going to turn it over to Shane Foreman. That concludes what I would like to say. And he's from Diagnostic Health Care Markets and will discuss the distribution of patients, etcetera.

HEARING OFFICER HANSTED: Thank you, Doctor.

DR. THOMPSON: My pleasure.

MR. M. SHANE FOREMAN: Good morning. How are you?

HEARING OFFICER HANSTED: I'm well, thank you.

MR. FOREMAN: Good. I took your advice and I parked my jacket back there. I hope you don't

mind.

HEARING OFFICER HANSTED: Perfectly fine.

MR. FOREMAN: Good. Thank you for having me.

HEARING OFFICER HANSTED: You're welcome.

MR. FOREMAN: I'm Shane Foreman. I'm the founder and CEO of 3d Health, and I had pre-filed testimony that I'd like to adopt.

HEARING OFFICER HANSTED: Thank you.

MR. FOREMAN: No problem. I appreciate the opportunity to come. This is actually, over an 11-year period, the fifth time that I've come before OHCA around different market assessments, and I'll give you some of the examples of my previous work with similar methodologies before OHCA.

From a charge perspective, so we, as a company, completed the market assessment that is kind of the backbone of the CON application, and, at a really high level, we did a few things.

One was we wanted to test whether or not there was an underserved community or a documented need for PCI services in eastern Connecticut.

We wanted to understand, if there were, where is that? We also wanted to look at prevalence of

disease, and then treatments, and then, ultimately, we finish by taking a shot at estimating potential volumes for a program at Backus, and then, also, looked at potential impact on other facilities, so, at a high level, that's what you'll find in our detailed market assessment.

I wanted to take just a couple minutes and talk about our methodology around service area. So if you take a step backwards and think about service area, ultimately, what you're attempting to project is, for a given particular service in a particular geography, what's the likely patient base that you're going to serve?

And, so, we take a customized look at, on a service-by-service basis, and I'll talk you through some of the criteria that we consider, but when we complete market assessments, we look service-by-service, market-by-market to help understand what kind of patient draw can you expect?

So I'll give you a couple of examples. So if, in our region in eastern Connecticut, if I were looking at establishing a primary care practice, I would probably look back at the employed positions within our network and understand patient draw or patient origin for

a primary care practice, and, so, you'd probably look at like a five to eight-mile footprint on patient draw, so, obviously, it wouldn't be appropriate to say, oh, it's the Backus 75 percent patient area.

On the other end of the spectrum, if we were coming before you and saying we need additional hospital beds, I think the 75 percent service area with some immigration factor would make all the sense in the world as a particular service area.

An additional example is just outpatient imaging, so I actually came before OHCA three times from 2005 to 2007 with Danbury Hospital around outpatient imaging and took the exact same approach to customizing the service area.

As an example, in outpatient imaging, if we were going to establish an outpost and it was a freestanding center, we'd probably go look out and see what's a reasonable patient draw? Maybe a 15-mile draw.

On the other end, if we were looking at doing provider-based imaging on a hospital campus, we would probably rely more on the historic hospital definition of their service area, but really customize that to outpatient only, not consider the inpatient piece of the business.

And, so, for all three of the Danbury Hospital analyses that I completed I guess 10, 11 years ago, that's the approach that we took. That's the approach that we were successful in partnering with you guys in understanding and ultimately being approved.

Another example is probably the Plainfield project, where we worked with Backus to help understand is there an unmet need for emergency services? If so, what's a reasonable patient draw?

In that instance, we did a 15-minute drive time. Obviously, it was approved by OHCA and has been wildly successful.

So, from a service area perspective, I think what we've done in way of considering drive time makes all the sense in the world, because it's around urgency of time, in order to access this service, so I would take a very similar approach if we were talking about starting a stroke program as an example, so I think the 30-minute drive time is the best way to think about the region and define the region.

A couple things just for you to consider as you think about the service area, and then I'll move on. So this is a service that's not currently offered at Backus, and, as such, those patients aren't in the

patient origin data, so even if you wanted to rely solely on inpatient data, they're not in the inpatient data, because we don't provide those services today.

I mentioned travel time. That's a huge role here. Does not include outpatient data, so, with the two-midnight rule, there's some shift from inpatient PCI services to the outpatient arena, and understanding that and capturing that within our service area definition is an important factor.

Role of the EMS on this type of service, obviously, impact on other providers, and then, ultimately, what we did was we looked at, on a zip code-by-zip code basis, so not town-by-town, but zip code-by-zip code, what's the closest Connecticut PCI provider to that particular zip code if Backus had a program? So that's the service area.

Let's talk a little bit just about prevalence of disease. So prevalence of disease is an interesting one. So we certainly looked at volumes in the marketplace in this particular marketplace, and we understand what's happening at both the national and state level, as it relates to inpatient PCI services and, also, the shift to outpatient.

The interesting thing, though, is, if you

really want to try to get at is there a need, yes, looking at historic volumes can inform the conversation, but, obviously, if an area is underserved, all you're going to see is some level of consistency in the fact that they're not getting enough services.

And, so, what we did was we looked at a couple of different data sources, one being kind of the backbone of this was ChimeData, so we just looked at ChimeData and said what's the incidence of disease across the state and developed incidents per capita or per population, so, when we looked at is there a need and are we getting treatment within this region, it's really on a per capita basis, but it's using ChimeData, Massachusetts data, and then some national data when we wanted to look at the national point of comparison.

And when we did that, we found a couple of things. One is the incidence -- so acute MI in total is up in the region. Incidence of STEMI per 100,000 patients is about 104.3 per 100,000. As a point of comparison in the state, that's 83, and, in the nation, it's 81.9, so, obviously, STEMI per 100,000 is much, much higher within this particular region.

The preferred treatment primary PCI in the region is 18 percent below the State and eight percent

below the national, and then secondary PCI is 19 percent below the state and 41 percent below national.

When we think about who treats these patients today, so the Hartford family already treats about 50 percent of the primary PCI patients and an additional 25 percent of the secondary PCI patients, so this is already a big part of the Hartford family book of business.

When we looked at the defined region, based on the methodology that I just explained, L & M has just three percent of the primary PCIs, and this was from 2014, three percent in primary and five percent in secondary from that angioplasty region that we defined.

So, in conclusion, I'll leave you with a couple of things. One is, over the past 14 years, as the founder and CEO of 3d Health, you know, as it relates to service areas and defining service areas that make both strategic sense and prove out to be a well-representation of where patients would come from, we've probably worked with over 250 hospital and health system clients across the country and defined thousands of service areas, and, again, no one fit cookie cutter approach to this, in my opinion, makes sense and tells the story.

I think there is a clear need in this

region, so, again, completely totally understand what's happening at both a national level and a state level, but this is an isolated, underserved population, as it relates to these services.

And then, finally, impact, as you'll see from my pre-filed testimony, we believe that impact on L & M will be minimal, and that, to a large degree, these patients have already spoken, so they're underserved as it is.

L & M has a great program. If these patients wanted to go to that program, they would already be doing so, so certainly understand angst around excess capacity, but, ultimately, it's this patient population that makes those decisions, and for going on, what, eight years of operation, these particular patients have chosen not to, by and large, chose not to avail themselves of that service. Thank you.

HEARING OFFICER HANSTED: Thank you.

MR. COHEN: We have one last point, which is Dr. Kiernan is not going to present any testimony today. He's available for Cross-Examination, plus I'd like him to adopt his pre-filed testimony for you.

HEARING OFFICER HANSTED: Absolutely. If he can come up and do that now, I'd appreciate it.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: Good morning, Doctor.

DR. FRANCIS KIERNAN: Good morning. My name is Francis Kiernan. I'm the Director of the Cardiac Laboratory at Hartford Hospital, and I'd like to adopt my testimony.

HEARING OFFICER HANSTED: Thank you.

DR. KIERNAN: Thank you.

MR. COHEN: And Dr. Kiernan is available for Cross-Examination questions today.

HEARING OFFICER HANSTED: Thank you, counsel.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: Does that conclude your presentation?

MR. COHEN: That concludes our presentation.

HEARING OFFICER HANSTED: Okay. Attorney Volpe, you may proceed.

MS. VOLPE: Thank you --

HEARING OFFICER HANSTED: You're welcome.

MS. VOLPE: -- Hearing Officer Hansted. My name is Michele Volpe. I'm legal counsel for Lawrence

& Memorial, the Intervenor in this process. Yes, we're an Intervenor, but, you know, more importantly, we're a provider, and we're a provider to this community and the 230,000 patients the Applicant reports are underserved.

In all of the national data from experts and organizations specifically dealing with analyzing, studying this PCI procedure from a primary and elective perspective, as well as from this own Department's exhaustive studies and looking at these programs in our state, there's a lot of data, surveys, expert opinions that should not be overlooked when analyzing the need and access for this population.

With us here today, you know, at Lawrence & Memorial we have professionals, individuals, experts to speak about the proposal presented before you today.

Lawrence & Memorial Hospital is the only community-based hospital that is doing primary and elective PCI, so we are extremely well-versed to speak to what's needed to start and implement a program at a community-based hospital, who doesn't have surgical backup.

So we agree with my colleague, Doug, when he said, you know, 10 years ago, it would be extremely contentious and highly unlikely, however, I present to

you today that implementing a program, even a primary program, in a region with a hospital that is within 17 miles of an existing one to implement the same duplicative service, is not in the best interest of Connecticut or the patients in these communities. There's a lot of data that would run contrary to that.

Yes, patients don't like to drive. We understand that. Patients don't want to be inconvenienced, but it's not a question of inconveniencing a patient. We talk about the heart muscle. It's a question of whether patients in this region already have access within national standards to this service.

We're going to present to you today, as we have in our pre-filed testimony, that nearly half of these towns in this angioplasty region that they've created nearly half are within the national standards of a 30-minute drive time, and 95 percent of them are within a 35-minute drive time of a provider capable in already offering PCI services, both elective and primary.

That's compelling information. That's 95 percent of this region that's already being serviced in accordance with the national standards.

Some of the towns that they're stating

don’t have access to this critical service, they’re not even closer. They’re not even the closest provider for the patient in that region, so some of the common themes and backbones, as Mr. Foreman stated in his analysis, we do think that, while they don’t want to adopt the OHCA established service area and the CMS Medicare established service area and defining their service area, we think it would be very dangerous for this department and others in the state to follow a service area that doesn’t take into account the national standards, in terms of minutes and drive time. That is crucial.

Some of the other common themes are that we’re not going to see a shift in volume away from L & M. Well we’ve looked at our patient origin data from this region. We know how many patients we’re servicing from this region, and, by our own patient origin data and what’s been on file with OHCA, you know, we will easily lose 25 to upwards of 30 percent of our volume if this program were to be implemented.

So we all know that it’s not in the best interest for patients, in terms of quality, to have low volume providers in this area.

Again, all the national data, and I’ll quote, and this is an important point, this goes to the

heart of everything, and this is from the ACC/AHA expert consensus document, “Multiple low volume and partial service PCI centers within a geographic area diffuse PCI expertise, increase costs for overall health care system, and have not been shown to improve access. If the transfer time is less than or equal to 30 minutes, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital.” And reperfusion, as we know, is blood to the heart.

“The development of PCI facilities within a 30-minute emergency transfer time,” and, again, we are a mere 17 minutes away, “to an established facility is therefore strongly discouraged.”

I mean these are what the national experts are telling us. This is also evidenced in OHCA surveys and data and studies that have been conducted by this Department, so, again, common themes are that it’s not going to impact us. Of course it’s going to impact us, and it’s going to impact all patients, who go to access this service.

Having low volumes at multiple institutions with a duplicate service within the same service area is devastating, and we all know -- they say,

well, we might lose a few volume. Any number, any patients that we would lose volume for in performing this service is too many. We would purport it's too many. So we care about this region, as well.

Are there more cost-effective ways to deal with heart issues in this region, emergent heart issues? Of course there are. This office has looked at them. L & M is prepared to talk about them.

There's been studies and reports issued by the Office of Health Care Access to say it would be prudent for EMS to have 12-lead standard EKGs in EMS providers. With this, they can better detect whether or not somebody is experiencing a heart attack.

If this were to happen, they could redirect people very timely. It takes a lot of time to setup a cardio cath lab. By everyone's own admission, it could take 50 minutes or more, so we're not going to save time.

What's going to save time and what's going to help this population is outfitting our EMS providers, so we hope Mr. Allard is able to be here to address that.

This office has stated that that would be the most cost-effective way to bring services to this region.

And there's also been a common theme, that this population is sicker. We have presented in our pre-filed testimony and for the record lots of reports from the economic office in the state and others that shows that this patient population is not sicker.

There have been information in the record to say that, if the patient, if the community has income of less than $50,000, that equates to a lower health quality of the patient. Those statistics relate to less than 25,000 in annual income, and we would purport that this region is not any sicker than the rest of the state when you look at and compare it to the other regions in the state, and we have done that for everyone.

So, again, you know, our position is, and we've presented it in the pre-file and you're going to hear it today, there is not an unmet need for this service.

In fact, if this were to be implemented, it would impact existing providers, but, more importantly, it will affect quality, and we all know that volumes equate to quality. There have been a lot of smarter people than us, who have looked at this issue, in terms of the national experts, and studied it, and would argue that there is no -- that we need to strongly

discourage implementing this type of program with a hospital that has capability within such a short distance of Backus and, also, within -- the fact that nearly 95 percent of those individuals have access to a capable provider.

I know the Applicant doesn't want us to look at out-of-state providers, but that's silly. You know, Dr. Foley said, you know, the poor patient, who has a heart attack at the Woodstock Fair. Well UMass is closer than Backus to the Woodstock Fair, and Backus is not even within the standard 30-minute drive time from Woodstock, so we would argue, and as would every other national expert, that that patient should go to UMass.

With that, I'd like to start and introduce some of the Lawrence & Memorial representatives, who are here to share information about this important decision OHCA has before them.

I'd like to have Mr. Bruce Cummings, President of Lawrence & Memorial, come up and adopt his pre-file and say a few words.

HEARING OFFICER HANSTED: Sure.

MS. VOLPE: Thank you.

HEARING OFFICER HANSTED: Good morning.

MR. BRUCE CUMMINGS: Good morning, ladies

and gentlemen. My name is Bruce Cummings. I'm the President and CEO of Lawrence & Memorial Hospital. I hereby adopt my pre-filed testimony.

HEARING OFFICER HANSTED: Thank you.

MR. CUMMINGS: Thank you. I'd like to say a few words to L & M's presentation and speak against the application submitted by The William W. Backus Hospital.

While I have great respect for my colleagues at Backus and Hartford Hospitals, I believe the primary PCI program and the elective PCI program that the Applicant proposes are duplicative and fundamentally flawed in their conception.

I included in my pre-filed testimony a detailed summary, outlining all of the deficiencies and the failure of Backus to meet the CON requirements.

L & M has been serving the region for over 100 years, and we have over 2,400 professional technical and support personnel in virtually every medical specialty, and our mission is to improve the health of our region.

L & M is still continuing to develop a strong primary and elective angioplasty program to serve patients and to offer a level of care in the region that meets or exceeds national standards.

On collaboration with the Yale School of Medicine and the Yale-New Haven Heart and Vascular Center, L & M has been a leader in Connecticut for angioplasty performed at a Community Hospital without surgical back up. And we've had a very successful record of performing angioplasty, the emergency angioplasty, for the past five years.

At L & M, the interventional cardiologists are on call 24/7 to provide this service, and they are always in close communication with paramedics in the field and the emergency department staff and are ready for an emergency procedure, even before the patient arrives at the hospital.

The Medical Director for our primary and elective program is led by Dr. Brian Cambi, a Yale School of Medicine Interventional Cardiologist, here with me today. Dr. Cambi maintains a permanent residence in our primary service area.

As with all of L & M services, our angioplasty program is focused on providing innovative high-quality care to the community and will make every effort to continue to do so.

However, OHCA approval of any portion of the application before them today will make it

dangerously difficult for L & M's program to remain viable.

I'm going to introduce three individuals, who will speak in more detail about the various deficiencies in the Backus application. First, Dr. Cambi, the head of the angioplasty program at L & M, will speak to the clinical issues with it.

Second, Dr. Daniel Rissi, our Chief Medical Officer, will speak to the operational and administrative flaws in the application.

And, last, my colleague, Seth Van Essendelft, the Chief Financial Officer, will speak to the financial concerns in the application.

So for myself and my colleagues at L & M, we appreciate the opportunity to be here today to provide detailed information outlining the reasons why the application before you should be denied. Thank you very much.

HEARING OFFICER HANSTED: Thank you.

DR. BRIAN CAMBI: Good morning.

HEARING OFFICER HANSTED: Good morning.

DR. CAMBI: My name is, as Bruce alluded to, is Dr. Brian Cambi, and I adopt my pre-filed testimony.

HEARING OFFICER HANSTED: Thank you.

DR. CAMBI: I am an interventional cardiologist on the faculty at Yale School of Medicine, and I'm the Medical Director of the L & M Heart and Vascular Center, in affiliation with Yale-New Haven Hospital's Heart and Vascular Center.

Unlike what Dr. Foley mentioned, I just want to sort of correct one thing. I've been running L & M's primary angioplasty program for acute MI since 2008.

You'll remember that, in 2006, there was an initial foray, headed by a community-based private practitioner, who, after eight months, asked that the program be closed, then, in 2008, it was renewed, and I became Director at that time.

More recently, in 2013, after this office's approval, I've begun overseeing an elective PCI program at Lawrence.

I live in East Lyme, Connecticut, as Bruce mentioned, and spend greater than 80 percent of my time on campus at Lawrence & Memorial.

Our program is the only of its kind in the state, I think putting me in a unique position to comment on all aspects of a community PCI program.

I'm here today to speak against the

application submitted by Backus Hospital. While I have great respect for my cardiology colleagues, both at Backus and Hartford Hospitals, I believe both primary and elective PCI services that the Applicant proposes are unnecessary to meet the health care needs of our community and fundamentally flawed in their conception.

In the clearest of terms, Backus should be denied its proposed primary and elective PCI services, as approval would run counter to the latest clinical guidelines regarding PCI programs without on-site surgical backup.

As importantly, the CT Department of Health's own published report regarding statewide PCI facilities would suggest that this program is redundant and unnecessary.

We all know it's critical to restore normal blood flow to compromised heart muscle, as many have spoken to already today, for patients, who are suffering an acute heart attack. There is a large body of literature that demonstrates primary percutaneous coronary intervention PCI is the ideal treatment strategy for such patients, provided they can be delivered in a timely fashion.

It is impractical, however, for PCI

centers to be available within every 30-minute radius throughout our state or country, otherwise, every town would have a PCI Center, and you could down to Stop & Shop and get your angioplasty for a heart attack, which is simply impractical.

In fact, the 2014 update on PCI without on-site surgical backup consensus statement from SCAI, ACC and AHA has gone so far to say that establishing PCI centers within 30 minutes of each other is highly advised against, as redundant PCI centers only drive quality down by creating low volume institutions and increased cost unnecessarily for the system.

Even the CT DPH 2015 report on hospital transfers of emergency coronary angioplasty patients notes, quote, “There is no indication of unmet need in Connecticut while there appears to be excess capacity for PCIs.”

The previously-mentioned 2014 update on PCI guidelines statement goes on to recommend patients presenting to a non-PCI-capable facility be transferred to a PCI-capable center providing reperfusion, or door-to-balloon times, or restoration of blood flow to heart muscle, can be delivered within 120 minutes. If this cannot be accomplished, these guidelines suggest, then

medical therapy with fibrinolysis remains the ideal treatment strategy.

It is my contention that we can easily adhere to these recommendations, without beginning another program at Backus, as L & M is a mere 21 minutes from Backus. Michele mentioned 17 minutes, but, if my recollection serves me, it's 17 miles, 21 minutes.

MS. VOLPE: Right. Thank you, Dr. Cambi.

DR. CAMBI: Sure. This is well within the guideline recommendation of less than a 30-minute drive time, transfer time between non-PCI and PCI-capable facilities.

Concerningly, the Applicant describes their difficulty achieving reperfusion times less than the recommended 120 minutes when transferring STEMI patients to a PCI-capable facility, such as Hartford or Yale-New Haven Hospital.

Backus cites long transfer times to PCI-capable centers and persistent internal difficulties in improving their door-in and door-out times, despite extensive attempts to do so, as key factors contributing to their non-adherence to the guidelines.

An important point, though, and one that I really want to drive home, Backus fails to mention in

their application that, in the last five years, they have transferred three patients to L & M, which is the closest PCI program and a mere 21-minute drive time away. Transfers to Hartford Hospital and Yale-New Haven Hospital are twice as long.

I would say that patient outcomes would be improved, as we'd all agree, if they had been open sooner and they had availed themselves of the L & M program.

Currently, L & M receives STEMI transfers from another non-PCI-capable center or hospital, rather, that's actually farther away than Backus at 27 minutes westerly.

Not only do we achieve guideline recommended reperfusion times of less than 120 minutes in these transfer STEMIs, but our door-to-balloon time in the last fiscal year for these very same patients was less than 90 minutes.

Even with the Applicant's inability to improve its internal efficiency, if Backus had routinely chosen to avail itself of our program, I believe patient care would have been substantially improved and guidelines would have been met.

L & M has no backlog and has two dedicated catheterization labs, as well as the staff and resources

to accommodate additional patients.

Even patients in areas north and east of Backus can receive optimal care without a program at Backus if clinical guidelines are adhered to.

In its application, Backus describes a timeline of 50 minutes from activation, they get word that there's a heart attack, to cath lab readiness. None of the patients in their service area or newly-defined angioplasty region are longer than a 50-minute ride to a PCI facility.

Therefore, it's likely that reperfusion times would be similar or better if these patients were brought to the nearest facility either in this state or a neighboring one.

The Applicant's inability to comply with the national standard door-in/door-out time of 30 minutes, Backus's average is greater than 70 minutes as their exhibit attests to and actually is substantially higher than the average door-in/door-out times for other non-PCI-capable facilities in our state, also raises concerns for heart attack patients, who develop complications during their PCI procedure, should the Applicant's proposal be approved.

Backus's inability to transfer patients in

a timely and efficient manner will negatively impact these critically-ill patients receiving timely care at a tertiary facility, should the need arise for them to be transferred.

Patients, as we all know, suffering from a sudden heart attack are critically ill and have a high mortality rate. Ideal treatment necessitates a comprehensive team approach. I know this well.

Backus Hospital has not cared for STEMI patients in many years. Similarly, the vast majority of acute coronary syndrome patients, non-STEMIs, have been transferred from Backus's facility to tertiary facilities for their intervention. This has left many of the supporting nurses, technologists and other medical providers largely inexperienced in dealing with this unique patient population.

Similarly, in the cardiac catheterization laboratory, the experience of the supporting staff is critically important. While the cath lab nurses and interventional radiology technologists at Backus have much experience in performing percutaneous interventions in peripheral blood vessels, the skill set required to care for heart attack victims is quite different.

One must recognize that procedures are now

occurring in the vessels that surround the patient's heart, resulting in a brand new unique set of hemodynamic consequences and potential complications. Patients are often unstable and even in cardiogenic shock compared with patients receiving an angioplasty on a blood vessel in their leg, for example.

There are also unique devices to the treatment of heart attack victims, like intra-aortic balloon pumps that are quite complex and require constant monitoring in the critical care unit after the procedure.

These staffing requirements are outlined nicely in Table 4 of the SCAI/ACC/AHA 2014 update on PCI without on-site surgery.

The Applicant fails to address any of these deficiencies and, in my opinion, would be creating an environment of inexperienced supporting providers that may lead to unnecessary complications.

You know, providing PCI in a community hospital is a very rewarding experience, but it can be very challenging, and it's quite different than providing the same service in a large tertiary environment, like Yale or Hartford.

With nearly 10 years of experience behind me, I can tell you treating critically-ill heart attack

victims, without any house staff, fellows, or supporting physicians, can be daunting.

One of the keys to our success was establishing my role to serve as Medical Director and dedicated physician champion, as the guidelines recommend, who lives and works in the community and provides care.

This has led to extremely strong relationship in the workplace and created an atmosphere of trust, emblematic of any successful team.

Members of the team know each other extremely well. They know their individual roles, as well as their colleagues' practice habits, including strengths and weaknesses.

This kind of intimate understanding among team members cannot be over-emphasized and is vital to successful patient care in critically-ill STEMI patients.

Without having named a Medical Director of the program, who lives and works on site in the community as I do, the Applicant fails to recognize this critically-important component to a successful program.

Now much of my remarks thus far have addressed the Applicant's failure to establish need for a primary PCI program, but they're also applying for

elective program, so I'd like to speak for a moment about that.

By its very name, this service is not emergent. It's elective, so it can be planned. Unlike acute heart attack victims, these patients are stable and many are outpatients.

The Applicant's suggestion that time is of the essence in their application for this group of patients is misleading and not supported by any guideline recommendation.

What is discussed in detail in the guidelines, however, is rigorous criteria for facilities to safely perform PCI on elective patients and rigorous criteria for the kinds of patients that are appropriate to receive this elective treatment at a PCI center, without on-site cardiothoracic surgical backup.

In fact, in all the studies that examined the safety and efficacy of performing elective PCI off-site centers, each participating site had already established primary PCI centers that were well-run, with high-quality outcomes and appropriate volumes, and their diagnostic cardiac catheterization labs had an annual volume of more than 300, none of which applies to Backus Hospital.

The guidelines warn against inexperienced operators performing elective procedures at off-site centers. Now this is an awkward thing for me to speak about, because, you know, the interventional cardiologists sort of have a bond with each other that transcends things like this, but I think it's important to note that Backus Hospital mentions in their application that they have two interventional cardiologists on staff. Both completed training less than a year ago. Their lifetime experience performing PCI is small, if not, negligible.

One such physician, Dr. Chua Chiaco, is named as playing a significant role in the coverage of their proposed program. Asking him to perform elective angioplasty in a novel or a new elective PCI program in a community hospital, without on-site mentorship of a seasoned, experienced interventional cardiologist, is warned against in the guidelines and I believe a setup for failure and, quite frankly, not fair to Mike.

The other interventional cardiologist they mention as having privileges at Backus is employed by Yale and actually comes to L & M to do his elective work and I've been mentoring since he started last summer.

People often ask me if I get apprehensive

performing PCI on heart attack victims. My answer often surprises them. While I'm confident performing both procedures, it is much less stressful, in my opinion, in the emergency setting.

In some heart attack victims, these patients are dying. You're trying to stabilize them. You're trying to save a life where otherwise one would likely to be lost.

In elective patients, they're like me and you. They come to the cath lab, they have a diagnostic procedure, they were okay, and then you try to fix a blockage, and there's a chance you could take a patient that was all right and make them critically ill. That can be much more unnerving.

It is for this reason that elective patients must be selected carefully to minimize the chance of developing a complication.

L & M follows the guidelines closely and focuses on selecting low-risk patients with low-risk lesions, the kind of patient pool described as, quote, "The best scenario for PCI, without on-site surgery," end quote.

Patients, who are high risk or who have lesions that are high risk, continue to be treated more

effectively and safely at a tertiary facility like Hartford or Yale.

The Applicant fails to recognize that a significant proportion of patients are inappropriate to have their elective procedure done at a community hospital, without on-site surgery.

This has led to an over-estimation of the number of cases that could be appropriately handled at their facility.

It's quite concerning that Backus has stated repeatedly that 100 percent of the volume from their region currently migrating to Hartford Hospital will shift to Backus.

This will either be an unsafe situation for patients, or as an oversight in Backus's understanding of the patient type most appropriate to receive care at their facility. In either case, OHCA should be concerned.

Furthermore, Backus makes a common mistake in assuming that all non-ST elevation MI patients, so non-emergent patients, will be suitable for PCI.

The truth is, many of these patients will not. PCI is not the recommended treatment for some of them. Many will need bypass surgery. Many others will

have their heart attacks for reasons other than obstructive heart blockages. Some may have a condition, called myopericarditis, an inflammation of the heart muscle. Some may have a cardiomyopathy, such as stress-induced cardiomyopathy, some may have coronary dissection, some may have congestive heart failure, and others may have demand-related heart attacks from the stress of another medical illness.

The overwhelming majority of these cases will not require PCI, but are more appropriately treated with medical therapy.

Let me just say one more thing before I close. I really applaud John's comments, in terms of trying to reach an underserved population that they perceive in the far reaches of the State, and he talks about their hypertension and their lipids.

I think it's great that they're moving more services out in that direction and setting up offices, etcetera, but I think John would agree that angioplasty PCI doesn't make hypertension better. It doesn't make hyperlipidemia better. Those are more ground roots efforts with better patient education and doctors on the ground.

Lastly, the guidelines have recommended

trying to achieve a volume of 200 cases for all PCI programs in community hospitals without on-site surgery. There's a clear correlation between quality and volume, with optimal quality outcomes associated with case volumes greater than 200.

If Backus were to be granted a primary PCI program, or an elective one, or both, it will significantly lower case volume at Lawrence.

The State will then have two programs with subpar volume and, in all likelihood, lower quality outcomes, compared with a single robust program currently operating at L & M with appropriate volumes, high-quality outcomes and low complication rates.

All this will come at a significant financial cost on an already stressed health care system. I fail to see how any of this is good for our patients or the health care communities we serve.

In closing, I would like to drive home the following point. If our overriding objective is to improve the cardiovascular care of the region and is unencumbered by financial gain and interest in expanding market share, then there is, indeed, no unmet need for the citizens of this region in Connecticut.

The solution is to simply start adhering

to the most recent updated guidelines put forth by SCAI/AHA/ACC and those of this very body. If Backus had done so and been transferring their STEMI patients to the nearest PCI facility at Lawrence, optimal reperfusion times would have undoubtedly been achieved and will continue to be achieved in these patients.

If we are truly interested in continuing to improve care for our citizens with heart attack, rather than investing millions into unnecessary duplicative programs, we should invest in educating our patients about the warning signs of coronary disease, and, furthermore, significant efforts and resources should be allocated to identify STEMI patients earlier in the field by streamlining the way 12 leads are required and transmitted to PCI centers to facilitate direct transfer.

I'll be happy to answer any questions now or at the conclusion. Thanks for your attention. I know that was long.

HEARING OFFICER HANSTED: Thank you, Doctor.

DR. DANIEL RISSI: Good morning.

HEARING OFFICER HANSTED: Good morning.

DR. RISSI: My name is Dr. Daniel Rissi,

and I would like to adopt my pre-filed testimony.

HEARING OFFICER HANSTED: Thank you.

DR. RISSI: I am the Vice President and Chief Medical and Clinical Operations Officer at L & M. I oversee medical affairs and clinical operations, but I have also managed the strategy and planning functions at L & M.

I would like to address the administrative and operational flaws in Backus Hospital's CON application.

While my pre-filed testimony, as well as that of my colleagues, calls into question most of the rationale put forth by Backus's CON, I need to highlight some key deficiencies for OHCA's consideration.

If approved, Backus's application will have far reaching negative implications for L & M. Backus has not clearly defined the patient population to be served, and, therefore, its volume projections are highly suspect.

Backus has used a contrived service area, which it calls the angioplasty region. Clearly, with a target volume to achieve, the Applicant has created a made up service area merely in an attempt to hit minimum thresholds established by national clinical experts.

Backus fails to use the primary service area, based on its own discharge data, and as has been historically defined for purposes of OHCA. The angioplasty region is even more expansive than Backus's primary and second service areas, based on its own community health needs assessment.

The angioplasty region does not include certain towns in the southern region of its PSA, presumably to downplay the tremendous harmful impact that even approval of primary PCI will have on L & M's developing PCI program.

The most important point that should not be lost is that 95 percent of this angioplasty region is already within or nearly within the national guidelines for travel time.

Specifically, one half of the towns in the angioplasty region are within 30 minutes of an existing PCI-capable facility. Nearly all of the other half are closer to another PCI facility than Backus or within a few minutes of another PCI-capable facility.

Of equal importance, regardless of how the service area is defined, Backus has not demonstrated a clear public need for primary or elective PCI services.

All data and research put forth by

national experts and by the Connecticut DPH have shown PCI volume declining and have projected further declines in large part due to enhanced medical management, alternative therapies, and other preventative steps.

Backus's 24 percent growth in angioplasty services over the next few years is an overstatement, based on all available leading research, guidelines, and Connecticut's own data.

Backus paints a picture of the angioplasty region that is in contrast to the actual statistics of the composition of its residents.

For example, despite Backus's claim, the angioplasty region is not older. The percent of residents age 45 and above is exactly the same as Connecticut's average age.

Moreover, according to Backus's sources, the percent of residents 65 and older in the angioplasty region is less than Connecticut's rate, 15 percent versus 16 percent, so, clearly, there is a disconnect between Backus's assertion regarding the region and the statistical data of the area.

The Applicant also suggests the angioplasty region has a low socioeconomic status and a high percentage of households with median incomes less

than $50,000, which translates into high prevalence for coronary artery disease.

This is untrue. According to data from the Connecticut Economic Resource Center, only two of the 28 towns in the angioplasty region are in Backus's primary service area, have median incomes of less than $50,000.

Backus is incorrect in its assessment of the income levels of its contrived market and also incorrect in its use of the data.

As noted in the April 2015 Connecticut DPH report, titled The Burden of Cardiovascular Diseases in Connecticut, increased prevalence of coronary artery disease is tied to annual incomes of less than $25,000, not the $50,000 that Backus references, so, clearly, there is no correlation that can be made between the household incomes of the region and the increased need for PCI services.

Also, according to the Eastern Region Community Health Assessment provided by Backus in its CON application, the eastern Connecticut region actually maintains the fastest decreasing heart disease mortality rate in the state, despite the claims by Backus that this area is completely underserved.

Additionally, Backus states to OHCA that rates of high blood pressure, diabetes and elevated cholesterol are high in the area, but fails to openly share that patients in the market have similar or better statistical rates for these conditions compared to the state or to the nation, and that residents in the angioplasty region are managing their condition by taking actions to control these issues.

A close look at the data provided in the Backus CON for the eastern region, which L & M has analyzed and provided in the pre-filed documentation, clearly shows these comparisons.

National guidelines are advising against the very program that Backus is proposing, and the Connecticut DPH has stated there is no unmet need for PCI in the state.

Multiple PCI centers that are duplicative have been shown to degrade quality by creating low volume centers. Research has emphasized the logical placement of PCI centers and a more regional approach to STEMI care.

National studies support a focus on pre-hospital care and rapid transfer from non-PCI facilities to PCI-capable facilities.

The Connecticut DPH October 2015 report on angioplasty patients confirms this by stating very clearly that, because of declining PCI volumes, there should be a greater focus on system level care for STEMI patients, not more PCI centers.

Initiatives, like Connecticut's Mission Lifeline, have supported such approaches. Although frequently referenced in Backus's argument, the OEM's 2012 guideline does not take into consideration the very recent and best expert opinion regarding PCI services.

While the OEM's 2012 guideline has improved care for many patients by ensuring timely access to PCI for STEMI patients, it is inappropriate to use this one document as the basis for another PCI center in Connecticut with all the new research, guidelines and expert opinion that indicate Backus's program is duplicative and not in the best interest of the patients.

Backus's proposal is not consistent with national or Connecticut standards and guidelines. Backus does not abide by the established ACCF, AHA and SCAI guidelines adopted by OHCA, which discourage the establishment of duplicative services within a 30-minute time frame.

Further, the same guidelines do not

support the development of a directly competitive program. These guidelines specifically state that competitive programs are not in the best interest of the community.

It is undeniable that angioplasty services at Backus will directly compete with L & M's establishing primary and elective angioplasty program.

Backus has estimated 51 angioplasty cases were from the Backus OHCA-defined service area, and that would be a significant loss to L & M.

The Backus application does not meet the requirements for establishing primary or elective angioplasty services on any level and, therefore, should be denied.

Thank you for allowing me to testify.

HEARING OFFICER HANSTED: Thank you, Doctor.

MR. SETH VAN ESSENDELFT: Good morning.

HEARING OFFICER HANSTED: Good morning.

MR. VAN ESSENDELFT: My name is Seth Van Essendelft. I'm the Vice President of Finance and Support Services at Lawrence & Memorial, and I'm here to adopt my pre-filed testimony.

HEARING OFFICER HANSTED: Thank you.

MR. VAN ESSENDELFT: In my role at Lawrence & Memorial, I oversee the financial operations of our acute hospitals, Lawrence & Memorial, as well as Westerly Hospital and the Lawrence & Memorial Medical Group.

Thank you for the opportunity to be here today and to speak against this application submitted by Backus, as the Applicant's proposed primary or elective PCI programs will have a significant implication, as you've already heard from some of my colleagues, on the financial and quality aspects of the program already approved and established at Lawrence & Memorial.

In 2013, L & M received the CON application and approval to establish an elective angioplasty program, in addition to the existing primary program, and we've been developing this program and providing outreach to our neighboring facilities, hospitals, which include Backus and Westerly in Rhode Island.

We continue to invest significant resources in this program and personnel, which includes recruiting and retaining exceptional physician services, nursing and other key staff there to support this worthy program.

These investments also include technology and equipment, including two state-of-the-art cardio cath labs at L & M. If approved, the Applicant's proposal will reduce both primary and elective PCI volume at L & M.

This will lead to a definitive and quantifiable financial negative implication to our existing program and threaten the ongoing viability, quality and efficiency of that program.

Even approval of just the primary program alone at Backus will have a significant adverse impact on L & M's developing program.

Although Backus went through great lengths to contrive a segmented service area and articulate that there would be no intended negative implications to other existing programs, the facts simply don't support that assertion.

For example, they carve out towns from the angioplasty region, which actually already fall clearly within overlapping primary service areas of both hospitals.

A credible review, based on L & M's patient origin data, as also mentioned earlier by our attorney, would indicate that at least 25 percent, but

much higher, is possible to be pulled out of the L & M program and redirected to Backus if this application is approved.

The risk is due to the overlapping service areas, combined with steerage leverage exerted at Backus, as they are part of the health care, Hartford HealthCare system.

The comment earlier, that patients are already deciding, is a misleading comment. These are patients suffering from a heart attack, and, in most cases, the physician is making that call.

And as we already talked about earlier, the most efficient care for those patients would be to direct them to the nearest established program.

At the low end of the range, from my estimates, L & M's incremental losses would be expected to be in excess of a million dollars, given the significant fixed cost nature of this program and investments already made by L & M.

While this negative financial impact will be felt acutely at L & M, it is not limited to our hospital. There will be negative implications to other programs, as well, and, indeed, the financial strength of Connecticut's health care system.

Connecticut hospitals, as you know, are facing tremendous financial challenges, which is leading to the consolidation and, in some places, reduction of programs in existence today, even essential services (coughing).

It is imperative that hospitals carefully plan strategic investments. In this case, Backus has proposed a very costly solution to an unneeded health care service. Rather than creating duplicative services, Backus, as a sponsoring hospital, could opt for a simple solution in leveraging existing technology already available and deployed throughout the EMS system to more quickly and effectively identify and route patients directly to the most appropriate center.

As evidenced in earlier commentary, cases from the L & M catchment area today that should already be serviced by L & M are being subverted and transferred to Hartford Hospital.

Despite being nearly double the transit time, Backus patients are being transferred there, due in part because of their alignment with Hartford Hospital.

If approved, primary PCI or elective PCI services at Backus will adversely impact health care cost, quality and sustainability.

As my colleagues have addressed, the addition of duplicative and costly primary or elective angioplasty services at Backus Hospital is not carefully planned, as Backus has also not demonstrated a public need or adequately identified the service area.

As it is unlikely that Backus will reach these projected utilization figures without significant financial strain to L & M's program, Backus is doing a disservice to the residents of the state by directing scarce resources to a program that will offer more harm than benefit, while weakening the existing quality and patient care of a previously-established and approved program in existence.

Based on a clear showing of the unprofitability, as offered in their own exhibit, which appears to be very aggressive in its assumptions, with an added FTE estimated at only two, for an example, and the negative financial implications to L & M, other angioplasty programs in the state as a whole, it's very questionable why Backus is actually seeking this approval.

I'm confident that OHCA will consider the lack of financial viability in this proposal and deny both the primary and the elective angioplasty requests.

And I, too, would be happy to answer any questions. Thank you so much for your time and consideration.

HEARING OFFICER HANSTED: Thank you.

MS. VOLPE: That concludes our presentation as an Intervenor.

HEARING OFFICER HANSTED: Okay, thank you. Thank you, both counsel. I just want to make a quick clarification to the record.

In the beginning, I said that the Applicant, William Backus Hospital, has been designated as a party. In addition to William Backus Hospital, Hartford Hospital has also been designated as a party.

And now what I'd like to do, as I stated in the beginning, is turn to any public commenters we have here today, or public officials. Do we have anyone still in the room? Okay, we have a couple of folks.

Ladies before gentlemen. Thank you.

MS. DEB HINCHEY: Thank you. Thank you, all, for allowing me this time. My name is Deberey Hinchey. I am currently the Mayor in the City of Norwich, and I come before you to speak in favor of allowing this process to go forward at Backus Hospital.

I am the Mayor of a City, who struggles.

There are 40,000 people in the city, and Backus Hospital is our community hospital. For many years, Backus was a standalone before they became associated with Hartford Hospital, and there is great sentiment among the people, who live in Norwich, for this hospital and the health care that they have provided the citizens that live in the area.

I am not a health care expert, however, I, for the past 30 years, prior to being elected Mayor, I am a clinical social worker, who did home care, and I know the repercussions of family members having to go farther away to get their health care. It's very difficult.

At the end of my career, I worked as a Hospice social worker, and it was very difficult for patients' families, who are critically ill, to have to travel.

Transportation in our area is difficult as it is, and, so, having the availability of this, being able to have this procedure right there within the City limits is invaluable to the individuals, who would use it.

I'd also like to say that, as the Mayor of the City, as I said, it struggles, both economically, job-wise. We work hard to bring better health care to

the City, to provide programs that help people to live healthier lives. I've spent a lot of my working career helping people do that, and I believe that Backus Hospital and this service would aid in providing a healthier community.

I applaud Backus Hospital for trying to provide this for the citizens that I care so deeply about and who have such need, and, so, I would ask you to please consider on the positive note this application.

HEARING OFFICER HANSTED: Okay, thank you.

MS. HINCHEY: Thank you very much for your time.

HEARING OFFICER HANSTED: You're welcome. Good morning.

MR. PAUL SWEET: Good morning. My name is Paul Sweet. I'm currently First Selectman of the Town of Plainfield and have been for 22 years.

I've been in public life for over 40 years, and one thing that I, first of all, want to say that I support the application by Backus.

Secondly, I'd like to appeal to this panel on a different level, representing people, representing the men and women of not only my community, but northeastern Connecticut.

Plainfield was a major benefactor of the Backus emergency room being placed in our community, and, from that time, we've seen nothing but growth and good will continue.

The people of our community in this program, certainly, when you talk about people, we're talking about thousands of people. We're talking about Backus Hospital being a hospital that is used by many folks up where I come from.

The common sense would tell us, with a population like we have, that this program is needed, and, quite frankly, Backus, being part of the Hartford network, certainly provides all kinds of services to us now.

It makes sense that this type of program be approved for this site, simply because, up in the northeast, we travel quite a ways to have tests done.

When you talk about heart procedures in Plainfield or the surrounding community, what comes to mind is Hartford Hospital, people go to Hartford Hospital, or, if you're in the far north, you may go to Massachusetts to UMass, but that being the case, there's a great population.

We live in a very rural part of the state,

and you go 395, yes, you can get off in Plainfield, but Plainfield, once you leave the center, it becomes very rural, and it continues to be rural into Canterbury, Sterling, Voluntown, Killingly.

It's not easy for our people just to get anywhere to have a procedure done. On a nice day, you certainly can travel and take in a day, but a lot of times it just seems to be fate that, when you've got to go have a test done and you've got to drive to Hartford, it's either raining, or it's snowing, or there's some type of traffic, construction, and you're backed up for miles.

Just coming up here this morning, I was trying to see what it was like to drive from Plainfield to here and make sense of the ride, until we saw that Downtown exit was closed, and now the Garmin on the dashboard is recalculating where we are.

Now that's a funny story, because, trust me, we saw quite a bit of Hartford this morning trying to find this place, but that's a real reality with folks that have people that get transferred up to Hartford Hospital. Whether it's hot, whether it's rain, whatever it may be, we've got folks that aren't familiar with this neck of the woods.

Backus Hospital is clearly the hospital of many people in our neck of the woods, and, again, I just want to appeal, as someone that's been on the ground for over 40 years in public life, appeal to the panel that our folks need this program. This is a needed program for us.

I'm not picking and choosing. I'm not a hospital professional, like folks in this room today, but I'm just telling you the truth of the fact, that this procedure being done in Norwich is going to be a big deal for us folks up in the northeast, so I'll leave it at that.

It's been a long morning, but I would hope and urge you to approve the application, based on the needs of the people from our area of the state. Thank you.

HEARING OFFICER HANSTED: Thank you. Is there anyone else in here that wishes to give public comment? No, I don't see anyone, so, at this point, we'll take a break. I guess we might as well make this our lunch break. It's 11:35. If everyone could be back here by let's say 12:45, we'll hear argument on the motion and the objection.

And for those folks that aren't involved

in that argument, you know, feel free to take a longer lunch. Just check back in for the remainder of the proceeding here today, so, at this point, we'll break until 12:45. Thank you.

(Lunch recess)

HEARING OFFICER HANSTED: Okay. We are back on the record. We are going to hear argument from the Applicant on their motion in limine, dated March 22, 2016, and argument by Lawrence & Memorial Hospital and their objection to the motion in limine, which is dated March 23, 2016.

Just before we begin, I mean, obviously, we're getting later in the day, we have to adjourn this hearing at 3:00 p.m., so there's a probably good probability that we won't finish today, so I'll talk to counsel after the hearing today, and we'll discuss some further dates.

Okay. Counsel, did you want to begin?

MR. COHEN: Sure. Thank you.

HEARING OFFICER HANSTED: You're welcome.

MR. COHEN: As you mentioned, we filed a motion in limine to preclude L & M's pre-filed testimony related to out-of-state providers. They, in their pre-filed testimony, indicated that there are out-of-state

providers to service the needs of this community.

In short, we believe that, under the OHCA rulings, that OHCA is allowed to exclude volume data from out-of-state patients that are treated at Connecticut health care facilities in its evaluation of a Certificate of Need.

Now we haven't said that you can't consider those. In fact, you have considered them in the cases that were cited by L & M, indicate that, in at least one situation, you have. It was Greenwich Hospital.

Their service area included 11 out-of-state cities and towns, and the closest provider was 11 miles. I'm sorry, 18 New York State cities and towns, and the closest provider near Greenwich was Westchester Medical Center, which was, I believe, 11 miles away.

We don't have those situations here. The situation here is extremely different. We're not talking about something that's 11 miles from our hospital.

These facilities that are out-of-state are not subject to OHCA approval, not subject to your oversight, not subject to reporting obligations, not subject to OHCA's quality control measures.

They can shutdown without OHCA having any

involvement at all in that. There's no role for OHCA to play in the need for the facilities. You don't have your typical rigorous oversight and reporting obligations that you have with the Connecticut facilities.

Moreover, as we've discussed here today and will discuss, I'm sure, in the response to the Cross-Examination questions, there's a continuity of care.

You have an out-of-state provider, could be different EMR, different insurance requirements. Our practitioners have found that, when their patients go out-of-state, that there are significant, potentially significant insurance issues that may apply.

The patients could face long delays in health care costs, or, in some instances, may not be able to use health care at all. As I mentioned, there's an EMR issue.

So, for all of those reasons, we believe that, in this particular application, with the hospitals as distant as they are from Backus Hospital, it's wholly inappropriate to consider the availability of out-of-state medical centers, out-of-state PCI centers to provide these services for our Connecticut residents.

More appropriately, it would be to allow Backus to provide these services to the residents in its

angioplasty region.

So, for those reasons, we believe that all of the discussion and evidence related to out-of-state providers should be stricken from their pre-filed testimony, and they should not be allowed to testify regarding those matters.

HEARING OFFICER HANSTED: Thank you, counsel. Attorney Volpe?

MS. VOLPE: We speak in opposition of the motion, and we believe the motion should be denied for a variety of reasons.

One is, the Declaratory Ruling that Applicant's counsel would have you rely on doesn't speak of out-of-state providers. It talks about out-of-state patients.

This is an entirely different set of facts and scenario here. We're dealing with access to care for a region, for a population, for an in-state population having access to care, so the ruling that they would like you to rely on deals with patient volume, not provider, out-of-state providers.

In addition, by their own admission in their application, they have used UMass data, and this office has asked for questions, and completeness

questions, and issues with UMass data, and I quote from 459 of their own application. It says, “To complete a PCI volume and market share analysis in the service area, 3d collected Massachusetts inpatient data for fiscal year 2012 and extrapolated volumes.”

So, I mean, they can’t have it both ways. They can’t ask us to not be able to speak to their application when they’ve, in fact, used UMass numbers and statistics.

In addition, OHCA has great discretion, as to what it can and cannot look at. There’s nothing in the statutes, in the regulations, in your own policies that prohibits you from looking at out-of-state providers and whether or not Connecticut patients have access to needed services from an out-of-state provider.

As important, at least four of the towns in their angio region are closer to UMass, significantly closer, so, from our perspective, it is important to take that into account, because you have to look -- when the national guidelines for SCAI, you know, AHA, when they ask you to look at those, they don’t say put blinders on.

If a provider is within a 30-minute drive time, if you have to cross the state border, so be it. It’s, again, it’s access to care, immediate access to

care and need.

So we would argue that OHCA has discretion to look at out-of-state providers, factor it into a needs analysis, determine whether it impacts access for Connecticut patients.

So, I mean, our arguments are outlined in detail in our motion before you. We realize you haven't had a lot of time with it. We didn't have a lot of time with it either. We got it last night.

From our perspective, I think it would be egregious not to allow a discussion of out-of-state providers in this proceeding. It's already been in the docket from day one.

Our position is that their motion should be denied. Thank you.

HEARING OFFICER HANSTED: Thank you. Counsel, do you have any follow-up?

MR. COHEN: Yeah. On the use of Mass data, that's kind of ironic. All we were doing with that was to determine by zip code where the patients from UMass came from, and what we found was that there was a percentage of patients that were serviced at UMass that came from our service area, and that went into our calculations.

In addition, the UMass facility is not significantly closer. It's about the same distance for much of that area as Backus Hospital is.

And then, finally, we know that the case that we cite doesn't look at out-of-state providers. It looks at out-of-state patients, and it looks at whether OHCA can consider a determination of need out-of-state patients in calculating whether there's a need.

What we're talking about is, by analogy, making the same kinds of arguments with regard to out-of-state providers, saying that the out-of-state providers shouldn't be allowed to be used in addressing needs of in-state Connecticut patients, so thank you.

HEARING OFFICER HANSTED: You're welcome. So if I preclude the out-of-state information from the Intervenor, do I preclude the out-of-state information in your application?

MR. COHEN: Well the out-of-state, again, the out-of-state information in our application is only related to patients in Connecticut that are serviced out-of state. That's what we're trying to demonstrate, that there is a need that some of these patients are going out-of-state, because Backus doesn't have a program.

MS. VOLPE: And if I may?

HEARING OFFICER HANSTED: Sure.

MS. VOLPE: Some of these patients are going out-of-state, because it's significantly closer to go to UMass. I mean they say not, but, I mean, we can look it up, but, you know, if you're looking at Thompson, it may be 35 miles from there to Backus, but it's 24 to UMass.

I mean could we be off a few miles here or there and based on our source? You're not going to be off 11 miles. I'm sorry. Minutes. Again, it's minutes.

We might be off a few minutes, but you're not going to be off substantially that amount of minutes. That's true of Thompson, Woodstock, Putnam and Pomfret.

I mean they're minutes, several minutes apart, some as many as 11 minutes, so it is significant, and I think it should be accounted for.

And, again, when OHCA is doing its analysis, if it's using its own reports and data and surveys and I know you don't recognize precedent, but precedent with other providers, when you're doing your own analysis for this particular service, okay, you have to take into account the closest proximity provider, who is capable of delivering PCI services.

That's what the national guidelines, which

we've all been throwing around, state, as well as your own, so I think it's not prudent or reasonable to suggest that we not factor in an out-of-state provider, who happens to be considerably closer in drive time.

HEARING OFFICER HANSTED: All right, thank you, counsel. I'm going to reserve judgment on the motion in limine. I will issue a written ruling within a week, by next Friday, which I believe is April 1st, if I'm correct.

MR. COHEN: April Fool's Day.

HEARING OFFICER HANSTED: Okay. I'll make it the day before. April 1st, I'll issue a decision by that date, but, for purposes of today's hearing, I want to hear that information, and, if I decide to rule in favor of the motion in limine, then we can exclude that information subsequent to the hearing.

Counsel, if you want to begin with Cross-Examination, or if you have any further Direct of your witnesses, or did you want Attorney Volpe to --

MR. COHEN: I thought we had said that Attorney Volpe was going to Cross-Examine our witnesses first.

HEARING OFFICER HANSTED: That's fine. Did you have any more Direct?

MR. COHEN: I may after Attorney Volpe Cross-Examines our witnesses.

HEARING OFFICER HANSTED: Okay,

MR. COHEN: But, at this point, I do not.

HEARING OFFICER HANSTED: Okay. All right. Attorney Volpe, do you want to proceed?

MS. VOLPE: Okay, so, just in the interest of having all of the questions answered, I think there was some discussion, as to we would possibly propose a question, and they would determine on their team who is best suited to answer it. Is that a reasonable protocol that we're going to implement in the questioning?

MR. COHEN: Yes.

HEARING OFFICER HANSTED: That's fine with me, Attorney Volpe, as long as we can keep it somewhat organized.

MS. VOLPE: Sure.

HEARING OFFICER HANSTED: The other alternative is if you just want to call up his witnesses one-by-one and do all your questioning of that witness.

MS. VOLPE: Yeah. I think we may call them up, just for ease of the room setup. It might be easier if we have them come up, because, you know, everyone is sort of scattered in the room.

HEARING OFFICER HANSTED: Absolutely.

MS. VOLPE: If that would be okay.

HEARING OFFICER HANSTED: Whoever is testifying I want to sit up front here in front of the microphone.

MS. VOLPE: Okay.

HEARING OFFICER HANSTED: But I'll leave it up to counsel who they want to answer the question.

MR. COHEN: Thank you.

MS. VOLPE: Okay, so, if he would, we would like to have Mr. Foreman from 3d come on up and answer some questions for us.

HEARING OFFICER HANSTED: And, just remember, you're all still under oath.

MS. VOLPE: Hi, Mr. Foreman.

MR. FOREMAN: Hi.

MS. VOLPE: Was it you or your company that conducted the market analysis for William Backus Hospital?

MR. FOREMAN: Both.

MS. VOLPE: You and your company?

MR. FOREMAN: Correct.

MS. VOLPE: Okay and --

HEARING OFFICER HANSTED: Can you hear

okay?

COURT REPORTER: You have to repeat that, because you need to have the microphone on.

MR. FOREMAN: Yup. Sorry.

MS. VOLPE: Okay, thank you. And please ask me to repeat something if it’s not clear, or if you can’t hear me.

So have you or your company ever done a PCI services market analysis for a hospital?

MR. FOREMAN: We have.

MS. VOLPE: Specific to PCI services?

MR. FOREMAN: We have.

MS. VOLPE: And who have you done that for?

MR. FOREMAN: We’ve probably done a bunch of them across the country, so, off the top of my head, I don’t remember.

MS. VOLPE: Have you done any in Connecticut?

MR. FOREMAN: No.

MS. VOLPE: Okay. Have you done any in Massachusetts?

MR. FOREMAN: I don’t remember.

MS. VOLPE: Okay.

COURT REPORTER: Make sure you keep your voice up.

MR. FOREMAN: Okay. Sorry.

MS. VOLPE: So, based on the detailed analysis you conducted for Backus, were you asked by representatives of Backus to do that analysis or Hartford Hospital? Do you recall who retained you?

MR. FOREMAN: I think my consulting agreement was with Backus.

MS. VOLPE: Okay and when you did the analysis, did your findings -- what did your findings show for national PCI trends? What did they determine for national PCI trends?

MR. FOREMAN: We focused, actually, on the local market.

MS. VOLPE: So did you look at national trends for this service?

MR. FOREMAN: We compared the local market to national benchmarks.

MS. VOLPE: And did you recall what the trend showed for a national PCI volume?

MR. FOREMAN: For PCI volume?

MS. VOLPE: Correct.

MR. FOREMAN: We looked at incidence of

the disease and the incidence of treatment at a national level and then compared that to the local reality within the defined geography.

MS. VOLPE: Okay, but, for purposes of a national trend, if you will, in PCI, do you know is it going up, down, staying the same? Do you recall?

MR. FOREMAN: It was irrelevant for our study, because we were focusing on what was happening within this geography.

MS. VOLPE: Okay, so, based on the analysis you conducted, did you look at ChimeData for specific Connecticut trends?

MR. FOREMAN: We did.

MS. VOLPE: And what did your analysis show, since you said you focused primarily on the local Connecticut? What did your analysis show for the state of Connecticut's trend in PCI?

MR. FOREMAN: PCI incidence?

MS. VOLPE: Volume.

MR. FOREMAN: PCI volume. That over the last '09 to '15, inpatient volumes have basically been flat sometimes, and I looked at it within this region, but sometimes it would pop up a little bit. Other times, down a little bit, but basically flat. The big

transition --

MS. VOLPE: Oh, that's okay. You answered my question. It was flat. That was my question.

MR. FOREMAN: Okay.

MS. VOLPE: How many or what is the number of the cities and towns in the angioplasty region you defined? How many are there? Do you recall?

MR. FOREMAN: I don't recall. I can look for you.

MS. VOLPE: Sure. Why don't we look?

MR. FOREMAN: And all of our analysis was done at a zip code level, not a Town level.

MS. VOLPE: But all of the data and charts from OHCA and you weren't presented at the Town level, so --

MR. FOREMAN: Depending on what you're talking about. It looks like 26 towns.

MS. VOLPE: Okay and, just for the record, can you, for the record, let us know what page you're or what reference you're looking at to come up with that number 26?

MR. FOREMAN: Yeah. I'm looking at my own market assessment in my notes.

MS. VOLPE: Okay, so, that's the number

that we came up with, too, so 26. And when you did your market analysis, in terms of what did you use to determine the drive time in minutes from those zip codes or towns, if you will, to Backus Hospital? What was your source?

MR. FOREMAN: A software company, called Maptitude.

MS. VOLPE: Okay and do you know what the national standards state is the appropriate drive time in minutes for a patient to have access to these services, these PCI services?

MR. FOREMAN: Which PCI services?

MS. VOLPE: Let’s just use primary, which is emergent.

MR. FOREMAN: Right.

MS. VOLPE: Do you know what the national standards for, say, SCAI, or AHA, or ACC?

MR. FOREMAN: I do, but I think we have people that probably have a lot more experience with that than I, so I’m probably not going to weigh in on the standards.

MS. VOLPE: Okay, but you did the drive in minutes, and that’s important for purposes of -- you determined the region for them. You determined the

service area, correct?

MR. FOREMAN: Correct.

MS. VOLPE: Right and, in doing that, determining the service area, which you say is the backbone of the application, we agree, and the service area is ultimately what OHCA is looking at in access.

Let me ask you a different question. When you do a market analysis for a health provider, do you always do it based on a specific service, as opposed to a region recognized by CMS or local Department of Public Health designated areas? Do you always make it service-specific?

MR. FOREMAN: I always make it specific to the analysis, so if I were doing a net income guarantee for an independent physician, I would use the CMS service area, 75 percent service area.

If I were looking at adding beds to a hospital, I would use the general service area, but I do make it specific, based on the circumstance.

It’s basically are you starting a Cabela’s, or are you starting a Subway? People travel two hours for a Cabela’s, but they won’t travel 10 minutes for a Subway.

MS. VOLPE: Right, but do you exclude

national criteria? Since you're saying you do it service-specific, wouldn't you look at what the national quality criteria guidelines are for a drive time in minutes in establishing a service-specific region?

MR. FOREMAN: Yeah. I said I made it circumstance-specific, and here what we were using is drive time as one of the key factors, along with all the other factors that I mentioned this morning, including it's not a service currently offered at Backus, so, looking at their historic patient origin data and relying on that doesn't make sense, travel time, as I mentioned.

It doesn't include outpatient data, so that that transition that I mentioned in volume from inpatient to outpatient is not considered, the role of EMS, and then just looking at the closest zip codes for primary service area or for primary services, rather.

MS. VOLPE: Okay, so, let me ask you another question, then. Do you know, since you did the analysis and you did it through the Maptitude, do you know how many towns in the angioplasty region that you created for them have a PCI-capable provider within a 30-minute drive time? Do you know how many towns in your region?

MR. FOREMAN: Yes.

MS. VOLPE: How many?

MR. FOREMAN: So the way that we did it was to look at this was a prospective analysis to determine --

MS. VOLPE: I don't want to cut you off, Mr. Foreman, but Mr. Hansted --

HEARING OFFICER HANSTED: I heard the question was how many providers are in that area?

MS. VOLPE: How many?

MR. COHEN: Well I'm going to ask for clarification. Do you mean from the edge of the town? Do mean from the center of town? Do you mean from the farthest side of the town?

MS. VOLPE: Sure. Use the center. I'm talking about whatever Maptitude analysis resource he used.

MR. COHEN: Well that's what he was starting to explain when you cut him off. He was going into exactly that issue, so, if he could continue, that would be great.

HEARING OFFICER HANSTED: I'll let him continue, just to get some background on how he came up with the number.

MR. FOREMAN: So we looked at -- the

regions are driven, as I mentioned this morning, off of zip code-by-zip code what the closest PCI provider would be if Backus Hospital was a PCI provider, so, given that, it's 20 within the 30 minutes of Backus Hospital.

HEARING OFFICER HANSTED: And that's for both elective and primary?

MR. FOREMAN: Correct.

MS. VOLPE: Well I think you've answered a question I didn't ask. I think you're saying that, for 20 of the towns in the region, Backus would be within a 30-minute drive. That's not my question.

My question is how many towns in the angioplasty region have access to another capable PCI provider than Backus within a 30-minute drive?

MR. FOREMAN: So those towns that I just mentioned, Backus is the closest.

MS. VOLPE: But that's not my question.

MR. COHEN: If you'd let him finish.

HEARING OFFICER HANSTED: Her question is, if Backus did not have the program, those towns, what would be the closest providers of this service? Is that accurate, Attorney Volpe?

MS. VOLPE: Actually, thank you. What I'm asking is how many of those towns, based on your

Maptitude, have a PCI-capable provider within a 30-minute drive time? I mean if you don't have that answer --

HEARING OFFICER HANSTED: Did you want to have another individual answer the question?

MS. VOLPE: Does anyone know that answer?

MR. COHEN: Well the analysis was not, as Mr. Foreman indicated, he looked at zip code-by-zip code, so the question is town-by-town, as I understand it.

I don't know if you can answer town-by-town how many towns are within the 30-minute drive time of L & M.

HEARING OFFICER HANSTED: No, no, that's not the question.

MS. VOLPE: No, that's not the question.

HEARING OFFICER HANSTED: Do you want to repeat your question again?

MS. VOLPE: Sure, I will, and, again, we want to get to the answer, so any way we can get to the answer let's do it.

We said there's 26 towns. If those towns have multiple zip codes, you would be able to tell us that, Mr. Foreman. I'd be surprised if these rural towns had multiple zip codes, like they do down in Greenwich, but if there are multiple zip codes and there are more

than -- how many zip codes did you find in your angioplasty region? Let me start with that.

MR. FOREMAN: I don't know, because we did roll -- so we did all the analysis at a zip code level and then rolled it up into towns for purposes of --

MS. VOLPE: Well which is it, though?

HEARING OFFICER HANSTED: She wants to know the amount of zip codes in your analysis.

MR. FOREMAN: The number of zip codes? I don't know if I have it.

MS. VOLPE: Okay, so --

MR. COHEN: We can do a late file on that, if you'd like.

HEARING OFFICER HANSTED: Do you want it?

MS. VOLPE: I think we have it in our application, I mean in our Intervenor. We've shown how many existing providers there are within a 30-minute drive time required of the national criteria. We have it, and we have it on page, you know, 22 of our pre-filed testimony on 35 stamped, so it's in the record.

What I wanted to know, since you developed this region and it is the backbone of the CON analysis and this Department is charged with applying criteria to this service for the purposes of determining access for

Connecticut residents, I think it's important to know whether these patients have access within the national and Connecticut guidelines. That's what we're trying to get an answer to, Hearing Officer Hansted.

HEARING OFFICER HANSTED: So you testified that you don't know right now the zip codes, the number of zip codes?

MR. FOREMAN: Correct.

HEARING OFFICER HANSTED: Is that in your report somewhere?

MR. FOREMAN: I mean it's in my work product, yeah.

HEARING OFFICER HANSTED: Okay.

MR. FOREMAN: So, I mean, I can easily get that.

HEARING OFFICER HANSTED: I'll order that as Late File No. 1.

MS. VOLPE: And, so, again, I was saying that to try to accommodate getting a response. If there's going to be a late file specific to that issue, we'd also ask that it be done by town, which is in accordance with the charts that OHCA has requested that the Applicant has provided the data.

MR. COHEN: So if I can get some clarity,

are you talking about the center of town, the edge of town?

MS. VOLPE: Sure. The center of town. Sure.

HEARING OFFICER HANSTED: We can go by the center of town.

MR. COHEN: Okay and that's Late File 2?

HEARING OFFICER HANSTED: Late File No. 1.

MS. VOLPE: Well I think it's one late file, but the information is going to be presented in zip code and town.

HEARING OFFICER HANSTED: Two separate sections.

MS. VOLPE: By zip code and town.

MR. COHEN: Okay.

MS. VOLPE: From your developed angioplasty region.

Okay, so, a lot of my questions deal with this specific issue, as they relate to Mr. Foreman. I will ask him a couple of other questions. Please feel comfortable to defer.

One is are you familiar with the 90-minute door-to-balloon time that you cite in the 3d analysis?

MR. FOREMAN: I am.

MS. VOLPE: Okay and do you know what facilities this 90-minute time period applies to?

MR. FOREMAN: I do.

MS. VOLPE: And what does it apply to?

MR. FOREMAN: Facilities with PCI.

MS. VOLPE: Correct, so, do you know what the minute time period is for facilities like Backus without PCI?

MR. FOREMAN: I do.

MS. VOLPE: And what is that?

MR. FOREMAN: One hundred and 20 minutes.

MS. VOLPE: Okay and I'm going to ask a similar question that I asked for the towns. Do you know how many towns are within the 125-minute drive time?

MR. COHEN: One twenty-five?

MS. VOLPE: I'm sorry, 120.

MR. FOREMAN: That's not how we did our analysis.

MS. VOLPE: Okay, so, are you aware that for patients presenting at Backus -- you said the national quality standard is the 120. Why did you exclude access to closer out-of-state hospitals in your drive time analysis? Why did you choose to do that?

MR. FOREMAN: Honestly, because I'm coming

to a State agency. I thought the solution of pushing patients out of the state would honestly be out of the question as a reasonable solution for those residents, so I didn't even consider it.

MS. VOLPE: We wouldn't characterize it as pushing. I understand you have, but it's in access. The State is concerned with access.

So another question. When you were retained, what is the hospital in the middle of this angio region? Do you know what hospital already exists in the middle of that region?

MR. FOREMAN: In the middle of?

MS. VOLPE: Of your angio. Right smack dab in the middle of that angioplasty region, what hospital is currently located there?

MR. FOREMAN: Backus?

MS. VOLPE: No.

MR. FOREMAN: The region that I define?

MS. VOLPE: Yeah. There's another hospital in that county. Windham. Windham Hospital. Are you familiar with Windham?

MR. FOREMAN: Oh, yes.

MS. VOLPE: Okay. Did you look at whether or not Windham is closer for the patients in this angio

region to receive PCI services?

MR. FOREMAN: As opposed to?

MS. VOLPE: Backus.

MR. FOREMAN: No.

MS. VOLPE: Okay, so, do you know, as the consultant for Backus, which is affiliated with the Hartford health system, did they ever consider Windham for services?

MR. FOREMAN: I don't know.

MS. VOLPE: Can anyone answer that question?

HEARING OFFICER HANSTED: Wait, wait. Excuse me. If you're going to testify, I need you up here in front at the microphone.

MR. COHEN: Can I move this closer?

HEARING OFFICER HANSTED: Sure. Court reporter, will that pick up? Okay.

DR. FOLEY: I'll try to speak louder. In answer to your question, it's a good question.

HEARING OFFICER HANSTED: Just identify yourself.

DR. FOLEY: Oh, I'm sorry. John Foley, Dr. Foley from the East Region Cardiology.

HEARING OFFICER HANSTED: Thank you.

DR. FOLEY: So it's a good question geographically, but the hospital, itself, is very small, essentially 20 to 25-bed hospital, with no cath facilities, and, you know, pared down operations in terms of what we offer cardiovascular-wise.

MS. VOLPE: So there's no diagnostic?

DR. FOLEY: It would be a strategic and operation of a possibility to really develop a program like this at Windham. You just have the see the facility and know the community.

MS. VOLPE: Okay.

MR. COHEN: While we're waiting, there is a -- we don't need the late file. It's, in completeness questions, I think it's 1455, is the analysis by zip code. Yeah. Our completeness questions that we filed on December 30th. As I said, 1455, 1456, 57 and 58, so it goes into great detail by zip code.

MS. VOLPE: But it doesn't --

HEARING OFFICER HANSTED: Hold on, Attorney Volpe, one minute.

MS. VOLPE: Yeah, sure.

HEARING OFFICER HANSTED: Okay, Attorney Volpe?

MS. VOLPE: Yes, thank you. It's not

responsive to the question we've presented. What this data shows on page 1455 is whether Backus is within a 30-minute drive time to these towns and the zip code on the left.

The question that we've presented is, of your angio region, either your zip codes or your towns, how many other capable PCI providers currently exist in the region within this 30-minute standard?

MR. COHEN: This addresses that. It indicates where L & M is the closer provider.

MS. VOLPE: Not for all of them.

MR. COHEN: Well I think you have to ask the witness those questions.

MS. VOLPE: Well I did, and he didn't know it.

HEARING OFFICER HANSTED: Wait. Wait. Counsel, one at a time. She did ask the witness the question. I agree that this does not answer the question directly. It may for L & M, specifically, but I'd still like to see the late file, as ordered, which is, you know, within the identified region, how many existing PCI providers are available within a 30-minute drive?

MR. COHEN: L & M would be the only one that would be available.

MS. VOLPE: That's inaccurate.

HEARING OFFICER HANSTED: Well if that's what they want to testify, then that's their testimony. So it's your testimony that, within that 30-minute drive, L & M is the only PCI provider?

MR. FOREMAN: I don't think I'm -- could we ask the question to be repeated?

HEARING OFFICER HANSTED: Yeah. Why don't you repeat the question again?

MS. VOLPE: Okay. My question is Backus is not an approved PCI provider, so with the region you've defined, the angioplasty region, how many other PCI providers exist for this population within a 30-minute drive time?

MR. FOREMAN: Yeah, so, I'm going to have to get that, because our whole analysis was based on the framework of Backus obviously applying for these services.

HEARING OFFICER HANSTED: Right.

MR. COHEN: We have that information.

MS. JANETTE EDWARDS: It was included in your pre-filed testimony, or, to my estimation, as I look through your list, L & M is not the closest provider to these geographies, however, there are four out-of-state

providers that are at some times within a 30-minute drive time.

According to your list, Thompson, Connecticut is closer to UMass Memorial, a 24-minute drive time. Again, according to your analysis.

Again, just scanning through the list, I believe Putnam, Connecticut is within a 26-minute drive time to UMass Memorial, and I don't believe I see anybody else with under a 30-minute drive time that would serve this population.

MS. VOLPE: Colchester, St. Francis and Hartford Hospital are within 30 minutes.

MS. EDWARDS: Thank you.

MS. VOLPE: Columbia, St. Francis is, also. Hebron, St. Francis is within a 25-minute drive time. There are lots of towns within this region.

HEARING OFFICER HANSTED: Well, Attorney Volpe, I don't want you to testify. We understand the question. Do you feel her answer at this point has answered your question?

MS. VOLPE: Well it's really whether or not there's enough information in the record to establish how many PCI providers are within a 30-minute drive to this region. I think that is the access issue, and we

want to make sure that there's enough information in the record for that to be known, based on these 26 towns that Mr. Foreman has said make up their angio region. We want to make sure we're all working off the same data points.

MR. COHEN: Mr. Hansted, we'll file a late file by zip code, so that we can resolve --

MS. VOLPE: And town.

HEARING OFFICER HANSTED: And town.

MR. COHEN: By zip code and town, so that we can resolve this issue.

HEARING OFFICER HANSTED: Thank you.

MS. VOLPE: Based on the center.

HEARING OFFICER HANSTED: And if it's duplicative information, that's fine. We'll accept it as a late file.

MR. COHEN: With regard to town, we'll pick the center of the town.

HEARING OFFICER HANSTED: The center of town.

MR. COHEN: I don't know, Shane, how you deal with zip code. Does the map have the center of the zip code?

MR. FOREMAN: We can do it that way.

HEARING OFFICER HANSTED: Do it by center

of town.

MR. FOREMAN: I can simplify it.

HEARING OFFICER HANSTED: Okay, thank you.

MS. VOLPE: Okay. Thank you, Mr. Foreman. I think --

MR. FOREMAN: Thank you.

HEARING OFFICER HANSTED: Thank you.

MS. VOLPE: Thank you.

HEARING OFFICER HANSTED: Counsel, do you have any Redirect?

MR. COHEN: I thought we were going to wait until the end, but I do have --

HEARING OFFICER HANSTED: No, she's done with her Cross. I'll allow you to Redirect.

MS. VOLPE: With Mr. Foreman I am, yes.

HEARING OFFICER HANSTED: With Mr. Foreman.

MR. COHEN: Okay, sure. I do have a couple of Redirect. The first is you started to say the data is flat with regard to PCIs, and then you said the big transition, and Attorney Volpe cut you off and said you answered the question. Can you continue to answer the question, please?

MR. FOREMAN: Sure. So what I've seen

thus far when the Intervenors have talked about volume within this market, they're ignoring outpatient, and, so, they're looking at inpatient only and looking at the trends within inpatient only, and depending on which inpatient case we're talking about, some are up, some are down. By and large, they're flat year-over-year, but the big transition starting October 1st of 2013 was the two-midnight rule, which basically took a lot of elective inpatient cases and made them outpatient cases.

So the notion, that volume within this defined geography is dramatically going down, is absolutely not true if you count outpatient cases.

MS. VOLPE: Okay. If --

MR. COHEN: Thank you. And, to continue --

MS. VOLPE: Well just while we're on that question --

HEARING OFFICER HANSTED: No. Just allow him to finish.

MS. VOLPE: Okay.

MR. COHEN: To continue, if you can look at page six of your report, which is page 453 of the filing with OHCA, there was a question regarding what are the 26 towns. Does this describe the towns?

MR. FOREMAN: Correct.

MR. COHEN: Okay, thank you. That was unclear. One of the issues that was raised in the testimony that we heard this morning was the impact on L & M with the granting of a program at Backus Hospital.

Can you please comment on what you heard this morning, which was that 25 --

MS. VOLPE: Well I would object. That's not appropriate.

HEARING OFFICER HANSTED: No, no. Wait, wait, wait. No. This is Redirect. If he talked about it on Cross, I'll allow it. If he did not, I'm not allowing it.

MS. VOLPE: It did not come up in my questioning. The Hearing Officer gave you an opportunity to offer additional presentation.

HEARING OFFICER HANSTED: So I won't allow that on Redirect.

MR. COHEN: Nothing further.

HEARING OFFICER HANSTED: Nothing further? Okay. Counsel, you had one follow-up question?

MS. VOLPE: I did, based on his response, specific to the response. Mr. Foreman, you were relying on outpatient saying that those numbers weren't taking

into account. Do you know if a STEMI patient is that considered an emergent inpatient or outpatient? Do you know?

MR. FOREMAN: Obviously, the elective is the only category with the outpatient.

MS. VOLPE: Okay, so, STEMI, you would agree, is an emergent, is all inpatient data?

MR. FOREMAN: Correct.

MS. VOLPE: Okay. We don't have any further questions.

HEARING OFFICER HANSTED: Okay, thank you.

MS. VOLPE: Thank you.

HEARING OFFICER HANSTED: Thank you.

MS. VOLPE: We have some questions for Dr. Kiernan.

HEARING OFFICER HANSTED: Okay. Dr. Kiernan?

MS. VOLPE: Hi, Dr. Kiernan.

DR. KIERNAN: Hello.

MS. VOLPE: I realize you didn't offer testimony today, and, so, this is really based on your pre-file. If you're more comfortable deferring to Dr. Thompson, that's appropriate, as well, because I know he did offer testimony today, so we'll just leave it up you

what your preference is, okay?

DR. KIERNAN: Certainly.

MS. VOLPE: So will you be the one overseeing the services if they were to be implemented at Backus Hospital for emergent PCI?

DR. KIERNAN: That's likely to be the case, although we haven't formally worked that out.

MS. VOLPE: Okay, so, you're still deciding on who that would be?

DR. KIERNAN: Yes.

MS. VOLPE: Okay, so, would that individual be -- who might that individual be, who would be responsible for overseeing the emergent services?

DR. KIERNAN: The current plan is to, as Dr. Thompson indicated, make this an extension of the Hartford Hospital angioplasty program with physicians currently practicing in Hartford Hospital rotating down there.

Whether or not there would be a specific on-site director or it would be directed from Hartford Hospital has not been worked out yet.

MS. VOLPE: So it would be a rotation, then, with a different doctor rotating?

MR. COHEN: I'm going to object. That's

not what the witness said.

MS. VOLPE: I'm trying to understand.

HEARING OFFICER HANSTED: He's answered. They don't know yet.

MS. VOLPE: They don't know, okay.

HEARING OFFICER HANSTED: Yeah. Let's move on.

MS. VOLPE: Will the program at Backus have a medical director?

DR. KIERNAN: Again, I'm not sure. I would certainly expect that it would, but, again, that has not been formally determined to my knowledge.

MS. VOLPE: Okay, so, in your pre-filing, you state that Dr. Michael Chua Chiaco, who is a private physician, has agreed to provide PCI coverage, is that correct, or is that still being considered?

DR. KIERNAN: That is being considered.

MS. VOLPE: So although the pre-file said he has agreed to provide PCI coverage, has there been a change in circumstances?

DR. KIERNAN: As we thought about the program, we recognize the importance of having experienced operators performing in these cases, so our intention would be to use experienced operators from

Hartford Hospital.

There would be an opportunity perhaps to mentor and work with local providers, who would be involved in the program, and determine whether or not they would be capable of providing that coverage.

MS. VOLPE: Okay, so, I mean, has Dr. Chua Chiaco, since he's been put forth by the Applicant, has he ever done a case at Hartford Hospital for PCI?

DR. KIERNAN: No, he has not.

MS. VOLPE: Okay. I'm not going to ask you anymore question on him. I think you've answered them. Thank you.

Are you aware of whether Backus transfers emergent PCI cases to Lawrence & Memorial?

DR. KIERNAN: I've only seen that or heard that discussed today in the record, but I have no specific knowledge of that.

MS. VOLPE: Okay, so, who -- and you may not be the appropriate person. There might be someone else, who is more appropriate to answer the question. Why doesn't Backus, which is transfer patients to L & M, which is the closest --

MR. COHEN: Dr. Kiernan, you can stay up there, also.

HEARING OFFICER HANSTED: Please introduce yourself.

DR. KYLE McCLAINE: Hello. I'm Kyle McClaine. I've been an emergency medicine physician at Backus since the year 2000, EMS Medical Director at Backus since 2005.

I'm currently the Regional Medical Director for EMS for Region 4, which includes L & M, Backus, Day Kimball and Windham.

I'm also the co-Chairman of the Connecticut EMS Medical Advisory Committee, which is a standing Board of the EMS Advisory Board.

HEARING OFFICER HANSTED: Okay, thank you. Attorney Volpe, your question?

MS. VOLPE: Yes. In that capacity, are you aware of how many minutes L & M is to Backus?

DR. McCLAINE: Yes, and part of the regional plan that was developed with all four hospitals upon the State of Connecticut setting a 30-minute standard of care for transport time, and I'll correct counsel Volpe --

HEARING OFFICER HANSTED: Well, first, just answer her question.

DR. McCLAINE: So, yes. Actually, can you

clarify that part of your question again?

MS. VOLPE: My question is do you know how many minutes it takes to get from your hospital to L & M?

DR. McCLAINE: From Backus to L & M, yes, it takes about 21, 22 minutes.

HEARING OFFICER HANSTED: Okay, thank you. Attorney Volpe?

MS. VOLPE: And how long does it take to get from Backus to Hartford Hospital?

DR. McCLAINE: I'll ask Greg Allard, American Ambulance, who does the transfers. I believe it's in the high twenties, low thirties. Greg, can you clarify?

HEARING OFFICER HANSTED: Is he here?

DR. McCLAINE: Greg Allard is in the back of the room.

HEARING OFFICER HANSTED: Okay, why don't you have him come up?

MR. COHEN: He has to be sworn in.

MS. VOLPE: Yeah, he hasn't been sworn in. That's okay. So is it twice as long, or are you saying -- I mean you're a doctor. You're making a decision. A patient presents himself.

DR. McCLAINE: So it is close, but it's a

little bit closer to L & M.

MS. VOLPE: Closer to L & M?

DR. McCLAINE: Yup.

MS. VOLPE: Okay and, so, if L & M is closer, why does Backus not transfer patients in need of PCI services to L & M?

DR. McCLAINE: So the cases at Backus Hospital that get transferred to L & M are ones that have already been missed by the primary EMS response. Since the inception of L & M's program and after the State helps with a 30-minute guideline for EMS, every EMS case that is identified pre-hospital does go to L & M now, and that includes areas north of Backus.

The ones that are actually diagnosed at Backus Hospital, where you're already in a transfer time of the 120 minutes, this is with the 120 and 90-minute discussion that has been bouncing around the room, it's not 90 minutes or 120 minutes drive time.

It's first medical contact to expectation of a device. That's the 90 and 120-minute standards. A 30-minute drive time is a separate standard, which helps a facility to move towards a 90 or 120-minute timeline, depending on who they are and what they do, so Backus is identified as a 120-minute, not a primary angioplasty

place, so our goal is to get people to definitive care within the 120 minutes.

HEARING OFFICER HANSTED: Okay, now, you mentioned expectation of device. What does that mean?

DR. McCLAINE: So the 90 and the 120-minute standards are first medical contact, which frequently is EMS, which I oversee, and device is catheter in the cath lab.

HEARING OFFICER HANSTED: Okay.

DR. McCLAINE: So that's not door to parking lot. That's not drive time. That's including all the internal processes of all the hospitals involved, and the EMS agencies, and the inter-facility transfer agreements, and EKG acquisition, so I can speak to that.

MS. VOLPE: So let me ask my question directly. You've established that L & M is closer than Hartford, so I'm not talking about a patient in the field. I'm talking about in the ER.

A patient presents, and the hospital professional realizes this patient needs to go somewhere where they have PCI-capable services. Why are they not sent to L & M when it's a closer facility?

DR. McCLAINE: Because the patients that are in the ER at that time are outside, are looking to be

outside of the 90-minute standard, and the 120-minute standard is our expectation that we're able to try to realize 120 minutes for them transferred to several different sites.

MS. VOLPE: But what is your time now? What is the time? You're saying the 90 and 120 are the standard, but what, in reality, is Backus doing? What is your current time?

DR. McCLAINE: So the actual inter-facility transfers are outside of my EMS expertise. They know a little bit more about the actual ED, once they're in the ED and transferred out. They can give you more -- someone else in the room can give you better numbers than I can about the exact number, but it is our goal to hit 120, and that's what we work to do, and we don't always hit it.

MS. VOLPE: But you don't, right. You don't. I mean I think the Applicant states you don't, so what we're trying to determine is why don't you, and we're trying to understand why, if there's a need issue and access, why are patients not transferred to Backus, from Backus to L & M, when it is the closest PCI-capable facility when you're not hitting these national numbers that you'd like to be?

DR. McCLAINE: So the way the question is framed assumes that all the patients in play are already at Backus Hospital, and that is not the case.

MS. VOLPE: Well if they're not evaluated in the field, which you said is already happening, and they're coming to L & M, if they're presenting at your doorstep, you know, either by EMS or showing up, because EMS didn't make the diagnosis in the field, you clearly are transferring patients, who need these services, and you're not transferring them to L & M, so we're trying to understand why.

DR. McCLAINE: Correct. So I can speak as a physician in the department and say that, in the cases where someone walks in the door with crushing chest pain and they're 40 years old, they are the ones that are getting 120 minutes, because those are the ones, and I can tell you the ones that come in by EMS they stay on the stretcher, they get their EKG, and they're back out the door with the same ambulance crew, so I can tell you that those cases are the easy ones.

I think, to actually look at the ones that exceed 120 minutes, there are processes in each hospital that are never perfect, but I think the majority of those cases are delayed presentations.

This is the 80-year-old septic patient with a fever of 102, where you do a routine EKG at a later time when they don't have chest pain, and then you see if (indiscernible) or a patient, who has a trauma, who crashed their car, because they had a cardiac event in their car, and they are at a trauma center, which Backus is and Lawrence is not, and the STEMI rules of transfer are superseded by the trauma rules of evaluation at a trauma center, or a pregnant patient, who is in labor, or a septic patient, all things that mean you can't go directly to the cath lab are the reasons where you don't and you transfer them out.

MS. VOLPE: Okay, thank you.

DR. McCLAINE: For the 40-year-old --

HEARING OFFICER HANSTED: Just let him finish.

MS. VOLPE: Okay.

DR. McCLAINE: For the 40-year-old person, who comes in with crushing chest pain, walks through the door, or comes in by EMS, where they say, Mr. Paramedic Intercept, we don't have an EKG, but this person doesn't look well, those are not 120 misses.

HEARING OFFICER HANSTED: Okay, so, what you're saying, I think, is it's not necessarily the case

that you're missing the 120, because it takes longer to get to Hartford Hospital than L & M?

DR. McCLAINE: Right, but what I'm trying to extend, and this may not be part of her original question, so you can stop me if you wish --

HEARING OFFICER HANSTED: No, I want to hear the information.

DR. McCLAINE: Is that, when you look at this program and how it's developed, we are looking at regions that are far enough away from Backus, where by the time you build in the transfer time to us, you've already violated the 30-minute transfer driving rule.

You, then, have to stabilize. Even at a 15-minute turnaround, you then have to drive 20 minutes to L & M. You're not going to hit a number that's 90.

Yes, we can do 120 with L & M or 120 with Hartford in many of these cases, but the inception of this thing from my standpoint as an EMS provider is that we want 90 minutes to be the standard at Backus, not 120 forwarding on to L & M, or Hartford Hospital, or any other PCI center, and that was the true goal.

Inherent in there they are 120 minutes from someone, who came from Norwich, was a delayed presentation. What was it? There are cases to look at

case-by-case. The larger goal is to set a 90-minute standard for the communities that surround this proposed cath lab versus a 120-minute standard that is currently the standard by where we are, which would change that fundamental number from 90 to 120.

And even I think the other folks in the room can verify that there is a survival benefit and a heart benefit to the difference in those two numbers, and that is what we can achieve with a PCI --

HEARING OFFICER HANSTED: Okay. All right, thank you, Doctor.

MS. VOLPE: Okay. If the doctor could be provided with page 26 of the Applicant's application, I think it would be helpful in responding to my specific question, and I'll ask it again.

MR. COHEN: Hold on. Hold on one second until we get it out. Are you talking about bates stamped page 26?

MS. VOLPE: Let me just make sure. No. 473.

HEARING OFFICER HANSTED: Let's go off the record just for a minute, just so we can take the time to make sure we're all on the same page here.

(Off the record)

HEARING OFFICER HANSTED: Okay, so, we're talking about page 473 of the application. Attorney Volpe, you may proceed.

MS. VOLPE: Yes, so, can you tell us what is the median door-to-balloon time in minutes for Backus?

DR. McCLAINE: They said from 2011 through May of '15 the median time is 134 minutes.

MS. VOLPE: Okay, so, that's clearly below the standards required, right, and Hartford Hospital is further, correct? So, again, if you want to hit the quality standards, why is Backus not referring to a closer PCI-capable facility?

DR. McCLAINE: I see the question, and I see the data. I don't have an answer.

MS. VOLPE: Okay.

DR. FOLEY: May I just?

HEARING OFFICER HANSTED: Yes. Just identify yourself, please?

DR. FOLEY: John Foley. So, at the beginning of this period, we started to look at door-to-balloon times in every patient and certainly discovered that it was unacceptably high, and we have been sort of attacking this in trying to go through metrics within the emergency room, in terms of -- they used to call

cardiology. Cardiology would weigh in on an opinion, see the patient, if possible. There were inherent delays in the process that we have eliminated, so I think that the more recent record would reflect that our door-to-balloon times continue to improve, not that in every case we meet them, but that we are significantly better now than we were during the initial period of this monitoring, where we had some really, you know, we approached the MI similar to other cardiac issues, and we know that that's not appropriate.

The ER is equipped with decision-making capabilities to transfer drug boxes to eliminate pharmacy. We've done a lot of internal process changes to address what was an unacceptably high door-to-balloon time.

MS. VOLPE: Okay, so, can I ask you, Dr. Foley, why does Backus not transfer PCI patients to L & M when it's closer? And we've all established it's closer by miles, by drive time, so why do they not get transferred?

If we are genuinely worried about heart muscle and time period, why are they not going to the closest PCI provider?

DR. FOLEY: So I think, in answer to the

question, if you look at the groups that we have within Norwich, so we now have a Yale group, I was a member of that group initially, we weren't necessarily part of Yale when I was there, but they are now, but we were certainly aligned with Yale, so physician preference and patient preference, patient history, many of these people have had prior interactions with either Yale or Hartford before, so we respected those relationships.

From a care fragmentation and communication point of view, it made a lot of sense, it makes a lot of sense that we are providing care within a system, which we have found, just like if you were asking a Yale physician here where do they send their patients from the emergency department, it would Yale-New Haven.

So if the question is why don't patients from the emergency department at Hartford Hospital, I mean at Backus Hospital, you know, not go to Lawrence, I would say, well, when the docs from Yale are on, they're sending the patients not to Lawrence, but to Yale-New Haven Hospital, and they're on call in an equal amount of time that we are, so I think even Yale recognizes that within the framework of a system and communication that it's better care to stay within that aligned model.

MS. VOLPE: Dr. Foley, if a patient

presents themselves at the ER, however they get there, they're dying of a heart attack, I don't think they're determining a preference, they're not deciding, oh, I, you know, I like Yale better, send me to Yale.

It's the professional, who is making the decision, and you have a closer PCI-capable. I still, from a layman's perspective, tell us why aren't those patients going to a closer facility that can take care of their immediate need?

DR. FOLEY: Because the care provided historically was the patients were sent more to Yale than to Hartford. That is now different. The care that these dying patients are getting has been excellent, and the outcomes have been excellent.

And from an institution and a provider standpoint, in our best opinion at the time, that was the best place to send them, because we're not talking -- we're talking about, you know, we're talking about outcomes, and the outcomes have been good.

MS. VOLPE: Right, but how can you say it's been excellent if you're not meeting quality minute standards? If your median time is 134, how is that excellent when it falls below the national heart organization standards, the SCAI and that? How is that

excellent?

DR. FOLEY: Well I'm not sure that I would agree that our door-to-balloon now is 134 minutes, and I think that that's data that we can certainly look at, but I thought it was less than that.

MS. VOLPE: That's what's been established in the application.

DR. FOLEY: Okay, so, I'm sorry. Your question?

MS. VOLPE: My question was you're saying these patients are getting excellent quality service, and I guess, again, I'm not a doctor, but if somebody said, well, the standard of care for this service is 120 minutes to get what they need and you're doing it in 134, how is that excellent quality service care?

DR. FOLEY: I think the question is great, because it recognizes quality of care is important and time to cath and balloon is important, which is why we're sitting here.

We're asking, actually, for a cath lab, so that we can hold to the standards of 90 minutes, which is certainly quicker than 120.

We acknowledge that what we're providing now is not the type of care we'd want to provide, nor the

care that we could provide. That's why we're sitting here, you know, with this application.

MS. VOLPE: Right, but if you have a provider in your service area within a short period of time minute drive and that provider could do it within the same time period if you were to have a duplicative service, again, why aren't these patients being sent to the closest PCI provider?

DR. FOLEY: Well I would disagree that, if we had a cath lab, that it would be the same amount of time.

MS. VOLPE: How long does it take to setup a cath lab for a patient when they present?

DR. FOLEY: But it wouldn't also involve tying up an ambulance and transferring a person from one place to another with all the communication issues of talking about the patient and how much is done at Hospital A, and then how much is delayed to Hospital B.

If we had a cath lab, were we able to activate a cath lab, I can't imagine that my colleagues in cardiology would agree that opening an artery quicker in the same institution isn't better than transfer, by the same reason that the transfer to Hartford is we're being, you know, sort of looked at for door-to-balloon

time of over 120. We're saying we should be shorter.

HEARING OFFICER HANSTED: Doctor, I understand that you're here to get that program, to try to get that program, but the question really is, aside from Backus having a PCI program, historically, it's clear from the evidence in the record that Backus Hospital has been transferring patients in higher quantities to both Yale and Hartford Hospital rather than L & M, and L & M is clearly closer than either of those two hospitals. Why has that been done?

DR. FOLEY: I'd have to say that it's historical. It is, to some degree, historical practice with providers at institutions being aligned with and able to communicate and negotiate care.

HEARING OFFICER HANSTED: So it's physician referral?

DR. FOLEY: And patients, when I've been asked, you know, we ask them where they want to go. In the case of a patient that comes in in shock, you're right. We're not asking them, but patients are asked in the emergency department where they want to go.

I mean they're given the choice, and they're selecting Harford or Yale, and that's the way they're going.

HEARING OFFICER HANSTED: I understand that, and I don't disagree with that, to the extent you've testified to that, but is there a certain amount of physician referral pattern going on here?

DR. FOLEY: Well I think, in a referral pattern, it's another way really of saying, you know, communication and relationships and trust.

HEARING OFFICER HANSTED: Right.

DR. FOLEY: And trust, that I'm now taking a very sick person and putting them in an ambulance and sending them to someplace, and who is going to be on the other end, and who is going to take care of them, and that is a relationship historically, which I felt very comfortable with patients going to Hartford.

HEARING OFFICER HANSTED: That's fine. I'm not belittling.

DR. FOLEY: Oh, no, no, no. I hear you.

HEARING OFFICER HANSTED: I'm just trying to get that out there. I think that's the elephant in the room here.

DR. FOLEY: Sure.

HEARING OFFICER HANSTED: And we just need to -- I think that's what you're trying to get at, Attorney Volpe, and I want to try and get an answer to

this question today.

DR. FOLEY: Sure. And I hope I've answered it. I know I talk a lot. Sorry.

HEARING OFFICER HANSTED: That's all right.

MS. VOLPE: Thank you. So maybe this is better directed to Dr. Foley. Does Backus routinely care for STEMI patients in the hospital now?

DR. FOLEY: I would say we do not routinely care for STEMI patients now. In the emergency department, but, no, we're not admitting STEMI patients for obvious reasons. Angioplasty is better.

MS. VOLPE: So do you have current support staff, nursing staff techs, who are comfortable with these patients if you're not currently taking care of them?

DR. FOLEY: And that question or those comments came up earlier, and I think it's an important question, and I'll try to be very brief.

HEARING OFFICER HANSTED: No, no, no. I did not mean to cut you off.

DR. FOLEY: Oh, no, no, no, but I know. My wife tells me I go on, and on, and on.

HEARING OFFICER HANSTED: Take your time.

DR. FOLEY: So it's not the first time, but I'll try to be brief. So when I first came to Backus in 1999, we handled MIs all the time, because we didn't have a thing called angioplasty readily available. We familiarized everybody, and the outcomes were not very good, so I'm glad we're not returning to that, but we treated those sick patients, and now we are triaging them, and the goal is to get them into a cath lab quickly.

So do we have nurses and doctors, who can take care of a STEMI? Absolutely. Do we take care of a lot of them? Absolutely not. Like with any program, and I would argue that before Lawrence & Memorial did PCI, their staff would have been in the same situation, and it behooves us to train, we've begun that training.

Our cath lab nurses and intervention radiology nurses have not only switched with each other, so that we're learning the whole idea about being on call and how to handle balloons and wires, but they've also gone to Hartford Hospital and got a training in the cath lab, so I just wanted to, for the record, to say that the training, the advanced training for these folks, is not just in an interventional radiology suite, because I agree that that's not comparable training, but the

training has already begun with the staff.

Will we have to do a lot more?

Absolutely. There are already committees in place. Becky Durham, who is one of our sort of Directors, who is behind me, can probably comment better than I, but we've already put in place the framework for how we would do the training needed, whether it would be balloons, or ICU, or whatever.

HEARING OFFICER HANSTED: Okay. Did you want to have her?

MS. VOLPE: No, I don't.

HEARING OFFICER HANSTED: Okay.

MR. COHEN: I thought the agreement at the beginning was --

HEARING OFFICER HANSTED: No, no, no, no, no.

MR. COHEN: -- that whoever is the best --

MS. VOLPE: To get my question answered.

MR. COHEN: -- able to answer the question.

HEARING OFFICER HANSTED: But if she's --

COURT REPORTER: I can only record one person at a time.

HEARING OFFICER HANSTED: And I get to

talk. If she's satisfied with that answer, then she can move along.

MR. COHEN: I can address it on Redirect, then.

HEARING OFFICER HANSTED: You can address it on Redirect.

MS. VOLPE: So I'll just stay with you, Dr. Foley. Improving patient care and access is priority, would you agree?

DR. FOLEY: Absolutely.

MS. VOLPE: Okay and, as a sponsoring hospital with EMS, do you think it's appropriate to put the funding into detecting these patients, who need this service out in the field? I think that the importance is quickly identifying the need, right, and the concern when someone presents.

MR. COHEN: I think Kyle, Dr. McClaine --

MS. VOLPE: Would it be better to identify them in the field, even before they present at the hospital?

DR. McCLAINE: So the point that you're alluding to is the transmission of 1280 EKGs and who is (coughing) and what you can do with them, and that's a great question, and the answer is, when you have a choice

of two places within equally distant or less than 30-minute distance between them, then using an EKG to tell you where you're going to go, whether one is a PCI center or one is not, is a very good thing.

When you're up in the north and you're beyond the 30-minute mark to a PCI center and you don't have the ability to choose where you're going, a BLS provider, specifically, has to go to the closest facility, and then it becomes a transfer situation.

So you're making reference to the BLS 12-lead acquisition project that the State of Connecticut put forward, and I was on the committee that was approving that pilot program and approving the stuff through the CHEMSMAC, which we then gave to the Commissioner, who then released that statement, and it was done for a very specific reason, and that was in the western part of the state.

There were three hospitals in very close proximity to one another. One was a cath lab, two are not, and there's a paucity of paramedics in that region of the state, and there was no one to do an EKG, so the BLS provider was at the house in five minutes, they were looking at someone, who has chest pain. They don't know whether they were having a heart attack or not, and

they're looking at two hospitals. They can almost see them both from the guy's mailbox, and they're saying where do we go?

So they said this is a spot where we need more paramedics. We can't get more paramedics. Who else can do an EKG? So they piloted a program, by which the hospitals agreed we need to decide who has a STEMI and not, because we want primary less than 90-minute angioplasty instead of getting into the 120-minute ballgame with transfers.

So what they did was is they had a system, where they can't even look at the EKG. They have a black box, they attach it to the patient, it gets beamed to one of the hospitals, who then reads the EKG and says that's a STEMI. Go to the PCI center. That's not a STEMI. Go to the other hospital. And they piloted that program, and it worked very well, but that was a very specific need, where you had two hospitals close together and you had to pick which one.

Now, in Norwich, that still exists, and anywhere where there's a paramedic that's already taken care of. Paramedics have been doing EKGs for a long time. They don't have to transmit them. They can transmit them, but their own reading of the EKG is a

national standard that's adequate with an acceptable false positive and negative activation of a cath lab, so paramedics can read EKGs. If they can transmit them, that's great, too, but they're not the problem.

The problem is the BLS provider, and this is exactly one of the access to care issues in the northern part of the state, where you exceed a 30-minute drive time to Lawrence & Memorial Hospital, and you have BLS providers and a paucity of paramedics, as well, to be truthful, and herein lies the problem, whether or not the BLS provider or the paramedic gets an EKG, if you're more than 30 minutes past L & M, is a problem, because then you're into the -- you're supposed to stop at the closest hospital, and then you become a transfer patient, and a transfer patient sets up a different standard of times, but it's also not the best for the patient.

You're looking for, you know, if you're the patient, you want to offer every patient the ability to get their vessel opened in 90 minutes, so a primary PCI center.

So to cut through what will likely be a question later, why not BLS 12-lead transmission now, because they don't have a choice. They're still going to the same hospital, regardless.

And the next thing is, if we have a cath lab, would there be BLS 12-lead transmission? Absolutely. It's part of my plan, because then you have an option.

If you're near the Backus Plainfield, 10 minutes past Backus Plainfield towards Day Kimball and you get a 12-lead that says it's a STEMI, now you can drive down to Backus for your primary PCI versus stopping at Backus Plainfield or Day Kimball and then getting transferred to UMass.

HEARING OFFICER HANSTED: Okay, thank you.

DR. McCLAINE: Or Hartford.

MS. VOLPE: So the cost of implementing this EKG 12-lead, are you familiar with --

DR. McCLAINE: Yeah, so, you have to ask each ambulance to buy a unit that would do transmission. You have to get a hospital to buy the equipment and the ability to receive it and interpret it, and if you're a place that's going to, then, offer the patient a different option, it's much less than the cost of flying somebody or taking them out of network.

It's not a huge cost, but it is a real cost that you have to ask the Town to do and each ambulance in the Town to do. It's actually something,

where it was piloted for the reason that I told you earlier, and that is one of the few towns in Connecticut that actually to do it. None of the Lawrence & Memorial services have BLS providers doing transmission of 12 leads by BLS and, currently, none of Backus do either, because we're not giving them a choice where they're going to do something different with the data and there is a cost, but in cases, where you can make a patient outcome difference, it's worth the cost.

MS. VOLPE: If Backus receives information on a patient from an ambulance 12-lead EKG that they require a PCI, what does Backus do?

DR. McCLAINE: Backus doesn't receive that information at all. If the person is within 30 minutes, Backus never hears about it, and it becomes one of your, L & M's cases, or Hartford's cases, or wherever they can get in 30 minutes, depending on where they are.

If they're in Colchester, they're going right to Hartford. If they are in towns, such as Ledyard, Lisbon, like that, they go right to L & M, because there is a cath lab within 30 minutes, and they've identified the STEMI, so we never even hear about it.

MS. VOLPE: Right, because there's a cath

lab available within 30 minutes.

DR. McCLAINE: Right.

MS. VOLPE: Of all those.

DR. McCLAINE: And by this town analysis, there is 11 of 28 towns that are within 30 minutes of a PCI center, not including Backus.

MS. VOLPE: Correct.

DR. McCLAINE: And there are 17 of 28 that Backus would be the closest and for primary angioplasty, too, that is not within 30 minutes of L & M or anyone else.

MS. VOLPE: Well the or anyone else, I don't know that that's --

DR. McCLAINE: There are 17 of 28 people, towns that are not on your list that Backus would be the closest town, closest cath lab to and within 30 minutes where no one else is in 30 minutes.

MS. VOLPE: Well that last statement is not accurate, and I think we're going to get a late file on that.

DR. McCLAINE: Sure. And then, within each town and the other part of EMS that I think is hugely important, is that whether you do it by town, the center or town, the corner of town and zip code or not

does not take into account real life EMS, as I've been part of most of my whole life, and that is the center of town is not the only point of measure for real EMS response times.

You don't take into account weather, where you are close to the highway, where you have to turn around or not, and a thousand things that effect aeromedical transport, effect ground transport. There's several days, and I've sent a STEMI from Backus Plainfield to Hartford via 17 different ways, but, on a rainy, snowy day, when Life Star is not flying, it can be 40 minutes to get to Backus from Plainfield, not 17, and that's a real life thing that happens often, with traffic and weather.

And within each town, earlier it was discussed about do we do it from the center of town, do we do it by zip code, I'd say do it from 25 parts of every town and see what your real numbers are, because real transport times are not best case scenario Google maps on a sunny day, which is where all of these numbers come in.

And, to be truthful, on both sides of the coin, it should be looked at, but, in truth, real life transport, when you're 15, 20 minutes north of Backus,

which is 15 or 20 minutes down and then another 20 minutes to L & M, factoring in cath lab activation time and all that stuff, it's hard to make the 90, and it's hard to make the 90 even when you say you're within 30, but, for the strict analysis, there are several, 17 to be specific, where they can't make the 30 to anywhere else by this chart that was actually filed by you guys.

MS. VOLPE: So do you, personally, transfer patients to another PCI facility?

DR. McCLAINE: So, as a physician in the department, I have.

MS. VOLPE: Yes, you have.

DR. McCLAINE: And I've been one of the ones that have sent them to L & M, and I've been one of the ones that have sent them to Hartford.

MS. VOLPE: Oh, you've sent them to L & M?

DR. McCLAINE: I have.

MS. VOLPE: How many have you sent to L & M?

DR. McCLAINE: I was one of those three, and it was a snowstorm, and it was -- and I don't think we made 90 or even 120 on that patient, because I think even that snowstorm trip to L & M was probably an hour.

HEARING OFFICER HANSTED: Did you say you

sent three, or you were one of the three?

DR. McCLAINE: I sent one of those three.

HEARING OFFICER HANSTED: One of the three.

DR. McCLAINE: And I routinely send ones to Hartford, as well, but when I send someone to Hartford, they don't leave the EMS stretcher, and they turn around immediately.

HEARING OFFICER HANSTED: Okay.

MS. VOLPE: Okay, so, just in staying with that, because this is a question we wanted to get answered, you acknowledge that, over the years of us having the program, Backus has sent three patients to L & M.

You, personally, sent one, and can you tell us why you sent that one patient?

DR. McCLAINE: Yes. There was a snowstorm, and there was no way they were going to make even 120 in any direction, if I remember correctly, and that was picking, of all the bad scenarios, the one that was the best for the patient, and my own patients that I send to Hartford the same is true.

I don't send them, unless I expect they're going to make the metric.

MS. VOLPE: So you're confident that you can make the metric in sending your patients to another PCI facility within the quality times?

DR. McCLAINE: I am.

MS. VOLPE: Okay and even though we've established the median time is longer than the quality set standards?

DR. McCLAINE: Right, and I'm one of the ones that does go back and say look at your times. If you can't make your metrics, then we have to do better, and we've looked at seeing what our options are.

MS. VOLPE: Okay and if you know you can't get a patient within the 120, which is the time period that you're held to as a non-capable PCI, what is the protocol? What do you do if you can't transfer a patient within the quality indicator time protocol?

DR. McCLAINE: So the standard ones are give lytics, or that's your option. If you can't make 120, you give lytics.

MS. VOLPE: Give lytics, is that another name for fibrinolosis?

DR. McCLAINE: Fibrinolytics, yes.

MS. VOLPE: So close.

HEARING OFFICER HANSTED: I don't know

what either of those are, so can you explain them?

MR. COHEN: Well you've got the right guy to answer the question.

DR. McCLAINE: So, as Dr. Foley mentioned, before the availability of mechanical opening of an artery, the best next thing we could do would be to give a, for a layman's term, clot busting medication, a medicine that dissolves an existing clot, and that was the only therapy that was available before angioplasty and PCI stenting and bypass surgery, that kind of stuff, and it's now been found in the literature to be substandard to opening the vessels in 120 minutes.

HEARING OFFICER HANSTED: Okay. Thank you.

MS. VOLPE: So because you're confident that you could meet the 120, even though you're not transferring them to Backus, I mean to L & M, you're transferring them to Hartford, you've never administered that drug, or have you administered that drug?

DR. McCLAINE: In the cases that I have had, I've now had to, but I would, if I really felt that there was no other option, but, to be truthful, along the way this is not static data point. There were a lot of steps along the way, where it was give the thrombolytic,

give half dose lytic, give lytic plus this, give lytic plus that, and there was a lot of variability amongst even the PCI centers, as to whether they wanted to do that, including some of the receiving PCI centers, saying in 120, 140, let's not do the thrombolytic, so those discussions just happened.

That's not absolutely been agreed upon all the way along. It's written as the current standard, and I think it would be the current answer that most ER physicians would give you and most cath labs would be okay with, but, in truth, there was a lot of resistance to getting really close to that number and not having the additional complications of the lytic.

And Dr. Cambi is an interventionalist, as well as others in the room, and I'm not, but that was thrown up as, you know, for close, let's not do that lytic. We don't want that mess.

MS. VOLPE: Okay, so, can we go back to this need for EMS to be equipped in the field to make a diagnoses?

DR. McCLAINE: Right.

MS. VOLPE: Do sponsoring hospitals play a role in that?

DR. McCLAINE: Yes, they do.

MS. VOLPE: And what is the role that they would play?

DR. McCLAINE: The state provides the bag of tricks that you have to sample from. The sponsor hospital decides in their own region what of those tricks could benefit a patient and be something that could be sustainable or feasible.

MS. VOLPE: So what can Backus do to improve this provision of EMS providers in the field with this capability?

DR. McCLAINE: So, currently, in the areas surrounding Norwich and the areas where we truly overlap, if there were two PCI centers, there’s a very, very good density of paramedics that currently obtain 12-lead EKGs and use them to make a decision and pick a destination hospital.

They do that well. They do that already. In the areas that are north of us, they currently don’t have anything to do with the information that they would get for the cost and the time that they spent. They’re not going to go to a different hospital.

The moment that an option exists, it opens up the discussion, as to say this is a spot where BLS 12-lead acquisition by non-paramedic providers could be

something that may help tell a patient which way to go and tell the ambulance which way to take the patient, and then you have to decide who is going to pay for all these ambulances to have this, and some costs will end up being shifted to them, a lot will be shifted to the hospitals, as well, and you have to, to justify that, you have to say, when they go their towns and say we're a volunteer ambulance for the town of, you know, pick your town north of Norwich, Canterbury, you know, and we're currently not able to make it somewhere, you know, if we do this, is it going to change which way we point on the highway, and the answer is currently no.

If there's an option, yes, and then we work on who is going to help them get that.

MS. VOLPE: So five million dollars could certainly pay for a lot of 12-lead EKGs in the field.

DR. McCLAINE: But, with all due respect, counsel, that doesn't change the fact that there's not a place for them to take the patient.

MS. VOLPE: Well I think, if we look at the chart within the quality 30-minute drive, there are lots, there are lots of places to take the patient with PCI capability --

DR. McCLAINE: You would have to find the

ones that don't have a paramedic available to do a timely EKG, which are very few areas, to be honest. Even within the zone, there are very few of those areas.

MS. VOLPE: Well, again, that's my question. It's all the same money. It's health care dollars. It's state resources. It's charitable organization. It's funding. It's patient. It's health plans.

DR. McCLAINE: My answer to your question, counsel, is that the extra money doesn't give them a place to go without another cath lab.

The ones that can get the data now use the data and go to the existing providers that they have. Extra EKGs in an area that doesn't have a cath lab, no matter how much you spend or don't spend, doesn't change the fact they don't have access.

MS. VOLPE: But, again, back to our question. Of the 26 towns, there are 24 of them within a 30 to 35-minute drive time to a PCI-capable facility, so our question is is the money better spent determining in the field whether this patient is presenting with a heart attack, based on a 12-lead EKG, than setting up a duplicative service within a 17-mile radius?

DR. McCLAINE: I hear what you're saying,

but the State of Connecticut set a 30-minute target, and, as we've talked about, there's a lot of arguing about exactly 20, or 30, or 35, or 40 within a town, but the EMS providers have the instructions from EMS, which is the same for L & M and Backus and Day Kimball and Windham, to say, if you are wherever the heck you are, 30 minutes to a PCI center, get the EKG and go there, and my answer to you is is that none of them have currently raised their hand to say I've got two choices. If I could just get that EKG, I would direct the patient for you. That does not currently exist.

With another PCI center in the region, there are some times when that would exist, and you now have a choice between the PCI center and the non-PCI center, but not everybody who is weak and dizzy is going to the PCI center automatically.

HEARING OFFICER HANSTED: Thank you, Doctor.

MR. COHEN: One of our other witnesses has some additional information on this.

DR. THOMPSON: So this is Paul Thompson. I'm the Chief of Cardiology at Hartford Hospital. I want to point out that I think this is a moot point, because I tried to buy these four ambulances and was told that it

was a Stark Law violation, that I was giving money to a group that could potentially refer patients to my institution.

DR. McCLAINE: So I think, as far as the Stark Law goes, it basically says if you're going to do something for one, you have do it for all, and you can't use it to --

HEARING OFFICER HANSTED: Right. No, I'm familiar with it.

DR. McCLAINE: Yeah. My apologies. So I was faced with that. I was faced with that very question and -- I'll direct it to you. I'm sorry. In that we would offer, if it were to be offered, if we could find a place that we can do an EKG and redirect a patient, we would have to say we will help you fund this, if we're going to do it for everybody, and we absolutely will, but what has really happened since this 12-lead pilot program began was that there was only one pocket of the state, like I said, that had within the confines of here to the parking lot there were two hospitals, one was a PCI, one wasn't, and the paramedic wasn't there for 10 or 15 more minutes, and the BLS provider was saying I don't know where it is. Where do I go?

And it answered that question for them

beautifully, and it still does, but it doesn't answer the question that we have here.

HEARING OFFICER HANSTED: Right. Okay, thank you, Doctor. Let's move on from this question. I think we've heard enough.

MS. VOLPE: Sure. Gladly. And this might be more appropriate for one of the physicians, who is familiar with the guidelines, the ACC/AHA 2014 guidelines and the DPH 2012, so I guess --

HEARING OFFICER HANSTED: Wait. Before you get to your question, who would be most familiar with this?

MR. COHEN: Well I think it would be Dr. Kiernan and Dr. Foley.

MS. VOLPE: Nice to have you back, Dr. Kiernan. So in the application, you rely heavily on the 2012 guidelines for STEMI patients in your application and you ignore the guidelines in the most recent ACC/AHA for 2014, stating, you know, here's the criteria, here's the update on PCI without on-site surgical backup for emergency transfers, so, specifically, why is that? Why are you relying on that, as opposed to the most recent ones? Do you know?

DR. FOLEY: I think your question is why

do we not rely on the latest --

MS. VOLPE: Correct.

DR. FOLEY: -- iteration.

MS. VOLPE: Yes.

DR. FOLEY: And I don't know if it's a timing of submission and preparations in the court, but now that I've come up here (multiple conversations) it's a rationale question about why the guidelines we chose were the ones we chose.

MS. EDWARDS: We submitted the 2014 guidelines with our application.

MS. VOLPE: Right, but your application, if you submitted a 2014, they state that, if you have a PCI-capable facility within a 30-minute drive, that you should not have another facility with PCI capability, so how do we reconcile that? How do you reconcile that for this Commission?

DR. KIERNAN: That's correct. The guidelines do recommend not establishing another center within a 30-minute drive of another center, however, we're talking about writing services to patients that are well north of L & M, for example. It would be closer for them to come to Backus for treatment, and that's the rationale.

MS. VOLPE: So, based on that, your recommendation would be to have this Commission go against the national guidelines and allow --

MR. COHEN: I'm going to object to that, because that wasn't what his testimony was. His testimony wasn't that he was going to go against the guidelines, and counsel is summarizing and misstating the exact items. Can you read them to us, please?

HEARING OFFICER HANSTED: No, no, no, counsel. I don't want you to ask that question. I don't think I want him to testify, as to whether or not he wants the zip code against the national guidelines.

I think it's clear what they're asking for. They've submitted evidence, and we know what the guidelines are, so we'll make the determination whether or not it goes against the guidelines or in favor of.

MS. VOLPE: Okay, as long as everyone is aware of the guidelines.

HEARING OFFICER HANSTED: They're in the record, the 2014 guidelines.

MS. VOLPE: Okay. Just give me one moment.

HEARING OFFICER HANSTED: And just while they're speaking, just for the record, the guidelines

start on page 112 for the record.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: You're welcome.

MS. VOLPE: Okay. Our next questions relate to the financials of the project.

HEARING OFFICER HANSTED: So, Doctor, you can have a seat.

MS. VOLPE: Thank you, Dr. Foley. Thank you, Dr. Kiernan.

HEARING OFFICER HANSTED: Relate to the financials, so your financial individual.

MR. DAN LOHR: Good afternoon. I'm Dan Lohr, Regional V.P. of Finance.

HEARING OFFICER HANSTED: Good afternoon.

MS. VOLPE: Dan, I have to go easy on you, Dan. I like you, Dan. I'm kidding.

HEARING OFFICER HANSTED: Not that she doesn't like you.

MS. VOLPE: I like everyone else, but I particularly like Dan.

HEARING OFFICER HANSTED: Do we have a conflict here, Attorney Volpe?

MS. VOLPE: No conflict.

HEARING OFFICER HANSTED: Okay.

MS. VOLPE: So, Dan, what is the cost of implementing this program for the hospital?

MR. LOHR: Cost, in terms of the capital you've referred to earlier in the five-million-dollar, four-and-a-half-million-dollar range, annual cost, if you refer to that, is a loss of the program.

It ramps from I think the mid-$300,000 loss up to maybe a five or five and a half.

MS. VOLPE: Five and a half?

MR. LOHR: 500,000.

MS. VOLPE: 500,000, okay. So, of the initial capital outlay of the five million in capital, where would that be coming from in the hospital's resources? Would that be a debt service, or do you have money on hand?

MR. LOHR: It would be funded from operations.

MS. VOLPE: Funded from operations, okay. And, so, you have five million dollars in capital available to fund this?

MR. LOHR: Yes.

MS. VOLPE: Without changing any of your other programs?

MR. LOHR: Yes.

MS. VOLPE: Okay and how will the continued losses for the program be funded? How will those be funded?

MR. LOHR: In the projections, we're continuing to project a positive bottom line, so the losses would be funded from operations.

MS. VOLPE: Okay and is it Backus's position that no other programs would be discontinued or suffer funding, based on implementation of this program?

MR. LOHR: My opinion, and I'll perhaps defer to more the strategy-minded individuals, but there's enough of an operating margin to cover the program, so there shouldn't be any other reductions.

MS. VOLPE: Okay, so, I just want to make sure I asked this question clearly. Implementation of this program would require no, absolutely no other programmatic changes at the hospital, in order to implement this program?

HEARING OFFICER HANSTED: In terms of cost?

MS. VOLPE: Cost, correct. Thank you, Kevin.

MR. LOHR: In terms of cost, I don't believe so.

MS. VOLPE: Okay and, as part of the application, I think it's on 381, your financials -- let me make sure. The date, the stamp is it -- oh, 1443. Thank you. That is really tiny. 1443.

MR. COHEN: If you can hold one second, I'll get it out.

MS. VOLPE: Yes. Page 1443.

MR. COHEN: Wow, it is small.

MS. VOLPE: Do you have a bigger copy for Mr. Lohr?

MR. COHEN: Do you have magnifying glasses?

MS. VOLPE: Nobody has a bigger copy for Mr. Lohr? Let me share my copy with you.

MR. COHEN: This is what CFOs have to deal with.

HEARING OFFICER HANSTED: Can you read it okay? I mean I don't want you testifying if you can't read it.

MR. LOHR: No, I can see it. I can see.

HEARING OFFICER HANSTED: Okay.

MS. VOLPE: We just want to see if we can get you a bigger copy.

MR. LOHR: This is fine. Really, this is

fine.

HEARING OFFICER HANSTED: I just want to go off the record for a minute.

(Off the record)

MS. VOLPE: Okay, so, we've already had Dr. Thompson and I believe Dr. Foley testify that they'd be bringing in staff, as needed, to deliver these services in accordance with, you know, proper staffing requirements, and you may not know the answer to this particular question, but the Applicant had stated a certain level of staffing for their cath lab and, then, in the application, and then changed it in the completeness questions.

So, according to your projections on this financial, how many new staff would be required for this program?

MR. LOHR: Down toward the bottom of the page, I believe it's line D, we're projecting basically two additional staff for the program incrementally, which would not include the --

HEARING OFFICER HANSTED: If you could just keep your voice up for the microphone, please?

MR. LOHR: Sure. Two additional staff for the program, which would not include the call, on-call

physicians.

MS. VOLPE: So no physicians are in this FTE number?

MR. LOHR: No.

MS. VOLPE: Okay and the staff that would be new, based on this projection, what area would they come from? Are they administrative? Are they clinical?

MR. LOHR: They would be clinical.

MS. VOLPE: Okay, so, two additional clinical staff, and who would those be?

MR. COHEN: Well we have someone, I think, who is better able to answer that question.

HEARING OFFICER HANSTED: Okay, why don't you have them come up, if they can better answer it?

MR. COHEN: Becky? This is on staffing questions.

MS. VOLPE: Well it is, as it relates to the financial pro forma, but, yes, let's get this.

HEARING OFFICER HANSTED: Right, so, she'll answer the questions specific to who will the staff be, period.

MR. COHEN: Correct.

MS. VOLPE: Yes.

MS. REBECCA DURHAM: I can do that. My

name is Rebecca Durham, Backus Hospital. The staff would be one cardiovascular technician and one registered nurse.

HEARING OFFICER HANSTED: Okay, thank you.

MS. VOLPE: So the one cardiac tech and the one registered nurse would be new hires?

MS. DURHAM: That's correct.

MS. VOLPE: And, so, the existing staff that would be redirected, who would they be? Let me rephrase that for you. The existing staff that would be redirected, would they be techs, nurses, or a combination? Do you know what's required to staff the cath lab? What is the staffing requirement for one cath lab?

MS. DURHAM: For our current cath lab, we have two techs. One is a C.V. tech, one is a tech at the table, and a registered nurse.

MS. VOLPE: Okay and that's for a diagnostic lab, correct?

MS. DURHAM: That is correct.

MS. VOLPE: And for a primary PCI cath, what would the staffing needs be?

MS. DURHAM: For Monday through Friday, it would still be two techs and an RN, with the ability to

pull in an RN to help, as needed, and then, on the off shifts, the on-call staff would be the same, a tech, or two techs, C.V. tech, tech at the table, an RN, and the ability to shift resources from our ICU if the patient was deemed unstable and needs the second nurse to come to help.

MS. VOLPE: So you, right now, you would have two cath labs, you're saying, with four techs in total, and potentially two to three nurses, right, if you have two -- you're proposing to have two cath labs in this.

MS. DURHAM: So if you're talking about two cath labs in the procedure room, we would have a nurse in each room, and then a C.V. tech, and a tech at the table in each room.

MS. VOLPE: And, so, based on this, they're proposing only two FTEs, so you have enough now to overstaff your current cath lab, since you have just a diagnostic cath lab now?

MS. DURHAM: Currently, our staff is cross-trained with our interventional radiology nurses, so we have a combination of staff, so we do currently have enough staff to be able to perform those procedures.

MS. VOLPE: And do you know what the

staffing standard is for the guidelines for an interventional cath lab?

MS. DURHAM: Not off the top of my head.

MS. VOLPE: Does anybody know that? Because it's changed. I think it's important for the record.

HEARING OFFICER HANSTED: Counsel, do you have someone that is qualified to testify?

MR. COHEN: Yes, we do.

HEARING OFFICER HANSTED: Okay. Just identify yourself for the record, please?

MS. MARIANE CARNA: This is Mariane Carna. So the same staffing levels, at Hartford Hospital, two RNs in the room to one technician would be the same standard we would apply at Backus Hospital at pulling our policies and protocols across the institute.

MS. VOLPE: Okay. I don't have any other questions on your staffing. For Mr. Lohr, I just want to make sure we don't have any other financial questions. Just give me one second.

Okay, so, the funding for this program, if it's going to be in conjunction with Hartford Hospital, since they are going to be providing a lot of the clinical expertise, is it contemplated that there would

be a financial arrangement for the provision of those services to Backus from the Hartford Hospital doctors?

MR. LOHR: The financial arrangement would be call coverage.

MS. VOLPE: So they would just be paid for call coverage. Is it built into this pro forma, the call coverage payments?

MR. LOHR: Yes.

MS. VOLPE: Okay and where are those?

MR. LOHR: They're netted in the revenue.

MS. VOLPE: So is it a separate line item?

MR. LOHR: No.

MS. VOLPE: I did work for Arthur Andersen one year, a few years, but I'm not a financial person. Is it in here? Is the call coverage number a line item in here?

MR. LOHR: It's netted in there. Call coverage is about a million dollars a year.

MS. VOLPE: So that's part of the five million initial?

MR. LOHR: No.

MS. VOLPE: A million every year?

MR. LOHR: Right, which is included to come down to the net.

MS. VOLPE: But it's not a separate line here?

MR. LOHR: No.

MS. VOLPE: So where is it picked up in the cost structure?

MR. LOHR: I believe it's netted in the revenues.

MS. VOLPE: On your operating expenses, Dan, it doesn't appear anywhere?

MR. LOHR: No.

MR. COHEN: Can you identify what line it's on for everyone?

MR. LOHR: It would be in lines one through 13 read by payer.

MS. VOLPE: So the call coverage is in the operating revenue?

MR. LOHR: Um-hum.

MS. VOLPE: And can you explain to us how that works?

MR. LOHR: It's just a reduction of the revenue. We haven't finalized yet how to, in terms of billing for the services and the call coverage, that arrangement, so it's netted down, so it's properly excluded from operating results. It's just, for this

presentation, it's netted against the revenue.

MS. VOLPE: Okay, so, it's netted against the revenue. It's not built in as a cost. You're saying it would be an offset to revenue, because these providers, as they rotate through, would bill through Hartford Hospital?

MR. LOHR: Right now, that is the plan, yes.

MS. VOLPE: Okay and, so, it's not built in as a cost. What about the, in terms of building the program, since Backus doesn't have somebody with expertise now to build the program, there would be some cost associated with retaining individuals from Hartford to build out the program. Is that factored in anywhere?

MR. LOHR: Yes. There would be, I'm sure, director fees.

MS. VOLPE: Medical Director fees?

MR. LOHR: Medical Director fees.

MS. VOLPE: Right, and are those fees in here?

MR. LOHR: Yes.

MS. VOLPE: And where are those?

MR. LOHR: There's an estimate for those included in line three.

MS. VOLPE: Physician fees?

MR. LOHR: Yes.

MS. VOLPE: So that's for the -- so what's in that number for physician fees? It's not the call number. What is in that physician fee number?

MR. LOHR: It's directorships.

MS. VOLPE: Okay and, so, it's still being worked out. There's a chance that there could be additional cost within the system for implementing the service or are we pretty confident this is it?

MR. LOHR: At the moment, this is our best estimate. There could be additional cost. The cost may be less, depending on reimbursement arrangements on billing.

MS. VOLPE: Okay. Just one second. I just have to ask a finance question myself. We do have some follow-up questions for you, Dan, and some of these -- I think one you'll probably be able to do, and one you might need to redirect.

MR. LOHR: Okay.

MS. VOLPE: It is a financial question. So, based off of this pro forma, why are there no contractual write-offs in the gross revenue? Is the gross revenue really already met in this? We didn't see

any write-offs, no contractual write-offs.

MR. LOHR: Right. The way the model was built up, it was built on net reimbursement.

MS. VOLPE: Without any. Is it realistic not to have any contractual write-offs?

MR. LOHR: If you go from net revenue, you're in the same situation. The scale is balanced.

MS. VOLPE: Okay, so, I mean, Hartford HealthCare, you know, as a tertiary facility, I mean, their costs and rates are presumably higher than Backus, so what would the costs relative to the Backus rates be, because, usually, costs at a tertiary center are usually higher than they are at a community hospital, right?

MR. LOHR: I'm not sure I understand your question when you said costs and then rates.

MS. VOLPE: Well --

MR. LOHR: You're at two ends of the spectrum.

MS. VOLPE: Would Backus be getting the same -- like you didn't factor in any contractual write-offs for these services, so, presumably, you're saying it equals out, because you may not be collecting the revenue for the on-call doctors. They may be billing directly through the Hartford system, so the payers would be

paying rates not as they would at a community-based hospital for the service.

They presumably would be paying at a much higher rate at a tertiary facility, so, you know -- I mean is it fair to say that the payers would be paying more for these services at a community-based hospital than they would at --

MR. LOHR: Yeah. I would say that's not fair to say, principally because, for physician reimbursement, it's off of a fee schedule. It's Medicare fee schedules and Medicare fee schedule, generally.

MS. VOLPE: Right, sure, for Medicare, but for a commercial payer I mean.

MR. LOHR: Commercial payer pretty much the same thing. I mean they're pushing toward fee schedules.

MS. VOLPE: Okay, so, you think it would be the same fee schedule for a Backus interventionalist billing than a Hartford Hospital interventionalist billing?

MR. LOHR: I believe it would be.

MS. VOLPE: Okay. All right. Okay, I think we may be done. I just want to check one more thing for follow-up.

Thank you so much, Dan. We don't have any additional questions for you.

MR. LOHR: Okay.

MR. COHEN: If you're done with that witness, I just have a couple of Cross.

MS. VOLPE: Sure.

HEARING OFFICER HANSTED: I'll allow you to Redirect, yes.

MR. COHEN: Redirect. Sorry. Thank you.

HEARING OFFICER HANSTED: That's all right.

MR. COHEN: I got caught up. There were some questions earlier, Dan, about funding this from operations, funding the cost here. Can you comment on Backus's financial situation, profitability and the like?

MR. LOHR: Yes. For the last two fiscal years, I believe, as reported in one of the hearings, recently, Backus has had the highest operating margin percentage in the state, the last -- 16 percent, 14 percent.

The last couple of years, the operating margin, in terms of dollars, has been in the neighborhood of 40 million dollars.

MR. COHEN: So that 40 million dollars is

what?

MR. LOHR: The excess of revenue over expenses, operating margin.

MR. COHEN: So, in your opinion, expending I think you testified four and a half million dollars, and then, between 300,000 and 550,000 per year, can a hospital like Backus accommodate those costs easily?

MR. LOHR: I believe so, yes.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: Is that all?

MR. COHEN: Hold on just one second. Okay, thank you very much, Dan.

HEARING OFFICER HANSTED: Okay. This is probably a good breaking point. We're going to have to go into another day. We have to adjourn by 3:00 p.m.

Just a couple of housekeeping matters. The late file, Late File No. 1, I'll order that due by April 1st.

MR. COHEN: Okay.

HEARING OFFICER HANSTED: And with respect to the second hearing day, we will notify both the Applicant and the Intervenor.

I want to schedule for a date after we receive the transcript for this portion of the hearing,

just so we can reference back to this portion, if need be, and I won't put the court reporter on the spot, as to when that will be due, but we will notify you about the next hearing date.

MS. VOLPE: Thank you.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: Okay, so, with that, just before we adjourn, are there any members of the public, who want to comment on the proposal?

Okay, hearing none, I will adjourn until the next hearing date. Thank you, all, for coming.

MR. COHEN: Thank you.

MS. VOLPE: Thank you.

HEARING OFFICER HANSTED: You're welcome.

(Whereupon, the hearing adjourned at 2:52 p.m.)

HEARING RE: THE WILLIAM W. BACKUS HOSPITAL
MARCH 23, 2016

AGENDA

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Greer, Leslie

From: Mercier, Carlene M. <CMercier@brownrudnick.com>
Sent: Monday, June 06, 2016 3:26 PM
To: User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org
Subject: Docket No. 15-32031 / Lt. Requesting Excusal of Whitehead & Cummings
Attachments: Lt. OHCA re_ Excusal of Whitehead & Cummings dated 6_6_16.PDF

Good Afternoon,

Please find attached a request to excuse Mr. Whitehead and Mr. Cummings from attendance at the continued hearing in this matter.

Best Regards,
Carlene

BROWNRUDNICK

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

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ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

185 Asylum
Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

June 6, 2016

VIA E-MAIL
(ohca@ct.gov; kevin.hansted@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON – Excusal of David A. Whitehead and Bruce Cummings from June 14th Hearing

Dear Ms. Martone:

Hartford Hospital and The William W. Backus Hospital (the "Applicants") and the Intervenor hereby request that David A. Whitehead, Senior Vice President and Chief Strategy and Transformation Officer at Hartford Healthcare and Mr. Bruce Cummings, President and Chief Executive Officer at Lawrence + Memorial Hospital be excused from the continued public hearing in this matter on June 14, 2016. As you will recall, Mr. Whitehead and Mr. Cummings both filed Pre-Hearing Testimony in this matter and on March 23, 2016 entered direct testimony into the record. Additionally, after the first public hearing, Mr. Whitehead was appointed by the Governor to be a member of the Certificate of Need Task Force.

The attorneys for both parties agreed that these two senior executives would not be subject to cross-examination and their appearance at the continued hearing was not required. Therefore, the Applicants, in conjunction with the Intervenor, are requesting that Mr. Whitehead and Mr. Cummings be excused from attending the continued public hearing.

Very truly yours,

BROWN RUDNICK LLP

By: Robert J. Anthony /cm
Robert J. Anthony

cc: Michele M. Volpe via e-mail (michelemvolpe@aol.com)

Greer, Leslie

From: Armah, Olga
Sent: Wednesday, June 08, 2016 8:00 AM
To: Mercier, Carlene M.; User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org
Subject: RE: Docket No. 15-32031 / Lt. Requesting Excusal of Whitehead & Cummings

Good morning Carlene,

A request pertaining to a hearing needs to be in the form of a motion that can be ruled upon. Please file a motion regarding this request.

Thanks.

Olga

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

From: Mercier, Carlene M. [mailto:CMercier@brownrudnick.com]
Sent: Monday, June 06, 2016 3:26 PM
To: User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Armah, Olga; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org
Subject: Docket No. 15-32031 / Lt. Requesting Excusal of Whitehead & Cummings

Good Afternoon,

Please find attached a request to excuse Mr. Whitehead and Mr. Cummings from attendance at the continued hearing in this matter.

Best Regards,
Carlene

Greer, Leslie

From: Mercier, Carlene M. <CMercier@brownrudnick.com>
Sent: Thursday, June 09, 2016 2:55 PM
To: Armah, Olga; User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; kgg@bvmlaw.com; jlo@bvmlaw.com
Subject: RE: Docket No. 15-32031 / Motion Requesting Excusal of Whitehead & Cummings
Attachments: Motion for Excusal of Mr. Whitehead & Mr. Cummings.PDF

Good Afternoon,

Please find the same request (to excuse Mr. Whitehead & Mr. Cummings on 6/14) in Motion format. Please let me know if you have any questions.

Best,
Carlene

BROWNRUDNICK

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

> **From:** Armah, Olga [mailto:Olga.Armah@ct.gov]
> **Sent:** Wednesday, June 08, 2016 8:00 AM
> **To:** Mercier, Carlene M.; User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Fernandes, David; Martone, Kim
> **Cc:** michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org
> **Subject:** RE: Docket No. 15-32031 / Lt. Requesting Excusal of Whitehead & Cummings
>
> Good morning Carlene,
>
> A request pertaining to a hearing needs to be in the form of a motion that can be ruled upon. Please file a motion regarding this request.
>
> Thanks.
>
> Olga
>
> ***Olga Armah***
> Office of Health Care Access (OHCA)

ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

185 Asylum
Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

June 9, 2016

VIA E-MAIL
(ohca@ct.gov; kevin.hansted@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON – Excusal of David A. Whitehead and Bruce Cummings from June 14th Hearing

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital, please find enclosed for filing a Motion for the Excusal of Mr. Whitehead and Mr. Cummings in this matter.

Very truly yours,

BROWN RUDNICK LLP

By: Robert J. Anthony /cm
Robert J. Anthony

cc: Michele M. Volpe via e-mail (michelemvolpe@aol.com)

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

IN RE: THE WILLIAM W. BACKUS HOSPITAL AND	**:**	**DOCKET NO. 15-32031-CON**
HARTFORD HOSPITAL'S CERTIFICATE OF NEED	**:**	
APPLICATION TO ESTABLISH A PRIMARY AND	**:**	
ELECTIVE PERCUTANEOUS CORONARY	**:**	
INTERVENTION PROGRAM AT BACKUS HOSPITAL	**:**	**June 9, 2016**

THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S MOTION FOR THE EXCUSAL OF MR. WHITEHEAD AND MR. CUMMINGS

Hartford Hospital and The William W. Backus Hospital (the "Applicants") and the Intervenor hereby request that David A. Whitehead, Senior Vice President and Chief Strategy and Transformation Officer at Hartford Healthcare and Mr. Bruce Cummings, President and Chief Executive Officer at Lawrence + Memorial Hospital be excused from the continued public hearing in this matter on June 14, 2016. As you will recall, Mr. Whitehead and Mr. Cummings both filed Pre-Hearing Testimony in this matter and on March 23, 2016 entered direct testimony into the record. Additionally, after the first public hearing, Mr. Whitehead was appointed by the Governor to be a member of the Certificate of Need Task Force.

The attorneys for both parties agreed that these two senior executives would not be subject to cross-examination and their appearance at the continued hearing was not required. In addition, the parties have agreed that any questions on the content of their Pre-File Testimony and Direct Testimony can be redirected to other witnesses. Therefore, the Applicants, in conjunction with the Intervenor, are requesting that Mr. Whitehead and Mr. Cummings be excused from attending the continued public hearing.

Respectfully submitted,

Hartford Hospital and
The William W. Backus Hospital

By: Robert J. Anthony / cm

Robert J. Anthony
Brown Rudnick LLP
CityPlace I, 185 Asylum Street
Hartford, CT 06103-3402
(860) 509-6517 (tel.)
(860) 509-6501 (fax)
ranthony@brownrudnick.com
Juris No. 403862
Its Attorney

CERTIFICATION

I hereby certify that a copy of this filing was served by electronic mail on this 9th day of June, 2016, via electronic mail only, to the following counsel of record:

Michele M. Volpe
Attorney for Lawrence + Memorial Hospital, Inc.
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, Connecticut 06511
michelemvolpe@aol.com

Robert J. Anthony

Robert J. Anthony
Brown Rudnick LLP

62489170 v1-WorkSiteUS-032836/0002

Greer, Leslie

From: Hansted, Kevin
Sent: Wednesday, June 08, 2016 7:06 AM
To: Olejarz, Barbara
Cc: Greer, Leslie; Riggott, Kaila; Schaeffer-Helmecki, Jessica
Subject: FW: Certificate of Need Application Docket No. 15-32031
Attachments: DOC060716.pdf

Importance: High

Barbara, please add this to the record.

Kevin T. Hansted
Staff Attorney
Department of Public Health
Office of Health Care Access
410 Capitol Ave., MS #13HCA
P.O. Box 340308
Hartford, CT 06134
Phone: 860-418-7044
Email: kevin.hansted@ct.gov

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-----Original Message-----
From: Stancato, Laurie [mailto:Laurie.Stancato@umassmemorial.org]
Sent: Tuesday, June 07, 2016 3:12 PM
To: Hansted, Kevin <Kevin.Hansted@ct.gov>
Cc: Riggott, Kaila <Kaila.Riggott@ct.gov>; Schaeffer-Helmecki, Jessica <Jessica.Schaeffer-Helmecki@ct.gov>; Armah, Olga <Olga.Armah@ct.gov>; Carney, Brian <Brian.Carney@ct.gov>; Fernandes, David <David.Fernandes@ct.gov>
Subject: Certificate of Need Application Docket No. 15-32031
Importance: High

Please see the attached letter.

Thank you!

.....
The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, transmission, re-transmission, dissemination or other use of, or taking of any action in reliance upon this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from any computer.

UMassMemorial Medical Center

University Campus
55 Lake Avenue North
Worcester, MA 01655

June 2, 2016

VIA EMAIL (kevin.hansted@ct.gov) and US MAIL

Attorney Kevin Hansted, Staff Attorney
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Ave.
MS #13HCA
Hartford, Connecticut 06134-0308

Re: Certificate of Need Application; Docket No. 15-32031
Establish and Operate a Primary and Elective Angioplasty Program at The William W. Backus Hospital

Dear Attorney Hansted:

This letter is in reference to the above captioned Certificate of Need ("CON") Application before the Connecticut Department of Public Health division of Office of Health Care Access. UMass Memorial Medical Center ("UMass") already provides primary and elective angioplasty to patients in the following towns listed in the CON Application: Putnam, Killingly, Thompson, Woodstock and northern Plainfield. UMass provides local access to primary and elective angioplasty services to Connecticut residents of our service area and we have been successful in that effort.

UMass and Day Kimball Hospital (Putnam, CT) have a long-standing, 10+ year relationship focused on ensuring timely access to angioplasty for residents in Day Kimball's service area. As the closest angioplasty provider, there is an established process to transfer STEMI or emergent patients who present at Day Kimball to UMass, and door-to-balloon times are consistently well below the recommended timeframe set forth in the latest clinical guidelines. Direct feedback from Day Kimball to UMass providers has been positive in each case, as well as in ongoing quality assurance reports. In addition, EMS serving northeastern Connecticut are accustomed to travel patterns to UMass that minimize time to device for STEMI patients. Our relationship with Day Kimball and local EMS is very strong. UMass has been providing education to Day Kimball emergency department staff and local EMS providers for years. The proposal put forth by Backus Hospital is detrimental to patients as it disrupts this streamlined access to care and established clinical partnership.

In fiscal year 2015, UMass provided 1428 total angioplasty procedures (approximately 360 STEMIs or emergent cases). Our primary and elective angioplasty program has the capacity to continue to serve the needs of the Connecticut residents and communities and we are not aware of any backlog of cases in our service area.

UMass supports Lawrence + Memorial Hospital in its opposition of the above captioned CON on the grounds that, among other reasons, (i) there is no public need for another primary and/or elective angioplasty program in the eastern Connecticut area; (ii) William W. Backus Hospital ("Backus") has not satisfactorily identified the population to be served; (iii) Backus has failed to comply with policies and standards adopted by the Office of Health Care Access; (iv) Backus has failed to comply with well-established clinical guidelines; (v) Backus has failed to comply with the Statewide Health Care Facilities and Services Plan; (vi) there is no lack of capacity and the services will result in duplicative services; (vii) the services will have a negative effect on quality, accessibility and cost effectiveness of healthcare services in the community; and (iix) the proposed services are not financially feasible and will negatively impact the financial strength of the health care system in Connecticut. UMass agrees on all counts.

It is UMass's position that the service area identified in Backus's CON Application is already well-served by a number of high-quality angioplasty providers, including our own. This being the case, we share Lawrence + Memorial's concerns that the establishment of more angioplasty services in the service area will further dilute volumes for existing providers and make it more difficult for hospitals like ours to maintain adequate volume.

We respectfully request that this letter be part of the official record.

Sincerely,

Jay Cyr, RN, MSN, MBA
Sr. Vice President, Surgical Services
UMass Memorial Medical Center
55 Lake Ave N, Worcester, MA 01655

(774) 441-6765 Laurie.Stancato@umassmemorial.org
(774) 441-6765 Jen.Sheils@umassmemorial.org

cc: Kaila Riggott, OHCA Staff (kaila.riggott@ct.gov)
Jessica Schaeffer-Helmecki, OHCA Staff (Jessica.Schaeffer-Helmecki@ct.gov)
Olga Armah, OHCA Staff (olga.armah@ct.gov)
Brian Carney, OHCA Staff (Brian.Carney@ct.gov)
David Fernandes, OHCA Staff (David.Fernandes@ct.gov)

Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Thursday, June 09, 2016 2:28 PM
To: Armah, Olga; michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; Mercier, Carlene M.
Cc: User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David; Greer, Leslie
Subject: Certificate of Need Application Docket No. 15-32031
Attachments: 15-32045 Administrative Notice signed.pdf

Good Afternoon--

Attached please find an Order Regarding Administrative Notice pertaining to the upcoming hearing on June 14th. We will be e-mailing you an electronic version of the referenced document tomorrow.

Thank you,

Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

Docket No: 15-32031-CON

June 9, 2016

**In re: The William W. Backus Hospital/Hartford Hospital,
Establishment of a Primary and Elective PCI at William W. Backus Hospital**

ORDER REGARDING ADMINISTRATIVE NOTICE

The Office of Health Care Access, for purposes of analyzing and rendering a decision in the application filed under Docket Number 15-32031-CON, is hereby taking administrative notice of Exhibit W, Day Kimball Healthcare Community Health Needs Assessment Implementation Strategy, September 11, 2015 (12 pages).

Kevin T. Hansted
Hearing Officer
Office of Health Care Access, DPH

Connecticut Department of Public Health

Phone: (860) 418-7001• Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Thursday, June 09, 2016 3:25 PM
To: 'Mercier, Carlene M.'; Armah, Olga; User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David
Cc: michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; kgg@bvmlaw.com; jlo@bvmlaw.com
Subject: RE: Docket No. 15-32031 / Motion Requesting Excusal of Whitehead & Cummings
Attachments: 15-32045 Order.pdf

Attached please find a Hearing Officer Hansted's response.

Thank you,

Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

---

From: Mercier, Carlene M. [mailto:CMercier@brownrudnick.com]
Sent: Thursday, June 09, 2016 2:55 PM
To: Armah, Olga; User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; kgg@bvmlaw.com; jlo@bvmlaw.com
Subject: RE: Docket No. 15-32031 / Motion Requesting Excusal of Whitehead & Cummings

Good Afternoon,

Please find the same request (to excuse Mr. Whitehead & Mr. Cummings on 6/14) in Motion format. Please let me know if you have any questions.

Best,
Carlene

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

IN RE: THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S CERTIFICATE OF NEED APPLICATION TO ESTABLISH A PRIMARY AND ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM AT BACKUS HOSPITAL

DOCKET NUMBER: 15-32031-CON

ORDER

On June 9, 2016, the Applicants filed a Motion for the Excusal of Mr. Whitehead and Mr. Cummings from the hearing to be held in this matter on June 14, 2016.

After careful consideration, the Applicants' Motion is hereby ORDERD:

GRANTED

6/9/16
Date

Kevin T. Hansted
Hearing Officer

Greer, Leslie

From: Michele Volpe <michelemvolpe@aol.com>
Sent: Thursday, June 09, 2016 4:03 PM
To: Schaeffer-Helmecki, Jessica
Cc: Mercier, Carlene M.; Armah, Olga; User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David; Cohen, Douglas A.; Robert J. Anthony; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; kgg@bvmlaw.com; Jennifer O'Donnell
Subject: Re: Docket No. 15-32031 / Motion Requesting Excusal of Whitehead & Cummings

Great, thank you.

Michele M. Volpe
Bershtein, Volpe & McKeon P.C
105 Court Street
New Haven, CT 06511
Phone: (203) 777-6995
Fax: (203) 777-5806

This transmittal may be a confidential attorney-client communication or may otherwise be privileged or confidential. If it is not clear that you are the intended recipient, you are hereby notified that you have received this transmittal in error; any review, dissemination, distribution or copying of this transmittal is strictly prohibited. If you suspect that you have received this communication in error, please notify us immediately by telephone at 1-203-777-5800, or e-mail at jlo@bvmlaw.com and immediately delete this message and all its attachments.

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On Jun 9, 2016, at 3:24 PM, Schaeffer-Helmecki, Jessica <Jessica.Schaeffer-Helmecki@ct.gov> wrote:

Attached please find a Hearing Officer Hansted's response.

Thank you,

Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TABLE OF THE RECORD

APPLICANTS: **Hartford Hospital and The William W. Backus Hospital**

DOCKET NUMBER: **15-32031-CON**

PUBLIC HEARING: **March 23, 2016 at 9:30 a.m.**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room**
Hartford, Connecticut

EXHIBIT	DESCRIPTION
A	Letter from Hartford Hospital and The William W. Backus Hospital (Applicants) dated September 30, 2015 enclosing the Certificate of Need (CON) application to Establish and Operate a Primary and Elecive Angioplasty Program under DocketNumber 15-32031, received by OHCA on September 30, 2015. (1437 Pages)
B	Letters of support in the matter of the CON application filed under Docket Number 15-32031, received by OHCA on various dates. (3 pages)
C	OHCA's letter to the Applicants dated October 30, 2015, requesting Additional information and/or clarification in the matter of the CON application under Docket Number 15-32031.(7 Pages)
D	Designation letter dated December 16, 2015 of Hearing Officer in the matter of the CON application under Docket Number 15-32031. (1 page)
E	Applicants responses to OHCA's letter of October 30, 2015 along with a revised Exhibit 24, dated December 30, 2015, in the matter of the CON application under Docket Number 15-32031, received by OHCA on December 30, 2015. (49 Pages)
F	Letters of support in the matter of the CON application filed under Docket Number 15-32031, received by OHCA on January 11, 2016. (2 pages)
G	OHCA's letter to the Applicants dated January 29, 2016 deeming the application complete in the matter of the CON application filed under Docket Number 15-32031. (1 page)

H	OHCA's request for legal notification in the *Norwich Bulletin* of OHCA's Notice to the Applicants of the public hearing scheduled for March 23, 2016, in the matter of the CON application under Docket Number 15-32031, dated February 10, 2016. (4 pages)
I	OHCA's letter to the Applicants dated March 9, 2016 requesting prefile testimony and enclosing issues in the matter of the CON application under Docket Number 15-32031. (4 pages)
J	Letter from Lawrence + Memorial to OHCA dated March 16, 2016 noticing the appearance of Bershtein, Volpe & McKeon, P. C. on Behalf of Lawrence + Memorial Hospital and Petition of Lawrence + Memorial Hospital, Inc.for Intervenor Status with full rights of cross-examination in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 16, 2016. (11 pages)
K	Letter from the Applicants to OHCA enclosing Prefile Testimony and responses to issues dated March 9, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 17, 2015. (48 pages)
L	OHCA's Ruling on the Petition of Lawrence + Memorial Hospital to be granted intervenor status in the matter of the CON application under Docket Number 15-32-31, dated March 17, 2016. (1 page)
M	Letter from the Intervenor to OHCA dated March 18, 2016 enclosing Prefile Testimony in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 18, 2016. (74 pages)
N	Letter from the Applicants to OHCA dated March 23, 2016 enclosing a Motion in Limine in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 23, 2016. (6 pages)
O	Letter from the Intervenor to OHCA dated March 23, 2016 enclosing Intervenor's opposition to the Applicants' Motion in Limine Limine in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 23, 2016. (7 pages)
	The following was added into the record at the hearing held on March 23, 2016
P	Notice of Appearance of Attorney Douglas A. Cohen, from Brown Rudnick LLP on behalf of The William W. Backus Hospital dated March 23, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 23, 2016. (2 pages)
Q	Oral Testimony of Bruce Cummings, Dr. Brian Cambi, Seth Van Essendeflt and Daniel Rissi, MD in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 23, 2016. (11 pages)
R	OHCA's letter to the Applicants dated March 31, 2016 enclosing ruling on the Motion in Limine filed by the William W. Backus Hospital and Hartford Hospital and Opposition thereto filed by Lawrence + Memorial Hospital, Inc.in the matter of the CON application under Docket Number 15-32031. (2 pages)

S	Letter from the Applicants to OHCA dated April 1, 3016 enclosing the Late Files in the matter of the CON application under Docket Number 15-32031, received by OHCA on April 1, 2016. (6 pages)
T	Transcript of the hearing held on March 23, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on April 7, 2016. (202 pages)
U	Letter dated June 6, 2016 requesting excusal of David A. Whitehead and Bruce Cummings from the June 14, 2016 hearing, in the matter of the CON application under Docket Number 15-32031, received by OHCA on June 6, 2016. (3 pages)
V	Letter from UMASS Memorial to OHCA dated June 2, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on June 7, 2016. (2 pages)
W	OHCA's letter to the Applicants dated June 9, 2016 enclosing and Order Regarding Administrative Notice in the matter of the CON application under Docket Number 15-32031. (1 page)
X	OHCA's letter to the Applicants dated June 9, 2016 enclosing ORDER Granting the Applicants' Motion in the matter of the CON application under Docket Number 15-32031, received by OHCA on June 7, 2016. (1 page)

Late file requested at hearing held on March 23, 2016, due on April 1, 2016.

- Zipcodes from center of town along with towns within the angioplasty region to the nearest PCI facility regardless if the provider is in the state.

STATE OF CONNECTICUT

OFFICE OF THE ATTORNEY GENERAL

Office of Health Care Access

TENTATIVE AGENDA

HEARING

Docket Number: 15-32031

Hartford Hospital and The William W. Backus Hospital

Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

June 14th, 2016 at 9:00 a.m.
(Continued from March 23, 2016)

I. **Reconvening of the Public Hearing**

II. **Applicant/Intervenor Direct and Cross Examination**

III. **OHCA's Questions**

IV. **Public Comment**

V. **Closing Remarks**

V. **Public Hearing Adjourned**

An Equal Opportunity Provider
(If you require aid/accommodation to participate fully and fairly, contact us either by phone, fax or email)
410 Capitol Ave., MS#13HCA, P.O.Box 340308, Hartford, CT 06134-0308
Telephone: (860) 418-7001 Fax: (860) 418-7053 Email: OHCA@ct.gov

Olejarz, Barbara

From: Microsoft Outlook
To: Janette.Edwards@hhchealth.org
Sent: Friday, June 10, 2016 9:38 AM
Subject: Relayed: Backus Hearing

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

Janette.Edwards@hhchealth.org (Janette.Edwards@hhchealth.org)

Subject: Backus Hearing

* * * COMMUNICATION RESULT REPORT (JUN. 10. 2016 9:27AM) * * *

FAX HEADER:

TRANSMITTED/STORED : JUN. 10. 2016 9:25AM FILE MODE	OPTION	ADDRESS	RESULT	PAGE
644 MEMORY TX		912037775806	OK	5/5

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: MICHELE VOLPE

FAX: 203 777-5806

AGENCY: BERSHTEIN, VOLPE AND MCKEON

FROM: OHCA

DATE: 6/10/16 **Time:**

NUMBER OF PAGES:
(including transmittal sheet

Comments:

Please see attached information regarding the hearing that is being held on June 14th for DN15-32031-CON

PLEASE PHONE Barbara K. Olejarz IF THERE ARE ANY TRANSMISSION PROBLEMS.

Phone: (860) 418-7001 ***Fax: (860) 418-7053***

410 Capitol Ave., MS#13HCA
P.O.Box 340308
Hartford, CT 06134

-----Original Message-----
From: Schaeffer-Helmecki, Jessica
Sent: Thursday, June 09, 2016 2:28 PM
To: Armah, Olga; michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; Mercier, Carlene M.
Cc: User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David; Greer, Leslie
Subject: Certificate of Need Application Docket No. 15-32031

Good Afternoon--

Attached please find an Order Regarding Administrative Notice pertaining to the upcoming hearing on June 14th. We will be e-mailing you an electronic version of the referenced document tomorrow.

Thank you,

Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

Updated: September 11, 2015

DKH DAY KIMBALL HEALTHCARE

Community Health Needs Assessment Implementation Strategy

INTRODUCTION

Day Kimball Healthcare (DKH) is an independent, non-profit, integrated medical services provider with more than 1,200 employees including more than 300 associated physicians and other licensed independent providers. Our network is comprised of Day Kimball Hospital (The "Hospital") , Day Kimball Healthcare Centers in Danielson, Dayville, Plainfield, and Putnam, Day Kimball Medical Group, Day Kimball Home Care, Day Kimball Hospice & Palliative Care of Northeastern Connecticut ("Hospice"), and Day Kimball Home Makers ("HomeMakers").

On September 1, 1894 Day Kimball Hospital of Windham County opened its doors, the inspiration of two sisters, Miss Elizabeth and Gertrude Vinton, who had a vision for the "Windham County Infirmary. " Mrs. M. Day Kimball donated $5,000 for the construction of the infirmary building in memory of her recently deceased son, Day Kimball, with the condition that the institution be named after him. Other Kimball family members pledged an additional $4,000, and with the $9,000 total donations, Day Kimball Hospital was born.

In coordination with our affiliated healthcare centers, Day Kimball Hospital, a 104-bed acute care community hospital in Northeast Connecticut, offers acute and general medical/surgical care, a 24-hour emergency department, a birthing center, obstetrics and gynecology, pediatrics, hematology and oncology, cardiopulmonary, mental health programs and much more. Our highly-skilled physicians offer comprehensive services that integrate primary care medicine with specialties like emergency medicine, cardiology, neurology, women's health, cancer treatment, general surgery and more. For the over 90,000 members of our communities, we offer high-quality, comprehensive medical services delivered by skilled medical professionals close to home.

Of the total population in Northeast Connecticut, some 40,000 seek primary and specialty care, while approximately another 32,000 take advantage of DKH's inpatient, outpatient (ambulatory care), diagnostic and emergency services. (Note: approximately 26,500 of our medical group patients also use these services.)

Day Kimball Healthcare provides numerous programs to promote health and wellness, a variety of support groups, services and programs throughout the community to enhance the quality and accessibility of healthcare service.

BACKGROUND

In 2012 and 2013 Day Kimball Healthcare (DKH) participated in an eight-member consortium of Windham County Healthcare Providers that developed and funded a Community Health Needs Assessment (CHNA). The consortium members were Day Kimball Healthcare, Windham Hospital, Natchaug Hospital, Generations Family Health Center, United Services, VNA East and Northeast District Department of Health.

The primary goals of the community health needs assessment were to:

- Partner and collaborate with local healthcare providers
- Identify community health needs in Windham County
- Develop a blueprint for health and wellness programs in the community
- Assist with community benefit requirements.

The Windham County Consortium engaged The Center for Research and Public Policy (CRPP), an independent research firm to conduct a comprehensive assessment. CRPP conducted qualitative and quantitative research which utilized the following to identify and prioritize healthcare needs in Windham County:

- **Focus groups** (qualitative) – a total of 86 participants became involved in seven focus groups. The core composition of each group included: First Responders, Latinos, Community Leaders, School Based Health, Boomers, Faith Based and Youth.
- Comprehensive **Telephone surveys** (quantitative) – a total of 630 telephone surveys were conducted among residents of the 15 municipalities served.
- **State and Federal data**

Through this study, health needs were identified that are prevalent among residents across all socioeconomic groups, races and ethnicities, as well as health issues that highlight health disparities or disproportionately impact the medically underserved and uninsured.

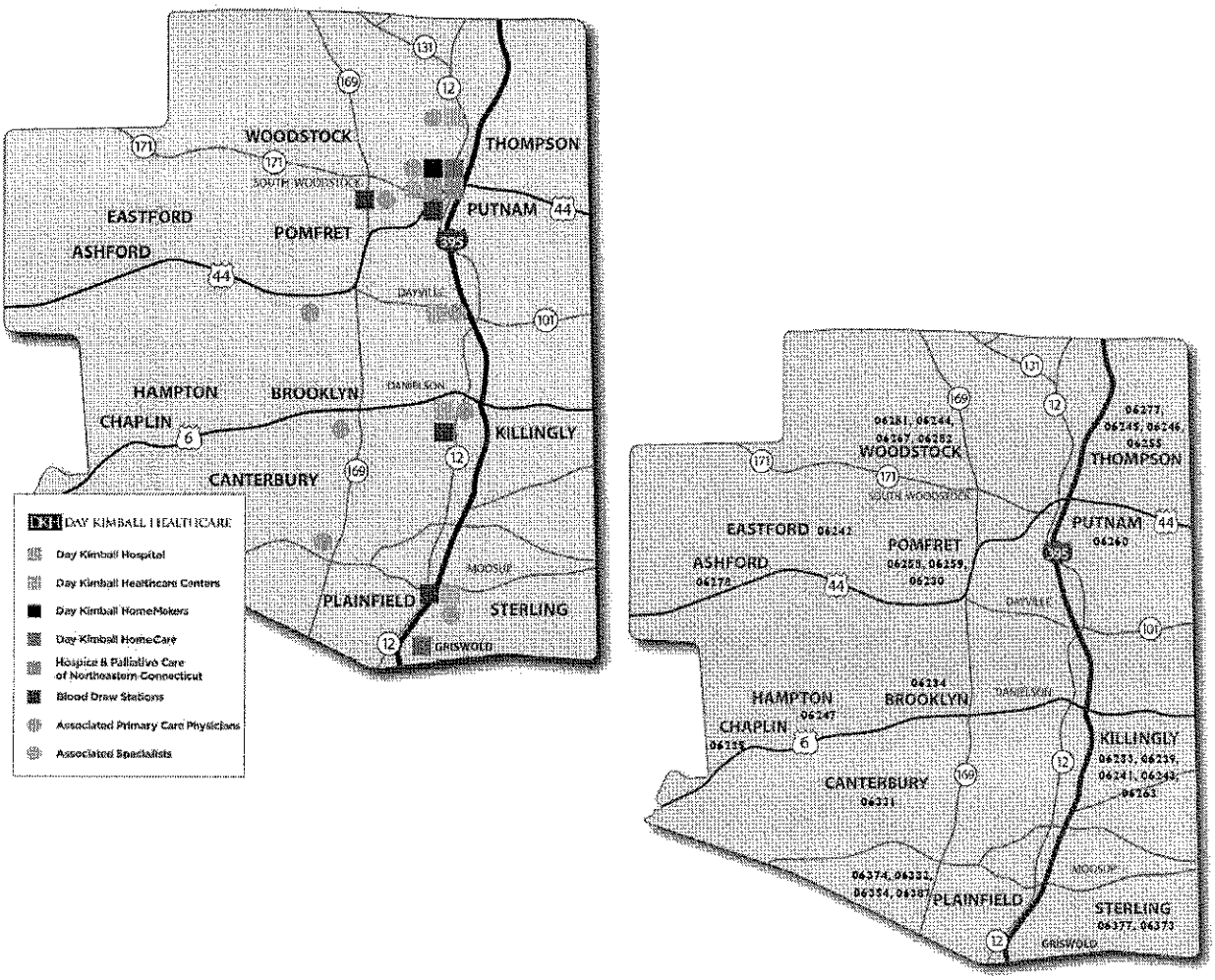
Major areas of healthcare needs include chronic disease, behavioral health and preventative healthcare. Specifically, Day Kimball Healthcare's priority areas include:

1. Cardiovascular Disease
2. Diabetes
3. Obesity
4. Breast Cancer
5. Depression/Suicide
6. Tobacco Cessation
7. Substance Abuse
8. Flu Shots
9. Child Abuse

SERVICE AREA

The population in Windham County ranges from long-term multi-generational families, to newly emigrated residents from urban areas. There is a wide range of socio-economic factors including very high income to poverty; advanced education to incomplete high school and home ownership to several towns where the majority of residents are renters. Windham County encompasses a rural area in the northeast corner of the state where 11.7 percent of residents live below the federal poverty level.

DKH's main service area is comprised of 13 of the 15 towns in Windham County with the primary area being in the Northeast corner of Connecticut. The maps below depict DKH's primary service area.



DKH's secondary service area extends south of Canterbury, Plainfield and Sterling in New London County and is comprised of Jewett City, Griswold, Hopeville, Pachaug, Lisbon, Glasgow and Voluntown.

STRATEGIES TO ADDRESS COMMUNITY HEALTH NEEDS

Day Kimball Healthcare (DKH) has used the qualitative and quantitative research data provided by CRPP to address the top nine healthcare priority areas. DKH continues to leverage direct delivery of service through our collaborations with such organizations as HealthQuest Northeastern Connecticut, The Northeast District Department of Health and Generations Family Health Center - FQHC, to meet the healthcare needs of the community. Below is a summary of the services and programs provided that directly address the healthcare priorities

Cardiovascular Disease/Stroke

There is a documented high incidence of heart disease in Northeastern Connecticut[1]. To combat this, DKH has developed a high-quality, comprehensive and coordinated program of cardiac care. As part of this "chain of survival", paramedics are trained to administer life-saving treatments before the patient even reaches the hospital. Also, DKH continues to work closely with UMASS for STEMI patient transfers via Life Star helicopter within 90 minutes of admission to the emergency department and meets regularly to review STEMI data.

DKH was designated as a Primary Stroke Center by the State of Connecticut Department of Public Health in March of 2012 and also, in December of 2014, received the Advanced Certification Primary Stroke Center designation from The Joint Commission. These designations were achieved by providing comprehensive care for all patients presenting with stroke symptoms including a complete administrative infrastructure supporting and guiding the process of stroke patients. In addition, clinical practice guidelines and policies were put in place, which reflect an interdisciplinary approach to care. Stroke education for staff, patients, families, the community and the EMS System are also executed regularly. Specific quality improvement initiatives are in place to provide ongoing assessment and evaluation for performance in caring for stroke patients.

In an effort to promote general cardiac wellness, the Day Kimball Nursing staff participates in many community health events focused on the geriatric community to provide education including nutrition and physical activity in addition to counseling regarding accessibility of services they may require.

Diabetes

DKH is proud to offer a diabetes management program as part of an enhanced coordinated care program facilitated through our Primary Care Practitioners to help adolescents and adults living with Type 1 or Type 2 diabetes, pre-diabetes, or gestational diabetes to manage their condition and maintain their health.

Specialized care plans are developed to provide patients with individualized treatment and medication management. Patients are provided with education and instruction about how to

[1] http://wwwn.cdc.gov/CommunityHealth/profile/currentprofile/CT/Windham/

perform diabetic self-care, including the importance of home blood glucose-testing, how nutrition and exercise impact diabetes, strategies for lifestyle modifications and much more.

Obesity

Recent studies have shown that obesity exacerbates schizophrenia and bipolar disorder, and that physical changes in the brain do occur as a result of this disease. It may be partially due to this link in co-morbidities, that Northeastern CT has such a volume of both of these types of patients.

General awareness about nutrition and health food choices is greatly lacking in the Northeastern CT region. Day Kimball Healthcare is working on combatting this by offering an overeaters anonymous program every Wednesday at 6:00 p.m. for support in recovery from compulsive over eating, binge eating and other eating disorders at the hospital. Also, the Day Kimball Nursing staff participates in many elementary school age health fairs where education is provided to the students and teachers about the importance of nutrition to help combat obesity from a young age.

Breast Cancer Awareness

Breast cancer is one of the most common types of cancer we observe in the population of Northeast Connecticut.

To better serve this population, DKH instituted a Breast Health Program in 2011, which has prospered over the last three years both in terms of helping our patients avoid long commutes for treatment and the quality improvements found within our treatment process.

At the inception of the Breast Health Program, time into treatment for a woman diagnosed with breast cancer was over 30 days, and approximately 20 percent of our population diagnosed with a breast cancer chose to seek treatment at distant facilities for a variety of reasons. DKH heard the concerns of our community and launched the Breast Health Program complete with a full time Nurse Navigator to improve our ability to serve local women diagnosed with breast cancer.

The Breast Health Program diagnoses about 50 cases of breast cancer per year from the 8,000 mammograms performed at DKH. Thanks to the program, a patient diagnosed with breast cancer will now experience a smoother, more efficient transition into her first treatment. In 2013 DKH exceeded the 30 day national standard of care for "time to first treatment" and came in at 25 days. In the last three years, DKH has augmented its staff of cancer care professionals to facilitate the delivery of efficient, high quality cancer care.

DKH has a disproportionately high number of women who are Asian-American coming in with higher stage breast cancers, and that many of our higher stage breast cancers are from the state of CT defined under-served towns of Putnam, Plainfield and Danielson.

In response to this observation, DKH has made a concerted effort to reach out to the Asian-American community by contacting employers and local community groups with literature

translated into Asian languages and an Asian-American Registered Nurse in an attempt to engage the communities in discussions and navigation into screening services.

DKH oncology staff was present for approximately 18 hours in the community doing breast cancer awareness/education programs in Plainfield in July and August of 2015. A total of 37 women received verbal and written education and information regarding breast cancer screenings from this outreach program.

Depression / Suicide

In 2014, DKH Outpatient Behavioral Health Clinic treated approximately 550 cases of depression and other forms of mental illness in patients between the ages of 17-80. Depression is a serious medical illness with mood, cognitive, and physical symptoms and is associated with higher rates of chronic disease, increased health care utilization, and impaired functioning. DKH recognizes that all aspects of health are interrelated, and we understand the importance of caring for the whole person.

Day Kimball Healthcare's behavioral health services help address these unhealthy days providing care to people of all ages to address a wide range of behavioral and psychiatric conditions through a caring and comprehensive approach that's integrated with the rest of the patients' medical care. As part of our Day Kimball Healthcare's integrated care approach, our Behavioral Health team also communicates with the primary care practitioners to ensure best possible care of both mind and body.

Day Kimball Healthcare's adult outpatient behavioral health care provides diagnostic evaluations, individual, family and group therapies, medication management, and follow-up treatment for a wide variety of behavioral and psychiatric conditions. Our compassionate team of psychiatrists, psychotherapists, Advanced Practice Registered Nurses (APRNs), social workers, and professional counselors work together to offer a comprehensive array of services and a variety of specialized treatments. Our providers also specialize in serving the needs of specific populations including the elderly, women and the LGBT community.

Tobacco Cessation

Windham County had the highest smoking rates for both men (16.9 percent) and women (14.4 percent) in 2012[2]. At 15.6 percent, Windham was the only county with an overall smoking rate above the national average[3].

Strategy:

- Offer smoking cessation groups
- Maintain smoke-free campuses at all Day Kimball Healthcare sites
- Advertise community education programs offered in the Shopper's Guide, Turnpike Buyer, Villager and Reminder newspapers as well as through social media.

[2] http://vizhub.healthdata.org/us-health-map/
[3] http://www.countyhealthrankings.org/app/connecticut/2015/measure/factors/9/description

- Host and/or participate in community education programs
- Participate in ongoing education conversations on radio station WINY 1350 AM
- Provide Nicoderm patches for inpatients
- Education at high school wellness fairs to discourage smoking/encourage cessation

Substance Abuse

Northeast Communities Against Substance Abuse (NECASA), working with DCF and the State Police trained the Killingly School system and the Brooklyn School system in Drug Endangered Children's issues. Also, the Governor's Bill on Prescription Drug Abuse mandates training for physicians that prescribe opioids. This bill was signed in July 2015[4].

Studies done by The Eastern Regional Mental Health Board for 2015 showed a pressing need for more general public education about substance use issues, including problem substances, risk factors, warning signs, etc.[5] Participants in the focus groups voiced significant concern about the growing problems with heroin addiction and overdose in the local community. In addition, several mayors and selectmen in the DKH area have specifically identified heroin as a top concern within their communities.

In addition, Day Kimball Healthcare uses a validated screening tool approved by the Center for Medicare/Medicaid Services (CMS). This Audit-C tool (used by the Veteran's Administration) is performed on all eligible behavioral health inpatients. It consists of asking questions about the frequency and number of alcoholic drinks that they consume as well as the estimated number of times in the past year that they have consumed six or more drinks in one occasion. The information abstracted from these screenings is reported to CMS as well as The Joint Commission (TJC). This data is instrumental in the tracking alcohol abuse and binge drinking statistics for our region.

Flu Shots

Influenza is a highly contagious and serious illness. To help protect its patients and their families and their healthcare workers and their families, DKH offers annual influenza vaccines. It is strongly recommended that all Day Kimball Healthcare staff and volunteers, whether they have direct or indirect patient contact, including employees, private physicians, contracted and vendor personnel, volunteers and students receive annual influenza vaccination at no cost. Refusal of the flu vaccine means following the hospital policy of properly wearing a hospital approved mask while at work in any portion of the healthcare system, including patient homes, wherein patients are intended to be examined, treated or otherwise engaged during the influenza season. Vaccines are also provided at various work sites on all shifts to accommodate a broad spectrum of employees.

Day Kimball Healthcare (DKH) is not only committed to providing a safe environment for patients and healthcare workers (HCW), but also for the members of our service community.

[4] http://www.necasaonline.org/Customer-Content/WWW/News/PDFs/Priorities_Report_2015_updated_version_.docx

[5] http://www.changingmindsct.org/uploads/5/8/0/4/58045789/priorities_report_2015_updated_version.pdf

Day Kimball Healthcare hosts influenza immunization clinics with increased staffing at a variety of different locations throughout the Northeast Connecticut community during the flu season, as well as consistent participation in several community health fairs each year and hosting an annual influenza and pneumonia program helping to provide immunizations to the members of the Northeastern Connecticut community.

Child Abuse

According to recent numbers compiled by Connecticut's Child Advocacy Centers in 2013[6], Windham County had, by far, the highest incidence of child sexual abuse per capita in the state. Children who live, learn, grow and play in Windham County are at a higher risk for being sexually abused before they reach adulthood than children in other areas of the state. In fact, more than 3000 reports are placed annually to Department of Children and Families.

In order to address this staggering statistic, in 2013 Day Kimball Healthcare began an initiative of education and community outreach for employees. Day Kimball has chosen a nationally-recognized, evidence-based training curriculum provided by Darkness to Light and is called Stewards of Children, Child Abuse Prevention. Darkness to Light's mission is to empower people to prevent child sexual abuse.

The Stewards of Children program raises awareness of the prevalence and consequences of child sexual abuse. This is done by educating adults about the steps they can take to prevent, recognize and react responsibly to the reality of child sexual abuse. Day Kimball's senior management identified five key departments comprised of 400 employees who would have the most exposure to children and where the training would have the most impact. This training goes above and beyond normal training requirements and directly impacts our community. Day Kimball is providing this training to its employees at no cost. The short-term goal, utilizing two internal trainers, was to train those 400 employees by June of 2014 with a long-term goal of having all employees trained by 2018. This would make Day Kimball a partner in prevention with Darkness to Light.

It is Day Kimball's hope that this program will empower community members to identify the early signs of child abuse and respond appropriately thus reducing Windham County's per capita rate. We have already seen positive results from attendees as was evident when a member went to her school system to clarify policies and procedures around this topic. This rippling effect is exactly the outcome we wish to achieve.

They are: Day Kimball Medical Group's pediatrics and OB/GYN practice groups, which see more than 9,500 children and 6,500 women respectively; the maternal child health team at Day Kimball Hospital which delivers about 600 babies annually; the inpatient and outpatient care teams for adolescent behavioral health services which engages 260 teens each year; and the hospital's emergency department which sees almost 30,000 patients each year of which 3,900 are under the age of 18 years old. There are 400 employees who represent the care teams for these

[6] http://www.d2l.org/site/Connecticut.htm

areas of patient services. Day Kimball's goal is to orient these clinicians and allied providers to child abuse, what it is, how to prevent it and how to stop it.

The greater impact comes when it is considered that approximately 428 people were trained, of which approximately 350 live in northeast Connecticut, will easily touch more than half of the 92,000 residents of the region. The level of awareness and education about child abuse that this group can deliver to the friends and family served through Day Kimball Healthcare is staggering – in a good way. The program will have immediate impact on this issue that greatly influences the health and wellbeing of every person within the abused child's sphere of life. Plus it's an impact that goes beyond statistics – it will literally change the culture of northeast Connecticut by teaching our community how to break the barriers that cause child abuse.

MONITORING PROGRESS & MEASURING RESULTS

Cardiovascular Disease

- AMI Core Measures
- AMI Mortality Rates
- AMI Readmission Rates

Diabetes

- CMS HEDIS Measures
- Commercial Payer Pay for Performance Measures
- NCQA Quality Measures

Obesity

- NCQA Quality Measures (childhood obesity)
- CMS HEDIS Measures
- Commercial Payer Pay for Performance Measures

Breast Cancer Awareness

- Day Kimball Cancer Registry Measures

Depression / Suicide

- Number of Outpatient Behavioral Health Visits
- Inpatient Behavioral Health unit average daily census
- Readmission rates to psychiatric inpatient units

Tobacco Cessation

- Number attending Smoking Cessation Programs
- NCQA Quality Measures – smoker screening and smoking cessation counseling

Substance Abuse

- CMS/TJC 'Alcohol Use Screening' Measure on qualified Behavioral Health inpatients
- Beginning 1/1/2016: CMS/TJC Sub Measure 2 – 'Alcohol Use Brief Intervention Offered/Provided' for the same population.

Flu Shots

- DKH employee vaccination rates
- Number of flu shots administered in community clinics
- Number of flu shots ordered and dispensed to Day Kimball Medical Group practices

Child Abuse

- DKH mandated 'Darkness to Light' employee training sessions
- CT Child Advocacy Center reporting measures

SUMMARY

Based on an overview of Day Kimball Healthcare's progress in these nine community health need areas, and the success of various programs, the biggest challenges now and in the coming years will be in the areas of behavioral health, smoking cessation, substance and child abuse.

DKH will continue to assess and address the health needs within our community through partnerships with local healthcare organizations. There is also potential for broader offerings of education leveraging the resources and expertise of our newest partnership with Hartford Health Care

In addition, a 2018 community health needs assessment report will update the information herein as outlined by the IRS guidelines.

Olejarz, Barbara

From: Armah, Olga
Sent: Monday, June 13, 2016 1:58 PM
To: Olejarz, Barbara
Cc: Greer, Leslie
Subject: FW: Certificate of Need Application Docket No. 15-32031
Attachments: Day-Kimball-Healthcare-Community-Health-Needs-Assessment-Strategy_2015.pdf

Hi Barbara,

I sent the attached out separately from Exhibit W, the administrative notice. How do you want to add it to the table?

Thanks.

Olga

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

-----Original Message-----
From: Armah, Olga
Sent: Friday, June 10, 2016 10:49 AM
To: michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; Mercier, Carlene M.
Cc: User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David; Greer, Leslie; Schaeffer-Helmecki, Jessica
Subject: RE: Certificate of Need Application Docket No. 15-32031

Good morning,

Please find attached a copy of the referenced document.

Thanks.

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

BROWNRUDNICK
185 Asylum Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

June 13, 2016

VIA E-MAIL
(ohca@ct.gov; kevin.hansted@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON – Supplemental Letters of Support

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital, please find enclosed for filing supplemental letters of support in this matter.

Very truly yours,

BROWN RUDNICK LLP

By: Robert Anthony /s/ cs
Robert J. Anthony

cc: Michele M. Volpe via e-mail (michelemvolpe@aol.com)

brownrudnick.com

Town of Franklin
Office of the First Selectman
Franklin Town Hall
7 Meeting House Hill Road, Franklin, Connecticut 06254

TELEPHONE: 860-642-6055 EXTENSION: 16 FAX: 860-642-6606

WEBSITE: www.franklinct.com EMAIL: franklin@99main.com

The Town of Franklin is an equal opportunity provider and employer.

June 9, 2016

Bimal Patel, President

The William W. Backus Hospital

326 Washington Street,

Norwich, Connecticut, 06360

Dear Mr. Patel,

Please accept this letter of support for the development of a Primary and Elective Percutaneous Cardiac Intervention (PCI) program at The William W. Backus Hospital.

Although I am not a healthcare expert, I do know that timing is everything when it comes to a cardiac emergency, and residents in my community deserve to have timely access to PCI.

From what I understand, residents of this region are currently unable to access a PCI-capable facility within a 30-minute drive time. This lack of access should not exist– our families, friends and neighbors should not be at a disadvantage when it comes to their health, just because of where they live.

Having this service available at Backus Hospital would improve quality of life, make our region a more attractive place to live and, most importantly, save lives.

Please accept this letter of support – Backus should be applauded for its commitment to offering Percutaneous Cardiac Intervention, close to home for patients.

Sincerely,

Richard L. Matters

Franklin First Selectman

Town of Sterling

Town Hall
1183 Plainfield Pike
P.O. Box 157
Oneco, Connecticut 06373-0157

Assessor:	860-564-3030	Revenue Collector:	860-564-7563
Building Official:	860-564-2275	Selectmen:	860-564-2904
Economic Development:	860-564-4752	Town Clerk:	860-564-2657
Library:	860-564-2692	Treasurer:	860-564-8488
Recreation:	860-564-2136	Wetlands Agent:	860-564-2275
Registrar of Voters:	860-564-2654	Zoning Official:	860-564-2275

June 13, 2016

Bimal Patel
President
The William W. Backus Hospital
326 Washington Street
Norwich, Connecticut, 06360

Dear Mr. Patel,

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Please accept this letter of support.– Backus should be applauded for its commitment to offering Percutaneous Cardiac Intervention, close to home for patients.

Sincerely,

Russell M. Gray

Russell M. Gray
Sterling First Selectman

"This institution is an equal opportunity provider and employer."

Greer, Leslie

From: Mercier, Carlene M. <CMercier@brownrudnick.com>
Sent: Wednesday, June 15, 2016 2:37 PM
To: Armah, Olga; User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; kgg@bvmlaw.com; jlo@bvmlaw.com
Subject: Docket No. 15-32031-CON – Supplemental Letter of Support
Attachments: Hartford Healthcare _ Backus - Add_l Letter of Support 6_15.PDF

Good Afternoon,

Please find attached an additional letter of support in this matter.

Best Regards,
Carlene

BROWNRUDNICK

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

****

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****

ROBERT J. ANTHONY, ESQ.
direct dial: 860-509-6517
e-mail: ranthony@brownrudnick.com
http://www.brownrudnick.com

BROWNRUDNICK
185 Asylum Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

June 15, 2016

VIA E-MAIL
(ohca@ct.gov; kevin.hansted@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON – Supplemental Letter of Support

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital, please find enclosed for filing a supplemental letter of support in this matter.

Very truly yours,

BROWN RUDNICK LLP

By: Robert J. Anthony/cm
Robert J. Anthony

cc: Michele M. Volpe via e-mail (michelemvolpe@aol.com)

62493347 v1-WorkSiteUS-032836/0002

brownrudnick.com

TOWN OF BOZRAH
TOWN HALL
1 RIVER ROAD
BOZRAH, CT. 06334
Telephone: (860) 889-2689 • Fax: (860) 887-5449

David A. Whitehead, President
The William W. Backus Hospital
326 Washington Street
Norwich, CT 06360

Dear Mr. Whitehead,

Please accept this letter of support for the development of a Primary and Elective Percutaneous cardiac Intervention (PCI) program at the William W. Backus Hospital.

Although I am not a healthcare expert I am a former Connecticut State Trooper and Emergency Medical Technician so I do know that timing is everything when it comes to emergency cardiac care.

Having this service at Backus Hospital would improve the quality of life, and that service which your facility already provides. Again, please consider this very important addition to your offerings.

Sincerely,

Glenn S. Pianka
First Selectman

State of Connecticut
CONNECTICUT GENERAL ASSEMBLY
HARTFORD, CONNECTICUT 06106-1591

RECEIVED
JUN 14 2016
Office of
HEALTHCARE ACCESS

June 14, 2016

Attorney Kevin Hanstead, Hearing Officer
Office of Health Care Access
Department of Public Health
410 Capitol Avenue
PO Box 340308
Hartford, CT 16134

Testimony in support of Docket No. 15-32031-CON
CT Department of Public Health,
47- Capitol Avenue, Room C, Hartford, CT
June 16, 2016 9 a.m.

We the undersigned would like to offer our strong support for the Backus Hospital request for the Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital (Docket No. 15-32031-CON).

On behalf of our constituents we want to support Backus Hospital's proposal to establish a primary and elective angioplasty program. Many residents in our districts who suffer from heart attack symptoms currently must travel more than 30 minutes to receive care, which is not fair when you take into account that every second counts in these situations.

Just because we are part of a rural region in Eastern Connecticut does not mean that we should not have access to life saving care like most other residents in the state of Connecticut do. In addition to the rural nature of this region, there are also economic and geographic barriers that many of our residents face.

Many of the towns in our districts are designated as either "Health Professional Shortage Areas" or "Medically Underserved Areas." It is also an area at a higher risk for coronary artery disease due to an older population that is more prone to risk factors including age, obesity, diabetes and smoking rates.

Research shows that the sooner patients suffering from heart attack symptoms receive treatment, the better. If Backus offered angioplasty services, it would likely improve outcomes and quality of life for residents and most importantly, save lives.

We urge you to approve the proposal to offer angioplasty services at Backus so that residents of this region have convenient and timely access to these lifesaving services, close to home, in their own community.

The current lack of access should not exist – our families, friends and neighbors should not be at a disadvantage when it comes to their health just because they live in northern New London or Windham counties.

Sincerely,

Representative Paul Brycki
45th District

Senator Catherine Osten
20th District

Representative Kevin Ryan
139th District

Representative Linda Orange
48th District

Representative Emmett Riley
46th District

Representative Doug Dubitsky
47th District

PUBLIC HEARING
INTERVENOR
SIGN UP SHEET

June 14, 2016 (continuation from March 23, 2016)
9:00 a.m.

Docket Number: 15-32031-CON
Hartford Hospital and The William W. Backus Hospital
Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

PRINT NAME	Phone	Fax	Representing Organization
Michele Volpe			L+M Council
Kate Tomasso			L+M Council
Shraddha Patel			L+M
Seth Van Essendelft			L+M
Brian Cam[illegible]			L+M

Hartford Hospital and The William W. Backus Hospital

PRINT NAME	Phone	Fax	Representing Organization
Dan Rissi			UM

PUBLIC HEARING

APPLICANT

SIGN UP SHEET

June 14, 2016 (continuation from March 23, 2016)
9:00 a.m.

Docket Number: 15-32031-CON
Hartford Hospital and The William W. Backus Hospital
Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

PRINT NAME	Phone	Fax	Representing Organization
Janette Edwards	860 243 4168		HHC
DAN LOHR	860-823 6368	860-823-6329	HHC

PUBLIC HEARING
GENERAL PUBLIC
SIGN UP SHEET

June 14, 2016 (continuation from March 23, 2016)
9:00 a.m.

Docket Number: 15-32031-CON
Hartford Hospital and The William W. Backus Hospital
Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital

PRINT NAME	Phone	Fax	Representing Organization
Bimal Patel	860-462-2961		Backus Hospital - HHC

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TABLE OF THE RECORD

APPLICANTS: **Hartford Hospital and The William W. Backus Hospital**

DOCKET NUMBER: **15-32031-CON**

PUBLIC HEARING: **March 23, 2016 at 9:30 a.m. (Continued on June 14, 2016)**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room**
Hartford, Connecticut

EXHIBIT	DESCRIPTION
A	Letter from Hartford Hospital and The William W. Backus Hospital (Applicants) dated September 30, 2015 enclosing the Certificate of Need (CON) application to Establish and Operate a Primary and Elecive Angioplasty Program under DocketNumber 15-32031, received by OHCA on September 30, 2015. (1437 Pages)
B	Letters of support in the matter of the CON application filed under Docket Number 15-32031, received by OHCA on various dates. (3 pages)
C	OHCA's letter to the Applicants dated October 30, 2015, requesting Additional information and/or clarification in the matter of the CON application under Docket Number 15-32031.(7 Pages)
D	Designation letter dated December 16, 2015 of Hearing Officer in the matter of the CON application under Docket Number 15-32031. (1 page)
E	Applicants responses to OHCA's letter of October 30, 2015 along with a revised Exhibit 24, dated December 30, 2015, in the matter of the CON application under Docket Number 15-32031, received by OHCA on December 30, 2015. (49 Pages)
F	Letters of support in the matter of the CON application filed under Docket Number 15-32031, received by OHCA on January 11, 2016. (2 pages)
G	OHCA's letter to the Applicants dated January 29, 2016 deeming the application complete in the matter of the CON application filed under Docket Number 15-32031. (1 page)

H	OHCA's request for legal notification in the *Norwich Bulletin* of OHCA's Notice to the Applicants of the public hearing scheduled for March 23, 2016, in the matter of the CON application under Docket Number 15-32031, dated February 10, 2016. (4 pages)
I	OHCA's letter to the Applicants dated March 9, 2016 requesting prefile testimony and enclosing issues in the matter of the CON application under Docket Number 15-32031. (4 pages)
J	Letter from Lawrence + Memorial to OHCA dated March 16, 2016 noticing the appearance of Bershtein, Volpe & McKeon, P. C. on Behalf of Lawrence + Memorial Hospital and Petition of Lawrence + Memorial Hospital, Inc.for Intervenor Status with full rights of cross-examination in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 16, 2016. (11 pages)
K	Letter from the Applicants to OHCA enclosing Prefile Testimony and responses to issues dated March 9, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 17, 2015. (48 pages)
L	OHCA's Ruling on the Petition of Lawrence + Memorial Hospital to be granted intervenor status in the matter of the CON application under Docket Number 15-32-31, dated March 17, 2016. (1 page)
M	Letter from the Intervenor to OHCA dated March 18, 2016 enclosing Prefile Testimony in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 18, 2016. (74 pages)
N	Letter from the Applicants to OHCA dated March 23, 2016 enclosing a Motion in Limine in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 23, 2016. (6 pages)
O	Letter from the Intervenor to OHCA dated March 23, 2016 enclosing Intervenor's opposition to the Applicants' Motion in Limine Limine in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 23, 2016. (7 pages)
	The following was added into the record at the hearing held on March 23, 2016
P	Notice of Appearance of Attorney Douglas A. Cohen, from Brown Rudnick LLP on behalf of The William W. Backus Hospital dated March 23, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 23, 2016. (2 pages)
Q	Oral Testimony of Bruce Cummings, Dr. Brian Cambi, Seth Van Essendeflt and Daniel Rissi, MD in the matter of the CON application under Docket Number 15-32031, received by OHCA on March 23, 2016. (11 pages)
R	OHCA's letter to the Applicants dated March 31, 2016 enclosing ruling on the Motion in Limine filed by the William W. Backus Hospital and Hartford Hospital and Opposition thereto filed by Lawrence + Memorial Hospital, Inc.in the matter of the CON application under Docket Number 15-32031. (2 pages)

S	Letter from the Applicants to OHCA dated April 1, 3016 enclosing the Late Files in the matter of the CON application under Docket Number 15-32031, received by OHCA on April 1, 2016. (6 pages)
T	Transcript of the hearing held on March 23, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on April 7, 2016. (202 pages)
U	Letter dated June 6, 2016 requesting excusal of David A. Whitehead and Bruce Cummings from the June 14, 2016 hearing, in the matter of the CON application under Docket Number 15-32031, received by OHCA on June 6, 2016. (3 pages)
V	Letter from UMASS Memorial to OHCA dated June 2, 2016 in the matter of the CON application under Docket Number 15-32031, received by OHCA on June 7, 2016. (2 pages)
W	OHCA's letter to the Applicants dated June 9, 2016 enclosing and Order Regarding Administrative Notice in the matter of the CON application under Docket Number 15-32031. (1 page)
X	OHCA's letter to the Applicants dated June 9, 2016 enclosing ORDER Granting the Applicants' Motion in the matter of the CON application under Docket Number 15-32031, received by OHCA on June 7, 2016. (1 page)

Late file requested at hearing held on March 23, 2016, due on April 1, 2016.

- Zipcodes from center of town along with towns within the angioplasty region to the nearest PCI facility regardless if the provider is in the state.

STATE OF CONNECTICUT

OFFICE OF THE ATTORNEY GENERAL

OFFICE OF HEALTH CARE ACCESS

HARTFORD HOSPITAL AND THE WILLIAM W. BACKUS HOSPITAL

ESTABLISHMENT OF A PRIMARY AND ELECTIVE PCI PROGRAM AT THE WILLIAM W. BACKUS HOSPITAL

DOCKET NO. 15-32031-CON

JUNE 14, 2016

9:00 A.M.

DEPARTMENT OF PUBLIC HEALTH
470 CAPITOL AVENUE
HARTFORD, CONNECTICUT

POST REPORTING SERVICE
HAMDEN, CT (800) 262-4102

. . .Continued verbatim proceedings of a hearing before the State of Connecticut, Office of the Attorney General, Office of Health Care Access, in the matter of Hartford Hospital and The William W. Backus Hospital, Establishment of a Primary and Elective PCI Program at The William W. Backus Hospital, held at the Department of Public Health, 470 Capitol Avenue, Hartford, Connecticut, on June 14, 2016 at 9:00 a.m. . . .

HEARING OFFICER KEVIN HANSTED: Okay, we're going to get started here. Welcome back, everyone. This is a continuation of a hearing held on March 23, 2016 regarding Docket No. 15-32031, pertaining to an application filed by Hartford Hospital and The William Backus Hospital for the establishment of a primary and elective PCI program at The William Backus Hospital.

At this time, I would ask all those individuals, who are going to testify, to please stand, raise your right hand, and be sworn in by the court reporter.

(Whereupon, the parties were duly sworn

in.)

HEARING OFFICER HANSTED: Okay, thank you, all. Just before we get started, if you could pass around the microphone and just identify yourselves for the record, those folks, who were just sworn in, one at a time? Thank you.

MR. SHANE FOREMAN: Shane Foreman.

MS. JANETTE EDWARDS: Janette Edwards.

DR. JOHN FOLEY: John Foley.

DR. PAUL THOMPSON: Paul Thompson

DR. FRANCIS KIERNAN: Francis Kiernan.

DR. KYLE McCLAINE: Kyle McClaine.

MS. MARY ANN CARNA: Mary Ann Carna.

MR. DANIEL LORER: Dan Lorer.

MS. REBECCA DURHAM: Rebecca Durham.

MR. STUART MARKOWITZ: Stuart Markowitz.

MR. BIMAL PATEL: Bimal Patel.

MS. SHRADDHA PATEL: Shraddha Patel.

DR. BRIAN CAMBI: Brian Cambi.

MR. SETH VanESSENDFELT: Seth VanEssendfelt.

DR. DANIEL RISSI: Daniel Rissi.

HEARING OFFICER HANSTED: Okay, thank you, everyone. And, according to my records, we left off with

Mr. Lorer on the stand. He was being Cross-Examined, and I understand there's some clarification that needs to be done by Attorney Cohen, so, if you want to proceed in that manner, you may do so.

MR. DOUG COHEN: Okay. Mr. Hansted, if we could have elected representatives go first, and then we'll move to Mr. Lorer, if that's okay.

HEARING OFFICER HANSTED: That's fine. I didn't know if you wanted to do the clarification first.

MR. COHEN: Yeah, and we have a letter that we would like to provide for the record now. We have copies for everyone.

HEARING OFFICER HANSTED: Okay.

MR. COHEN: Thank you.

MR. KEVIN RYAN: Good morning, Mr. Hansted. I'm Kevin Ryan, the State Representative for the 139th District. I am here representing the Norwich area legislators, which include Paul Brycki, Emmett Riley, Linda Orange, Doug Dubitsky, as well as Senator Catherine Osten, and I am here to provide testimony to the docket number you've mentioned.

We offer strong support for the Backus Hospital request for the establishment of a primary and elective PCI program at the William W. Backus Hospital.

On behalf of our constituents, we want to support Backus Hospital's proposal to establish a primary and elective angioplasty program. Many residents in our districts, who suffer from heart attack symptoms, currently must travel more than 30 minutes to receive care, which isn't fair, when you take into account that every second counts in these situations.

Just because we're part of a rural region in Eastern Connecticut does not mean that we should not have access to life-saving care, like most other residents of the state of Connecticut.

In addition to the rural nature of this region, there are also economic and geographic barriers that many of our residents face.

Many of our towns are in districts that are designated either health professional shortage areas or medically underserved areas.

It is also an area at a higher risk for coronary artery disease, due to an older population that is more prone to risk factors, including age, obesity, diabetes and smoking rates.

Research shows that the sooner patients suffering from heart attack symptoms receive treatment the better. If Backus offered angioplasty services, it

would likely improve outcomes and the quality of life for residents and, most importantly, save lives.

We urge you to approve the proposal to offer angioplasty services at Backus, so that the residents of the region have convenient and timely access to these life-saving services close to home in their own community.

The current lack of access should not exist on families, friends and neighbors, should not be at a disadvantage when it comes to their health, just because they live in Northern New London or Windham Counties. Thank you for your time.

HEARING OFFICER HANSTED: Thank you, sir, and we will add the letter to the record.

MR. COHEN: We also filed some additional documents yesterday afternoon. I see that you have them. I just want to make sure. They were two separate letters of support. I think it was 2:00 or 3:00 they were filed. Okay, great. Thank you.

HEARING OFFICER HANSTED: Those are exhibits marked as Z on the Table of the Record.

MR. COHEN: Thank you. Mr. Hansted, as we discussed, we have one clarification from Mr. Lorer that we'd like to discuss now. I do have other questions for

him, but I thought, if Ms. Volpe would want to Cross him on this question, that we do that first.

HEARING OFFICER HANSTED: That's fine. You may proceed.

MR. COHEN: Thank you. Good morning, Dan.

MR. LORER: Good morning.

MR. COHEN: Can you clarify your answer regarding physicians' call coverage? You indicated that the physician call coverage is not a separate line item, but it's netted out in revenues. Can you please explain that?

COURT REPORTER: Please grab a microphone.

HEARING OFFICER HANSTED: Everyone, please remember, if you're going to speak, just grab the microphone. I understand it's a little difficult passing these around, but please be conscientious of that.

MR. LORER: Sure. My name is Dan Lorer. At the last hearing, I misspoke in response to the question on where the physician on-call compensation is recorded.

It is included on line B-1, which is salaries and wages, so the numbers don't change from the exhibit. I misspoke by indicating they were netted against the revenues.

HEARING OFFICER HANSTED: Thank you. Attorney Volpe, do you have any Cross?

MS. MICHELE VOLPE: No, I don't have any further questions for Mr. Lorer.

HEARING OFFICER HANSTED: Thank you.

MR. COHEN: Before we get into some Redirect of these witnesses, there's a couple of administrative matters that we'd like to discuss with you. The first is the UMass letter that we received yesterday, and the UMass letter raises significant issues that none of them are new, but I think we'd like to have our witnesses have an opportunity on Redirect to address those, some of the points in that letter.

HEARING OFFICER HANSTED: You may do that. I don't have an issue with that. Understand that, obviously, UMass isn't here to be examined on those questions.

MR. COHEN: Sure.

HEARING OFFICER HANSTED: Attorney Volpe, do you have any issue with that?

MS. VOLPE: Well I mean only to the extent that it's responsive to our testimony. I mean that's what's subject to Cross and Redirect. I mean no new evidence can be offered at this time in the proceedings.

HEARING OFFICER HANSTED: Right. Right, so, Attorney Cohen, like Attorney Volpe just stated, as long as it's relevant to their testimony, I'm okay with it, however, as I stated, UMass is not here to be Cross-Examined or even questioned directly, so I'd like to have UMass here to question them, so I don't want to get into a situation, where we're left having you make statements or your witnesses are making statements that can't be verified by UMass.

MR. COHEN: Well that's actually the problem with accepting a letter like this. UMass has made statements throughout this letter that are inaccurate, incorrect, misleading, and they're not here to -- we're not able to Cross-Examine them on this letter.

If we can't discuss this letter, whether or not it was raised in the Cross-Examination, then we're going to object to it as extremely prejudicial.

This letter raises a significant number of things, as I said, that we have -- that are incorrect. The record is replete with them.

We've been transparent in how we presented our application today. This letter, as I mentioned, has some misleading and incorrect information.

For example, Backus would be the closest --

MS. VOLPE: He's offering Direct testimony. Now I would object. The letter was presented for the record. I mean we're not here -- you offered letters from the First Selectman of Sterling and Franklin, and we don't have an opportunity to talk to them about their statements in the letter either, which may not be accurate, so I think it's been submitted, it's added to the record.

It's no different than any other letter of support, so we would object with Attorney Cohen offering any additional testimony on the letter.

HEARING OFFICER HANSTED: Attorney Cohen, I'm going to sustain that objection. The letter from UMass was received by my office on June 2nd. We didn't receive any objection from your office until just right now.

The letter is part of the record. We'll give it due weight, if it's due any weight at all, but I'm not going to allow you to offer any evidence to contradict that letter.

MR. COHEN: Okay.

COURT REPORTER: Can I go off the record

for one second?

HEARING OFFICER HANSTED: Sure.

(Off the record)

COURT REPORTER: Okay, I'm all set.

HEARING OFFICER HANSTED: Okay, we're back on the record. Is this picking up okay now?

COURT REPORTER: Yup.

HEARING OFFICER HANSTED: Okay. Attorney Cohen, you may proceed.

MR. COHEN: Yes. One more administrative matter. The late-filed exhibit that we filed, I have some Direct questions for our witness on that. I don't know when you'd like to do that; at the end of this hearing, at the beginning.

HEARING OFFICER HANSTED: Is that Exhibit Z, the late file? No, that's a supplemental support letter.

MR. COHEN: The Late File 1 that we filed I guess it was a week or two after the hearing. June 1st. April 1st. I'm sorry, right. April 1st.

HEARING OFFICER HANSTED: Okay. Just for the record, that's Exhibit S on the Table of the Record. You may question your witness now on that, if you want to proceed in that manner.

MR. COHEN: All right, well, since Mr. Lorer is here, if I can just spend two minutes Redirecting him on a couple of issues to clarify the record?

HEARING OFFICER HANSTED: Sure.

MR. COHEN: So, Dan, you indicated that you're the Regional V.P. of Finance. Is this position responsible for Backus Hospital?

MR. LORER: Yes, it is.

MR. COHEN: Just to clarify your answer from Ms. Volpe's Cross-Examination, can you tell us what the capital cost of the PCI program will be at Backus and the annual loss for the program?

MR. LORER: As I mentioned in the previous hearing, the capital cost for the program at this point our estimate is between four and a half million dollars and five million dollars of capital investment.

The annual loss begins in a projection of just under $400,000, and, in year five, it goes up to about $705,000.

MR. COHEN: Okay, thank you. Do hospitals ever operate a program or a service at a loss?

MR. LORER: Yes, we do.

MR. COHEN: And why is that?

MR. LORER: Community, service community commitment.

MR. COHEN: And is Backus in a financial position to absorb that loss?

MR. LORER: Yes, we believe we are.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: Attorney Volpe, do you have any Cross?

MS. VOLPE: I have no questions.

HEARING OFFICER HANSTED: Okay.

MR. COHEN: This is regarding the late-filed exhibit. I wanted to just ask a couple of Direct questions. Did you prepare the exhibit, Mr. Foreman, or was it prepared under your direction?

MR. FOREMAN: Yes, it was prepared under my direction.

MR. COHEN: And do you have any clarifications or corrections to the late-filed exhibit?

MR. FOREMAN: I do have one clarification. On the second page of the late file, page 1551, in point number three, I'd just like to clarify that 14 of the 38 zip codes, which is 37 percent of the zip codes and 22.3 percent of the population, have an out-of-state provider as the closest PCI provider by drive time, so we did not

specify drive time, so 11 of those zip codes are outside of the 30-minute drive time.

MR. COHEN: Okay. I just want to clarify briefly. How is this exhibit different from that which was provided in the CON and the completeness responses?

MR. FOREMAN: So our original assessment included Backus Hospital as a potential PCI provider, and it also assumed that leaving the state of Connecticut was not optimal, so we did not include out-of-state, and then we also utilized Maptitude as the planning tool in the original assessment.

Within the late file that you have, we used only existing PCI providers, and we included out-of-state providers, and we used Google maps. Since the Intervenors had used Google maps, we thought it would aid you in making an apples-to-apples comparison.

MR. COHEN: Thank you. So looking at the late-filed exhibit, which breaks down to who has access to PCI services, can you summarize your findings?

MR. FOREMAN: Sure. Interestingly, the late file completely confirms and validates our original assessment, so when we think about the late file and what you have before you, the things that haven't changed is the angioplasty regions made up of the 38 zip codes that

we previously discussed.

The 38 zip codes aggregate into 26 towns. In 2015, from a total population perspective, there were 231,419 residents within the angioplasty region.

When we looked at incidents of disease, acute MI is still up within the same region.

MS. VOLPE: I'm going to object to that --

HEARING OFFICER HANSTED: Are you picking her up?

MS. VOLPE: I can speak up. I'm going to object, because now --

HEARING OFFICER HANSTED: Hold on, Attorney Volpe.

COURT REPORTER: It's not working?

HEARING OFFICER HANSTED: No.

COURT REPORTER: Okay. Let me go off the record for a second.

HEARING OFFICER HANSTED: Wait. Now it's back. Okay. Attorney Volpe, do you need a microphone?

MS. VOLPE: I'll project my voice.

HEARING OFFICER HANSTED: Well I just want to make sure the court reporter --

MS. VOLPE: Can you get me? I'll talk over this way. I'll speak this way, but don't think I'm

not directing my question. I'm objecting to Mr. Foreman's remarks, because I think the late file speaks for itself, and it's specific to numbers, so he's going on to talk about disease in the region, which is not part of the late file, so I'm objecting. This is an opportunity for Redirect on submission.

MR. COHEN: This is Direct Examination of our witness, and I'm going through the late file and highlighting various issues that we think you, as the Hearing Officer, need to take a look at, so I think it's perfectly fine.

We gave a lot of leeway on their testimony, whether it was far a field or not. The idea here is to try to get facts. Nothing that Mr. Foreman is saying is inaccurate. It is facts related to this late-filed exhibit.

MS. VOLPE: Attorney Cohen had his opportunity to get in the facts, and the reason the late file was required was because they were deficient in the submission of their facts.

I think the late file speaks for itself. We don't have any questions on the late file.

HEARING OFFICER HANSTED: I'm going to allow the testimony, Attorney Volpe. I will allow you

Cross-Examination on what he's testifying to at this point.

MR. COHEN: Go ahead.

MR. FOREMAN: Thank you. So, as I mentioned, acute MI within the region specified in the late file is up about 12.6 percent over a six-year period.

When we looked at incidence of disease specifically stemming within the late file region, it's above both state and national rates, and when we looked at primary and elective PCI preferred treatment for these patients, primary PCI in the region is 18 percent below the state and eight percent below the nation in total, and, in elective PCI, it's actually more significant.

It's 19 percent below state and 41 percent below what we would expect across the U.S., so an elective PCI, when you compare that patient population to the remainder of the nation, they get the preferred treatment 41 percent less often than we would expect.

For all 38 of the zip codes within the late file, Backus Hospital would be the closest PCI provider.

L & M treats very few of these patients today, so when we look at the region and look at the

patients that L & M is treating out of this region, they have about a three percent inpatient market share, and then, when we look at PCI, specifically, they treated 12 patients out of this region in 2013, 22 in 2014, 32 in 2015, and just eight in the first two quarters of 2016.

When we look at who is the dominant market leader within the L & M region, it's actually Yale-New Haven Hospital at 51 percent.

So let's talk about what did change within the late file. So the demonstrated need actually went up. When we did our original assessment and we used Maptitude and were conservative in our estimate, we estimated 146,000 people didn't have proper access to PCI within the 30-minute drive time, and when we looked at this using their strategic planning tool, that number actually grew to 160,230 people, so over 160,000, based on the late file, do not have access to PCI services within the 30-minute drive time.

And then, finally, an additional, just over 18,000 people from that region, are actually forced to go out-of-state for care, as well.

MR. COHEN: Thank you, Mr. Foreman. No further questions at this time.

HEARING OFFICER HANSTED: Attorney Volpe,

do you have any Cross?

MS. VOLPE: I don't have any questions for Mr. Foreman.

HEARING OFFICER HANSTED: Thank you.

MR. COHEN: Thank you. I'd like to proceed with questions for Dr. McClaine. These are Redirect questions.

MS. VOLPE: I'm going to object. You had an opportunity to Redirect at the time I Crossed the witness. Now is not an opportunity to Redirect.

MR. COHEN: That's absolutely not true. There was no opportunity to Redirect. When you look at the record, the only folks that we had an opportunity to Redirect were Mr. Lorer and Mr. Foreman, and I will not ask any Redirect questions of those two individuals.

There's absolutely nothing in the record that reflects an opportunity to Redirect the rest of my witnesses. I've gone through the record, through the transcript with a fine-tooth comb, and there's absolutely --

MS. VOLPE: -- because you didn't ask a question. You didn't ask. You didn't present them on Redirect.

MR. COHEN: We --

MS. VOLPE: Excuse me. Hearing Officer Hansted gave us an opportunity to Redirect every time a witness was up there. You did not choose to Redirect.

MR. COHEN: If I can address that, there were specific instances, where you asked do you have any Redirect questions, and, as I said, it was only with regard to two individuals --

MS. VOLPE: And --

MR. COHEN: If I could finish, please? Mr. Foreman and Mr. Lorer. I specifically said with regard to both of those that I had no further questions.

The questions that Ms. Volpe asked were all over the board. She was not done with any of our witnesses, so we did not discern that she was done at any particular point in time, so I have a series of Redirect questions for several of our witnesses, primarily of the docs, and then we have some Redirect questions on some of the other issues, but we never had an opportunity to Redirect these witnesses.

HEARING OFFICER HANSTED: Okay, counsel, let me just stop you there, both of you. At the end of the day, what we really want out of these hearings is information. I don’t want to get bogged down on technicalities, as to who had an opportunity to Redirect

and who didn't and when that was done and when it was not done, so I'm going to allow the Redirect.

Again, Attorney Volpe, I will allow you to Cross again, if need be.

MS. VOLPE: Right, and I appreciate that, Hearing Officer Hansted. I just want to make it clear that the Applicant isn't going to be offering new testimony and new information. It has to be specific to what was directed to the witness, because it's not your responsibility to ask him every time whether he wants to Redirect.

He has to take the initiative after the witness has spoke, right then, when we have the facts before us, as to whether or not he wanted to Redirect, and he chose not to, so I understand your position, and it is a fact finding, and we want to have all the facts, but I want to make it clear that we're going to look at the testimony, we're going to see if it was a question presented that requires clarification, and I'm going to object if it's new information that was not in a question that we presented.

HEARING OFFICER HANSTED: Attorney Cohen, how many questions do you have for the doctor?

MR. COHEN: For Dr. McClaine, probably

around five or six.

HEARING OFFICER HANSTED: Okay. We're going to go off the record. I want you to review those questions with Attorney Volpe. I want you to come up with an agreement, as to which questions you both agree should be asked and what shouldn't be asked, and then we'll go back on the record and discuss those.

MR. COHEN: Okay.

MS. VOLPE: Thank you.

(Off the record)

HEARING OFFICER HANSTED: Can everyone hear me okay in the back of the room? Okay. We are back on the record, and, Attorney Cohen, if you want to proceed?

MR. COHEN: Thank you. We have with us Dr. Foley and Dr. Thompson, and I'm going to address several of the questions first to Dr. Foley.

Dr. Foley, do the demographics support your contention that the angioplasty region is a sicker population?

DR. FOLEY: It's nice to be back without a fever this time, so I'm not infectious, for the record, but, yes, I believe the demographics both numerically in the application support the contention that we are going

to be servicing well over 100,000 people, who don't have 30-minute access now.

I can tell you, also, anecdotally, from both living and working in the community, that our patients are sicker. Our application goes through that, in spite of the fact that there are more patients, who are having STEMIs, that there are less people having access to cath labs, so when you have more of a disease and less of care, you have to ask yourself why that happens, and our contention is it's access, and, so, I do believe that -- and it's hard for us to understand, because for many people, who live and work in Hartford, or New Haven, or areas where there are ready access, you just think that everybody has that access, but the patients that I deal with, and now we're out in the Putnam area, don't have access to this.

They don't have it, they don't feel like they have it, and this application I think is there's going to be life-saving therapy to a lot of people, who don't feel like that they have access to it now.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: Attorney Volpe, do you have any follow-up?

MS. VOLPE: Just let me confer.

HEARING OFFICER HANSTED: Okay. One moment. Do you need a microphone over on that end?

MS. VOLPE: We may.

HEARING OFFICER HANSTED: Okay.

MS. VOLPE: Okay, so, if we could direct them to page 59 of the application, the bates stamp? This is our pre-file on 59, along with your submission, which starts on page 133, the Community Health Needs Assessment for the Eastern Region.

MR. COHEN: Fifty-nine of?

MS. VOLPE: Of our pre-file.

MR. COHEN: Of the pre-file?

MS. VOLPE: And page 133, which is your Eastern Region Community Health Needs Assessment. So, Dr. Foley, do you have that in front of you?

HEARING OFFICER HANSTED: Just give him one moment.

MR. COHEN: Hold on. Are we having Redirect of Dr. Foley, or are we having their witness testify?

HEARING OFFICER HANSTED: No. We'll Redirect question-by-question.

MR. COHEN: Okay.

MS. VOLPE: It's specific to Dr. Foley's

statement, that this population is sicker in the state than other areas of the state, so it's specific to address that point that he made.

HEARING OFFICER HANSTED: Attorney Cohen, can you just hand the doctor your microphone?

MR. COHEN: Yeah, I just handed him -- oh, the microphone, yes.

HEARING OFFICER HANSTED: I apologize for the microphone situation. It's a little bit cumbersome.

DR. FOLEY: In the interest to give you I think an answer to the question, I would like to defer it to Janette, who understands the specifics of the detail.

I mean, when you look at the percentage of obesity rates and smoking, I know they're higher. When you look at the mortality rate in this population group, the mortality is higher, and that was shown, in terms of the heart disease mortality. It's 167.5 deaths per 100,000 for Windham County versus 153.4 for Connecticut, so their mortality rate is higher.

MS. VOLPE: All right, but now we're talking about mortality, and we were directing it specific to your statement, that this population is sicker than the rest of Connecticut and the U.S.

You know what? In the interest of moving

this proceeding along, we were going to have Dr. Foley look at the chart with the data that was extracted from their application, with a legend that shows where in the region they're better than Connecticut in the U.S. average, where they're similar, and where they're in a small percentage are worse, but, in the interest of time, we'll let Attorney Cohen ask his next question.

HEARING OFFICER HANSTED: Hold on. One at a time. You need a microphone.

MR. COHEN: I would ask you that you caution Ms. Volpe not to testify, which she just did. If she wants to ask a question, that's okay, but characterizing this as small numbers or whatever, I think that that's inappropriate.

She did that in the first hearing, and we didn't object to it, but given where we are today, I'd ask that she ask questions and not testify.

HEARING OFFICER HANSTED: Yeah. Let's just, for both sides, keep in mind that I don't want the attorneys testifying, and with respect to page 59 of the Intervenor's pre-file, you know, the document speaks for itself, and I think the doctor just testified, as to what he believes, so let's let that stand.

I mean we have enough in the record at

this point, so if you're okay with that, let's --

MS. VOLPE: I am, thank you.

HEARING OFFICER HANSTED: Thank you. Okay, Attorney Cohen, do you have another question?

MR. COHEN: If you can pass the mike back over? The next question is do you expect L & M's service area elective PCI referral patterns to change if Backus has a PCI program?

DR. FOLEY: No, I don't, and when you look at Backus Hospital, the group that I'm with, Hartford Medical Group, refers now to Hartford Hospital. We have a group in town that I used to be a member of that is Yale Medical Group cardiology service, and I would anticipate that their referrals to Lawrence will remain the same.

We hope, however, to provide a cath lab that they can practice in, and for the patients, who are local, who can avail themselves of transportation to Lawrence, we hope that they're an active part of our cath lab and able to take care of their patients, but I don't believe in any significant way their referral patterns will change, because doctors make the decisions, as to where they refer patients, not hospitals or systems.

HEARING OFFICER HANSTED: Attorney Volpe,

do you have any follow-up?

DR. CAMBI: I'm a little uncomfortable with how the hearing is being organized, but I'm happy to respond to that. John is a friend and a colleague. I respectfully disagree with that assertion.

I think that, if Backus were to get approval for an elective PCI program, naturally that will, unfortunately, erode some of the volume that comes to L & M.

If patients now see that this hospital has a program there, they're more likely to stay at that hospital, which will potentially pull volume from L & M.

I don't know that either one of us can prove that. We can anticipate what happens in the future, but, certainly, I see that as happening.

HEARING OFFICER HANSTED: Okay. Doctor, a fair point. I was just going to ask both doctors isn't it both speculation, I'm sorry, speculation on both your parts, as to how this would affect either program?

To me, there's no hard evidence in the record, and I don't know how you would come up with that evidence. I mean is that fair to say, that it's speculation?

DR. CAMBI: In terms of proving it

scientifically, yes. I mean, anecdotally, certainly there are large numbers of patients, now that there's a program at L & M, who previously got their intervention at Yale, who were doing it at L & M, so there's been some loss there.

I would expect a similar phenomenon to happen if Backus were to get a program, which would obviously harm L & M, in terms of volumes, finances and quality, but we can get into that later, but, in essence, you're right. I can't prove it to you scientifically.

HEARING OFFICER HANSTED: Right. Right.

DR. FOLEY: I would agree. I mean it's conjecture, based on the way I practice, and the fact that I know who from the Backus area are going to Lawrence now and who isn't, and I honestly can't see a significant change in the non-STEMI population group after we get a cath lab.

HEARING OFFICER HANSTED: Okay, so, let's move on from this subject.

MR. COHEN: We have a couple of questions for Dr. Thompson. Can you please explain exactly how the programs at Backus and Hartford will be integrated and how that relates to providing a standard of care for patients?

MS. VOLPE: I --

HEARING OFFICER HANSTED: Hold on. I want to hear the answer to this question, Attorney Volpe.

DR. THOMPSON: So I'm the physician co-Director of the Hartford HealthCare Heart and Vascular Institute, and Backus is part of Hartford HealthCare, so their cardiology group falls under our Cardiovascular Institute.

We're going to review and going to operate with the Backus cath lab as an extension of the Hartford Hospital cath lab, so the direct overall supervision will be provided of that cath lab, that interventional program, by Francis Kiernan, who is the Director of the cath lab at Hartford Hospital, again, the idea being that this is part of Hartford HealthCare Cardiovascular Institute. Backus is part of Hartford HealthCare Cardiovascular Institute, so the direct oversight of that program, the overall oversight will be by Fran Kiernan.

Now there will be a person on the ground. There will be a local Director, but in terms of morbidity and mortality conferences, quality control, all that sort of stuff, staffing, will be on the same model as Hartford HealthCare.

Now integrated, as well, and integrated in

making sure that, for example, relatively new interveners or operators in that lab, interventionalists in that lab will be supervised, as necessary, to their level of expertise, and we're going to do that both by allowing them to perform procedures at Hartford Hospital, so that their volumes are kept up, and, also, by using their simulation center.

We have a simulation center with a $200,000 module that simulates catheterizations. No, it does not replace clinical care, but it does facilitate the training.

This is not something that's totally novel to us, because we did help establish the Backus diagnostic cath lab in the first place, and that was done with oversight from Fran Kiernan, and, also, we've helped establish the Hospital of Central Connecticut oversight, so the take home message is that the Backus cath lab will be part of the Hartford HealthCare Heart and Vascular Institute and will be an extension of the cardiac catheterization lab at Hartford Hospital.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: Thank you. Attorney Volpe, do you have any follow-up?

DR. CAMBI: Hearing Officer Hansted, you

can reject me, but you made a comment that appealed to me before. You said this hearing is in the interest of finding facts and understanding the situation to the best of our ability.

It just occurred to me while they were talking that there is a significant way volume will be impacted at L & M if Backus were to get an elective program.

MR. COHEN: I want to object.

HEARING OFFICER HANSTED: Wait, wait, wait, wait, wait, wait. Microphone.

MR. COHEN: This is not the question that he's answering. If he wants to answer that question, Dr. Thompson testified regarding the integration of the Hartford --

HEARING OFFICER HANSTED: Okay. Attorney Volpe, do you have any follow-up on what Dr. Thompson just testified to?

MS. VOLPE: Regarding integration of the program?

HEARING OFFICER HANSTED: Yes.

MS. VOLPE: He didn't offer anything new. That's already in the application.

HEARING OFFICER HANSTED: Okay. Attorney

Cohen, I'd like you to give the doctor the microphone back, because I want to hear what he has to add to the previous question.

DR. CAMBI: Sometimes it's hard to think on the spot, and I was just reflecting on your question about volume loss.

At L & M, part of the elective volume, the non-STEMI volume, are on inpatients, patients, who come to the ER with chest pain, not having a heart attack, but chest pain, right? They get admitted to the hospital, and they have an abnormal stress test, they get an angiogram, and we identify a partial blockage that requires a stent. That's an elective case.

Well if those patients go to Backus and they now have a program, it doesn't matter who their doctor is. Insurance companies won't pay for them to be transferred to a hospital 10 minutes away if that service is already offered at the initial presenting hospital, and, so, you see, if patients are presenting near Backus and they have a chest pain syndrome and they go to Backus Hospital, whereas now they might come to L & M, we're going to lose that volume of elective cases, and I don't think John would disagree with that. That's fairly certain.

HEARING OFFICER HANSTED: Okay. Just a follow-up to that.

DR. CAMBI: Yeah.

HEARING OFFICER HANSTED: Is that true with any insurance plan?

DR. CAMBI: As far as I know, and, you know, I'm not an expert in --

HEARING OFFICER HANSTED: Right. Obviously, in your experience.

DR. CAMBI: In my experience, that we often run up against that. If the current level of service is offered at a treating hospital, insurances will not pay for the patient to go to another hospital for the same level of care, just because they want to, or because it's a patient preference, or because it's a doc preference.

HEARING OFFICER HANSTED: Okay, now, is that true in any situation, or just a situation, where the elective angioplasty is needed on a more short-term basis in the initial diagnosis?

DR. CAMBI: Correct. So that's why I didn't think of it at first. So there are multiple scenarios, in which people arrive at an elective PCI. One is where they come in as an outpatient, and maybe

they have some symptoms that are stable and a blockage is identified. While there, they can be sent wherever, okay?

The other scenario is, when they're admitted to the hospital with something that's not a heart attack, but something a little more urgent than a stable coronary disease as an outpatient, it's in that cohort, and that runs the spectrum from non-ST elevation MI to unstable angina to stable coronary disease.

There are patients in that spectrum that require admission to a hospital and get an elective PCI that I think are the biggest cohort that we stand to lose at L & M.

HEARING OFFICER HANSTED: Okay. Attorney Cohen, do you want to have someone follow-up on that?

MR. COHEN: Yeah. That leads to a lot of questions of Dr. Cambi. How many patients present at Backus today from the, I mean at L & M today from the Backus angioplasty area for non-STEMIs?

DR. CAMBI: I have no idea.

MR. COHEN: You'll be pleased to know that we have an idea, and we're going to address that.

HEARING OFFICER HANSTED: If you could just identify yourself for the record?

MS. EDWARDS: Sure. My name is Janette Edwards. We presented in our application that L & M today only holds three percent of the inpatient market share in the angioplasty region, as we've defined it for ourselves, and looking at L & M data that they submitted to OHCA as part of their agreed settlement for their elective PCI CON, year-to-date of 2016 there's been only four elective cases that have presented at L & M from the angioplasty region, and, in 2015, there were only four inpatient elective cases and six outpatient elective cases, so, in our estimation, patients today from the angioplasty region are not utilizing Lawrence & Memorial Hospital for these services, and any impact that our program would have would be immaterial.

HEARING OFFICER HANSTED: Okay. I think we've had sufficient testimony on this subject. Let's move along.

MR. COHEN: I believe you may have touched on this, but just to complete the thought, can you clarify the training that the staff would have, the Backus PCI staff would have?

DR. THOMPSON: So there are two groups that are being trained. One is the physicians, obviously. We're going to recruit people, who are

capable of doing that, but they'll be overseen in their performance by Fran Kiernan and his group. In other words, experienced operators would be overseeing less experienced operators, should we recruit, less experienced operators.

The second part of that is training the staff. Because we're an institute, one of the goals of an institute is have the same care throughout, because there's a rule in medicine that variance in care often means less quality care, so we'll have people trained both in our lab and, also, using the simulation center to nurses, techs, etcetera, to do everything the same way, so they'll be training both in live and, also, in simulation to make sure that we use the same standards of care throughout the system, and that, again, is using our, you know, $10 million training center that's used by many groups, including the Navy, and the Army, etcetera, etcetera. People come in to use our training center.

HEARING OFFICER HANSTED: Thank you. Attorney Volpe, nothing? Thank you.

MR. COHEN: Okay. At this point -- thank you, Drs. Foley and Thompson. At this point, we'd like Becky Durham to come up. I'm trying to limit the questions for you.

Ms. Durham, the Intervenors have stated that the Applicants ignored the 2014 SCAI ACC/AHA expert consensus document update on PCI without on-site surgical backup. Can you clarify the Applicant's use of the 2011 and '14 guidelines?

MS. DURHAM: Yes, I can. Becky Durham, for the record. We actually included both the 2011 and 2014 guidelines in our CON. Exhibit 1 was the 2014 guidelines. Exhibit 9, the 2011 guidelines.

We chose to use the 2011 guidelines for percutaneous coronary intervention in our figure four of the application, where we discuss some of the operational pieces of the program, and that is because it was the broader heart of the guidelines from 2011 versus the update in 2014.

The big thing about the guidelines that I want to make sure people understand is that, when the application goes in, that's a stagnant point in time. These guidelines come out every few years, and as we are part of the Heart and Vascular Institute with Hartford HealthCare, we have to look at these guideline as they come out and ensure, whenever you're building a program or continuing a high-quality program like at Hartford Hospital, that we're looking at the most up-to-date

guidelines as they come out, so, in 2016/'17, new guidelines can come out that we've got to ensure that we're utilizing for the best outcomes of our patients, and that's what we will be doing.

MR. COHEN: If I could follow-up, because it's directly related to this, and then we can --

HEARING OFFICER HANSTED: I'll allow that.

MR. COHEN: Okay, thank you. Comparing the 2011 and 2014 guidelines, can you briefly tell us how the application complies with both sets of guidelines?

MS. VOLPE: I'm going to object to that.

HEARING OFFICER HANSTED: Well, Attorney Volpe, I'm going to allow that, because I -- before you answer that question, it was my understanding that the 2014 guidelines would replace the 2011 guidelines. Is that not true?

MS. DURHAM: Correct. My personal opinion, and I think my colleagues would agree, is it doesn't replace, because it's very specific. The 2014 is without surgical backup, where the 2011 guidelines is guidelines for percutaneous intervention overall, so, you know, if you have a surgery, a site with surgery, that is not included.

HEARING OFFICER HANSTED: Right.

MS. DURHAM: So this is a more broader guideline.

HEARING OFFICER HANSTED: Okay, so, the 2014 update was only an update, as to specific subjects?

MS. DURHAM: Without on-site surgery.

HEARING OFFICER HANSTED: Without on-site.

MS. DURHAM: Correct.

HEARING OFFICER HANSTED: Okay, so, the 2011 guidelines still hold true for the with on-site?

MS. DURHAM: Correct. It does, yes. And I can go through very quickly, if you'd like to hear.

HEARING OFFICER HANSTED: No. As long as I know, generally speaking, that the 2011 still have some validity, that's fine with me.

MS. DURHAM: Correct.

HEARING OFFICER HANSTED: Okay, thank you.

MR. COHEN: And just to clarify, Mr. Hansted, the 2011 guidelines even have validity for a program like Backus, so there are aspects of that 2011 guidance that weren't addressed by the 2014 update.

HEARING OFFICER HANSTED: Okay. Attorney Volpe, did you have something?

MS. VOLPE: Well I think we do want to address that, because we have the 2011 guidelines and the

2014. I mean it has a reference to on-site surgical hospitals without on-site surgical backup and recommendations for 2011, which have changed.

HEARING OFFICER HANSTED: Okay. I want to hear that, because I want to know which guidelines are actually in effect at this moment in time. We just need a microphone for you, Doctor. Attorney Cohen, if you could give him the microphone?

MR. COHEN: Well if we wanted to have Becky Durham talk about the 2011 and ’14 guidelines?

HEARING OFFICER HANSTED: Well let me -- I want to hear from this doctor first.

DR. CAMBI: It’s my understanding the 2011 guideline, I agree with Becky, is a guidelines for percutaneous coronary intervention PCI, making no distinction in the title about on-site or off-site.

The 2014 updated guideline is specifically addressing PCI without on-site surgical backup, however, there is lots of information here in the 2011 guideline that specifically focuses on PCI in hospitals without on-site surgical backup, therefore, this document, anything this document speaks on --

HEARING OFFICER HANSTED: That document being the 2014 guidelines?

DR. CAMBI: ’14. Would trump or replace sections in this document that speak to PCI in centers without on-site surgical backup. Does that make sense?

HEARING OFFICER HANSTED: Right, and I believe she agreed with that.

DR. CAMBI: Okay.

MS. DURHAM: And I would just say, as I said earlier, as guidelines change, we have to adapt to those, so it’s not that we’re going to build a program on the 2011 guidelines. We’re going to say, in 2016, did a more focused update come? Those are the guidelines that we have to look at to ensure we’re having the best patient outcomes. Guidelines are a fluid process compared to an application, you know, that goes in at one point in time.

HEARING OFFICER HANSTED: Right, right, so I think we’re all on the same page. She’s just talking about what they would rely upon.

My general question was what would anybody rely upon, and I think we have --

MS. DURHAM: The most up-to-date guidelines.

HEARING OFFICER HANSTED: Right.

MS. DURHAM: Absolutely.

HEARING OFFICER HANSTED: Okay. All right, thank you, all.

MR. COHEN: Okay, thank you. Now we're going to have Dr. Kiernan come up and answer a couple of questions.

Thank you, Dr. Kiernan. There's been a lot said at the last hearing regarding 120 and 90-minute guidelines. As the Director of the Hartford Hospital cardiac lab, as an interventional cardiologist, can you please clarify for us what each of those standards are and what they apply to?

DR. KIERNAN: Certainly. My name is Francis Kiernan. The guidelines are actually performance measures. The guidelines have evolved over the years. Initially, for example, it was felt that if PCI could be performed for someone with an acute myocardial infarction, it should be performed within 120 minutes at a PCI-capable center.

As for the issue, that if you treated the patient with myocardial infarction earlier, they had better outcomes, and we hear the term throughout this hearing of time being muscle, but, more important, time equates to survival.

The highest risk period for someone with

acute myocardial infarction is early. Many people unfortunately pass away before they even get to the hospital. People, who are lucky enough to get to a hospital, have a much higher chance of survival.

The performance measure for patients, who present to a PCI-capable center, were adjusted, so that the hospital should be able to perform this procedure within 90 minutes of arrival at the door.

Now it was further recognized over the years that treating an acute myocardial infarction is not just a hospital-based effort. It really starts with EMS.

In the American Heart Association, American College of Cardiology, they’re referred to systems of care, and the systems of care bring the EMS system into the picture, so now we look at a concept of first medical contact. That is, when EMS first arrives on the scene, the expectation is that a PCI-capable center should be able to perform PCI within 90 minutes of that first medical contact.

Now what happens to a patient, who presents to a hospital without that PCI capability? Well, obviously, a decision has to be made. Now the decision tree consists of the two options.

One is to transfer the patient to a center

that can perform PCI. It's thought that that's reasonable if that process can be done within 120 minutes. The other option is to give a clot-busting drug, such as tPA.

Now why not just give tPA? Well many studies have shown that PCI for acute MI has a benefit over tPA, and that's a survival benefit, so it's more important to give this life-saving therapy, if possible, but it's only going to work if it's done quickly, and that's the reason for the development of these guidelines, which are really performance measures.

MR. COHEN: Thank you.

HEARING OFFICER HANSTED: Attorney Volpe, do you have anything?

MS. VOLPE: I'll ask the doctor --

DR. CAMBI: I guess I would just say that I completely agree with everything he said, except that the only thing I would suggest to the panel is that these guidelines are created and designed by a panel of experts, much like Dr. Kiernan, himself, after pouring over reams of scientific study and literature, to come up with a framework to help guide places like us in our situation on how best to allocate resources and deliver ideal standards of care.

And, so, as he points out, when a patient presents in an area without a PCI center, a decision needs to be made, and those decisions involve making a choice. If it's going to take me longer than 120 minutes to get this patient to a PCI-capable center and get that artery open, scientific evidence would suggest that that patient does better receiving thrombolytics.

In the Applicant's case, it takes them typically in this situation greater than 120 minutes to get that patient to a PCI-capable center. No thrombolytics were ever administered there, and patients weren't routinely sent to the nearest capable PCI center, which is L & M, so I agree with Dr. Kiernan on his point on how we think about guidelines and how they are designed to help us frame practice standards in our region.

HEARING OFFICER HANSTED: Okay. I just have one question for you, Doctor. So the 120 minutes, that's the time they need to get the patient to the hospital and to complete the procedure?

DR. KIERNAN: No. The 120-minute guideline refers to a patient, who presents to a hospital without PCI capabilities.

The 30 minutes additional time is the

transfer time, theoretically, so you'd make a decision, the patient presents at a non-PCI hospital, as to whether or not you can get them to a center that can perform the PCI within 120 minutes from first medical contact.

HEARING OFFICER HANSTED: Right, so, including the travel time?

DR. KIERNAN: It includes the travel time, absolutely.

HEARING OFFICER HANSTED: Okay. Right, so, the travel time really is, what we're looking at here, is the 30 minutes, because it's 90 minutes for the procedure?

DR. KIERNAN: Well yes and no. For example, if a patient arrives within, you know, 30 minutes of first medical contact to a non-PCI hospital, well then you have an additional 90 minutes to get them to a place to get the door open. You can't the vessel open theoretically. Now the earlier you do that, the better it is.

HEARING OFFICER HANSTED: Right. Okay, thank you.

MR. COHEN: Okay, thank you. Dr. Kiernan, will 100 percent of the PCIs performed at Hartford Hospital from the Backus angioplasty region shift to

Backus?

DR. KIERNAN: My expectation would be that they wouldn't, because, at a hospital without surgical backup on site, one would not want to do relatively high-risk procedures that require special equipment, such as atherectomy catheters, left ventricular support catheters, etcetera, because it just wouldn't be safe to do that.

So I think we were relatively conservative in our application by saying that I believe about 40 percent of the patients, who would be candidates for non-myocardial infarction angioplasty at Backus, would likely be transferred to a place that can offer a higher level of care that is with surgical backup.

MR. COHEN: Thank you.

MS. VOLPE: So, if I may, on page 1466 of your application, this is in your completeness questions on page 1466, the Applicant -- can you tell us what -- your testimony is directly contrary to what you submitted in your application. I'm asking the doctor the question.

HEARING OFFICER HANSTED: That was page 1466 of the application?

MS. VOLPE: Yeah. The completeness questions that OHCA presented asked for projected

angioplasty region, PCI volume shift to Backus, and, under the Hartford Hospital category, they put 100 percent would shift to Backus from Hartford in the region.

MR. COHEN: Janette Edwards would be the best person to answer this question.

HEARING OFFICER HANSTED: Well I'd like to have the doctor just clarify that, because it was his statement, so if he could clarify?

DR. KIERNAN: My understanding was that I honestly did not participate in the development of this, this graph that you're looking at, but I think that was a worst case scenario, but, from a medical perspective and as the potential future Medical Director of this laboratory, I can say that certainly 100 percent of the procedures would not be done.

I believe Ms. Edwards has some information on page 490 that 40 percent of cases were backed out on that particular.

MS. VOLPE: Okay, but this is an important point, because their testimony here today directly impacts their projections on volume.

MR. COHEN: Actually, I think Janette Edwards would be the best person to talk about this.

HEARING OFFICER HANSTED: Okay. Let's have Ms. Edwards address that.

MS. EDWARDS: So the chart on page 1446 actually is answering a different question than the way Attorney Volpe is framing it, so, on page 490 of our application, where we outline the potential Backus elective and total PCI volume projections, we clearly back out 40 percent of NSTEMI or potential elective volume, due to their complexity, understanding that those cases would still be better suited to be performed in a tertiary care location. On page --

HEARING OFFICER HANSTED: Let me just stop you there.

MS. EDWARDS: Sure.

HEARING OFFICER HANSTED: Is that the percent complex elective PCI?

MS. EDWARDS: Correct.

HEARING OFFICER HANSTED: 39.5 percent?

MS. EDWARDS: Yes.

HEARING OFFICER HANSTED: Okay. I see that is backed out.

MS. EDWARDS: We took 39.5 percent of that potential, our projected 486 potential cases, actually, so what we termed non-complex elective PCI originating

from the service area is 295.

HEARING OFFICER HANSTED: Okay and that's the 40 percent that the doctor just testified to?

MS. EDWARDS: Correct.

HEARING OFFICER HANSTED: Okay. I follow that.

MS. EDWARDS: So on the incompleteness questions, the question OHCA asked us was how the proposal will not result in a shift in volumes from existing providers and how there will be no impact on existing providers, and, due to the way we approached our projections, we wanted to try to get at this information in the most conservative and accurate way possible.

So the chart on page 1466 actually outlines a worst case scenario, illustrating to OHCA that even if, and I stress the word "if," 100 percent of the volume seen at Hartford Hospital originating from the Backus angioplasty region were to shift to Backus Hospital, there would be no impact in volume or compromising of the Hartford Hospital program.

Below that, what we did was we applied a 36 percent inpatient market share to all of the other volume originating from the angioplasty region to come up with the projected PCI volume shift to Backus, and you'll

note that, in total, we're only six cases off from our original projection, so it was just a different methodology to try to answer OHCA's question.

HEARING OFFICER HANSTED: Okay.

DR. CAMBI: That helps clarify the discrepancy. My only remaining comment --

MS. JESSICA SCHAEFFER-HELMECKI: Excuse me. Can I just follow-up quickly with one question while we're on the topic, just to clarify?

Why did we use the 36 percent for the market share shift?

MS. EDWARDS: So we used 36 percent, because, when you look at Backus Hospital alone, we did not look at Hartford HealthCare in totality, we really looked just at Backus Hospital for this market, Backus Hospital overall captures 36 percent of the inpatient market share for the total angioplasty region, as we've defined it, so those 38 zip codes, our inpatient market share at Backus is about 36 percent.

MS. SCHAEFFER-HELMECKI: Okay. The inpatient market share, not just specific to the angioplasty?

MS. EDWARDS: That is correct. As a way to try to project what we might actually have as a

potential impact, we used our inpatient market share.

MS. SCHAEFFER-HELMECKI: Okay, thank you.

MS. VOLPE: But that's to a different service area, though. Their inpatient 30 percent is to a different service area than angioplasty?

MS. EDWARDS: Correct.

HEARING OFFICER HANSTED: She stated that. We understand that.

DR. CAMBI: Thanks, again, for the clarification. I may be reading this wrong, as well, but it looks like the volume projections, based on the charts and graphs, are all shifts from existing providers.

I'm not making the connection on how this ties into unmet need.

MS. EDWARDS: Is that a question for me?

HEARING OFFICER HANSTED: Well, no, he can't question you. He's not an attorney.

MS. EDWARDS: That's what I thought.

HEARING OFFICER HANSTED: With all due respect, Doctor. If Attorney Volpe would like to question her, she may. She needs the microphone back. I know you hesitated, Attorney Cohen.

MR. COHEN: I did.

DR. CAMBI: Sorry.

HEARING OFFICER HANSTED: That's okay.

MS. VOLPE: So all of the volume projected is shown as a shift from existing providers, as opposed to an unmet need?

MS. EDWARDS: No. So, again, this question is answering a very specific -- the answer is answering a very specific question, as outlined by OHCA. What we have illustrated in our application is that patients from this region are suffering from NSTEMI and STEMI at a higher rate than the state or the nation, yet are receiving this intervention at a lower rate than the state or the nation, so, in our estimation, there's probably between 50 to 52 cases that are just not being served today.

MS. VOLPE: Okay, you've answered the question. Thank you. We do have a follow-up question for Dr. Kiernan.

HEARING OFFICER HANSTED: I just want her to be able to finish her statement in full.

MS. EDWARDS: And what I'd just like to point out is that, right now, the region that we've illustrated as our angioplasty region has 230,000 people, who are not receiving care in the same way, as you can see by our map.

They’re not receiving the same standard of care as the majority of the rest of our state, and, right now, according to our late file, there are 160,000 people, who have no access to this care within 30 minutes of a drive time.

So, in our estimation, yes, there’s 50 to 52 cases that are not being serviced right now in our service area, and the remaining individuals, who require this intervention, are forced to either leave the state or travel great distances to receive care.

HEARING OFFICER HANSTED: Thank you. Attorney Volpe, you had a question for the doctor?

MS. VOLPE: Dr. Kiernan, is it your position that the patients in the angioplasty region none of them can receive care within 120 minutes? I mean that is the national standard, correct?

DR. KIERNAN: That’s the national standard for a patient, who is transferred to another facility, and, obviously, it would depend upon, you know, the transportation system to get people to various hospitals, so, certainly, people within that region can receive care within 120 minutes.

MS. VOLPE: Right, so, they can receive care within 120 minutes, and that is -- excuse me. So

your statement is they can receive care within 120 minutes, and that is the national standard?

HEARING OFFICER HANSTED: That's what he testified to.

MS. VOLPE: Yes, thank you. I have no further questions.

MR. COHEN: Dr. Kiernan, along those lines, is getting someone into a cath lab and the vessel opened within 90 minutes better than 120 minutes?

DR. KIERNAN: I believe I testified to that previously. The earlier the angioplasty performed the better the outcomes, in terms of not only morbidity, but, also, mortality, so if you could have the procedure within 30 minutes, the expected outcomes would be even better.

MS. VOLPE: So, Dr. Kiernan, I think everyone would agree with that statement, that, you know, you need to open up the heart sooner, so then I would ask you why would someone presented to Backus are they not transferred to L & M, which is only 17 miles away, 21 minutes?

DR. KIERNAN: I would defer that question to the physicians at Backus, since I don't practice there.

MS. VOLPE: Okay.

HEARING OFFICER HANSTED: Do you want to have someone else testify?

MS. VOLPE: If you practiced at Backus, would you refer them to a closer facility?

HEARING OFFICER HANSTED: Well, Attorney Volpe, I'm not going to have him answer that question. That's pure speculation. He testified that he doesn't practice there.

MS. VOLPE: But he's going to be overseeing the program.

HEARING OFFICER HANSTED: I understand that, but there is no program yet, so if a doctor, who currently works at Backus, wants to testify, as to that question, then I'm happy to hear that, but not this particular doctor.

Attorney Cohen, do you want to present someone else to answer that question?

MR. COHEN: I have another question.

HEARING OFFICER HANSTED: Wait, wait, wait. We're still on Attorney Volpe's.

MS. VOLPE: I don't need that question answered. I think it was answered already.

HEARING OFFICER HANSTED: Okay. All

right, thank you.

MR. COHEN: Okay, thank you. Dr. Kiernan, can you address the issue of 50-plus minutes to activate the Backus cath lab that was discussed at the prior hearing?

DR. KIERNAN: Again, I think there was a little bit of misunderstanding there, in the sense that I believe the application presented a worst case scenario for activation of the cath lab.

We would certainly strive to employ a system, much like we use at Hartford Hospital, where we use pre-hospital ACGs to activate the cath lab while a patient is being transported to the hospital.

The cath lab staff is also en route to the hospital and often times ready to treat the patient within a few minutes of arrival, rather than 50 minutes of arrival.

In Hartford, we have a lab set up and prepared. A table is prepared, covered and ready to go, and we use the ER staff to help transport the patient to the laboratory and get the patient setup, so that we can perform the procedure quickly, and my expectation is that we would use that same system at Backus Hospital, much like we do at Hartford Hospital and as we do at our other

hospital in the system that provides emergency angioplasty at HOCC.

MR. COHEN: Thank you.

MS. VOLPE: We don't have any questions.

MR. COHEN: Okay. This is the last question for you, Dr. Kiernan. Did you consider the 2014 SCAI ACC/AHA expert consensus document and its statement, quote, "Multiple low volume and partial service PCI centers within a geographic area increase costs to the overall health system and have not been shown to improve access," and that, quote, "The development of PCI facilities within a 30-minute emergency transfer time to an established facility is, therefore, strongly discouraged," closed quote, in the context of this application?

DR. KIERNAN: Again, I think we have to understand the guidelines and, as Dr. Cambi said, our guidelines. They're the recommendations for best practice, however, the guidelines specifically have a statement that indicates that programs that are geographically isolated are exempt from this particular requirement.

I think, as other members of our team have testified, there are -- that this region is somewhat

geographically isolated, with approximately 160,000 people, who would be within a 30-minute drive time of this center, and, you know, another several thousand people that, you know, would be within a few minutes more than the 30-minute recommendation.

MS. SCHAEFFER-HELMECKI: So with regards to that geographically isolation standard, it says 30 minutes not from the town, correct? It's 30 minutes to the other facility, so even if a town is more than 30 minutes away, or a patient is more than 30 minutes away, the standard looks at hospital-to-hospital, correct?

DR. KIERNAN: The 120 minutes refers to a hospital-to-hospital transfer.

MS. SCHAEFFER-HELMECKI: Oh, excuse me. Not the 120 minutes. The 30 minutes, as to whether or not it's geographically isolated.

DR. KIERNAN: That's the expectation, that you should be able to get to a hospital within 30 minutes of being picked up by EMS.

MS. SCHAEFFER-HELMECKI: Well it defines geographic isolation to exist if the emergency transport time to another facility is 30 minutes or more, so L & M is 21 minutes, I believe? (Multiple conversations)

DR. KIERNAN: We're suggesting that people

north, to the north of L & M, not to the north, of Backus, rather, you know, within that 30-minute radius of Backus, it would be approximately 50 minutes to get to Backus if they were at the outer perimeter of the radius from Backus, if you will.

MS. SCHAEFFER-HELMECKI: But if they were presenting at Backus and they had to be transferred to another facility, it would be less than 30 minutes to get to L & M?

DR. KIERNAN: Yes.

MS. SCHAEFFER-HELMECKI: Okay, thank you.

MS. VOLPE: That addressed our question, and that is specific to what the guideline states.

HEARING OFFICER HANSTED: Attorney Cohen?

MR. COHEN: No further questions for Dr. Kiernan. We're done with our Redirect.

HEARING OFFICER HANSTED: Okay. Let's take a 10-minute break at this point, and then we'll get to you.

MS. VOLPE: Thank you.

MR. COHEN: Just so that we're clear, Mr. Hansted, after the break, what will occur?

HEARING OFFICER HANSTED: Attorney Volpe will proceed with her Cross.

MS. VOLPE: No.

HEARING OFFICER HANSTED: I'm sorry.

MR. COHEN: No. She's done her Cross already.

MS. VOLPE: Attorney Cohen will have the ability to Cross-Examine the Intervenor.

MR. COHEN: Correct.

HEARING OFFICER HANSTED: Thank you for clarifying that. It's been a very confusing two months' worth of hearing, coupled with the microphone passing. That's what will happen, Attorney Cohen.

MR. COHEN: Thank you.

(Off the record)

HEARING OFFICER HANSTED: Okay. We are back on the record. Attorney Cohen, if you want to proceed?

MR. COHEN: Thank you. Dr. Cambi, can you tell me what is L & M's service area?

MS. VOLPE: L & M's service area? Sure. I'm sure we have that.

DR. CAMBI: Primary? Secondary?

MR. COHEN: However you want to define what's your service area.

MS. VOLPE: We can provide that, but I

don't know that I have it right now.

HEARING OFFICER HANSTED: Okay.

MS. VOLPE: It's on the website. OHCA has it. I mean you can ask a question.

DR. CAMBI: I don't know the names of all the towns off the top of my head.

HEARING OFFICER HANSTED: Okay, so, he doesn't know at this present time. Would you like him to file a late file?

MR. COHEN: No.

HEARING OFFICER HANSTED: Okay.

MR. COHEN: Dr. Cambi, do you -- does your service area include all of the individuals in the Backus angioplasty region?

DR. CAMBI: No.

MR. COHEN: What individuals does it include?

MS. VOLPE: What individual or town?

MR. COHEN: Towns, zip codes, individual people, if he knows any.

HEARING OFFICER HANSTED: Well that would be tough to answer.

MR. COHEN: Out of 230,000, it would be.

DR. CAMBI: I can answer it. Maybe this

is the best way I can answer it. My service area is any patient that presents to me at L & M Hospital or is referred to me in my outpatient practice by another colleague.

I have patients that come as far as New York, Massachusetts and Rhode Island, so I consider all of those areas my service area.

MR. COHEN: How many patients from the Backus angioplasty region, as defined in this application, have you provided PCI services to?

DR. CAMBI: I don't walk around with that number, but I'd be happy to put them together for you.

MR. COHEN: Is there anyone on your witness panel that knows the answer to that question?

DR. CAMBI: Are you talking about in all my years performing interventions?

MR. COHEN: Well we can start with 2015. How many patients? This is a critical question, because you're claiming that this is going to have a significant impact on your program. You must have calculated how many patients are --

HEARING OFFICER HANSTED: Doctor, he's not talking specifically to you. He's talking about L & M's program.

MS. VOLPE: Well we can address the financial impact. I think that's your question.

MR. COHEN: Well I did not ask a financial --

HEARING OFFICER HANSTED: No, that wasn't the question. (Multiple conversations) One at a time, please.

MS. VOLPE: The numbers of patients that we service, I mean you provided the number, and we responded to it, so it's in the application.

MR. COHEN: Again, I'm going to ask. Their testimony was that this program will have a significant detrimental impact on them, because we are going to take many of their patients.

I want to know how many patients. The answer could be I don't know, but I want them to answer the question, as to how many patients.

MS. VOLPE: We're ready to answer the question.

MR. COHEN: Thank you.

MS. PATEL: This is Shraddha Patel. According to the data that actually Backus put together, based on our information that we provided, will go on a quarterly basis. There were 32 cases in fiscal year '15

that emanated from the angioplasty region, and that's about -- and we have a total of about 200 cases, so that's a significant portion.

MR. COHEN: Two hundred and 16 cases, is that correct?

MS. PATEL: Correct.

MR. COHEN: Okay and, in 2014, how many cases originated from the Backus angioplasty region?

MS. VOLPE: So that number was --

MR. COHEN: I'm sorry. I would like the witness to --

MS. VOLPE: No.

HEARING OFFICER HANSTED: She's just clarifying the question.

MS. VOLPE: So the number we just gave you was 2015, which is more recent. You'd like us to give you 2014?

HEARING OFFICER HANSTED: That was the question, yes.

MS. VOLPE: Okay. Do we have that? I mean we're looking through the application, because it's in there, because the Applicant provided it, so, I mean, we're happy to find it.

I think, if he wants to ask his follow-up

question, but, I mean, we testified in 2015 it was 32 cases, which is, you know, in excess of 15 percent of our --

HEARING OFFICER HANSTED: Okay, one moment. Attorney Cohen, we're looking for that information, also. Do you know that you've already supplied that to save us some time, because I'm happy to come back for a third day of hearing.

MR. COHEN: Page 487.

HEARING OFFICER HANSTED: Thank you. All right, do you have another question, based upon that volume?

MR. COHEN: Can you tell me how many procedures were performed from the Backus angioplasty region at L & M in 2014?

HEARING OFFICER HANSTED: We're going around in circles. You just said you supplied that information.

MR. COHEN: I'm going to follow-up.

HEARING OFFICER HANSTED: Okay and what page is that on?

MR. COHEN: This is on 487.

HEARING OFFICER HANSTED: Page 487.

MS. VOLPE: Yup, we have it.

HEARING OFFICER HANSTED: Okay.

MS. VOLPE: What's your question?

HEARING OFFICER HANSTED: What was the volume for 2014 from the Backus region?

MS. PATEL: Twenty-two cases.

MR. COHEN: And how many of those were primary?

MS. VOLPE: I mean just in the interest of time, he's asking us to restate things that's in his application, so if we can get to the question, I think that would be important.

HEARING OFFICER HANSTED: And that was what I was hinting at before. I'm happy to have you lead the witness if you want.

MR. COHEN: Fine. I thought I'd face objections to that, but would you agree that there were two primary angioplasties performed at Backus, at L & M from the Backus angioplasty region in 2014?

MS. PATEL: I'm sorry. Can you say that question again, please?

MR. COHEN: This is like pulling teeth. Please turn to page 487.

MS. PATEL: I have it here.

MR. COHEN: On the upper left-hand corner,

do you see primary PCI?

MS. PATEL: Yes.

MR. COHEN: How many do you see in 2014?

MS. PATEL: Two.

MR. COHEN: And elective PCI inpatient, do you see that reference?

MS. PATEL: Yes, I do.

MR. COHEN: Those are the patients that Dr. Cambi testified to earlier, is that correct, patients that present at L & M Hospital that are inpatient and need a cath, is that correct?

MS. PATEL: Correct.

MR. COHEN: Okay, so, what's the total there for 2014?

MS. PATEL: Well 2014, it's seven. It's very different in '15, fiscal year '15, but, for fiscal year '14, it's seven.

MR. COHEN: Fiscal year '15 is the high watermark, isn't that right?

MS. PATEL: I don't understand what you're saying.

MR. COHEN: So do you know the numbers for 2016?

MS. PATEL: No.

MR. COHEN: You presented two years, two quarters of data to OHCA. Do you know those numbers?

MS. PATEL: I do not.

MR. COHEN: Would it surprise you if there were four primary PCIs and four elective caths from the Backus region that presented at L & M?

MS. PATEL: I know that PCI volumes are declining statewide and nationally, so it doesn't completely surprise me that volumes from any town would be lower this fiscal year --

MR. COHEN: So your testimony is that you would have less caths, you would have less PCIs this year than you would last year?

MS. PATEL: Again, this year is not complete yet, so I can't answer that question, but you're asking me if I would anticipate lower volumes. Potentially, just because of how things are tending statewide and nationally.

MR. COHEN: Sure. So would it surprise you that, in 2015, the first two quarters, you had 70 PCIs done at L & M, I'm sorry, 2015, you had 70, and, in 2016, your data reflects that you had 85? That's a significant, approximately 20 percent, increase in PCIs, so do you want to restate your answer to the question?

DR. CAMBI: Those last numbers, just clarify for me, if you wouldn't mind. Are those primary PCIs or?

MR. COHEN: Total.

DR. CAMBI: Total. That wouldn't surprise me. As you know, we were granted elective PCI in 2013. As you begin a novel program, it's important to do the lowest risk patients first, and then, as the program matures and develops and word of mouth spreads, it's natural that volumes increase as time goes on.

MR. COHEN: So --

DR. CAMBI: Let me just finish, if you don't mind. So that doesn't surprise me, that volume has increased by that amount over those two time periods.

MR. COHEN: Okay, but that increase is all from other than the Backus angioplasty region. As I indicated to you a few moments ago, there's eight of 85 procedures in 2016 that you guys have reported.

That's OHCA data, so it shows that, in fact, there's an increase in PCIs being done at L & M Hospital.

DR. CAMBI: The only thing that registered to me was that, in the most recent complete fiscal year's worth of data you reported -- how many patients from

their angioplasty region?

MS. VOLPE: Thirty-two.

DR. CAMBI: Thirty-two, which is the highest number reported so far, in terms of fiscal year data that's complete, which makes sense to me, because volumes increasing.

If we were to lose that number, our volume would be substantially reduced, and, as you probably know, the metric for quality programs that combine elective and emergency PCI is 200.

MR. COHEN: We'll ask about that in a minute. So, Dr. Cambi --

DR. CAMBI: Mr. Hansted, can I finish my comment?

HEARING OFFICER HANSTED: No, no. You know what? Here's how we're going to proceed from now on. There's going to be a very direct question from Attorney Cohen. There's going to be a very direct answer from this side of the room, okay? Otherwise, we will go into a third day of hearing, all right? Thank you.

MR. COHEN: Thank you. Dr. Cambi, you did not know what L & M's service area is for angioplasty services, other than to say that you serve whatever patients come to your door, correct?

DR. CAMBI: I don't remember my exact words, but that was the essence of it. My job is to perform angioplasty and stenting in heart attack victims, not know what my service area is.

MR. COHEN: Do you serve patients -- have you served patients in the last two fiscal years from Norwich? You testified in your pre-filed testimony and in your hearing testimony that the 230,000 patients in this angioplasty region are patients that you serve, so have you served patients in Norwich?

DR. CAMBI: In fiscal year '15, over 15 percent of the patients that I've performed an intervention on or that were performed by a Lawrence & Memorial program came from the angioplasty region, yes, sir.

MR. COHEN: So you serve patients in the Northeast corner of the state?

DR. CAMBI: I cannot say for sure what zip code each patient came from.

MR. COHEN: You heard earlier that the inpatient discharge data reflects that, in the angioplasty region, only three percent of the patients are L & M patients.

MS. VOLPE: What's the question? Where is

the question?

HEARING OFFICER HANSTED: Well he's leading the witness, which, at this point --

MS. VOLPE: Well just ask the direct question, like the Hearing Officer requested. What is your question?

HEARING OFFICER HANSTED: What is the question, Attorney?

MR. COHEN: The question is that we take a great exception to their unfounded statements -- (multiple conversations).

HEARING OFFICER HANSTED: Wait, wait, wait, wait. Stop. I asked you what your question was, not what your exception was, so just ask your question to the witness.

MR. COHEN: Yeah. I'm asking how they can sit here and tell us that this 230,000 patient region is within their service area when they do not serve these patients. Three percent of the inpatient discharge from the -- (multiple conversations).

HEARING OFFICER HANSTED: Attorney Volpe, he did not testify that he doesn't serve those patients. He testified that he does not know the exact originating town for each of his patients.

MR. COHEN: I understand that. In the prior hearing and in their pre-filed testimony, they said that this area with 230,000 patients is within their service area. I'm trying to discern how they make that decision.

MS. VOLPE: That's not what he said, so please ask your question. I think he answered it.

MR. COHEN: Are the 230,000 patients that are in the angioplasty service area, angioplasty region, within the L & M service area?

DR. CAMBI: Again, I don't know how one defines service area. All I can tell you is, based on the data you provided us, that, in fiscal year '15, 32 patients came from, the way you define things, the angioplasty region, and, if we lost that volume, we would fall below the threshold needed to continue to run a quality combined PCI program.

That's really what you're getting at, right, how much volume, if your program went live, would come out of L & M? There's your answer, and that's its effect.

MR. COHEN: Is there anyone on the panel that can answer that question?

MS. VOLPE: Well what is the question?

MR. COHEN: Whether the 230 patients in the angioplasty, the Backus angioplasty region are within L & M's service area.

HEARING OFFICER HANSTED: The 230 patients from --

MR. COHEN: -- 230,000 patients are within the L & M service area. Either their CMS service area, 75 percent, or their set primary service area, their secondary service area --

HEARING OFFICER HANSTED: So you want to know what the overlap is between the L & M service area and the Backus service area?

MS. VOLPE: No, because they define it as an angioplasty region, so it's not their Backus service area. I think the operative question is you're saying, of these 230,000 patients, which you're defining as a separate angioplasty region for purposes of this application, how many are coming to L & M? I mean that's the question.

MR. COHEN: The question, again --

MS. VOLPE: Whether it's our service area or not --

HEARING OFFICER HANSTED: Attorney Volpe --

MR. COHEN: I want to know -- we'll parse it down. If the answer is we don't know, we'll move on. Of the 230,000 patients in the angioplasty region, how many of them are within any defined L & M service area? CMS service area at 75 percent? Primary, 25 percent?

HEARING OFFICER HANSTED: Attorney Volpe, do you have anyone here that can answer that question?

MS. VOLPE: I would ask how many are in Backus' defined CMS service area.

HEARING OFFICER HANSTED: No. My question, Attorney Volpe --

MS. VOLPE: We have the ability -- you're defining service area arbitrarily. If we're trying to determine a population that's being treated now, are we treating some of that angioplasty region? I think we answered that question.

MR. COHEN: We didn't ask that question.

MS. VOLPE: If you want us to do --

HEARING OFFICER HANSTED: Attorney Volpe, my direct question is do you have anyone here present today that can answer that specific question?

MS. VOLPE: The question being how many in their made up angioplasty region of towns are in our primary or secondary service area? Is that the question?

HEARING OFFICER HANSTED: How many of the 230,000 people?

MS. VOLPE: But the 230,000 come from a region, right?

HEARING OFFICER HANSTED: I understand that. I just want to know, yes or no, do you have someone here that can answer that question, however that question --

MS. VOLPE: That is not a question that --

HEARING OFFICER HANSTED: Well that's his question. My question is do you have someone that can answer that specific question?

MS. VOLPE: So, just to clarify the question from Attorney Cohen, his question is, of the 230,000 patients --

HEARING OFFICER HANSTED: No, people.

MS. VOLPE: Of the 230,000 people --

MR. COHEN: In the angioplasty region defined by Backus in its application, how many of those people are in any L & M-defined service area?

MS. VOLPE: We don't know the answer to that question.

MR. COHEN: Okay. They testified that there was in that area, yes. Next question. Dr. Cambi,

you testified at the last hearing that it is critical to restore normal blood flow to compromised heart muscle for patients who are suffering from a heart attack. Do you remember that testimony?

DR. CAMBI: Yes.

MR. COHEN: Do you agree that PCI is the preferred therapy to treat STEMIs?

DR. CAMBI: With the caveat that it needs to be delivered in a timely fashion, yes, sir.

MR. COHEN: Okay. Are you familiar with guidelines requiring that a patient is more than 30 minutes from the PCI-capable facility that that patient needs to be routed to the nearest hospital?

DR. CAMBI: Which guideline statement are you referring to?

MR. COHEN: I'm asking if you're familiar with any guidelines requiring a patient that's more than 30 minutes from a PCI-capable facility have to be routed to the nearest hospital or emergency department.

DR. CAMBI: I am not familiar with any national guideline that mandates --

MR. COHEN: I didn't say national guideline. I said any guideline.

HEARING OFFICER HANSTED: Attorney Cohen,

do you have a guideline in front of you that references the 30 minutes?

MR. COHEN: There is a Department of Public Health OEM guideline that's interpreted by the folks in the eastern region that require that if a patient is more than 30 minutes from a PCI-capable facility, they'd be routed to the nearest ED.

HEARING OFFICER HANSTED: What's the date of that document?

DR. CAMBI: 2012.

HEARING OFFICER HANSTED: So you're familiar with that document, Doctor?

DR. CAMBI: If it's the one I think it is, it's the 2012 state document.

HEARING OFFICER HANSTED: Attorney Cohen, is it dated 2012?

MR. COHEN: Yes, it is.

HEARING OFFICER HANSTED: Doctor, are you familiar with that document?

DR. CAMBI: I am.

HEARING OFFICER HANSTED: Okay. Next question.

MR. COHEN: Doctor, under that guideline to transfer a patient to a -- routed to the nearest

hospital if there's no PCI facility within 30 minutes, what happens in that situation if the patient is 50 minutes from a PCI-capable facility and 25 minutes from another ED, a hospital, or a standalone ED?

DR. CAMBI: Okay. You're creating a hypothetical patient, right?

MR. COHEN: Yes. There are real-life patients that fall into that category.

DR. CAMBI: Well we can't talk about them. It's a HIPAA violation, but there's a hypothetical patient, right, who is how many minutes from a hospital?

He's picked up by EMS. I just want to understand the nature of your question.

MR. COHEN: The patient is more than 30 minutes from a PCI-capable facility.

DR. CAMBI: Is he more than 30 minutes from any hospital?

MR. COHEN: No.

DR. CAMBI: Okay, so, he's picked up by an ambulance? EMS? He's driving? What's happening?

MR. COHEN: Either way, ambulance or EMS.

DR. CAMBI: So he calls 9-1-1, EMS gets there, he's having crushing chest pain, the guidelines state that that patient should be brought to the nearest

hospital, unless there is a PCI-capable hospital within 30 minutes. In that case, the patient should be brought directly there.

MR. COHEN: Thank you. So you agree that if the patient in the angioplasty region is more than 30 minutes from L & M and that patient is suffering chest pains or some other incident like that, that that patient should be brought to the nearest ED, is that correct?

DR. CAMBI: If the patient is more than 30 minutes from L & M and they're having chest pain and we don't have a STEMI identified, correct, they're just having chest pain, and you're worried about an MI, they get brought to the nearest treating emergency room.

MR. COHEN: Thank you.

DR. CAMBI: Do you want me to tell you what happens next?

MR. COHEN: I didn't ask that question.

DR. CAMBI: Okay.

MR. COHEN: Now I'd like to look at page six of your pre-filed testimony, which is page 0019 of your filing. There's a chart of travel time by town to the closest PCI provider.

MS. VOLPE: So is this Dr. Cambi's testimony?

MR. COHEN: No. It's your testimony.

HEARING OFFICER HANSTED: Your, being who?

MR. COHEN: The Intervenors.

MS. VOLPE: It looks like Mr. Rissi's. Dr. Rissi. So bates stamp 0?

MR. COHEN: 00019. It's in Dr. Cambi's pre-filed testimony.

MS. VOLPE: 19?

MR. COHEN: 19.

HEARING OFFICER HANSTED: Dr. Cambi's pre-filed testimony?

MR. COHEN: Yes.

MS. VOLPE: Okay.

MR. COHEN: Do you have that in front of you?

MS. VOLPE: We're getting that.

MR. COHEN: Okay. Let me know when you're ready to go. Specifically, on page 19, I'm looking at the chart. Travel times by town to the closest PCI provider.

MS. VOLPE: Okay. Ask your question.

MR. COHEN: Now this is directed to Dr. Cambi. Looking at the chart, Dr. Cambi, would you agree that there are 15 towns that have a drive time greater

than 30 minutes to the closest PCI provider? Is that yes?

DR. CAMBI: Yes.

MR. COHEN: Okay, thank you. Part of the DPH OEMS guidelines that we just discussed, wouldn't residents of those towns be routed directly to the closest ED and not to L & M?

DR. CAMBI: Well it depends on who is their medical oversight according to the specifics and the dated guideline from 2012, if I'm reading it correctly. Decision regarding appropriate destination hospital should be made in conjunction with indirect and/or direct medical oversight if transport time is greater than 30 minutes.

MR. COHEN: So if a person in Canterbury is having a heart attack or crushing chest pains and they're 21 minutes from Backus according to your chart and 38 minutes to L & M, they'd have to stop at Backus first, isn't that correct?

MS. VOLPE: No, it's not correct.

MR. COHEN: I'm sorry. I'd like the witness to respond.

MS. VOLPE: I'm giving him the guideline.

DR. CAMBI: That's not exactly what it

says here, no, sir.

MR. COHEN: Are you saying that's the way in the field that it's practiced, how you've just indicated, or is it practice that, if it's over 30 minutes to a PCI-capable facility, that's transferred to the nearest ED?

DR. CAMBI: I'm sorry. Could you just repeat your question again?

MR. COHEN: So in the field, as it's practiced today, if someone is more than 30 minutes from a PCI facility, where do they go? Do they go to the PCI facility, or do they go to the nearest ED?

DR. CAMBI: I can't tell you where all those patients go. I'm not privy to that information. I can tell you that the guidelines suggest they talk to someone with medical oversight to help guide them.

MR. COHEN: Do you agree that PCI is the preferred treatment for heart attack over thrombolytics, as you testified earlier, if performed within 120 minutes of onset?

DR. CAMBI: Yes.

MR. COHEN: And how about if it's performed within 90 minutes of onset?

DR. CAMBI: If primary PCI is performed

within 90 minutes, it is a better treatment than thrombolytics. That's your question?

MR. COHEN: Yes, thank you.

DR. CAMBI: I agree with that, yes.

MR. COHEN: Would you agree with the statement that the goal with regard to PCI patients is to clear the vessel as soon as possible?

DR. CAMBI: Well the primary goal is to save their life. The secondary goal is to minimize the amount of permanent heart damage.

MR. COHEN: And -- go ahead. Sorry.

DR. CAMBI: The best way to do that, if you can deliver a reperfusion strategy with a balloon, is to do so less than 90 ideally, less than 120 minutes if you transfer. If you can't do that, Attorney, and it takes you longer than 120 minutes, then the best treatment to reduce mortality and permanent heart damage is, indeed, thrombolytics.

MR. COHEN: So would it be better to open that vessel in 30 minutes rather than 120 minutes?

MS. VOLPE: We established this already. I'm going to object.

MR. COHEN: No, no, no.

MS. VOLPE: We've established this over

and over.

HEARING OFFICER HANSTED: He can answer the question.

DR. CAMBI: Yeah, I agree with my colleague, who mentioned it earlier. The sooner you can open the vessel, Attorney, data clearly shows the better off you are. The difficulty is you can't have a PCI program in every town.

MR. COHEN: I don't think anyone is suggesting that. So you would agree that time correlates to heart muscle as a general statement?

DR. CAMBI: Time to reperfusion correlates to extend of heart muscle damage and mortality. I would agree with that.

MR. COHEN: Thank you. So if a patient had access to PCI at Backus rather than having to be routed to Backus and then transferred to L & M or another facility, as a doctor, you'd agree that it would be better for the patient to be treated at Backus, correct?

DR. CAMBI: No.

MR. COHEN: Why not?

DR. CAMBI: Because -- this is going to be a long-winded answer. I'm sorry. First of all, you imply that Backus already has a well-established, high-

quality program, which they do not.

Secondly, in the application, you discussed that it takes 50 minutes to get the cath lab ready, and, so, that time, that small time savings by arriving at Backus sooner than L & M is completely lost when you consider how long it takes the cath lab to get ready.

Now I agree with Dr. Kiernan that that's not the case all the time, certainly, but approximately 25 percent in our experience, maybe 30 percent, are field activations. There are lots of patients, who drive themselves directly to the emergency room or who are transported with other ways, by other means, rather.

MR. COHEN: Okay, so, you remarked in the hearing that having PCI available within a 30-minute drive is impractical, and that, quote, and this is page 52 from the transcript, "You could go down to Stop & Shop and get your angioplasty for a heart attack."

You go on to say that the 2014 SCAI ACC/AHA guideline supports your conclusion. Are you aware that the conclusion of that document has the following qualifier that you neglected to mention, which is, quote, "New programs offering a PCI without on-site surgery are inappropriate, unless they can clearly serve

geographically-isolated populations?"

MS. VOLPE: Again, what's the question?

HEARING OFFICER HANSTED: No, he did.

MR. COHEN: I asked a question.

DR. CAMBI: The difficulty is that there is no geographic isolation in our state, based on its definition in the document you just referred to, because there is a PCI-capable hospital within 30 minutes, a non-PCI-capable hospital, such as your program, to remind you 17 miles, 21-minute drive time, therefore, the definition, the way it's described in this guideline, does not apply to your facility.

MR. COHEN: We'll address that, I guess, when OHCA has some additional questions for our witnesses. I think our witnesses disagree with those conclusions.

Dr. Cambi, at the last hearing, you stated that the Applicants do not sufficiently set out their staffing requirements and that they'd be creating an environment of inexperienced supporting providers that may lead to unnecessary complications. Do you recall that statement?

DR. CAMBI: In general, yes, sir.

MR. COHEN: So page 57 of the transcript.

How do you define experience in that context?

DR. CAMBI: I would say, having done a requisite number of procedures that involve balloon angioplasty, stenting in a cohort of patients, who are suffering from an ST elevation MI.

MR. COHEN: And what's that requisite number of patients?

DR. CAMBI: I don't have a hard data point or a guideline statement, but if you're asking me my opinion, I would say, for staff to be competent, on the order of 50-plus. We're talking about ancillary staff, or we're talking about interventional operators?

MR. COHEN: Interventional operators and ancillary staff, nurses and techs, so you can answer each individually, if you'd like.

DR. CAMBI: Yeah, sure. So the interventional operators there is some concrete guideline recommendation to maintain competency. You can correct me if something new has come out. Don't hold me to these exact numbers, but, in essence, you should do 70-plus interventions a year, roughly 11 of which should be ST elevation MI, and they usually give a grace period and let that ride over a two-year period, so on average.

In other words, some year you might have

less. Some year, you get more.

MR. COHEN: And how about for staff?

DR. CAMBI: That, I honestly I don't know what the minimum competency is for a cardiac cath lab nurse or a radiologic technologist, in terms of how many PCIs they need to be a part of to be considered competent, but I can tell you the more you have under your belt the higher the quality, the lower the complication rate. That's fact.

MR. COHEN: When did L & M's primary PCI program start? Do you recall?

DR. CAMBI: In 2006 was the first iteration. 2008, May.

MR. COHEN: I asked about primary.

DR. CAMBI: 2008.

MS. VOLPE: Is that in our pre-filed testimony? I mean is that a question that we presented in our pre-filed testimony?

MR. COHEN: It's related to these issues. I can go directly to the question.

HEARING OFFICER HANSTED: Is that in the pre-filed testimony?

MR. COHEN: I do not recall. Yes, it is in the pre-filed testimony. They talked about when their

program started and then when they got PCI.

HEARING OFFICER HANSTED: Okay, so, he answered it. 2008.

MR. COHEN: 2008. And when were you hired into that program?

DR. CAMBI: I was hired into this program -- we started in 2008, so I was already on the staff at Yale. I just sort of transferred over.

MR. COHEN: And when were you Board Certified?

DR. CAMBI: In interventional cardiology, 2007.

MR. COHEN: Okay, so, at the time that you -- did you practice by yourself at L & M as an interventionalist, or were you under the tutoring or mentoring of another physician?

DR. CAMBI: In the beginning, it was myself and Dr. Joe Brennan, who were running the program.

MR. COHEN: Was he an experienced physician?

DR. CAMBI: Yes.

MR. COHEN: Interventionalist?

DR. CAMBI: Yes.

MR. COHEN: Did he mentor you?

MS. VOLPE: Again, none of this is in our pre-file, so --

MR. COHEN: It's all directly related to it.

HEARING OFFICER HANSTED: Can I ask you what you're leading up to?

MR. COHEN: Well he's been testifying that our program is going to be with inexperienced practitioners and inexperienced staff. Our staff, as we've testified, is going to be trained at Hartford Hospital, and that they're not going to be inexperienced interventionalists, and I want to find out from him what is his position on what's experienced and inexperience.

And, in fact, our program will show greater experience in our staff and physicians than what he had when he was.

HEARING OFFICER HANSTED: Okay, so, why don't you just ask him what you think is qualified or inexperience versus experience?

MR. COHEN: I did. I did.

HEARING OFFICER HANSTED: Okay, so, let's move on from that, because you're asking his specific qualifications, and I believe he's already been qualified as a witness.

MR. COHEN: Okay, so, were you inexperienced at the time that you became the Medical Director of the PCI lab at L & M in 2008?

DR. CAMBI: No.

MR. COHEN: And why do you say that?

DR. CAMBI: Because I had been out of fellowship and already had the requisite numbers for angioplasty, in terms of the 70 and 11, because I was on staff at Yale-New Haven Hospital, an assistant professor there, and took routine call.

MR. COHEN: And how long were you on staff at Yale doing PCIs?

DR. CAMBI: I'm sorry. I missed that.

MR. COHEN: How long were you on staff at Yale doing PCIs?

DR. CAMBI: From --

MS. VOLPE: Why is this relevant?

HEARING OFFICER HANSTED: Let him answer the question.

DR. CAMBI: When I finished my fellowship until May of '08. I'm still on staff at Yale. I mean I've never left being on staff at Yale.

MR. COHEN: You said before you became the Medical Director of the PCI lab at L & M, that you were

on staff at Yale.

DR. CAMBI: Right. As the Medical Director of L & M, I remained on staff at Yale.

MR. COHEN: Thank you. That wasn't my question. How long before you were Medical Director at L & M were you on staff at Yale? You indicated that you were on staff. How long were you on staff at Yale?

DR. CAMBI: Approximately, 10 months.

MR. COHEN: Thank you. In your opinion --

MS. VOLPE: I have Redirect specific to that, if we can.

HEARING OFFICER HANSTED: Well why don't you let him finish his questions? I'll allow you Redirect once he's complete.

MS. VOLPE: Okay.

MR. COHEN: In your opinion, Dr. Cambi, what percentage of the PCIs that come into L & M cannot be done at a community hospital without on-site backup?

DR. CAMBI: So one percent of the PCIs. So we're eliminating now STEMIs, right?

MR. COHEN: Correct. It's only elective.

DR. CAMBI: Only electives. Of the elective cases that come into L & M, what percent do I think should be appropriately done at a tertiary center,

because they're too complex, right?

MR. COHEN: What percentage that come into a hospital like L & M, a community hospital, without on-site backup, need to be done at a tertiary center, correct. Elective patients.

DR. CAMBI: Okay. I think I'm going to answer this right. Twenty-four percent. Twenty-six percent.

MR. COHEN: So that means that approximately 26 percent of the patients that come in to L & M should be transferred to Yale or another facility for PCI services?

DR. CAMBI: No. I would object to the word transfer. They're not transferred directly.

MR. COHEN: Okay.

DR. CAMBI: It's elective, right, so there's no urgency.

MR. COHEN: Sure.

DR. CAMBI: But they should be, in my opinion, have their complex angioplasty procedure either because the blockage is complex or because the patient is complex at a tertiary facility, like Yale or Hartford, correct.

MR. COHEN: Okay, so, you heard Dr.

Kiernan's testimony this morning that approximately 30 percent of the patients or so, 30 or 40 percent of the patients wouldn't be treated at Backus. You heard that?

DR. CAMBI: I did.

MR. COHEN: Okay, thank you. Do you know what percentage of the patients in the L & M catchment area or their CMS area that present with PCIs, elective PCIs, are done at Yale?

DR. CAMBI: You're asking for the total volume of patients in the L & M catchment area? What percentage of those PCIs are done at Yale?

MR. COHEN: Yes.

DR. CAMBI: No.

MR. COHEN: Would you venture a guess?

DR. CAMBI: I would not.

MR. COHEN: Would you be surprised that 51 percent of the patients --

MS. VOLPE: What's the question?

MR. COHEN: -- in the L & M service area have their caths done at Yale?

DR. CAMBI: Would I be surprised?

MR. COHEN: Yes.

DR. CAMBI: Nothing surprises me.

MR. COHEN: But that number is larger than

the 24, 26 percent you said earlier, correct?

DR. CAMBI: Fifty-one is larger than 26, yes.

MR. COHEN: And why is that? Why do these patients go to Yale instead of L & M?

DR. CAMBI: You'd have to ask them.

MR. COHEN: How often do you practice at Yale?

DR. CAMBI: You mean on main campus?

MR. COHEN: In your pre-filed testimony, you indicated that you practiced at Yale. How often are you at Yale? I don't believe you specified main campus.

DR. CAMBI: Sure. I perform procedures at Yale-New Haven Hospital on average one day per week.

MR. COHEN: One day?

DR. CAMBI: Correct.

MR. COHEN: So that's about 20 percent of your time?

DR. CAMBI: Correct.

MR. COHEN: Are those on L & M patients primarily, patients from the L & M area?

DR. CAMBI: Mixed. Some are patients, whose procedures that we deem too complex to be done at L & M. Because I live on site and the Medical Director at

L & M, we've established a rapport, so we schedule that patient electively to be done down at Yale-New Haven Hospital, and then I see them back at L & M for follow-up, however, because I'm on staff at Yale-New Haven, I act like any other University interventionalist and do other patients that come in from New Haven, or from MidState, or from Backus, etcetera.

MR. COHEN: So if L & M increased its share of patients from the 51 or 49 percent that are at L & M service, from the L & M service area, to the 76 percent -- let me rephrase that.

If L & M increased its share of patients that go to Yale today, wouldn't that solve all of your concerns regarding volume and quality?

DR. CAMBI: Completely speculative.

MR. COHEN: Wouldn't it solve your concerns if you increased your share of patients that from your catchment area, from your primary service area that go to Yale?

DR. CAMBI: With all due respect, I can't comment on that without knowing things about those patients. I don't know anything about them.

MR. COHEN: So do you think all 51 percent of them presented you with indications that would require

that they go to Yale, as opposed to L & M?

DR. CAMBI: Maybe.

MR. COHEN: You earlier testified that it was I believe 24 percent.

DR. CAMBI: No. So you're mixing up patient populations.

MR. COHEN: Okay.

DR. CAMBI: Of the patients, who present to L & M, we do about 600 diagnostic cases a year. Of those patients requiring an elective procedure, correct, approximately 74 percent are safely done, in my opinion, at L & M. Twenty-six percent go to Yale. I agree with that. I can't comment on a cohort of patients that I know no specifics about.

MR. COHEN: Thank you.

DR. CAMBI: You're welcome.

MR. COHEN: We have no further questions for Dr. Cambi at this time.

HEARING OFFICER HANSTED: Okay, thank you, counsel. I think this would be a good time to break for lunch. It's now 12:30, so we'll report back here at 1:30, and, during the lunch break, I'd like counsel to get together and, when we come back, have three alternative dates for a third hearing date, in case we

need them, so discuss that while you have your people here.

(Off the record)

HEARING OFFICER HANSTED: Welcome back, everyone. We are back on the record, and Attorney Cohen has informed me that the parties have agreed that they don't have any further questions, so we are going to go directly to OHCA's questions.

MS. SCHAEFFER-HELMECKI: Good afternoon. I'm Jessica Schaeffer-Helmecki for the record, and, firstly, I'm not really sure who to direct this question to, so I will just pose it, and we'll bring up whoever the most appropriate person is.

Why has Backus chosen to apply for both elective and primary programs, as opposed to just the primary program?

MS. EDWARDS: Backus chose to apply for primary and elective, because we do see a need for both in our region, so the 30-minute drive time helped us to define our angioplasty region, and, through that analysis, we found that 160,000 people were beyond that 30-minute drive time to access a primary or an elective PCI provider.

When we looked through the demographic

information of our region, we see that folks in our angioplasty region have a lower socioeconomic status, have a higher degree of cardiovascular disease burden in the co-morbid conditions that cause NSTEMI or other conditions, which could necessitate an elective PCI, and, ultimately, we want to improve the care coordination for patients of this region, so elective PCI patients can be unstable.

Although time is a little bit more of a luxury, my understanding in an elective case should happen between 24 and 48 hours from the time it's determined an elective PCI has to happen.

I'm not a physician, but that's my understanding of the typical time frame to have an elective PCI, and, at this point, we don't believe that it's optimal care to have patients travel to urban centers, like New Haven, or Hartford, or Worcester, where they're going today to receive that care, when we could provide it as part of a comprehensive program at Backus Hospital.

MS. SCHAEFFER-HELMECKI: Actually, I'd like to revisit that 24 to 48-hour period estimate for the elective.

MS. EDWARDS: Sure.

MS. SCHAEFFER-HELMECKI: Where did that number come from? You referenced, I believe, for the first time on 1507, and we're just a little bit curious, as to the origins of that and, you know, whether L & M would agree with that 24 to 48-hour period.

MS. EDWARDS: So that was information that I have obtained from my clinical team, so I'd like to turn it over I believe to Dr. Kiernan to answer that question, if that's all right.

DR. KIERNAN: Francis Kiernan. As I think Dr. Cambi alluded to earlier, coronary artery disease really spans an entire spectrum of patients.

The patients that need the most urgent care are the ones with STEMI. Those are the ones that we need to treat as soon as possible to help improve survival.

Sort of the next run of patients are the patients, who are having what's called non-STEMI. That is that they're on the verge of having a STEMI, but it's not quite happened. Those patients generally we treat pretty urgently, within one to two days.

Now if a patient like that presents to a non-PCI hospital, they're usually transferred for care, rather than discharge.

There's another group of patients that are really quite elective. That is they may have symptoms, such as angina. They may have a stress test in their physician's office, etcetera, that shows they need an angiogram. An angiogram can be performed, and if the disease seems to be stable, that can be scheduled electively in the future, perhaps even several days down the road, so there's really a spectrum of disease that we're talking about.

MS. SCHAEFFER-HELMECKI: Okay, so, the 48 hours is not necessarily a hard and fast?

DR. KIERNAN: No, certainly not after a, quote, "elective angiogram." The time really is critical in the STEMI. It's somewhat critical in non-STEMI, but not quite as urgent.

MS. SCHAEFFER-HELMECKI: Okay, thank you. So would Backus be open to just a primary program and not an elective program?

MR. FOREMAN: It's interesting. When we looked at the treatment on a per capita basis within this region, the need for elective PCI was actually higher, so if you look at ChimeData and do it on a per-100,000 basis and compare that data for this region to the State of Connecticut and the U.S., actually elective PCIs are 19

percent lower than the state and 41 percent lower than the U.S., so just if you think about it in whether or not people are getting care, the need for elective is arguably higher than the need for primary, although primary is driven more by drive time, obviously.

MS. EDWARDS: And to answer your question regarding if Backus would be open to having only primary PCI, I think at this point we truly believe that providing care to all PCI patients closer to home is the better option, but we are happy to have a conversation with OHCA directly after the hearing, if you'd like, but I think that should take place in a different setting.

MS. SCHAEFFER-HELMECKI: Okay, thank you. And this goes back to elective and primary issue, but being that elective angioplasties are scheduled and treatment is not limited, in terms of time or distance, why is there a clear public need for such a program at Backus, particularly in light of the fact that there are five other hospitals currently performing angioplasties that could be reached within the ideal plus or minus 48-hour window?

MS. EDWARDS: So, again, I'd like to turn this over to one of my clinical partners, however, I think Dr. Foley actually, as a cardiologist practicing in

the east region, might be better suited to answer this question, but, again, I think we would be asking residents of the east region to leave their home communities to travel to unknown care teams to receive that procedure.

We're asking them to do that today. They're leaving their home community. They're traveling to a physician that they don't know, a program that they are not familiar with. It creates anxiety, undue stress on that patient, when we would be capable of providing that at Backus through the Hartford HealthCare Heart and Vascular Institute, but I'd like Dr. Foley to speak more about that.

DR. FOLEY: Thank you. John Foley. I think it's a great question, and I sort of divide the people, who are going to be getting electives, into two groups, so they are the people, who come into the hospital, whether with chest pain or something else, and they certainly need a catheterization, which leads to an elective procedure, and then there are those people we see in our office.

Certainly, the people, who start off in the hospital, would benefit from continuing their care in the hospital.

The other folks, however, have relationships with us in the outpatient setting. I would say that, just a few days ago, the three cardiologists in Putnam are now part of the Hartford Medical Group.

We're already beginning to see some of their volume coming down for visits both in our office and, also, at Backus. In Hartford, the cath lab is also seeing some of those patients, so some of the patients that we talked about that electively and not electively went to UMass are now coming really into the Hartford system, because the people, who drove the referrals to UMass, are now driving their referrals to within the system that they now function, which is Hartford HealthCare.

So I think we're going to start to see, again, referral patterns, which we talked about earlier, shoring up a bit, and having the volume in the east region at Backus Hospital will increase.

We know the patients. The patients want to stay at a hospital and the physicians that they know. They want me to do their procedure and help make decisions with respect to do they get a stent, do they a get bypass, do they medical therapy? Those are complex decisions that are made by people, who know them, and the

patients want those decisions made by those of us.

The other is the transportation. I had mentioned it seems like 100 years ago at our first hearing, and it's good that we'll probably only have two, but I made the comment that, you know, there were patients in tears in my office when I said that they had to go to Hartford Hospital, and I know that sounded very dramatic. We could say I'm very dramatic, but those are real cases.

For a patient to electively go to Hartford Hospital or to Yale to get caths is, for some of them, a deal breaker, so, you know, when we talk practical patient care, we see this playing out, so that's why I think the elective piece is really important.

The other is that, through Lawrence's program, they've shown that elective and emergent angioplasty done in the community hospitals can be done safely.

OHCA already has established that, and that's why I think, when you ask why are we going for both, it's because OHCA was at the forefront, like some other states in the country, allowing elective angioplasty and not just requiring just STEMI, and I think, if Connecticut is sort of a Petri dish, the

experiment has worked and worked safely. We're confident that our lab can continue that.

MS. SCHAEFFER-HELMECKI: Okay, thank you. And now I want to touch on the angioplasty region, as you've defined it, and, again, dealing with the elective versus primary issue, so your whole Backus angioplasty region is based primarily on drive time, correct, whereas the elective is not based on drive time, so how do you kind of describe your elective angioplasty region?

MS. EDWARDS: So I'd like Shane Foreman to answer this question.

MR. FOREMAN: Yeah, so, for purposes of the assessment, we thought it would be doubly confusing if we were trying to use two different service areas for primary versus elective, in particular, because, because those elective volumes are driven through physician referrals, it's kind of an open question, as to where that elective volume would go, because it is physician-driven.

MS. SCHAEFFER-HELMECKI: Okay.

DR. FOLEY: I would just add to that, when you look at the map and the geography of the angioplasty region, we have Day Kimball Hospital, which is the Putnam Group, which is now part of Hartford HealthCare. You

have Plainfield walk-in, which is a very busy urgent care center, where a lot of the patients with STEMIs start and certainly people of unstable angina.

The Plainville area in January will have cardiologists from our group practicing in that office. We have Norwich, and then we have Windham Hospital within our outpatient setting there, so the same geography that makeup the angioplasty region are served by outpatient offices, which provide care, so they kind of are one in the same.

MS. SCHAEFFER-HELMECKI: Okay.

MR. FOREMAN: Just a point of clarification. So we used the 30-minute drive time for both, which I think is what you --

MS. SCHAEFFER-HELMECKI: Yes.

MR. FOREMAN: Thank you.

MS. SCHAEFFER-HELMECKI: Okay, thank you. Now according to your application, Backus transferred to Hartford still routinely exceed the recommended 90 minutes. Firstly, why was that 90-minute standard used, rather than the 120 that we discussed earlier?

MS. EDWARDS: So we used the 90-minute standard, because that’s the standard that we believe we should be holding ourselves to, and that’s the standard

we would be needing if we had a PCI-capable program at Backus Hospital.

As we've discussed, minutes mean muscle, and, so, we are holding ourselves to that Gold standard of 90 minutes.

MS. SCHAEFFER-HELMECKI: So why --

MS. EDWARDS: I'm sorry. I think we have one more point.

MR. FOREMAN: I was just going to add to that. Our entire assessment, which, then, is baked into the application, we took the approach as if what would this look like if Backus had it, so, if you think about it, that's how we did the service area, based on drive time, based on if Backus had this program, and then, similarly, that's the reason we used the 90-minute, as well.

MS. SCHAEFFER-HELMECKI: Okay, so, why are you exceeding the door-to-balloon time for transfers?

MS. EDWARDS: Why are we exceeding our door-to-balloon time? Dr. McClaine, as an Emergency Department physician, would you mind answering this question?

DR. McCLAINE: Hi. Kyle McClaine. So what we had said earlier and I can clarify further was

that, currently, we do have all EMS providers take an identified ST elevation MI directly to a PCI-capable center if they're within 30 minutes, which is currently Lawrence & Memorial, and that subset of patients comes right off the top. Because most of the clear MI patients bypass Backus entirely now, especially from the EMS arena, the data subset for the patients that we had that were transferred out is a somewhat skewed population, and, as I was testifying before, that subset includes a lot of patients that come in with one thing and ended up having an MI identified later.

A lot of those patients were sick elderly patients from a nursing home, who had pneumonia, and then you do your routine EKG later, and there's an MI there, as well, because all the cards are falling as the patient is succumbing to an illness, or someone, who comes in with chest pain and were thinking about MI, were thinking about angina, and then subsequent EKGs performed over time demonstrate that the EKG changes, so there are some patients with delayed presentations, confounding variables, things like that, that are in that patient subset, and then there is the reality of patient referral patterns.

There is physician concern that are taking

care of patients. Patients are their primary focus, and they're worried about the possibility of needing to have a second transfer to a surgical backup center. They're already at the first hospital. Time has gone by, and, if they get transferred to another non-surgical backup, that there could be a potentially other transfer.

Then there's the belief that they are making the metric, and it's hard to know, when you have multiple different centers, where we send patients. There was Yale, there was St. Francis, there's Hartford, there are a few at L & M, that the feedback loop to the physicians probably should have been better over the years, and there are times that we did not know that we're not making 120, or I think our median was 134 on those patients.

So, first of all, I remember that the clearest MIs aren't even in that group. These are the ones that, for whatever reason, weren't as clear, most of them, but, even still, you know, once you do identify that you're not making 120, there were some things about, when you talk to a cath lab PCI provider, some of the physicians on the receiving end were also comfortable going beyond 120, because they believe PCI is better.

Even though, as we talk in this

application, the guidelines are the guidelines, real physician practice sometimes even favors going a little bit farther for the preferred therapy, so there's a lot of reasons.

There's physician referral patterns, as well, so there's a lot of things that go into that, but, overall, I think the biggest thing to say is that we're not trying to optimize a 120-minute system. We're not trying to make it 134, 120. If need be, we will continue to strive to do so, but what we're really trying to do is make this a 90-minute benchmark. We don't want 120 minutes.

MS. SCHAEFFER-HELMECKI: Okay, thank you. Now, also, referring to referral patterns, I don't know if you need to continue to speak to referral patterns, but Day Kimball's 2015 CHNA implementation plan indicated a working relationship with UMass Memorial to treat the STEMI transfers from Northeastern Connecticut. If Day Kimball does refer patients to UMass, will you still be able to meet your 200 procedures per year threshold?

MS. EDWARDS: So, yes, we believe that we will still be able to meet our 200 PCI threshold per year, and that's for a variety of reasons.

I think one is that the Day Kimball

community health needs assessment implementation strategy supports our application, that cardiovascular disease is one of the most pressing needs in our community. They list it as I think their first community health -- their community health need.

Additionally, they state that they are transferring patients via helicopter, I believe, to UMass, which is not ideal. That's not ideal for our health care system, as far as cost. It's also not ideal for our patients, but, ultimately, Bob Smanik, who is the President and CEO of Day Kimball Hospital, wrote a letter of support for our application, where he stated that Day Kimball looks increasingly more favorably towards Backus as a source for specialty care, and that he wholeheartedly sees a need for this procedure to be located at Backus Hospital to give his patients a Connecticut option, where, currently, they don't have a Connecticut option.

And then, finally, I think Dr. Foley has already mentioned that Dr. Bradbury and his two cardiologists on his team, who also wrote a letter of support in favor of our application, are now employed by Hartford HealthCare Medical Group, and, so, we believe that that physician referral relationship will result in

some patients coming to Backus for their care.

Dr. Foley, do you have something to add?

DR. FOLEY: Yeah. I think, just to amplify, and I know we're under time constraints, but the idea of referrals have come up, and referrals really are me to you, one provider to another provider. It's because we have a relationship. I know you. I know the quality of care you can do. We communicate.

I trained at UMass. Before that, I was a nurse at St. Vincent's. I lived in Worcester, so I'm familiar with the geography and with the players. Great hospital, but most, if not, all of the cardiologists that have ever worked at Day Kimball have come and trained at UMass.

I was a fellow, and I used to moonlight for their practice, so when you talk about how does a Day Kimball patient show up at UMass with chest pain and an MI, it's because cardiologists are seen in the emergency room and fielding the phone calls or consulting in the hospital, and they're referring to people, because they have a relationship, but those relations are now different, so hospitals can't guarantee anything.

Our hospital can't guarantee that every patient, who comes into our ER, is going to go to

Hartford Hospital. I make that decision, and it's an independent decision, and it's a complicated decision sometimes, but I think that that relationship, I just want to say, is predicated really more by the physicians and their practice patterns than Day Kimball Hospital and UMass as hospitalists.

MS. SCHAEFFER-HELMECKI: So what is the travel time distance between Day Kimball to UMass versus Day Kimball to Backus? And I know you provided that information. I apologize. I just can't remember it off the top of my head.

MS. EDWARDS: Sure. So, interestingly, and I don't have it from Day Kimball proper, I have it from Putnam, that's how we did it in our late file, St. Vincent Hospital is actually the closest PCI provider to Putnam, and, so, that drive time is 28 minutes versus it would be 33 minutes from Putnam to Backus Hospital while also, of course, providing patients a Connecticut option for their care, and that's assuming that those patients arrive at the Day Kimball Emergency Department and don't seek emergency treatment for their symptoms at our Plainfield Emergency Department.

MS. SCHAEFFER-HELMECKI: Okay and UMass was?

MS. EDWARDS: UMass I believe is a little bit further than St. Vincent's, probably I think maybe five more minutes past St. Vincent's.

MS. SCHAEFFER-HELMECKI: Okay.

MS. EDWARDS: Somebody is showing me that it's 34 minutes.

MS. SCHAEFFER-HELMECKI: Okay, thank you.

MS. EDWARDS: Thank you.

MS. SCHAEFFER-HELMECKI: Okay. I am all set. Thank you.

MS. OLGA ARMAH: Good afternoon. My name is Olga Armah. I don't know who is going to answer the questions, but whoever gets the question, they can answer.

Did the Applicants explore the possibility of improving emergency medical transportation systems to diagnose and to transfer STEMI patients, such as training for EMT or ECGs on more ambulances?

MS. EDWARDS: I think Dr. Kyle McClaine would be the best suited to answer this.

DR. McCLAINE: Forgive me. Kyle McClaine. Forgive me. Can you just restate? I got the gist of it. I think I have it properly, but I want to make sure that I do.

MS. ARMAH: I'm asking if you explored improving emergency medical transportation system.

DR. McCLAINE: So what I had testified to before was that all paramedics -- actually, this might be some clarification. All paramedics can perform EKGs. The problem is is where are your paramedics, and where is the density?

If you're in the Norwich area, if you're in the New London area, there's a paramedic every inch, and you're tripping on them. They're always going to get an EKG in a timely fashion, and they use that in the case of an identified ST elevation MI to direct their patient to the closest PCI center if it's within 30 minutes, so that's a system that has always existed.

The improvement thing was something I was actually part of, was that some places there's not enough paramedics, and there are two hospitals to choose from. You don't have a paramedic there to do an EKG, and your EMTs, your basic level EMTs are ready to go, your patient is in the ambulance, you're looking at two different hospitals, one has a PCI center and one does not, and you don't know where to go.

And a pilot program was done in the Western part of the state a couple of years ago, and I

was part of the body that evaluated that pilot, and that was to say they got a good point.

They can't get a paramedic there in a reasonable time, and their patient could have been at either hospital before a paramedic even gets there, so they trialed a program by which they attached a black box type device to the patient, and that was transmitted to one of the hospitals, the PCI center, who then interpreted the EKG that was done and told the EMS crew come to us. You have a STEMI, come to us. You don't have a STEMI, go to the other hospital, or the closest hospital, or whatever hospital you want to go to.

So when you have a choice in the matter, that is a great way to expand what EMS can bring to the table. If you're presently in all of the towns north of Norwich beyond a 30-minute drive time to L & M, if you get up to those towns, you don't have a choice where you're going, you know?

And, also, truthfully, for the lower part, the paramedic density is fine, but up around the Day Kimball area, the paramedic density is just like that other part of the state, in that there's not a lot of paramedics, but it's unlike that part of the state, in that there's not PCI centers versus non-PCI centers to

choose from, so the part of my testimony that I was trying to say was, when Backus has a PCI-capable center, now you have a choice.

Are you going to go to Day Kimball, or Backus Hospital, or the Plainfield freestanding emergency department, Windham Hospital, L & M Hospital? You're going to have choices now, you know, if you have that 30-minute drive time. Does that answer your question?

MS. ARMAH: Yes.

DR. McCLAINE: So expanding EMS capabilities, without a choice for them to do anything with the data, doesn't change the outcome for any patients presently.

MS. ARMAH: Okay. Thank you. Have you developed an agreement with ground or air ambulance service capable of advanced life support that guarantees a transfer vehicle will be on site to begin transportation to backup surgery within 30 minutes?

DR. McCLAINE: So you're speaking not about the primary phase, but if a PCI was performed at Backus Hospital and it was determined that you had then to take the patient to a tertiary care center?

MS. ARMAH: Yeah.

DR. McCLAINE: That would be my job to do.

It's a very easy job to do. It's very similar to the transport of other patients, and I'm the Medical Director over the ambulance service that currently takes all of L & M's patients to Yale when that happens, and they also have Life Star. We have a facility hanger, and one of the Life Star vehicles is at our hospital, so those two systems are in place already. They oversee the medical aspects and the design aspects of what happens, you know, for the paramedic training and the Life Star.

It's in place already. It's just a small change to redirecting it for Backus, so Hartford already has that in place with Life Star, and then the ground is me.

MS. ARMAH: So can we have a copy of that agreement? Can I have a copy of that agreement?

DR. McCLAINE: That Hartford Hospital has with Life Star?

MS. ARMAH: Yes.

DR. McCLAINE: Yes.

HEARING OFFICER HANSTED: That will be ordered as Late File No. 2, and how long do you need to get that to us?

MS. EDWARDS: Just to clarify, so I understand fully what the late file is, you're looking

for a copy of agreements between Life Star and Hartford Hospital? Just to clarify.

HEARING OFFICER HANSTED: Any agreement for transportation that would be used in the situation that was just described.

MS. EDWARDS: Okay. For ground or air?

HEARING OFFICER HANSTED: Ground or air.

MS. EDWARDS: Okay.

DR. McCLAINE: So, to clarify just a little bit further, as I said, right now, Backus doesn't have a PCI center, so there is no written agreement for something that doesn't currently exist.

What I was saying was that, basically, L & M has an agreement to get their patients off, and they use paramedics that I have medical control over, so the aspects of it that I oversee are, when you're transferring a patient, what equipment do you need, what level of provider do you have, and then the helicopter is a separate thing, but Backus does not have a PCI center, so there is no agreement.

I'm just saying that the technical nature of how that would be done would be under my direction from the ground and in correlation with Hartford Hospital's Life Star program from the air, and they

currently transfer patients from PCI centers, not just L & M, but all over the place.

This is their regular, every day business, so I don't know if there is a document that already exists that is what you're looking for. I think I was trying to describe the system, but, if I may redirect on that, I don't think that document does exist or that it would help you, but if your question was --

HEARING OFFICER HANSTED: No, I understand what you're saying, Doctor, so I will vacate that order for Late File No. 2.

MS. ARMAH: All right, thank you. So why has Backus chosen to concede patients from Ledyard and Montville to L & M?

MS. EDWARDS: So I'd like Shane Foreman to elaborate on this, however, our application and our analysis was based completely on drive time, and we used Maptitude software to determine drive time, and those two geographies were closer, when we look at primary PCIs, closer to transport to L & M, per our analysis.

I think Shane, though, has some additional statistics to share with you.

MR. FOREMAN: Yes, thank you. Janette is correct. So the reason that we left it out of the

angioplasty region for primary PCI is because those zip codes were actually closer to L & M than to Backus, but when we went and looked, Backus actually has relatively low market share within those zip codes, so when we look at the Oakdale zip code, Backus has a 39 percent inpatient market share, Ledyard was 20 percent, Uncasville was 48 percent, and Gales Ferry was 19 percent, but I think the more important point is those zip codes produce extremely low case volume, so when we looked at the actual number of cases that we're talking about, it's four, and that's elective, just to be clear, for elective cases.

MS. ARMAH: All right, thank you. Page 1510 of the application shows a proposed service area for approved L & M PCI service area. How does Backus propose to minimize a potential shift in elective PCI volume from L & M?

MR. FOREMAN: So, as I think we previously stated, we believe that elective is driven primarily from physician referral patterns, and we don't believe that anything we're proposing will interrupt any existing referral patterns between L & M Hospital and their physician base.

Then, also, again, we're talking about

extremely low volume, so when you look at the number of elective cases that L & M pulls out of this region, it's almost non-existent, so we don't believe that we're going to interrupt their referral patterns, but even if there was some interruption in referral patterns, we're really not talking about any cases anyway.

MS. ARMAH: Given with the addition of elective PCI, L & M is a low-volume provider. Your proposal predicts low volume for Backus, as well. What will be the viability of the two programs, that is Backus and L & M, and the financial impacts on the health care system of the region?

MS. EDWARDS: So we are proposing in our application to serve a very different market than L & M. As we've discussed earlier today, I believe L & M has treated four elective cases and four primary cases from the angioplasty region this fiscal year, the first two quarters for this fiscal year, so they're not serving the region that we're proposing to serve today.

Additionally, the providers, who are serving the angioplasty region, mainly Hartford hospital, Yale and UMass, they are high-volume providers, where we don't believe that the shift to Backus will cause any material disadvantage to those hospitals, and, clearly,

Hartford Hospital is a co-applicant with us on this application, and, so, they see the value in establishing this program at Backus Hospital.

So I think, although we were conservative in our estimations for volume at Backus at 216 cases in the first year, we do make that minimum 200 ACC/AHA SCAI guideline, and we do anticipate growing I believe to 222 cases in subsequent years at a minimum, so we don't believe that L & M is treating this region today, and those providers that are treating this region are high volume.

And then, finally, we do believe that there's unmet need in our service area, given, again, the high rates of STEMI and non-STEMI cases and then the low rate of intervention to treat those cases, so we also believe that there's unmet need today in the market.

MS. ARMAH: So if the Applicants will be operating at a loss for an extended period, will the program losses be passed on to the consumer? That's what we see from the financials.

MS. EDWARDS: So, no, the program loss won't be passed on to the consumer. I think Dan Lorer can speak to programs that -- the financial viability of the program if you have questions about that, however,

no, we consider this a community benefit to the angioplasty region, and it's within the mission of Hartford Hospital, Backus Hospital and Hartford HealthCare to provide such services.

I don't anticipate us passing this cost on to the consumer.

MS. ARMAH: So how will you cover the loss?

MS. EDWARDS: Through operations, through our operations. And, also, I should point out that the way we modeled the loss for the three years was we assumed that we had no uptick and any reimbursement from any of the payers associated with the cases, but that we did include inflation and increased cost to the hospital, which is why the loss actually worsens in years one, two and three. We were conservative in that regard, as well.

MS. ARMAH: You stated in the application that the incidence of myocardial infarctions in Northeast Connecticut have increased 13 percent above the state average.

Do you have reason to believe this is due to the lack of a PCI program and not a result of a need for earlier intervention, specialty intervention, or additional primary care providers in the area?

MS. EDWARDS: So I think that the, and I'll have Shane Foreman speak more to how, to the instance and how we calculated that, but I definitely think that you're asking two questions.

So one, that, absolutely, there is a need for additional primary care physicians in that region. In fact, 11 of our towns are listed as health professional shortage areas, and three of the towns in the angioplasty region are listed as medically underserved areas.

We articulated in our application that Backus is a great supporter and provider of multiple community benefit programs, including cholesterol screenings, blood pressure screenings, smoking cessation programs, weight loss programs.

We have a bariatric surgery program, so we're trying to put a solid foundation for preventive programs in place within this region.

We extend that all the way up into Plainfield and beyond as far as we can in partnership with Hartford HealthCare and Windham Hospital, as well, so really trying to take a comprehensive look at the preventive care that we provide to this community, however, those interventions and those programs take many

years to turn the tide of the health care, the health and disease burden or status of a community.

So, as you can see from the Robert Wood Johnson Foundation data that we shared over the course of the last several years, Windham and New London County have made very little stride in improving many of these metrics, and that's just because public health interventions take a really long time to take effect.

So although we're continuing to build our preventive care foundation, we believe that there is a need for a PCI program to treat patients, who are suffering from these conditions today.

So, Shane, do you want to talk about our incidence rates?

MR. FOREMAN: Sure. I think Janette is 100 percent right. I think the underlying demographics and health status of this community are probably driving most of that, and, for me, I've looked at literally thousands of markets across the country.

My best estimate of this is it's just an isolated geography with the lack of access, and, so, that's why you're seeing trend lines that are counter to what you're seeing across the rest of the state and what we're seeing across the country.

MS. ARMAH: Thank you. In the 2014 consensus document, the document recommends that the cath lab staff and interventionalists should arrive within 30 minutes of the STEMI activation call.

The same travel challenges identified for hospital patients presume to exist for the physicians. Do you have a plan to provide such coverage, 24-hour coverage?

MS. EDWARDS: Sure. I'd like Dr. Kiernan to speak to how it will approach call coverage at Backus Hospital.

DR. KIERNAN: Yes. Francis Kiernan. We would plan to have physicians stay in the area, for example, who are on call to be close to the center, and we would mandate that the nursing and technical staff be available within 30 minutes.

We have that same system at Hartford. In fact, some of our nurses and technologists, who live out of our 30-minute window, actually stay in the hospital during their call periods, so that would be something that would be enforced.

MS. ARMAH: Thank you.

MR. DAVID FERNANDES: Good afternoon. My name is David Fernandes, and my questions will pertain to

Lawrence & Memorial.

My first question is how will access be maintained for towns in the angioplasty region that are more than a 30-minute drive to the nearest PCI provider?

MS. VOLPE: How would we maintain servicing them?

MR. FERNANDES: Correct, because I believe, on page 19 of the pre-filed testimony, the chart had 58 percent of the towns outside of the 30-minute travel time, so how would you maintain access to those potential patients?

MS. VOLPE: Well I think I'll let Dr. Cambi answer that.

DR. CAMBI: So I just want to make sure I understand your question. You're supposing a Backus proposal doesn't exist?

MR. FERNANDES: Correct.

DR. CAMBI: How would we maintain the 30-minute drive time for those patients, who live beyond those regions?

MR. FERNANDES: Correct.

DR. CAMBI: Yeah, I'm glad you brought that up. It's my contention that, throughout this hearing, we've lost a bit of focus.

The 30-minute drive time isn't what's important here. It's opening the blood vessel within guideline-recommended times of 90 minutes that they present to your facility or 120 minutes with inter-facility transfer, and, so, what I propose is that, in those patients, who are a greater than 30-minute drive time from Lawrence and arrive at Backus with an ST elevation MI, that Backus transfers those folks to us, where we demonstrated that we're more than capable in opening that artery in less than 120 minutes, certainly, and, in most cases, less than 90 minutes.

When you consider that a hospital similar to Backus in the form of Westerly is farther away than Backus, currently transfers patients arriving at its facility to us, and we open the artery in a median door-to-balloon time of 89 minutes, well below the 134 that Backus is currently getting and well within guidelines for a program either receiving inter-facility transfers or as if those patients were presenting directly, and, so, my solution to the problem in maintaining access for the patients you describe is not to invest millions of dollars in a new PCI program, but to develop mandates, greater EMS education and greater technology, so that those patients could be more effectively triaged to

Lawrence & Memorial Hospital, or Hartford, or UMass, or other programs in Rhode Island.

So, in that way, that's how we maintain appropriate access and guideline-directed care to those patients you describe.

MR. FERNANDES: Thank you. What is the potential number of cases that would shift from L & M to Backus if a program is approved?

MS. PATEL: So this is Shraddha Patel. The data that Backus provided in their CON application, our patient origin data, when we looked at that very closely, they speak to fiscal '15 numbers, 32 cases came to L & M from their angioplasty region.

That's significant, given that we have 216 cases total. What Backus failed to acknowledge, and I believe OHCA kind of addressed this in the completeness questions, is what about the towns of Ledyard and Montville, which are in the OHCA-defined service area for Backus Hospital?

That's another 19 cases, so that's a total of about 51 cases that would be potentially removed from L & M's populous of caseload with a Backus program in place.

MR. FERNANDES: So 51 total?

MS. PATEL: For fiscal year ’15, I’m talking about that patient origin data, but we also feel it could potentially be more. You just never know. Again, we talked about referral patterns and where EMS takes folks, so 51 is a conservative number from our vantage point.

DR. CAMBI: And I would just dovetail on that. You know, Backus creates a picture, where patients with ST elevation MI, who are currently coming to L & M, that won’t be disrupted, but you have to remember that there’s going to be some borderline zones, where EMS is in between Backus and L & M, where, currently, they all come to L & M.

Those patients are also going to now be going to Backus Hospital. Patients with STEMIs also often have, as Dr. Kiernan can attest to, an underlying burden of coronary disease that may and often requires additional now elective interventions.

Those are additional case volume numbers that would be lost to Backus, so it’s difficult for this panel, but important for you to understand that there is significant volume loss that can sometimes be hidden in the way you sort of carve out the data and create regions and so forth.

I thought I made this point, but my colleagues are reminding me to make it again, that if Backus were to get a primary PCI program, because of some of the volume shift we discussed, it would be difficult for us to maintain our ongoing quality metrics, as our threshold would fall below that sort of magic 200 number that you here discussed about in a lot of the guidelines and literature, but I think I said that earlier.

HEARING OFFICER HANSTED: I just want to go off the record for one minute.

(Off the record)

HEARING OFFICER HANSTED: Okay, we're back on the record.

MR. FERNANDES: Okay. This is most likely going to be a late file, but I'll ask the question. What would the estimated revenue loss to the L & M program if the Backus program is approved?

MS. VOLPE: I think we can probably be responsive to that today. Can you repeat the question?

MR. FERNANDES: Sure. What would the estimated revenue loss to the L & M program if the Backus program is approved?

MR. VanESSENDFELT: My name is Seth VanEssendfelt. I'm the Chief Financial Officer. In my

testimony I had filed, the net financial implication is we expect somewhere around $1 million, round numbers, and, so, it's not just the revenue, as we've talked about and had these discussions, even as Dan testified about the program. There's a pretty significant amount of fixed cost that goes into maintaining the program, and, so, the revenue loss has a significant impact, because there's very limited impact to expenses, so the expense structure kind of stays in place, despite lower volume.

For example, the revenue offset is almost one-for-one with the financial loss, so the revenue might be a little higher than $1 million, but the net financial impact is probably around $1 million, and that's, again, based on the assumptions that Shraddha outlined, as far as what we see as potential volume loss, based on '15 numbers.

Obviously, it's hard to forecast future implications.

MR. FERNANDES: Thank you. And then one last question. Would you explain why Backus has predicted 80 percent retention rate on page nine of the pre-filed testimony is unreasonable?

MS. VOLPE: The retention from --

MR. FERNANDES: I believe that was the 80

percent that they had come up with, as far as market share. Let me just get you the specific page number.

MS. VOLPE: Thank you.

MR. FERNANDES: So it's Exhibit R. I'm sorry. Pre-filed testimony, page nine, question seven.

MS. VOLPE: Do you have the bates stamp?

MR. COHEN: 0009.

MR. FERNANDES: Yes.

MS. VOLPE: Of our pre-file?

MR. COHEN: Yes.

MS. VOLPE: Okay, thank you.

MS. PATEL: I'm going to try to answer this question. So why we feel the 80 percent is unreasonable is, when we looked at our own internal data, statistics that come out of Chime, we were actually only retaining 54 percent of the STEMI cases that emanated from our primary service area.

Patients don't necessarily have their heart attack at home. They're out and about elsewhere, so I think some of the patient origin data can be misleading at times, so we felt that the 80 percent was grossly overstated, just judging by our experience, having done this for six, seven years. It didn't seem feasible to achieve that sort of rate.

MS. EDWARDS: May I just add a point of clarification? Is that allowed in this? So the 80 percent, which we talk about on page 489 of the application, that is our actual emergency department market share from the towns within 30 minutes of a drive time from Backus Hospital, so we utilized 80 percent, which, again, is the actual Hartford HealthCare ED market share from this region, because we assume that these STEMI cases are emergent cases, and they would be seeking care at Backus via EMS or otherwise, just like any other case.

So we have an 80 percent east region ED market share within that angioplasty region, and that's where that number came from.

MS. PATEL: Can I add something? We, if we did our own PSA, Primary Service Area, analysis for ED, it would be similar, if not, higher, so I think 80 percent is what we attract for ED patients only, but we're talking about STEMI patients. It's a whole different type of population. Fifty-four percent is what we're seeing. The 80 percent is probably similar to what L & M would see if we actually ran that analysis.

MR. FOREMAN: And I just have one additional point. I think, if you looked at their PCI

market share and thought about it in conjunction with their partner, which all those cases are leaving their region, it would probably be higher than 80 percent, the partner being Yale.

So if you think about what between the two of them, if you're attempting to compare apples-to-apples, what we're talking about is a Hartford HealthCare East Region as a health system, and what they and their partner at Yale will get out of that market is probably 80 percent, if not, higher.

MR. FERNANDES: Thanks.

MS. PATEL: I just have a clarifying question for the Backus team, but I know I can't do that.

MR. FERNANDES: That pretty much concludes that questions I had.

MS. SCHAEFFER-HELMECKI: Just one last point. There were a few late files that we wanted to request.

Firstly, we want to see, on page 1516, we wanted to see the table on that page updated to include fiscal year 2015 data.

HEARING OFFICER HANSTED: Page 1516, and that will be Late File No. 2.

MS. SCHAEFFER-HELMECKI: Okay and then the

second item, we also wanted the school year 2015 data added for the table provided on page 62 of the initial application, please.

HEARING OFFICER HANSTED: That will be Late File No. 3. All right, that concludes OHCA's questions and the late files.

I understand counsel would like to give brief closing statements, so I'll allow that. Attorney Cohen?

MR. COHEN: Bimal Patel is going to make a short statement, and then I'll have a very short conclusion after that.

MR. PATEL: Hi. Good afternoon. My name is Bimal Patel. I'm the President of East Region Hartford HealthCare. It's two hospitals; Windham Hospital and Backus Hospital.

Hearing Officer Hansted and the rest of the team, thank you for your questioning and wonderful conversation about the details.

I make rounds with communities, and about over the last six months, probably got 15 different communities that serve or that lives in the East Region.

Basic premise of that population is about access and the travel; access by site, location,

difficulties in travel. I'll give you a quick example. In Baltic and Sprague are the two, who are the most in-need towns among all 15 that I met so far.

Patients line up or the people line up for a food program three hours before the door opens at Sprague Community Center. Eighty percent of those people line up every other week for the food share. They come by walking to the area. The town population is 1,500 people.

The combined population of Sprague and Baltic is really less than 5,000. That tells you the health disparities what we are serving.

So with that note, let me tell you the testimony that we have put in front of you and they asked that we put in front of you is real, that there's a clear need for Backus to establish primary and elective PCI program to provide the much-needed cardiovascular health.

We do everything in prevention. Our Nurse Practitioner, Alice Fasanti(phonetic), goes over there and serves them to improve health conditions. I haven't seen anybody else do that work in the East Region. My team does that work, up and down in more than a 1,000-square-mile radius of the East Region.

We have 160,000 people, about 69 percent

of the population at least, do not have a 30-minute guideline. We heard about that today enough. We have 231 people, or thousand, rather, live in our Backus angioplasty region, who could afford and deserve a better access than what they have today.

We have heard from ourself, Backus Hospital, Hartford HealthCare. We have heard from a Town elected official on both days of hearing. You heard from me. You heard from Day Kimball. You heard from our EMS leader, who provides service in the East Region. You heard from the physicians, and you heard from patients. All of them are citing that there's a need.

And if you look beyond this minutia of the data and the details and step back, and if you live in that community, where a minute counts, you want to really put yourself in their shoes and figure it out, whether this program is viable or needed or not.

Our program is supported by one of the best programs that the State of Connecticut has to offer, which is Hartford Hospital's program, so it is not a community program. It is in a hand, partnership, hand-holding with them, and it's going to be an absolutely robust program, and I personally stand behind that.

Financially speaking, we've gone through

capital investment, operational investment, etcetera, and there are two schools of thought; whether we will increase the cost, or whether we'll increase the access, whether we'll increase the bottom line, or whether we'll erode someone else's market share.

I look at this as beyond those arguments. While we can afford it, Backus Hospital has committed as a not-for-profit organization to invest in both prevention, as well as intervention, and this is to demonstrate that we're going to do that fully for the population that we serve up and down 395 in the East Region.

So I recommend, urge and encourage OHCA to approve the application that is in front of you. It's for very critical life-saving care that our patients in the East Region need or the population in the East Region needs. Muscle health counts by minutes, and we want to make sure that we intervene in a timely manner.

No hospital, I repeat, no hospital, including L & M Hospital or any other, would be grossly impacted, because this is a delta in the need. It is not about market share grabbing from one to fulfill the other when you sit back and understand what's going on in that vast 1,000 square mile area of Eastern Connecticut.

So approving this application would satisfy this unmet need for patients and will bring the standard of care of angioplasty that does not exist today.

Backus Hospital is fully capable in the East Region to provide the services, improve access, decrease the cost, because moving patients from location-to-location adds up costs, and, most importantly, it will be timely intervention that is much needed today.

So on behalf of Eastern Connecticut and the large population that lives in there that do not have the same access that the rest of Connecticut does, I ask that this appeal, this application be reviewed and approved, and I would urge you to do that. Thank you.

MR. COHEN: Thank you, Bimal. Hearing Officer Hansted and OHCA staff, thank you for your time, your openness to our proposal, and, most importantly, your patience over the two full days of hearings.

As OHCA has said repeatedly in other decisions, CON applications are decided on a case-by-case basis and do not lend themselves to general applicability, due to the uniqueness of facts in each case.

OHCA must consider the factors set forth

in the Connecticut General statutes. As you know, Title 19a, Section 639a. Each of the criteria used by OHCA in evaluating CON applications has been met through our application, our completeness responses, our pre-filed testimony, and our testimony over the two days of hearings.

OHCA and the Intervenors have probed and pressed our witnesses on a wide variety of topics related to the application and our other filings. Let me just highlight a few of the factors that you consider in reviewing a CON application and how we've met them.

First, public need. We've clearly demonstrated a public need for this proposal. There is, as we've testified and as it's shown in our application, an unmet significant need in the isolated part of this state. There's much in the angioplasty region. There's higher coronary disease, higher STEMIs, cardiac incidents, and much lower, 20 percent, approximately 20 percent lower than the rest of the state with regard to PCIs and 41 percent lower than the national rates. Now isn't that really just the definition of need?

The Backus angioplasty region is a community that is not part of the L & M service area. As you've seen from our testimony, three percent of the

inpatient data, discharge data from the Backus angioplasty region use L & M Hospital. This proposal will improve access to these life-saving services for the 230,000 individuals in our region, and 160,000 of them will have the life-saving services within 30 minutes.

The next criteria is unnecessary duplication of services and impact on the diversity of health care providers and patient choice.

We've demonstrated that we will not duplicate services. As I said, L & M does not provide services in this region. We've demonstrated a minimal impact on L & M, with a larger impact on Hartford Hospital and other large providers, where this proposed program will not have any impact on their volume or quality. This program will significantly improve patient choice to a vast isolated underserved population.

Finally, let me say a few words about L & M's primary argument, that this program will take significant volume from L & M, thus affecting L & M's quality.

We have shown through real data that our program will not impact L & M's PCI program in any way, and one of the tasks that you have as OHCA is to weigh these minimal impacts against the tremendous improvement

in access for the vast majority of the 230,000 underserved folks in the Backus angioplasty region.

As we've talked about, Yale receives over 125 annual, annually over 125 PCIs from the L & M service area. Our minimal impact can easily be offset by L & M slightly increasing their share of these procedures.

There's only one program east of the river, the Connecticut River. We need to do better and to provide these life-saving procedures to this population with a clear unmet need and provide the same standard of care that other residents of Connecticut enjoy.

DR. CAMBI: I can go? Thanks, guys, for allowing me the opportunity to speak to you again today and make a few closing comments.

I will refer the panel back to my pre-filed testimony and, also, the robust discussion we've already had here today. My intent is not to be repetitive, but to highlight some key themes and flesh out some additional points that went unsaid.

Throughout all the pre-filed testimony, oral arguments and hearing discussion, the panel has heard a great deal of information about statistics, drive times, zip codes, finances, losses and other data.

I would like to, in the end, refocus the discussion on what's most important here, and that's patient care.

As cardiologists, physicians, in general, nurses, health care workers and leaders in the field, as most of us are in the room, we are charged with providing the best care possible in the safest manner possible while keeping in mind what's best for the overall health care of the region and the system of health care delivery as a whole. Undoubtedly, a daunting task.

When it comes to the ideal treatment of coronary artery disease, as you've heard today, the first distinction that must be made is between heart attack, STEMI, and stable coronary artery disease.

Heart attack, as you know and as you've heard, is a life-threatening emergency, caused by a completely obstructed artery that must be dealt with rapidly to minimize the chance of permanent heart damage or death.

Stable coronary artery disease, on the other hand, gives providers the luxury of time to plan out and execute optimal treatment strategies, which may include PCI, but may just mean medications, bypass surgery, or a combination of the like.

Patients with stable coronary artery disease undergoing an elective PCI are not dying of a heart attack. They are stable, the procedure is scheduled, and patients can travel to care right now within a reasonable time frame for treatment at any number of existing high-quality providers in New London, Hartford, Worcester, Providence, New Haven, Norwich, Springfield, etcetera.

Percutaneous Coronary Intervention, or PCI, stenting for the emergency treatment of heart attack is the central issue we should be focusing on when discussing the establishment of a novel PCI program.

Although the same procedure of PCI can be used in the treatment of stable coronary disease, it should not even be considered in a center that has not yet developed a safe, effective, high-quality emergent Percutaneous Coronary Intervention program.

Until you have demonstrated the capability to care for critically-ill heart patients in life-threatening situations, you cannot reasonably expect patients to put their trust in you to treat stable, non-emergent, non-life-threatening disease.

What if something went wrong? What if there were complications? You would be putting these

patients at risk before you've demonstrated you are equipped to handle coronary artery disease in its emergent state, so let us put aside Backus' application for elective PCI, where treatment times are irrelevant, and just talk about their application to develop an emergency PCI program.

It is true that immediate restoration of normal blood flow to a heart muscle that has a completely block artery is the ideal treatment for heart attack.

It is also true the ideal way to restore blood flow in these situations is by delivering a stent to open up the blocked artery compared with delivering IV medication, as you've heard; fibrinolytics, clot busters, thrombolytics that can dissolve the obstruction.

This only holds true providing the stent can be delivered in a timely fashion. National standards say less than 120 minutes when it's an inter-facility transfer. We've talked about that a lot today.

The challenge is that it takes a great deal of expertise to learn how to do this in a safe and effective way, not just expertise of the treating interventional cardiologist, but, also, the expertise of the nurses, the technologists, who support the physician.

Furthermore, it takes the expertise of

supporting personnel, including vascular surgeons, neurologists, neurosurgeons on site, should complications arise. Does Backus Hospital have a neurosurgeon or neurologist on site? Does Backus Hospital have a vascular surgeon on their medical staff?

The resources required to establish such centers are vast; time, capital, personnel. It is impractical to have an emergency PCI center in every town or every other town, and, so, we are left with a dilemma.

We know time is muscle and that opening a blocked artery as soon as possible is critically important for our patients, but establishing PCI centers in every town is not possible, so, to help, leaders in our field have developed guidelines and recommendations to help plan for the most effective allocation of limited resources that maximizes patient outcomes.

Panels of experts from groups, like the AHA, American College of Cardiology and SCAI, have poured over the thousands of studies from the scientific community and provide us an invaluable resource when considering applications like the one before this panel.

It’s clear from their recommendations that two emergency PCI centers within 30 minutes of each other are redundant. They go on to say multiple low volume and

partial service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health care system, and have not been shown to improve access.

The Applicants claim that, despite these recommendations from national and statewide health care leaders, this region of our state is somehow special and in need of additional PCI center, has a large population that is being underserved and not getting ideal treatment for heart attack.

They claim that their desire for such a program is not for financial gain or capture greater market share, but to help these patients in need get appropriate care.

I disagree on all counts, and here's why. For eight years, L & M Hospital has run a primary PCI program for heart attack. It is a mere 21-minute drive time from Backus Hospital.

As the panel has heard, less than a handful of patients were transferred from Backus to our center for immediate treatment of their heart attack.

It was only in the case of a record-breaking snowstorm and in one other case, because a treating ER doc had the courage to tell me, quote,

"Politics be damned. I'm sending this guy to you." He was a young attorney, who had sustained cardiac arrest while waterskiing and was being called out of this world, and he sent him to me, we took care of it, and the patient did fine.

Instead, the vast majority of patients have been sent to tertiary care centers, like Hartford, with a median door-to-balloon time over the last five years of 134 minutes.

This information was provided by the Applicant in graphic form on page 26 of the 3D assessment. Contrary to their assertion, that this time is improving, a closer look at this graph reveals that, since 2014, median times are in the 150 to 200-minute range.

I need to highlight that all these times are well above the guideline recommended threshold of 120 minutes for patients transferred to another facility.

In fact, the guidelines would recommend that these patients would have fared better if they had received thrombolytics, clot busters, rather than delayed PCI and long door-to-balloon times, as they currently receive now.

I would also just point out that when my

colleague was speaking about that graph, he suggested that many of those numbers are outliers. Well, when we look at these metrics, people, who have a good reason for a delay in their PCI, old patients, patients, who can't provide consent, patients, who have ongoing other critical illnesses, drop out of the metric, so I would suggest that these patients are, indeed, the ones we need to be paying attention to.

The guidelines would go on to point out that these same patients would have done even better if they had been transferred to Lawrence & Memorial Hospital, the nearest PCI center.

Why do I say that? Because we already received transfers from outside hospitals that are farther away than Backus' 21-minute drive time from our facility. L & M's median door-to-balloon time in these patients is less than 90 minutes, better than the required 120 for inter-facility transfers, certainly better than the data presented on patients transferred from Backus to Hartford and even better than the national standard of less than 90 minutes for patients presenting directly to a PCI center through the ER.

So although I agree that there are patients that have not received ideal care for their

STEMI, I disagree wholeheartedly with the cause and the Applicant's proposed solution. The cause is clearly because these patients have not been transferred to the nearest PCI center in L & M. The solution is to compel providers to do so.

So what, then, is the answer to improve outcomes of our patients' cardiac care in this region and to improve access to timely PCI?

It is certainly not to invest in a redundant center of Backus, but, rather, in improving infrastructure, the identification of STEMIs in the field, and mandating the transfer of eligible patients to the nearest PCI center, whether coming from pre-hospital or neighboring emergency rooms. As I said, Westerly Hospital has done this with great success.

The Applicant's response to the idea that patients should be transferred to the nearest PCI center is predictable and unfortunate. They suggest that a driving force in their current practice pattern is because of patient and physician referral patterns, as well as hospital affiliations.

I would like to take a minute to explore this. When someone is having a life-threatening emergency, referral patterns and patient preferences are

no longer an issue.

For example, let's say I was in Hartford with my children at the Connecticut Science Museum, went to a local clinic with chest pain on the way home, they identify a STEMI, I would expect to be brought to the nearest capable PCI center. I would not expect that the emergency room doc would get on the phone to track down my PCP in Branford, find out what cardiologist he would refer me to, and then have the ER doc reach out to that cardiology group and arrange transfer down to New Haven.

The notion, that the Applicant's emergency room takes the time, when someone is having a sudden heart attack, to track down their primary provider or cardiologist, to find out what their preference is, or ask the patient, who is in critical condition, where they would like to go, is inconceivable and not standard of care.

I would go so far as to say it's an injustice to patients to weigh affiliations and market share above the best course of treatment.

Another consequence of establishing a redundant PCI center is not immediately obvious and is one I would like to now turn your attention.

There is a clear association between

volume and quality. That is to say higher volume centers have better outcomes and lower complication rates. For the last eight years, L & M has established a PCI center for emergency PCI. We treat over 100 acute MIs each year, which is on par with the volume of acute MIs that come in through the doors of Yale-New Haven Hospital's ER.

We have a very low complication rate and have a proven track record of high quality care. We have also demonstrated that we have additional capacity to handle transfers from other non-PCI centers.

Approving the development of a new center in such close proximity to ours will undoubtedly impact our volume and, consequently, our quality.

You've heard that, in fiscal year '15, 35 cases would be lost. That sounds like a small number, but when you're talking about a low volume institution, its impact is significant.

We have been steadily improving each year to try to reach this quality metric of 200 cases. If the Backus program were to be approved, we would almost certainly be prevented from reaching this quality standard.

While L & M's program would suffer from

declining volumes, I also have great concerns about the projected volumes the Applicant anticipates for their proposed program.

On page 1466 of their completeness responses, the Applicant suggests that all the cases currently leaving their hospital for Hartford would be treated with PCI on site at Backus, should their application be approved.

This is simply untrue and reveals a fundamental lack of understanding about performing elective PCI at centers without surgical backup.

The guidelines tell us that the most appropriate patients to have their elective procedures done at an offsite center should be low-risk patients with low-risk lesions.

In our experience at L & M, this is less than 75 percent of patients, who are found to have a lesion that requires PCI. Other patients remain appropriate to have their PCI procedures done at tertiary care centers.

Furthermore, and this is important, in our experience, roughly 15 percent of our entire diagnostic cath lab volume, which is over 600 cases, has a PCI performed at L & M.

Applying this formula to Backus' fiscal year '15 cath lab volume of 234 cases, which, by the way, is below the minimum threshold to even have a diagnostic cath lab, would result in 35 elective cases per year, numbers well below standards.

Another cohort of patients that Backus mistakenly assumes can exclusively be treated with PCI at their hospital are those patients, who sustain a non-STEMI. The truth is that many of these patients will not need PCI at all, but instead need medical therapy, or bypass surgery, or are having a non-STEMI for reasons other than an obstructed artery.

If PCI is indicated, many will be better served receiving their PCI at a tertiary care center for reasons stated above.

And, so, volume is the key issue in this application, both the certain reduction in volume at L & M Hospital, which will lead undoubtedly to a diminution in quality; like the old adage says, practice makes perfect, as well, what will certainly be lower than anticipated volumes at Backus.

We are left, then, should this program be approved, with exactly what the guidelines warn against; two low-volume redundant centers, with substandard

quality, causing significant financial strain and drain on the health care system of our region.

Before I finish, I would like to appeal to this panel to consider what might be the best way to improve the quality of care delivered to patients with coronary artery disease suffering acute heart attack.

I would urge you to put your resources not into a redundant expensive program that stands to reduce quality, but, rather, into education, equipment, EMS personnel and executive mandates that help identify earlier recognition of STEMI in the pre-hospital arena and facilitate expeditious transfer of these critically-ill patients to the nearest PCI center, be they in Hartford, Massachusetts, Rhode Island, or New London.

I thank you all so much for your time, attention, and allowing me the opportunity to speak today.

HEARING OFFICER HANSTED: Okay, thank you, everyone. Just one point of housekeeping. The late files that were ordered will be due on June 21st. Does that give you enough time? Okay.

Before we adjourn, is there anyone here, who would like to give public comment on the matter before us?

Hearing and seeing no one, I will adjourn this hearing. Thank you, everyone.

(Whereupon, the hearing adjourned at 3:00 p.m.)

AGENDA

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Greer, Leslie

From: Mercier, Carlene M. <CMercier@brownrudnick.com>
Sent: Tuesday, June 21, 2016 3:22 PM
To: Armah, Olga; User, OHCA; Hansted, Kevin; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Fernandes, David; Martone, Kim
Cc: michelemvolpe@aol.com; Cohen, Douglas A.; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; kgg@bvmlaw.com; jlo@bvmlaw.com
Subject: Docket No. 15-32031-CON - Late File No. 2 & 3
Attachments: Hartford Hospital _ Backus Late File No. 2 & 3.PDF; Hartford Hospital _ Backus Late File No. 2 & 3.DOCX

Good Afternoon,

Please find attached the responses to the late files requested of the Applicants at the public hearing on June 14th.

Best Regards,
Carlene

BROWNRUDNICK

Carlene M. Mercier
Paralegal
Brown Rudnick LLP
CityPlace 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6538
F: 860.509.6501
www.brownrudnick.com

****

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****

ROBERT J. ANTHONY, ESQ.

direct dial: 860-509-6517

e-mail: ranthony@brownrudnick.com

http://www.brownrudnick.com

BROWNRUDNICK

185 Asylum
Street
Hartford
Connecticut
06103
tel 860.509.6500
fax 860.509.6501

June 21, 2016

VIA E-MAIL
(ohca@ct.gov; kevin.hansted@ct.gov; jessica.schaeffer-helmecki@ct.gov; olga.armah@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov; kimberly.martone@po.state.ct.us)

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134

Re: Docket No. 15-32031-CON – Late File 2 & 3

Dear Ms. Martone:

On behalf of Hartford Hospital and The William W. Backus Hospital (the "Applicants"), enclosed for filing is the information requested of the Applicants during the second part of the Public Hearing (June 14, 2016) on this docket.

Very truly yours,

BROWN RUDNICK LLP

By: Robert J. Anthony /cm
Robert J. Anthony

cc: Michele M. Volpe via e-mail (michelemvolpe@aol.com)

62496646 v1-WorkSiteUS-032836/0002

brownrudnick.com

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

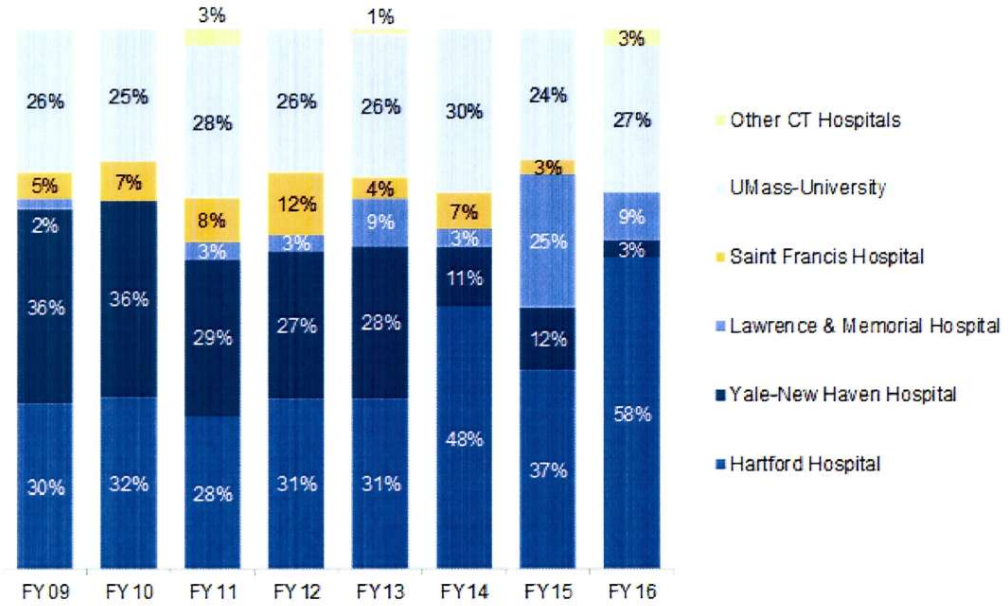
IN RE: THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S CERTIFICATE OF NEED APPLICATION TO ESTABLISH A PRIMARY AND ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM AT BACKUS HOSPITAL	:	**DOCKET NO. 15-32031-CON**
	:	**June 21, 2016**

THE WILLIAM W. BACKUS HOSPITAL AND HARTFORD HOSPITAL'S LATE FILE No. 2 & No. 3

At the June 14, 2016 public hearing in this docket, The William W. Backus Hospital and Hartford Hospital (the "Applicants") were asked to update the data contained in the Pre-Filed Testimony of M. Shane Foreman on page 1516 (Late File No. 2) and the data contained in the CON, Figure 20 on page 62 (Late File No. 3). The updated data follows.

Applicants' Response for Late File No. 2 (page 1516)[1]:

Service Area Primary PCI Market Share Trend



- Hartford Hospital currently treats the most Primary PCI patients originating within the service area.

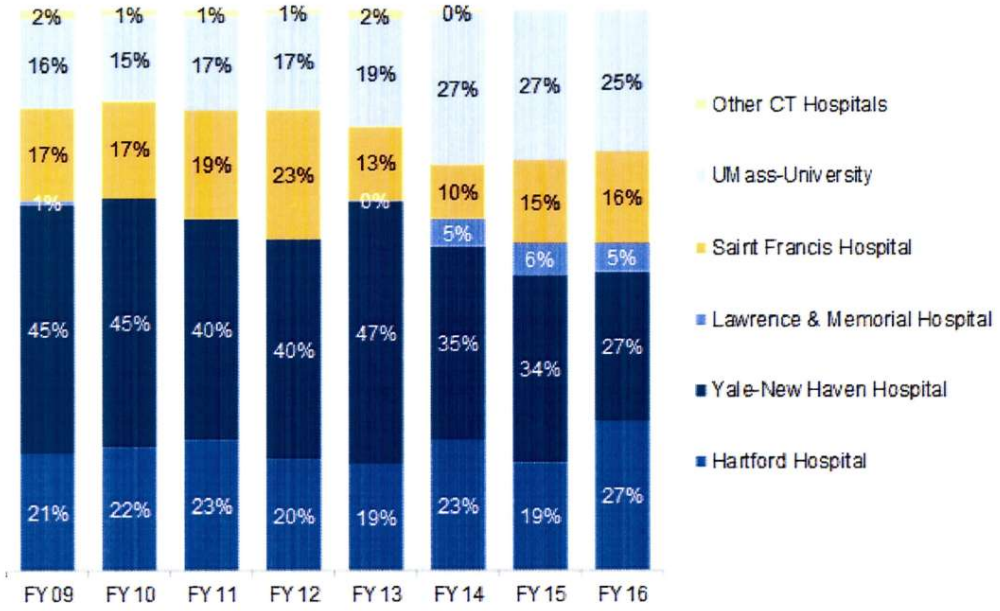
Source: CHIME; State of Massachusetts; 3d Health Analysis

The percentage of residents of the Backus Angioplasty Region seeking care at Hartford Hospital for Primary PCI has increased 28% since FY 2009. From FY 2014-FY2016 Hartford Hospital treated an average of 48% of Primary PCI cases from the Angioplasty Region, with 58% of cases choosing Hartford Hospital for this service in FY2016 (through April). Yale New Haven treated 12% of Primary PCI cases in FY 2015 and only 3% of Angioplasty Region Primary PCI cases in FY 2016 (through April). St. Francis treats a very small percentage of the Angioplasty Region (3% in FY2015), and through April of FY2016 has provided no Primary PCIs to the residents of the Angioplasty Region. Since FY 2011, Lawrence and Memorial treated an average of 8.6% Primary PCI patients from the Angioplasty Region. These numbers, however, are quite variable. For example, in FY 2014 Lawrence and Memorial treated only 3% of Primary PCI patients from the Angioplasty Region, in FY2015 Lawrence and Memorial treated 25% of cases from within the Angioplasty Region, and in FY 2016 (April) Lawrence and Memorial treated 9%

[1] *Connecticut Hospital data for both charts derived from CHIME data. Fiscal Year 2015 represents a full year, October-September 2015. Fiscal Year 2016 is current through Quarters 1 and 2 (October – April 2016). Data represents the percentage of Primary or Elective PCI procedures in patients originating from the defined Backus Angioplasty Region by Hospital.*

of Primary PCIs originating from the Angioplasty Region. In FY 2016 27% of Angioplasty Region residents were forced to leave the State of Connecticut to seek this life saving standard of care. Establishing a program at Backus Hospital would improve access to this standard of care for the 231,419 residents of the Angioplasty Region, 69% who do not have access within a 30 minute drive time today.

Service Area Elective PCI Market Share Trend



- Over half of the service area Elective PCI patients are currently having to travel to either Hartford Hospital or Yale-New Haven Hospital.

Source: CHIME; State of Massachusetts; CHA Patient Census Reports; 3d Health Analysis

From FY 2009 to FY 2016 (through April) the percentage of Elective PCI patients originating from the Angioplasty Region treated by Hartford Hospital increased by 6%. In FY 2015 Hartford Hospital treated 19% of Elective PCI cases from the Angioplasty Region, growing to 27% in FY 2016 (through April). Yale New Haven Hospital's share of the Elective PCI cases originating from the Angioplasty Region decreased 18% from FY 2009-FY 2016. St. Francis treats an average of 16.25% of Elective PCI cases from the Angioplasty Region, and in FY 2015 as well as in FY 2016 (through April) St. Francis treated 15% and 16% of patients, respectively. Lawrence and Memorial Hospital has treated 5-6% of Elective cases originating from the Angioplasty Region since 2014. The remaining cases seek care out of State. Establishing care close to home for patients requiring Elective PCI services will improve the quality of life within the Angioplasty Region. These patients choose Hartford HealthCare providers more than any

other provider in the State for their care, as articulated on page 36 of the CON application. Establishing an Elective program at Backus through the Hartford HealthCare IIeart and Vascular Institute will bring experienced, world class physicians to the residents of rural North East Connecticut. Patients suffering from NSTEMI, Left Bundled Branch Blockages, and Unstable Angina will no longer have to be transferred or travel far distances to unfamiliar cities and facilities to receive their procedures. Residents of the Angioplasty Region will enjoy the same standard of care as the rest of the State of Connecticut (page 1448) if this service is established at Backus Hospital.

Applicants' Response for Late File No. 3 (page 62):

Figure 20 – Backus Hospital Diagnostic Catheterization Volume and Related Transfers

Fiscal Year	***Total Diagnostic Catheterizations***	***Transfers***	***% Transferred***
2012	*316*	*90*	*28.4%*
2013	*356*	*90*	*25.3%*
2014	*218*	*55*	*25.2%*
2015 - Actual	*237*	*46*	*19.4%*
2016 – Annualized	***230***	***33***	***14.3%***
5 Year Average	***271***	***63***	***23.2%%***

Over the past 4 years Backus has transferred out an average of 63 diagnostic catheterization patients each year, which equates to approximately 23% of annual procedures. These patients then undergo a repeat catheterization to clear the blockages found in the initial procedure. Often this requires another groin or radial puncture to the patient, and transfer via EMS, which can increase risk of bleeding, infection, and other complications. These patients are treated at a tertiary care institution by an unfamiliar care team. Stress and anxiety are increased for families and caregivers, and accessing appropriate follow up care, or other necessary related services, back in the patient's home community can be difficult. By establishing an Elective PCI program at Backus, patients will be able to have the diagnostic and elective procedure completed together, which will reduce costs to the system and patient, reduce the exposure to radiation and intravenous contrast used during the procedure, reduce the risk of bleeding and infection, reduce the stress and anxiety placed on the patient and family, reduce duplication of effort and cost to the health care system and improve the care coordination offered to residents of the Angioplasty Region.

Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Wednesday, June 22, 2016 3:44 PM
To: Michelle Volpe Esq. (mmv@bvmlaw.com); Cohen, Douglas A.
Cc: Mercier, Carlene M.; User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David; Martone, Kim; Armah, Olga; Anthony, Robert J.; Mack, David (David.Mack@hhchealth.org); Janette.Edwards@hhchealth.org; kgg@bvmlaw.com; jlo@bvmlaw.com
Subject: 15-32031 Closure of Hearing
Attachments: 15-32031 Closure of Hearing signed 6.22.16.pdf

Good Afternoon—

Attached please find a notification of the closure of the hearing associated with docket number 15-32031.

Please feel free to contact me if you have any questions.

Thank you,

Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

June 22, 2016

VIA EMAIL ONLY

Mr. Douglas A. Cohen, Esq.
Brown Rudnick LLP
Attorney of Record, Applicants
185 Asylum Street
Hartford, CT 06103
dcohen@brownrudnick.com

Ms. Michelle M. Volpe, Esq.
Attorney of Record, L+M Hospital
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd floor
New Haven, CT 06511
mmv@bvmlaw.com

RE: Certificate of Need Application; Docket Number: 15-32031-CON
Establishment of Angioplasty Program at William W. Backus Hospital
Closure of Public Hearing

Dear Mr. Cohen and Ms. Volpe:

Please be advised, by way of this letter, the public hearing held on March 23 and June 4, 2016 in the above referenced matter is hereby closed as of June 22, 2016. OHCA will receive no additional public comments or filings.

If you have any questions regarding this matter, please feel free to contact Jessica Schaeffer-Helmecki at (860) 509-8075, Olga Armah at (860) 418-7070, or David Fernandes at (860) 418-7032.

Sincerely,

Kevin T. Hansted
Hearing Officer

KTH:jssh

Greer, Leslie

From: Greer, Leslie
Sent: Thursday, August 25, 2016 3:46 PM
To: 'Janette.Edwards@hhchealth.org'; 'RAnthony@brownrudnick.com'; 'mmv@bvmlaw.com'
Cc: Armah, Olga; Schaeffer-Helmecki, Jessica; Fernandes, David; Riggott, Kaila; Hansted, Kevin; Martone, Kim
Subject: The William W. Backus Hospital Propsed Final Decision
Attachments: 32031_201608251403.pdf

Tracking:

Recipient	Delivery	Read
'Janette.Edwards@hhchealth.org'		
'RAnthony@brownrudnick.com'		
'mmv@bvmlaw.com'		
Armah, Olga	Delivered: 8/25/2016 3:46 PM	Read: 8/25/2016 3:50 PM
Schaeffer-Helmecki, Jessica	Delivered: 8/25/2016 3:46 PM	
Fernandes, David	Delivered: 8/25/2016 3:46 PM	
Riggott, Kaila	Delivered: 8/25/2016 3:46 PM	
Hansted, Kevin	Delivered: 8/25/2016 3:46 PM	
Martone, Kim	Delivered: 8/25/2016 3:46 PM	

Attached is the proposed final decision for The William W. Backus Hospital DN: 15-32031-CON.

Leslie M. Greer
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS#13HCA, Hartford, CT 06134
Phone: (860) 418-7013 Fax: (860) 418-7053
Website: www.ct.gov/ohca

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Office of Health Care Access

Proposed Final Decision

Applicants:

The William W. Backus Hospital
326 Washington Street,
Norwich, CT 06360

Hartford Hospital
80 Seymour Street,
Hartford, CT 06102

Docket Number: **15-32031-CON**

Project Title: **Establishment of a Primary and Elective Percutaneous Coronary Intervention Program at Backus Hospital without On-Site Surgical Backup**

Project Description: The William W. Backus Hospital ("Backus") and Hartford Hospital ("Hartford") (Backus and Hartford are herein collectively referred to as the "Applicants") seek authorization to establish and operate a primary and elective percutaneous coronary intervention ("PCI" or angioplasty) program at Backus without on-site cardiac surgical backup, at an associated capital cost of $4,982,053.

Procedural History: The Applicants published notice of their intent to file a Certificate of Need ("CON") application in *The Bulletin* (Norwich) on September 7, 8 and 9, 2015. On September 30, 2015, the Office of Health Care Access ("OHCA") received the CON application from the Applicants for the above-referenced project. On January 29, 2016, OHCA deemed the application complete.

On March 9, 2016, the Applicants were notified of the date, time, and place of the public hearing. On February 11, 2016, a notice to the public announcing the hearing was published in *The Bulletin* (Norwich). Thereafter, pursuant to Connecticut General Statutes ("Conn. Gen.

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Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph
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Stat.") § 19a-639a(f)(2), the public hearing regarding the CON application was held on March 23, 2016 and continued on June 14, 2016.

Commissioner Pino designated Attorney Kevin T. Hansted as the hearing officer in this matter. The hearing was conducted in accordance with the provisions of the Uniform-Administrative Procedure Act (Chapter 54 of the General Statutes) and Conn. Gen. Stat. § 19a-639a(f)(2).

On March 16, 2016, Lawrence + Memorial Hospital ("L+M") filed a petition requesting intervenor status. L+M was granted intervenor status with full rights in this matter on March 17, 2016.

On March 22, 2016 the Applicants filed a Motion in Limine to preclude use of data regarding out-of-state PCI providers. On March 23, 2016 L+M filed an objection to the Applicants' Motion in Limine. On March 31, 2016, Hearing Officer Hansted denied the Applicants' motion and sustained L+M's objection. The public hearing record was closed on June 22, 2016.

Findings of Fact

1. Backus is a 233-bed/bassinet acute care hospital, located at 326 Washington Street in Norwich, CT, and is affiliated with Hartford. Exhibit A, p. 13.

2. Hartford is an 867-bed major teaching hospital affiliated with the University of Connecticut School of Medicine and a regional referral center serving New England. Hartford's Henry Low Heart Center is a full service cardiac provider that offers the following services:
   a. Cardiac catheterization, angioplasty, electrophysiology and rehabilitation programs;
   b. A congestive heart disease center;
   c. Echocardiography;
   d. Extracorporeal membrane oxygenation;
   e. A heart failure infusion program;
   f. Heart surgery and transplants;
   g. Nuclear cardiology; and
   h. A transcatheter aortic valve replacement program.

   Exhibit A, p. 13, 24.

3. Backus currently offers the following inpatient and outpatient cardiac services:
   a. Diagnostic cardiac catheterizations;
   b. Pacemaker insertions, evaluations and follow-ups;
   c. Implantable cardiac defibrillator insertions, evaluations and follow-ups;
   d. Stress testing;
   e. Nuclear cardiac imaging;
   f. Cardiac imaging services;
   g. Echocardiology;
   h. 24- and 48-hour monitoring;
   i. ECG testing;
   j. Electrical cardioversions;
   k. Intra-aortic balloon pumping;
   l. Vascular surgical services offered by interventional radiology staff such as peripheral angioplasty and stenting;
   m. Heart failure program that offers monitoring and a program coordinator for patients beyond the inpatient setting; and
   n. Three phase cardiac rehabilitation program consisting of inpatient, outpatient and outpatient maintenance.

   Exhibit A, p. 20-21.

4. The Applicants are proposing the expansion of cardiac services at Backus by establishing and operating a primary and an elective PCI program without on-site cardiac surgical back-up. Backus' 12-bed critical care unit would be the primary unit for all post-PCI patients. Exhibit A, pp. 13, 21.

5. Angioplasty is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a diagnosed blockage in the heart. An expandable balloon is passed through the artery and inflated, flattening blockage-causing plaque and allowing for improved blood-flow. Exhibit A, p. 14.

6. Primary PCI is used to treat emergency situations, such as ST-Segment Elevation Myocardial Infarctions ("STEMI"), which occur when an acute coronary thrombosis blocks a coronary artery. Elective PCI is often a scheduled procedure following extensive cardiac testing or a post-cardiac event to relieve chest pain and related symptoms. Exhibit A, p. 14.

7. STEMI patients requiring primary PCI, need the most urgent care and are treated on an emergency basis. Elective PCI procedures for patients with non-ST-segment elevation myocardial infarction ("NSTEMI") are often scheduled, but ideally take place within 24-48 hours of diagnosis, effectively reducing the risk of future cardiac events. Ex. A, pp. 14-15; Ex. BB, Transcript, Dr. Francis J. Kiernan, Director of Cardiac Laboratory, Hartford Hospital, pp. 103-104.

8. Hartford provides comprehensive cardiac services and performs more than 1,000 angioplasties annually. Hartford and Backus have entered into an agreement for the emergency transfer of patients to Hartford for off-site surgical backup for urgent cases at all hours and for elective cases at mutually agreed upon hours, as well as the necessary training and oversight of the proposed PCI program at Backus. Ex. A, pp. 46, 99, 892-93.

9. The Applicants submitted the following agreements, policies and protocols:
   - Primary PCI Patient Selection Guidelines
   - 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention and How Backus Will Meet the Standards
   - Elective PCI Patient Selection Guide
   - Transfer Protocol and Agreement between the Applicants
   - Cardiac Surgery Transfer Agreement Between Hartford and Backus
   - Clinical Guidelines for Transfer of Catheterization Lab Patients to Acute Care Facility

   Ex. A. pp. 88, 84-87, 89, 892-897

10. The Applicants claim benefits of the proposal include:
    a. Improved access for an area of the state that:
       (i) is "geographically isolated" from the nearest PCI provider;
       (ii) has an older population with a relatively higher risk than the state for coronary artery disease;
       (iii) has current rates of emergency/primary and elective PCI interventions for residents that are significantly below state and national levels leading to relatively higher rates of morbidity and mortality;
    b. Minimized out-of-pocket costs associated with second hospital admission and duplicative procedures; and

c. Improved future care coordination and management for patients with heart conditions.

Exhibit A, p. 13.

11. The ACC/AHA STEMI Guidelines provide that "door-to-balloon" time, measured from the time a patient presents at the emergency department of a PCI-capable hospital to the time a balloon is inflated to open the occluded artery, should not exceed 90 minutes. The recommended door-to-balloon time for patients presenting at a non-PCI capable hospital from which the patient must be transferred to another hospital is 120 minutes. Exhibit A, pp. 47, 500.

12. The presence of a PCI program on-site at Backus would obviate the need for revascularization following a cardiac catheterization diagnosis, enabling the diagnostic and elective procedure to be completed together. This would reduce patient exposure to radiation and intravenous contrast used during the procedure. Ex. A, p. 62.

13. The Statewide Health Care Facilities and Services Plan states that hospitals seeking to establish an elective PCI program without on-site cardiac surgery must:
    a. Meet the conditions required in the American College of Cardiology Foundation/American Health Association/Society for Cardiovascular Angiography and Interventions ("ACCF/AHA/SCAI) Practice Guideline (the " Guideline") for percutaneous coronary intervention without on-site surgical backup; and
    b. Demonstrate a clear public need for the program. Specifically, the Guideline indicates that it is only appropriate to consider the initiation of the PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community as competition with another PCI program in the same geographic area may not be in the best interests of the community.

    Exhibit A, pp. 38-39, 47.

14. The Applicants' proposed service area ("proposed service area") included a) towns within a 30 minute drive-time to Backus, and b) towns outside of the 30-minute radius but for which Backus would be the closest PCI-capable facility in Connecticut. This classification excluded out-of-state PCI providers.

TABLE 1
APPLICANTS' PROPOSED SERVICE AREA

Towns within a 30-minute drive time of Backus Hospital			Towns for which Backus would be the closest in-state PCI provider
Bozrah	Killingly	Preston	East Haddam
Brooklyn	Griswold-Lisbon	Scotland	Hampton
Canterbury	Hebron	Sprague	Pomfret
Chaplin	Killingly	Sterling	Putnam
Colchester	Mansfield Center	Voluntown	Thompson
Columbia	Norwich	Windham	Woodstock
Franklin	Plainfield		

Exhibit A, p. 35.

15. Based on fiscal year ("FY") 2015 inpatient discharges for Backus, the towns below comprise Backus' service area ("SA").[1] The Applicants' proposed service area included 20 towns beyond Backus Hospital's SA (Bozrah, Brooklyn, Columbia, Franklin, Hebron, Killingly, Lebanon, Mansfield Center, Scotland, Sprague, Sterling, Voluntown, Windham, East Haddam, Hampton, Pomfret, Putnam, Thompson and Woodstock). Additionally, the proposed service area omitted three towns that are in the SA (Groton, Ledyard and Montville).

TABLE 2
BACKUS HOSPITAL DISCHARGES, FY 2015

Patient Town	Discharges	% of Total Discharges	Cumulative %
Norwich	3,729	35%	35%
Griswold- Lisbon	1,169	11%	46%
Montville	910	8%	54%
Plainfield	843	8%	62%
Preston	346	3%	65%
Colchester	322	3%	68%
Canterbury	273	3%	71%
Ledyard	269	3%	73%
Groton	251	2%	76%
Remaining Towns/States	2,611	24%	100%
Total	**10,723**	**100%**	**100%**

Source: CT DPH, Office of Health Care Access Acute Care Discharge Database

16. The Applicants stated that they selected drive time as the basis for the proposed service area because of the "urgency of time, in order to access [PCI] services." Additionally, they stated that they selected 30 minutes as the perimeter of the drive time based on the Department of Public Health Office of Emergency Management Services, *Connecticut EMS STEMI Guidelines* ("DPH OEMS Guidelines"). Ex. T, Transcript, Mr. M. Shane Foreman, CEO, 3d Health, p. 34; Ex. K, Pre-filed Testimony, Foreman, 1543.

17. The stated goal of the DPH OEMS Guidelines is to "ensure that authorized EMS personnel obtain a 12-lead electrocardiogram in the field on all patients with suspected MI, thereby increasing the likelihood they will be transported for treatment with PCI intervention within 90 minutes of first medical contact." It directs emergency medical vehicles transporting a patient already identified as STEMI to bring the patient to a PCI-capable facility if it is less than 30 minutes away. It also states that emergency vehicles

1. SA is defined as towns that make up the top 75% of a hospital's discharges. CT DPH, *Statewide Health Care Facilities Plan* 76 (2014 Supplement.).

should be 12-lead echocardiogram-equipped to facilitate early identification of STEMI patients. Ex. A, p. 969-970.

18. There are proven beneficial outcomes associated with reducing the time between a patient's presentation at the emergency department to inflation of the balloon to open the occluded artery ("door-to-balloon time") during a primary PCI procedure. Ex. T, Transcript, Dr. Paul Thompson, Chief of Cardiology, Hartford Hospital, p. 29.

19. From 2011 through 2015, Backus' median door to balloon time for primary PCI was 134 minutes. Transport time to a PCI-capable hospital accounted for the largest portion of the door-to-balloon time. Ex. A, p. 473, 476.

20. Backus has historically transferred patients to Hartford and Yale New Haven Hospital for primary PCI, transferring only three patients in the past to the closest PCI-provider, L+M. The Applicants stated this was due primarily to referral patterns. Ex. T, Transcript, Dr. Kyle McClaine, EMS Director, Backus Hospital, p. 151-152; Ex. BB, Transcript, Dr. John Foley, Director of Cardiovascular Service Line, Hartford Medical Group, p. 138.

21. UMass Memorial Medical Center ("UMass") submitted a letter stating that it has an ongoing relationship with Day Kimball Hospital ("Day Kimball") and established protocols are in place for receiving NSTEMI transfer patients from Day Kimball. It also states that UMass' PCI program currently has capacity to continue treating transfers and referrals from Day Kimball. Ex. V; pp. 1-2.

22. UMass is the closest existing PCI provider, based on travel time, for four out of the six towns in northeast Connecticut the Applicants included in their proposed service area.

TABLE 3
TRAVEL TIMES FROM NORTHEAST TOWNS INCLUDED IN THE PROPOSED SERVICE AREA TO CLOSEST HOSPITAL*

Select Towns	Drive time to Backus Hospital	Drive time to UMass Hospital
East Haddam	27 minutes	78 minutes
Hampton	27 minutes	46 minutes
Pomfret	36 minutes	33 minutes
Putnam	33 minutes	26 minutes
Thompson	35 minutes	23 minutes
Woodstock	39 minutes	33 minutes

* Based on Google Maps travel time without traffic from center of town

23. Day Kimball, located at 320 Pomfret Street, Putnam, stated in its 2015 Community Health Needs Assessment and Implementation Plan that it "continues to work closely with UMass for STEMI patient transfers via Life Star helicopter within 90 minutes of

admission to the emergency department and meets regularly to review STEMI data." Ex. W, p. 4.

24. In 2010, towns in the proposed service area experienced an incidence rate of 104.3 STEMIs per 100,000; Connecticut overall experienced a rate of 83. Towns in the proposed service area experienced an incidence rate of 237.2 for NSTEMIs; Connecticut overall had a higher incidence of NSTEMIs at 242.3. Ex. A, p. 463.

25. Over a seven year period, patients in the proposed service area underwent fewer inpatient elective PCIs; declining from 316 in FY09 to 171 in FY15. This is consistent with state-wide trends. Ex. A, p. 466, 1499-1500.

26. The number of patients transferred for an elective PCI following a cardiac catheterization at Backus was 90 in 2012, 90 in 2013, 55 in 2014, 46 in 2015 and 33 in 2016 (annualized). The percentage of cardiac catheterization patients transferred from Backus to a PCI-capable facility also decreased, from 28.4% in 2012 to 19.4% in 2015. Ex. CC, p. 1570.

27. According to the SCAI/ACC/AHA's *Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup* ("2014 Guidelines"), multiple factors have contributed to the decline in PCI procedures, including "a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, and a reduction in incidence of STEMI…" Ex. A, p. 113.

28. According to the Applicants, there are an insufficient number of emergency advanced life support vehicles in the Backus region, with 15 covering 13 towns in the Backus region. Ex. A., p. 34.

29. The 2014 Guidelines state that "an institutional volume threshold of <200 PCIs/year was associated with worse outcomes" and therefore "continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned." It continues to say that "multiple low-volume and partial service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access." It defines "geographic isolation" as a hospital that is more than 30 minutes away from a PCI-capable facility by emergency transport. Ex. A, pp. 119-121.

30. L+M, a PCI-capable facility, is located 17 miles, or 21 minutes from Backus. Ex. T, Transcript, Dr. Brian Cambi, Director of Cardiology, L+M Hospital, p. 51.

31. Based on historic PCI utilization of residents originating from Backus' SA at other area hospitals[1], the Applicants project Backus would perform 163 PCIs in FY16, increasing slightly to 169 in FY18.[2]

TABLE 4
PROJECTED PCI UTILIZATION AT BACKUS HOSPITAL

Category	FY16	FY 17	FY18
Primary PCI	55	54	54
Elective PCI	108	111	115
Total	**163**	**165**	**169**

[1] Includes Backus SA patients receiving PCIs at: Hartford Hospital, Yale New Haven, Saint Francis, John Dempsey, The Hospital of Central Connecticut, UMass Memorial and Lawrence + Memorial Hospital.

[2] Assumes a retention rate of 100% of patients receiving PCIs at Hartford Hospital and 36% from other hospitals based on Backus' ED market share.

Ex. K, p. 1497; Ex. E, pp. 1458, 1466.

32. There are no PCI providers in the Applicants' proposed service area. However, the following hospitals have administered PCIs to 369 patients originating from Backus' SA in 2015.

TABLE 5
2015 PCI PROVIDERS TREATING PATIENTS ORIGINATING FROM BACKUS' SA

PCI Providers	Distance from Backus[1]	No. of PCIs Originating from Backus SA	No. of PCIs	No. of PCIs minus No. from Backus SA	% of PCIs from Backus SA
Hartford Hospital	40 minutes	50	1,099	1,049	4.5%
Yale New Haven Hospital	53 minutes	145	1,575	1,430	9.2%
Saint Francis Hospital	39 minutes	24	784	760	3%
John Dempsey Hospital	58 minutes	30	399	369	7.5%
The Hospital of Central CT	48 minutes	15	85	70	17.6%
UMass Memorial	60 minutes	54	~1,100	1,046	~5%
Lawrence + Memorial Hospital	21 minutes	63*	216	165	23.6%

[1] Distance based on Google Maps normal travel time

* Based upon 2015 inpatient discharge data. All other figures reflect 2014 inpatient discharge data.

Ex. A, p. 46; Ex. E, p. 1458.

33. In 2015, L+M performed 216 PCIs, 63 of those PCI patients originated from Backus' SA.

TABLE 6
2015 PCI PATIENTS FROM SA TREATED AT L+M

	2015 Town Totals		2015 L+M PCIs	
SA Towns	**No. Primary PCIs**	**No. Inpatient Elective PCIs***	**No. Primary PCIs**	**No. All Elective PCIs**
Norwich	17	31	10	3
Canterbury	3	3	1	
Preston	1	6	1	3
Plainfield	7	16		1
Colchester	7	8		
Griswold	3	18	2	
Lisbon	-	-		
Montville	10	15	3	2
Ledyard	7	10	6	4
Groton	-	-	20	7
TOTAL	**55**	**107**	**43**	**20**
		L+M Total	**121**	**95**
		No. Remaining at L+M	**78**	**75**

* Outpatient elective PCI data unavailable

Ex. A, pp. 1499-1500; Ex. M, p. 12.; Compliance Reporting for Docket No. 12-31769

34. L+M stated that it has additional capacity to handle transfers from other non-PCI centers. Ex. BB, Transcript, Dr. Cambi, p. 158.

35. The 153 primary and elective PCI patients that would remain at L+M if Backus were to have a PCI program and capture all patients from its SA towns falls below the 200 level recommended by the 2014 Guidelines. Exhibit A, pp. 1499-1500.

36. The Applicants and L+M submitted conflicting claims as to the average retention rate of patients from a PCI provider's service area. The Applicants initially based their projection assumptions on an 80% retention rate of PCI patients from their proposed service area based on observed emergency department market share from the area. L+M asserted that those seeking scheduled elective PCIs would not mimic emergency room patterns and that L+M experienced an overall PCI retention rate of 54%. The Applicants then based final projection rates on a 100% retention rate for patients who had previously received PCIs at Hartford and 36% for those visiting all other hospitals. Ex. A, p. 489; Ex. BB, Testimony, Ms. Edwards, p. 139; Ex. BB, Testimony, Mr. Bitmal Patel, President of the East Region and Senior Vice President, Hartford HealthCare, p. 139; Ex. K, p. 197.

37. L+M established its elective PCI program in 2013. Per the Agreed Settlement with OHCA approving establishment of its program, L+M is expected to perform a quantity of procedures above those recommended by the 2014 Guidelines. L+M has stated it is likely to fall well below the minimum threshold should Backus initiate its own PCI program. Ex. M, p. 26; OHCA Docket Number 12-31768-CON.

38. Backus projects a financial loss from the operation of a PCI program with increasing incremental losses from operations, from FY2017 through FY2019.

TABLE 7
PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2017	FY 2018	FY 2019
Revenue from Operations*	$4,750,000	$4,911,295	$4,970,474
Total Operating Expenses**	$5,208,730	$5,470,996	$5,676,231
Gain/Loss from Operations	($457,817)	($559,701)	($705,757)

* Net revenue per case remains flat and assumes no increase in payer reimbursement
** 2.68% inflation rate applied over five resulting in increasing expenses; 2.6 new FTE cardiology staff, on-call payment and call back pay to staff, 24/7 on call physician expenses at $125/hr. Exhibit A, p. 1409; Ex. BB, Transcript, Ms. Janette Edwards, Backus Hospital, p. 128.

39. Backus would need to perform 385 PCI procedures in year five of the program to break even financially. The Applicants project they would perform 233 procedures in the year 2020. Ex. A, pp. 68, 70.

40. Estimated capital expenditures associated with the proposal are almost $5 million. Capital costs would support an additional catheterization lab, new software and equipment upgrades. An additional 3% of net patient revenues would be committed to ongoing capital needs. The Applicants' proposed capital expenditures are as follows:

TABLE 8
TOTAL PROPOSAL CAPITAL EXPENDITURES

Purchase/Lease	**Cost**
Equipment (Medical, Non-medical Imaging)	$344,000
Construction/Renovation	$4,500,000
Other (specify) (*estimated 3% of operating revenue for additional capital needs*)	$138,053
Total Capital Expenditure (TCE)	**$4,982,053**
Total Capital Cost (TCO)	**$0**
Total Project Cost (TCE+TCO)	**$4,982,053**

Exhibit A, pp. 67, 77.

41. The Applicants would fund the proposal through Backus' income from operations. Exhibit A, p. 65.

42. The Applicants project overall gains from Backus' operations from FY17 through FY19.

TABLE 9
BACKUS HOSPITAL PROJECTED REVENUES AND EXPENSES WITH CON

	FY 2017	FY 2018	FY 2019
Revenue from Operations	$308,297,624	$317,799,924	$329,208,612
Total Operating Expenses	$270,537,970	$276,777,162	$285,116,496
Gain/Loss from Operations	$37,759,653	$41,1022,761	$44,062,116

Exhibit A, p. 1409.

43. The projected patient population mix for the proposed PCI program is as follows:

TABLE 10
BACKUS HOSPITAL'S PROJECTED PAYER MIX

Payer	Projected**					
	FY 2016		FY 2017		FY 2018	
	Volume	%	Volume	%	Volume	%
Medicare*	109	50%	110	50%	113	50%
Medicaid*	25	11%	25	11%	26	11%
CHAMPUS & TriCare	-	0%	-	0%	-	0%
Other Government	2	1%	2	1%	2	1%
Total Government	**135**	**62%**	**136**	**62%**	**140**	**62%**
Commercial Insurers	79	37%	80	37%	82	37%
Uninsured	2	1%	2	1%	2	1%
Workers Compensation	-	0%	-	0%	-	0%
Total Non-Government	**81**	**38%**	**82**	**38%**	**85**	**38%**
Total Payer Mix	**216**	**100%**	**218**	**100%**	**225**	**100%**

*Includes managed care activity
**Payor-weighted reimbursement by DRG based on the payor mix of all PCI patients originating from the proposed service area.
Ex. A, p. 1469

44. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations yet to be adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))

45. The CON application is inconsistent with the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))

46. The Applicants have not sufficiently demonstrated that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

47. The Applicants have satisfactorily demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))

48. The Applicants have not satisfactorily demonstrated that access to services, cost effectiveness and the quality of health care delivery would be maintained. (Conn. Gen. Stat. § 19a-639(a)(5))

49. The Applicants have satisfactorily shown that there will be no change in access to primary and elective PCI services to the relevant populations and payer mix, including Medicaid patients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6))

50. The Applicants have not satisfactorily identified the population to be served or that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7))

51. The Applicants' historical utilization in the area does not support this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))

52. The Applicants have not satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))

53. The Applicants have satisfactorily demonstrated that the proposal would not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10))

54. The Applicants have satisfactorily demonstrated that the proposal would not negatively impact the diversity of PCI providers in the area. (Conn. Gen. Stat. § 19a-639(a)(11))

55. The Applicants have satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or accessibility to care. (Conn. Gen. Stat. § 19a-639(a)(12))

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board, 309 Conn. 727 (2013).*

Backus is a 233-bed/bassinet acute care hospital, located at 326 Washington Street in Norwich, CT, and is affiliated with Hartford. *FF1.* Hartford is an 867-bed major teaching hospital affiliated with the University of Connecticut School of Medicine and a regional referral center serving New England. *FF2.* Backus currently offers inpatient and outpatient cardiac services including diagnostic cardiac catheterizations, cardiac imaging services, echocardiology, intra-aortic balloon pumping and vascular surgical services offered, such as peripheral angioplasty and stenting, by interventional radiology staff. *FF3.*

The Applicants are proposing to expand cardiac services at Backus to include a primary and an elective PCI program. *FF4.* Backus' 12-bed critical care unit would be the primary unit for all post-PCI patients. *FF4.* Hartford would provide off-site surgical back-up. *F8.* Hartford provides comprehensive cardiac services and performs more than 1,000 angioplasties annually and, in addition to tertiary back-up, would provide the necessary training and oversight of Backus' newly established PCI program. *FF8.*

<u>The Applicants have not satisfactorily identified the population to be served by the proposal</u>

Rather than basing the service area on Backus' inpatient discharges, the Applicants based the projected population to be served on a combination of a) towns within a 30-minute radius from Backus and b) towns for which Backus would be the closest PCI-provider by travel time. *FF14.* According to the Applicants, it selected drive time because of the "urgency of time, in order to access [PCI] service." The Applicants stated they selected 30 minutes as the perimeter of the drive time based on the DPH OEMS Guidelines. *FF16.*

The Applicants' proposed service area is inappropriate for three reasons. First, the Applicants failed to provide an adequate rationale for its selection of 30 minutes as the perimeter for the towns to be served. The stated goal of the DPH OEMS Guidelines is to "ensure that authorized EMS personnel obtain a 12-lead electrocardiogram in the field on all patients with suspected MI." It is intended to provide guidance to emergency transport vehicles as to what hospital patients who have a pre-hospital diagnosed STEMI should be directed. *FF17.* Although it is well established that the time to reperfusion correlates to the extent of heart muscle damage in a patient experiencing acute myocardial infarction ("AMI"), the Applicants provided no recognized standard that establishes that every town should be within 30 minutes of a PCI-

capable facility. The Applicants' basis for a 30 minute drive time standard misinterprets the standards and the purpose of the DPH OEMS Guidelines.

Second, for NSTEMI patients requiring an elective -- as opposed to primary -- angioplasty, timing is less critical. According to the Applicants, patients presenting with a one or more significant arterial blockages that are non-life threatening, or NSTEMI, should receive an elective angioplasty within 24 to 48 hours of being diagnosed. *FF7*. Therefore, the application of a travel time constraint of 30 minutes when identifying the projected population to be served by the elective angioplasty program is unfounded as patients may travel to existing elective PCI programs in the area within 24 to 48 hours.

Finally, the Applicants incorrectly state that several of the towns included in their proposed service area are closer to Backus than any other PCI-capable facility. Backus would not be the closest PCI-capable hospital for several of the towns it included in its proposed SA. For example, UMass would be the closest PCI facility for patients originating from Thompson, Putnam, Pomfret or Woodstock. *FF22*. Additionally, as the only acute care hospital in Northeast Connecticut, Day Kimball would likely be the hospital at which patients from that area (including Thompson, Putnam, Pomfret and Woodstock) showing signs of AMI would likely present. Day Kimball, as a hospital lacking PCI capabilities, has stated that it intends to transfer AMI patients to UMass. *FF23*. Due to Day Kimball's proximity to UMass and stated referral patterns, it is uncertain whether patients from multiple towns in the Applicant's proposed service area would seek treatment at Backus. Therefore, the Applicants have failed to adequately identify the population the proposed program may likely serve.

In order to assess whether there is a clear public need for the establishment of a new angioplasty program in a given region and a new program's anticipated impact on existing providers, it must be determined, in part, how many patients would likely receive treatment at the new program. Based on Backus' historic inpatient discharges, its service area, and projected population to be served, is: Canterbury, Colchester, Griswold, Lisbon, Ledyard, Montville, Norwich, Preston, Plainfield and Groton. *FF15*.

Based on declining utilization rates, the increasing use of non-surgical medications and alternate methods of treatment and diagnosis of cardiovascular events the Applicants have not demonstrated that there is a clear public need for a new angioplasty program in the service area.

The Applicants claim that towns in their service area experience elevated incidents of STEMI and NSTEMI compared to Connecticut overall and that this indicates an unmet need for PCI services exists in the proposed service area. While the proposed service area did have a 2010 incidence rate of 104.3 STEMIs per 100,000 people--higher than Connecticut's 83 -- its incidence rate of NSTEMI for the same period was lower than that of the state -- 237.2 compared to 242.3. *FF24*. This suggests that although there may be a need for primary PCI services to address STEMI patients in the area, the NSTEMI data provided by the Applicants does not support the need for an elective program. Additionally, according to Applicants-provided

inpatient elective PCI procedure volume, there is a declining trend in elective PCIs in the area -- consistent with the trend observed state-wide. *FF25.*

Furthermore, other indicators of the need for an elective PCI program in the area are also declining. The number and percentage of cardiac catheterization transfers from a non-PCI facility to a PCI-capable facility for elective angioplasties are two such indicators. The number of patient transfers for an elective PCI following a cardiac catheterization at Backus decreased from 90 in 2012 to 46 in 2015. The transfer rate similarly decreased, from 28.4% in 2012 to 19.4% in 2015. *FF26* This mirrors the state and national data indicating a declining need for elective PCIs.

According to the 2014 Guidelines, due to the increased use of non-surgical alternatives, the number of PCIs performed is likely to continue to decline. It states that drug-eluting stents, enhanced primary and secondary prevention efforts and a greater emphasis on medical therapy are increasingly replacing PCIs as the choice treatment in certain situations. *FF27.*

Additionally, as discussed above, the Applicants cite the DPH OEMS Guidelines as evidence of the need for a PCI program at Backus but misstate the standards and goals of the policy. The Applicants state that "[residents] to the north and east of Norwich do not have timely access to a Connecticut primary or elective PCI-equipped hospital within 30 minutes' drive time, as specified by DPH OEMS Guidelines." *Ex.A, p. 16.* However, the referred-to standard pertains to EMS transport of patients with pre-hospital-diagnosed STEMI and is intended to assess whether such patients should be transported to a PCI-capable hospital based on travel time, recommending STEMI patients be transferred to a PCI-capable hospital if one is less than 30 minutes away. *FF17.* The OEMS Guidelines make no indication as to the ideal location of PCI facilities and do not recommend that all towns be within a 30 minute drive time of a PCI facility.

The Applicants again cite DPH OEMS Guidelines regarding EMS transport, stating that STEMI patients should be identified in the field via an electrocardiogram (ECG) in effort to direct patients expeditiously to the appropriate level of care. The Applicants continue that there are only 15 emergency advanced life support vehicles with ECGs to cover 13 towns in the Backus region. The Applicants suggest that because there may be an insufficient number of ECG-equipped emergency transport vehicles, some patients may not be identified as STEMI prior to delivery at a hospital and therefore Backus requires PCI capabilities to treat these patients. *Ex. A, p. 34.* An insufficient number of ECG-equipped vehicles does not equate to the need for a PCI program at every hospital, but rather speaks to whether there is a need for additional appropriately-equipped emergency vehicles.

The Applicants-provided data shows that there may be elevated incidence of STEMIs in the Backus area, potentially warranting a primary PCI program. A shortage of ECG-capable emergency transport vehicles may also highlight the need for additional advanced life support vehicles in the region. However, the declining incidence of NSTEMIs in the region and declining number of cardiac catheterization patients transferred from Backus to an elective PCI-capable hospital do not demonstrate the need for an elective PCI program at Backus. As such, the

Applicants have not demonstrated a clear public need for the as-proposed PCI program at Backus.

The Application does not meet the ACCF/AHA/SCAI Guidelines for proposed PCI programs and, as such, is not consistent with the Statewide Health Care Facilities and Services Plan.

The Department of Public Health's *2012 Statewide Health Care Facilities and Services Plan* standards and guidelines for proposed primary and elective PCI programs draw from those set forth by ACCF/AHA/SCAI. The ACCF/AHA/SCAI Guidelines establish the appropriate minimum volume of PCIs that should be performed at both a facility and by the individual medical professionals administering the procedures. *FF13.*

A facility volume of fewer than 200 PCIs performed per year is, according to the 2014 update of the Guidelines, associated with worse patient outcomes. *FF29.* Therefore, it is recommended that a facility perform at least 200 PCIs per year, 36 of which should be primary PCIs. According to the Plan, "a facility with a volume of fewer than 200 procedures per year, unless located in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service." Geographic isolation exists if the emergency transport time from a non-PCI facility to a PCI capable facility is greater than 30 minutes. *FF29.*

In 2015, patients originating from Backus' service area received approximately 369 PCIs at existing PCI-capable hospitals. *FF32.* Based on a presumed 100% retention rate of patients who went to Hartford and 36% of those who went to the other six hospitals not affiliated with Backus, the Applicants projected Backus would initially perform 165 PCIs—55 of which were primary. *FF32,33,35.* This projection falls significantly short of the 200 procedures recommended by the Guidelines.

L+M, which provides both primary and elective PCIs, is a 21-minute drive from Backus. *FF30.* It can be expected that the emergency transport time would be potentially shorter. As such, Backus does not qualify as geographically isolated and, according to the Guidelines, should not establish a PCI facility due to the likelihood it would fall below the minimum volume recommended for even a low-volume operator.

The Guidelines also state that "[m]ultiple low-volume and partial service-PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access." *FF29.* Not only would Backus' PCI program be unlikely to meet the recommended minimum volume, it would likely have a negative impact on L+M patient volumes, creating precisely the multiple low-volume provider situation the Guidelines warn against. In 2015, L+M performed 216 angioplasty procedures. Sixty-three PCI patients originated from Backus' service area. *FF33.* Had those 63 patients gone to Backus, L+M would have performed only 153 PCI procedures, also falling below the recommended guidelines. *FF35.* L+M has stated that it has no backlog and can accept additional volume. *FF34.*

The Applicants have not satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of services or how the proposal is needed based on utilization at existing PCI providers.

As discussed above, maintaining a certain level of utilization at existing providers is considered necessary to upholding the competency of a hospital and its physicians in performing PCIs. According to the Applicants, residents from Backus' service area who receive PCI treatment currently do so at Hartford, Yale-New Haven Hospital, L+M, Saint Francis Hospital, John Dempsey Hospital, The Hospital of Central Connecticut or UMass Memorial. *FF32.*

The proposal will impact existing providers and the existing providers are not currently being fully utilized by the Applicants. L+M would likely be the existing PCI provider most impacted by the Applicants' proposal. L+M performed 216 PCIs in 2015, 63 of which originated from Backus' service area. *FF32,33.* The Applicants and L+M presented multiple estimates as to the number of patients from Backus' service area who would seek service at Backus rather than the existing hospitals. The proposed retention rate estimates varied from 36% to 80%. *FF36.* Regardless of the precise retention rate applied, either L+M or Backus would not reach the minimum 200 procedures recommended by the Guidelines if the proposal is approved.

Additionally, L+M established its elective PCI program subsequent to entering into an Agreed Settlement with OHCA in 2013. *FF37.* The agreement was based on the expectation that L+M would be able to perform the Guidelines-established minimum number of PCIs of 200 per year. L+M does not anticipate that it will be able to meet the Guidelines minimum and will not be able to comply with this term of the agreement if Backus establishes a program. *FF37.*

The Applicants state that Backus is currently unable to meet the 120 minute door-to-balloon guideline regarding transferring AMI patients to a primary PCI-capable hospital. *FF19.* From 2011 through 2015, Backus' median door-to-balloon time was 134 minutes and travel time to a PCI-capable hospital accounted for the largest portion of Backus' transfer times. *FF19.* However, according to the Applicants, Backus has only transferred three patients to L+M, which is 21 minutes away. According to the Applicants, due to referral patterns, Backus transfers the majority of patients in need of primary PCI to Hartford, 40 minutes away. *FF20,32.* As such, the Applicants have not provided sufficient evidence demonstrating a need for a PCI program. The majority of patients that would be treated at Backus are currently being treated by other providers and, therefore, this proposal represents merely a shift in patient volume due to siphoning patients from existing providers.

The Applicants would likely be able to absorb the financial losses of the program.

The Applicants estimate Backus would need to perform 385 PCI procedures for the program to break even financially, and do not anticipate performing the necessary number of procedures through 2020, at which point they project the program would perform approximately 233 procedures *FF39.* The Applicants also estimate the proposal would necessitate nearly $5 million of capital expenditures in the form of an additional catheterization lab, new software and

equipment upgrades, as well as 3% of net patient revenues for ongoing capital needs. *FF40.* The program would operate at a loss of $355,363 in FY16, increasing to $705,757 in FY19. *FF38.*

The Applicants' projections, however, were conservative and assumed no increase in payer reimbursement but included increased costs and accounted for inflation. *FF38.* Additionally, the Applicants project income gains from overall operations at Backus from FY17 through FY19, sufficient to compensate for the program's increasing year-to-year losses. *FF42.* Although the program in itself would not be financially feasible due to increasing losses, the Applicants would be able to absorb those losses. As such, the proposal is financially feasible.

The Applicants have not satisfactorily demonstrated how the proposal would improve quality, accessibility and cost effectiveness of health care delivery, including to indigent and Medicaid patients.

The presence of a PCI program on-site at Backus would obviate the need for revascularization following a cardiac catheterization diagnosis, allowing the diagnostic and elective procedure to be completed together. This would reduce patient exposure to radiation and intravenous contrast used during the procedure. *FF12.* Currently, when Backus performs a cardiac catheterization and discovers a partial blockage, a patient must schedule an elective PCI elsewhere and then have the catheterization re-performed at that time. With the proposal, Backus would be able to perform the elective PCI at the time of catheterization.

As discussed, there are indisputable benefits to minimizing the time between when a patient presents at the emergency department and when the colluded artery is reopened. *FF18.* AMI patients currently presenting at Backus must be transported to a PCI-capable hospital, delaying treatment. Although a primary PCI program at Backus would decrease transport time, the Guidelines state that the door-to-balloon time should be within 120 minutes. *FF11.* Currently PCI-capable hospitals exist in Backus' area to which Backus could transport patients and the 120 minute window could be met. *FF32.* Although the Applicants have demonstrated how the proposal would improve quality of care, it is unclear the extent of the improvement.

Despite these potential benefits of the proposal, the Guidelines state that the minimum number of PCIs a facility should perform is set to maintain the competency of the hospital and its physicians. *FF29.* Should Backus' proposed program not meet that minimum, it is possible competency may not be maintained. Furthermore, the proposed program risks syphoning enough patients from existing hospitals to also depress the number of procedures performed at other area hospitals. *FF32,33,35.* It is possible quality may be compromised not only at Backus, but surrounding PCI-providers, as well.

The proposal would, as the establishment of a new service, likely increase access to care for Medicaid and indigent patients as Applicants' projected payer mix is comprised of 11% Medicaid and 37% uninsured. *FF43.*

Based on the aforementioned findings of fact, the Applicants have failed to meet their burden of proof in satisfying the statutory requirements of Conn. Gen. Stat. §§ 19a-639. The Applicants have neither satisfactorily identified the patient population to be served with an elective and primary PCI program nor have they demonstrated, in light of decreasing utilization and the existence of other providers in the area, that there is a clear public need for the proposed service. Furthermore, the proposal is likely to have a detrimental effect on existing providers in the area and may negatively impact the quality of care afforded patients. Finally, the Applicants have not sufficiently shown that the proposal is consistent with the PCI standards in the ACCF/AHA/SCAI Guideline and Statewide Health Care Facilities and Services Plan. However, as the proposal is neither a termination nor consolidation of health care providers, the proposal would not negatively impact the diversity of providers or choice for patients in the area.

Order

Based upon the foregoing Findings and Discussion, I respectfully recommend that the Certificate of Need application of The William W. Backus and Hartford Hospital to establish a primary and elective PCI program without on-site surgical backup be DENIED.

By Order of the
Department of Public Health
Office of Health Care Access

8/25/16
Date

Kevin T. Hansted
Hearing Officer

Greer, Leslie

From: Armah, Olga
Sent: Wednesday, September 14, 2016 3:45 PM
To: Anthony, Robert J.; Michele Volpe (mmv@bvmlaw.com); Janette.Edwards@hhchealth.org
Cc: Schaeffer-Helmecki, Jessica; Riggott, Kaila; Greer, Leslie
Subject: RE: The William W. Backus Hospital Propsed Final Decision

Hi Bob,

Thank you for the update.

Regards.

Olga

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

From: Anthony, Robert J. [mailto:RAnthony@brownrudnick.com]
Sent: Wednesday, September 14, 2016 11:42 AM
To: Armah, Olga
Cc: Schaeffer-Helmecki, Jessica
Subject: RE: The William W. Backus Hospital Propsed Final Decision

Thank you Olga. Please be advised that Backus Hospital will not request an extension nor challenge the proposed decision.

Bob

From: Armah, Olga [mailto:Olga.Armah@ct.gov]
Sent: Wednesday, September 07, 2016 9:48 AM
To: Anthony, Robert J.
Cc: Schaeffer-Helmecki, Jessica
Subject: RE: The William W. Backus Hospital Propsed Final Decision

Hi Bob,

You may request a time extension from Deputy Commissioner Addo. Her email is Yvonne.Addo@ct.gov.

Thanks.

Olga

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

From: Anthony, Robert J. [mailto:RAnthony@brownrudnick.com]
Sent: Tuesday, September 06, 2016 12:05 PM
To: Armah, Olga
Subject: RE: The William W. Backus Hospital Propsed Final Decision

Hi Olga. Under the statute, if Backus decides to challenge the proposed decision, it must do so within 21 days from the mailing of the decision. Do you know whether an extension of time is possible? Thanks for your help.

Bob

Robert J. Anthony
Counselor at Law

Brown Rudnick LLP
City Place 1 185 Asylum Street
Hartford, CT 06103
T: 860.509.6517
F: 860.509.6617
ranthony@brownrudnick.com
www.brownrudnick.com

From: Armah, Olga [mailto:Olga.Armah@ct.gov]
Sent: Monday, August 29, 2016 2:32 PM
To: Edwards, Janette; mmv@bvmlaw.com
Cc: Cohen, Douglas A.; Anthony, Robert J.; Mack, David; Greer, Leslie; Schaeffer-Helmecki, Jessica; Riggott, Kaila
Subject: RE: The William W. Backus Hospital Propsed Final Decision

Hi Janette,

Pursuant to 19a-9-29(h) of the Regulations of Connecticut State Agencies:

Unless otherwise ordered by the presiding officer, any party who wishes to challenge a proposed final decision under section 4-179 of the Connecticut General Statutes shall file exceptions or a brief or request oral argument, within twenty-one(21) days of the mailing of the decision. Any party who wishes to present a brief or requests oral argument in support of a proposed final decision shall do so within thirty-five (35) days of the mailing of the decision.

Thanks.

Olga

Olga Armah
Office of Health Care Access (OHCA)
CT Department of Public Health
Phone: 860 418 7070
Fax: 860 418 7053
Mailto: olga.armah@ct.gov
Web: www.ct.gov/ohca

From: Edwards, Janette [mailto:Janette.Edwards@hhchealth.org]
Sent: Monday, August 29, 2016 11:51 AM
To: Greer, Leslie; Armah, Olga
Cc: dcohen@brownrudnick.com; Anthony, Robert J.; Mack, David
Subject: RE: The William W. Backus Hospital Propsed Final Decision

Leslie and Olga,

We received the proposed final decision for DN 15-32031-CON and are in the process of reviewing internally. Can you please provide me specifics on the procedure for proposed decisions, and timeframe for response? It will be helpful to our internal dialogue.

Thanks,
Janette

Janette Edwards, MPH, MBA
Vice President, Operational Integration

Hartford HealthCare

janette.edwards@hhchealth.org

www.hartfordhealthcare.org

From: Greer, Leslie [mailto:Leslie.Greer@ct.gov]
Sent: Thursday, August 25, 2016 3:46 PM
To: Edwards, Janette; RAnthony@brownrudnick.com; mmv@bvmlaw.com
Cc: Armah, Olga; Schaeffer-Helmecki, Jessica; Fernandes, David; Riggott, Kaila; Hansted, Kevin; Martone, Kim
Subject: The William W. Backus Hospital Propsed Final Decision

Attached is the proposed final decision for The William W. Backus Hospital DN: 15-32031-CON.

Leslie M. Greer
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS#13HCA, Hartford, CT 06134
Phone: (860) 418-7013 Fax: (860) 418-7053
Website: www.ct.gov/ohca

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****

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Office of Health Care Access

Final Decision

Applicants:

The William W. Backus Hospital
326 Washington Street,
Norwich, CT 06360

Hartford Hospital
80 Seymour Street,
Hartford, CT 06102

Docket Number: **15-32031-CON**

Project Title: **Establishment of a Primary and Elective Percutaneous Coronary Intervention Program at Backus Hospital without On-Site Surgical Backup**

Project Description: The William W. Backus Hospital ("Backus") and Hartford Hospital ("Hartford") (Backus and Hartford are herein collectively referred to as the "Applicants") seek authorization to establish and operate a primary and elective percutaneous coronary intervention ("PCI" or angioplasty) program at Backus without on-site cardiac surgical backup, at an associated capital cost of $4,982,053.

Procedural History: The Applicants published notice of their intent to file a Certificate of Need ("CON") application in *The Bulletin* (Norwich) on September 7, 8 and 9, 2015. On September 30, 2015, the Office of Health Care Access ("OHCA") received the CON application from the Applicants for the above-referenced project. On January 29, 2016, OHCA deemed the application complete.

On March 9, 2016, the Applicants were notified of the date, time, and place of the public hearing. On February 11, 2016, a notice to the public announcing the hearing was published in *The Bulletin* (Norwich). Thereafter, pursuant to Connecticut General Statutes ("Conn. Gen.

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DPH
Connecticut Department of Public Health

Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

Stat.") § 19a-639a(f)(2), the public hearing regarding the CON application was held on March 23, 2016 and continued on June 14, 2016.

Commissioner Pino designated Attorney Kevin T. Hansted as the hearing officer in this matter. The hearing was conducted in accordance with the provisions of the Uniform-Administrative Procedure Act (Chapter 54 of the General Statutes) and Conn. Gen. Stat. § 19a-639a(f)(2).

On March 16, 2016, Lawrence + Memorial Hospital ("L+M") filed a petition requesting intervenor status. L+M was granted intervenor status with full rights in this matter on March 17, 2016.

On March 22, 2016 the Applicants filed a Motion in Limine to preclude use of data regarding out-of-state PCI providers. On March 23, 2016 L+M filed an objection to the Applicants' Motion in Limine. On March 31, 2016, Hearing Officer Hansted denied the Applicants' motion and sustained L+M's objection. The public hearing record was closed on June 22, 2016.

On August 25, 2016 OHCA issued a Proposed Final Decision denying the Applicants' CON application. Pursuant to section 19a-9-29(h) of the Regulations of Connecticut State Agencies the Applicants had twenty-one days from the date the Proposed Final Decision was issued to file exceptions or a brief or request oral argument. On September 14, 2016 the Applicants notified OHCA that it would not challenge the Proposed Final Decision. Deputy Commissioner Addo reviewed the entire record in this matter.

Findings of Fact

1. Backus is a 233-bed/bassinet acute care hospital, located at 326 Washington Street in Norwich, CT, and is affiliated with Hartford. Exhibit A, p. 13.

2. Hartford is an 867-bed major teaching hospital affiliated with the University of Connecticut School of Medicine and a regional referral center serving New England. Hartford's Henry Low Heart Center is a full service cardiac provider that offers the following services:
   a. Cardiac catheterization, angioplasty, electrophysiology and rehabilitation programs;
   b. A congestive heart disease center;
   c. Echocardiography;
   d. Extracorporeal membrane oxygenation;
   e. A heart failure infusion program;
   f. Heart surgery and transplants;
   g. Nuclear cardiology; and
   h. A transcatheter aortic valve replacement program.

   Exhibit A, p. 13, 24.

3. Backus currently offers the following inpatient and outpatient cardiac services:
   a. Diagnostic cardiac catheterizations;
   b. Pacemaker insertions, evaluations and follow-ups;
   c. Implantable cardiac defibrillator insertions, evaluations and follow-ups;
   d. Stress testing;
   e. Nuclear cardiac imaging;
   f. Cardiac imaging services;
   g. Echocardiology;
   h. 24- and 48-hour monitoring;
   i. ECG testing;
   j. Electrical cardioversions;
   k. Intra-aortic balloon pumping;
   l. Vascular surgical services offered by interventional radiology staff such as peripheral angioplasty and stenting;
   m. Heart failure program that offers monitoring and a program coordinator for patients beyond the inpatient setting; and
   n. Three phase cardiac rehabilitation program consisting of inpatient, outpatient and outpatient maintenance.

   Exhibit A, p. 20-21.

4. The Applicants are proposing the expansion of cardiac services at Backus by establishing and operating a primary and an elective PCI program without on-site cardiac surgical back-up. Backus' 12-bed critical care unit would be the primary unit for all post-PCI patients. Exhibit A, pp. 13, 21.

5. Angioplasty is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a diagnosed blockage in the heart. An expandable balloon is passed through the artery and inflated, flattening blockage-causing plaque and allowing for improved blood-flow. Exhibit A, p. 14.

6. Primary PCI is used to treat emergency situations, such as ST-Segment Elevation Myocardial Infarctions ("STEMI"), which occur when an acute coronary thrombosis blocks a coronary artery. Elective PCI is often a scheduled procedure following extensive cardiac testing or a post-cardiac event to relieve chest pain and related symptoms. Exhibit A, p. 14.

7. STEMI patients requiring primary PCI, need the most urgent care and are treated on an emergency basis. Elective PCI procedures for patients with non-ST-segment elevation myocardial infarction ("NSTEMI") are often scheduled, but ideally take place within 24-48 hours of diagnosis, effectively reducing the risk of future cardiac events. Ex. A, pp. 14-15; Ex. BB, Transcript, Dr. Francis J. Kiernan, Director of Cardiac Laboratory, Hartford Hospital, pp. 103-104.

8. Hartford provides comprehensive cardiac services and performs more than 1,000 angioplasties annually. Hartford and Backus have entered into an agreement for the emergency transfer of patients to Hartford for off-site surgical backup for urgent cases at all hours and for elective cases at mutually agreed upon hours, as well as the necessary training and oversight of the proposed PCI program at Backus. Ex. A, pp. 46, 99, 892-93.

9. The Applicants submitted the following agreements, policies and protocols:
   - Primary PCI Patient Selection Guidelines
   - 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention and How Backus Will Meet the Standards
   - Elective PCI Patient Selection Guide
   - Transfer Protocol and Agreement between the Applicants
   - Cardiac Surgery Transfer Agreement Between Hartford and Backus
   - Clinical Guidelines for Transfer of Catheterization Lab Patients to Acute Care Facility

   Ex. A. pp. 88, 84-87, 89, 892-897

10. The Applicants claim benefits of the proposal include:
    a. Improved access for an area of the state that:
       (i) is "geographically isolated" from the nearest PCI provider;
       (ii) has an older population with a relatively higher risk than the state for coronary artery disease;
       (iii) has current rates of emergency/primary and elective PCI interventions for residents that are significantly below state and national levels leading to relatively higher rates of morbidity and mortality;
    b. Minimized out-of-pocket costs associated with second hospital admission and duplicative procedures; and

c. Improved future care coordination and management for patients with heart conditions.

Exhibit A, p. 13.

11. The ACC/AHA STEMI Guidelines provide that "door-to-balloon" time, measured from the time a patient presents at the emergency department of a PCI-capable hospital to the time a balloon is inflated to open the occluded artery, should not exceed 90 minutes. The recommended door-to-balloon time for patients presenting at a non-PCI capable hospital from which the patient must be transferred to another hospital is 120 minutes. Exhibit A, pp. 47, 500.

12. The presence of a PCI program on-site at Backus would obviate the need for revascularization following a cardiac catheterization diagnosis, enabling the diagnostic and elective procedure to be completed together. This would reduce patient exposure to radiation and intravenous contrast used during the procedure. Ex. A, p. 62.

13. The Statewide Health Care Facilities and Services Plan states that hospitals seeking to establish an elective PCI program without on-site cardiac surgery must:
    a. Meet the conditions required in the American College of Cardiology Foundation/American Health Association/Society for Cardiovascular Angiography and Interventions ("ACCF/AHA/SCAI) Practice Guideline (the " Guideline") for percutaneous coronary intervention without on-site surgical backup; and
    b. Demonstrate a clear public need for the program. Specifically, the Guideline indicates that it is only appropriate to consider the initiation of the PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community as competition with another PCI program in the same geographic area may not be in the best interests of the community.

    Exhibit A, pp. 38-39, 47.

14. The Applicants' proposed service area ("proposed service area") included a) towns within a 30 minute drive-time to Backus, and b) towns outside of the 30-minute radius but for which Backus would be the closest PCI-capable facility in Connecticut. This classification excluded out-of-state PCI providers.

TABLE 1
APPLICANTS' PROPOSED SERVICE AREA

Towns within a 30-minute drive time of Backus Hospital			Towns for which Backus would be the closest in-state PCI provider
Bozrah	Killingly	Preston	East Haddam
Brooklyn	Griswold-Lisbon	Scotland	Hampton
Canterbury	Hebron	Sprague	Pomfret
Chaplin	Killingly	Sterling	Putnam
Colchester	Mansfield Center	Voluntown	Thompson
Columbia	Norwich	Windham	Woodstock
Franklin	Plainfield		

Exhibit A, p. 35.

15. Based on fiscal year ("FY") 2015 inpatient discharges for Backus, the towns below comprise Backus' service area ("SA").[1] The Applicants' proposed service area included 20 towns beyond Backus Hospital's SA (Bozrah, Brooklyn, Columbia, Franklin, Hebron, Killingly, Lebanon, Mansfield Center, Scotland, Sprague, Sterling, Voluntown, Windham, East Haddam, Hampton, Pomfret, Putnam, Thompson and Woodstock). Additionally, the proposed service area omitted three towns that are in the SA (Groton, Ledyard and Montville).

TABLE 2
BACKUS HOSPITAL DISCHARGES, FY 2015

Patient Town	Discharges	% of Total Discharges	Cumulative %
Norwich	3,729	35%	35%
Griswold- Lisbon	1,169	11%	46%
Montville	910	8%	54%
Plainfield	843	8%	62%
Preston	346	3%	65%
Colchester	322	3%	68%
Canterbury	273	3%	71%
Ledyard	269	3%	73%
Groton	251	2%	76%
Remaining Towns/States	2,611	24%	100%
Total	**10,723**	**100%**	**100%**

Source: CT DPH, Office of Health Care Access Acute Care Discharge Database

16. The Applicants stated that they selected drive time as the basis for the proposed service area because of the "urgency of time, in order to access [PCI] services." Additionally, they stated that they selected 30 minutes as the perimeter of the drive time based on the Department of Public Health Office of Emergency Management Services, *Connecticut EMS STEMI Guidelines* ("DPH OEMS Guidelines"). Ex. T, Transcript, Mr. M. Shane Foreman, CEO, 3d Health, p. 34; Ex. K, Pre-filed Testimony, Foreman, 1543.

17. The stated goal of the DPH OEMS Guidelines is to "ensure that authorized EMS personnel obtain a 12-lead electrocardiogram in the field on all patients with suspected MI, thereby increasing the likelihood they will be transported for treatment with PCI intervention within 90 minutes of first medical contact." It directs emergency medical vehicles transporting a patient already identified as STEMI to bring the patient to a PCI-capable facility if it is less than 30 minutes away. It also states that emergency vehicles

1. SA is defined as towns that make up the top 75% of a hospital's discharges. CT DPH, *Statewide Health Care Facilities Plan* 76 (2014 Supplement.).

should be 12-lead echocardiogram-equipped to facilitate early identification of STEMI patients. Ex. A, p. 969-970.

18. There are proven beneficial outcomes associated with reducing the time between a patient's presentation at the emergency department to inflation of the balloon to open the occluded artery ("door-to-balloon time") during a primary PCI procedure. Ex. T, Transcript, Dr. Paul Thompson, Chief of Cardiology, Hartford Hospital, p. 29.

19. From 2011 through 2015, Backus' median door to balloon time for primary PCI was 134 minutes. Transport time to a PCI-capable hospital accounted for the largest portion of the door-to-balloon time. Ex. A, p. 473, 476.

20. Backus has historically transferred patients to Hartford and Yale New Haven Hospital for primary PCI, transferring only three patients in the past to the closest PCI-provider, L+M. The Applicants stated this was due primarily to referral patterns. Ex. T, Transcript, Dr. Kyle McClaine, EMS Director, Backus Hospital, p. 151-152; Ex. BB, Transcript, Dr. John Foley, Director of Cardiovascular Service Line, Hartford Medical Group, p. 138.

21. UMass Memorial Medical Center ("UMass") submitted a letter stating that it has an ongoing relationship with Day Kimball Hospital ("Day Kimball") and established protocols are in place for receiving NSTEMI transfer patients from Day Kimball. It also states that UMass' PCI program currently has capacity to continue treating transfers and referrals from Day Kimball. Ex. V; pp. 1-2.

22. UMass is the closest existing PCI provider, based on travel time, for four out of the six towns in northeast Connecticut the Applicants included in their proposed service area.

TABLE 3
TRAVEL TIMES FROM NORTHEAST TOWNS INCLUDED IN THE PROPOSED SERVICE AREA TO CLOSEST HOSPITAL*

Select Towns	Drive time to Backus Hospital	Drive time to UMass Hospital
East Haddam	27 minutes	78 minutes
Hampton	27 minutes	46 minutes
Pomfret	36 minutes	33 minutes
Putnam	33 minutes	26 minutes
Thompson	35 minutes	23 minutes
Woodstock	39 minutes	33 minutes

* Based on Google Maps travel time without traffic from center of town

23. Day Kimball, located at 320 Pomfret Street, Putnam, stated in its 2015 Community Health Needs Assessment and Implementation Plan that it "continues to work closely with UMass for STEMI patient transfers via Life Star helicopter within 90 minutes of

admission to the emergency department and meets regularly to review STEMI data." Ex. W, p. 4.

24. In 2010, towns in the proposed service area experienced an incidence rate of 104.3 STEMIs per 100,000; Connecticut overall experienced a rate of 83. Towns in the proposed service area experienced an incidence rate of 237.2 for NSTEMIs; Connecticut overall had a higher incidence of NSTEMIs at 242.3. Ex. A, p. 463.

25. Over a seven year period, patients in the proposed service area underwent fewer inpatient elective PCIs; declining from 316 in FY09 to 171 in FY15. This is consistent with state-wide trends. Ex. A, p. 466, 1499-1500.

26. The number of patients transferred for an elective PCI following a cardiac catheterization at Backus was 90 in 2012, 90 in 2013, 55 in 2014, 46 in 2015 and 33 in 2016 (annualized). The percentage of cardiac catheterization patients transferred from Backus to a PCI-capable facility also decreased, from 28.4% in 2012 to 19.4% in 2015. Ex. CC, p. 1570.

27. According to the SCAI/ACC/AHA's *Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup* ("2014 Guidelines"), multiple factors have contributed to the decline in PCI procedures, including "a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, and a reduction in incidence of STEMI…" Ex. A, p. 113.

28. According to the Applicants, there are an insufficient number of emergency advanced life support vehicles in the Backus region, with 15 covering 13 towns in the Backus region. Ex. A., p. 34.

29. The 2014 Guidelines state that "an institutional volume threshold of <200 PCIs/year was associated with worse outcomes" and therefore "continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned." It continues to say that "multiple low-volume and partial service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access." It defines "geographic isolation" as a hospital that is more than 30 minutes away from a PCI-capable facility by emergency transport. Ex. A, pp. 119-121.

30. L+M, a PCI-capable facility, is located 17 miles, or 21 minutes from Backus. Ex. T, Transcript, Dr. Brian Cambi, Director of Cardiology, L+M Hospital, p. 51.

31. Based on historic PCI utilization of residents originating from Backus' SA at other area hospitals[1], the Applicants project Backus would perform 163 PCIs in FY16, increasing slightly to 169 in FY18.[2]

TABLE 4
PROJECTED PCI UTILIZATION AT BACKUS HOSPITAL

Category	FY16	FY 17	FY18
Primary PCI	55	54	54
Elective PCI	108	111	115
Total	**163**	**165**	**169**

[1] Includes Backus SA patients receiving PCIs at: Hartford Hospital, Yale New Haven, Saint Francis, John Dempsey, The Hospital of Central Connecticut, UMass Memorial and Lawrence + Memorial Hospital.

[2] Assumes a retention rate of 100% of patients receiving PCIs at Hartford Hospital and 36% from other hospitals based on Backus' ED market share.

Ex. K, p. 1497; Ex. E, pp. 1458, 1466.

32. There are no PCI providers in the Applicants' proposed service area. However, the following hospitals have administered PCIs to 369 patients originating from Backus' SA in 2015.

TABLE 5
2015 PCI PROVIDERS TREATING PATIENTS ORIGINATING FROM BACKUS' SA

PCI Providers	Distance from Backus[1]	No. of PCIs Originating from Backus SA	No. of PCIs	No. of PCIs minus No. from Backus SA	% of PCIs from Backus SA
Hartford Hospital	40 minutes	50	1,099	1,049	4.5%
Yale New Haven Hospital	53 minutes	145	1,575	1,430	9.2%
Saint Francis Hospital	39 minutes	24	784	760	3%
John Dempsey Hospital	58 minutes	30	399	369	7.5%
The Hospital of Central CT	48 minutes	15	85	70	17.6%
UMass Memorial	60 minutes	54	~1,100	1,046	~5%
Lawrence + Memorial Hospital	21 minutes	63*	216	165	23.6%

[1] Distance based on Google Maps normal travel time

* Based upon 2015 inpatient discharge data. All other figures reflect 2014 inpatient discharge data.

Ex. A, p. 46; Ex. E, p. 1458.

33. In 2015, L+M performed 216 PCIs, 63 of those PCI patients originated from Backus' SA.

TABLE 6
2015 PCI PATIENTS FROM SA TREATED AT L+M

	2015 Town Totals		2015 L+M PCIs	
SA Towns	No. Primary PCIs	No. Inpatient Elective PCIs*	No. Primary PCIs	No. All Elective PCIs
Norwich	17	31	10	3
Canterbury	3	3	1	
Preston	1	6	1	3
Plainfield	7	16		1
Colchester	7	8		
Griswold	3	18	2	
Lisbon	-	-		
Montville	10	15	3	2
Ledyard	7	10	6	4
Groton	-	-	20	7
TOTAL	**55**	**107**	**43**	**20**
		L+M Total	**121**	**95**
		No. Remaining at L+M	**78**	**75**

* Outpatient elective PCI data unavailable

Ex. A, pp. 1499-1500; Ex. M, p. 12.; Compliance Reporting for Docket No. 12-31769

34. L+M stated that it has additional capacity to handle transfers from other non-PCI centers. Ex. BB, Transcript, Dr. Cambi, p. 158.

35. The 153 primary and elective PCI patients that would remain at L+M if Backus were to have a PCI program and capture all patients from its SA towns falls below the 200 level recommended by the 2014 Guidelines. Exhibit A, pp. 1499-1500.

36. The Applicants and L+M submitted conflicting claims as to the average retention rate of patients from a PCI provider's service area. The Applicants initially based their projection assumptions on an 80% retention rate of PCI patients from their proposed service area based on observed emergency department market share from the area. L+M asserted that those seeking scheduled elective PCIs would not mimic emergency room patterns and that L+M experienced an overall PCI retention rate of 54%. The Applicants then based final projection rates on a 100% retention rate for patients who had previously received PCIs at Hartford and 36% for those visiting all other hospitals. Ex. A, p. 489; Ex. BB, Testimony, Ms. Edwards, p. 139; Ex. BB, Testimony, Mr. Bitmal Patel, President of the East Region and Senior Vice President, Hartford HealthCare, p. 139; Ex. K, p. 197.

37. L+M established its elective PCI program in 2013. Per the Agreed Settlement with OHCA approving establishment of its program, L+M is expected to perform a quantity of procedures above those recommended by the 2014 Guidelines. L+M has stated it is likely to fall well below the minimum threshold should Backus initiate its own PCI program. Ex. M, p. 26; OHCA Docket Number 12-31768-CON.

38. Backus projects a financial loss from the operation of a PCI program with increasing incremental losses from operations, from FY2017 through FY2019.

TABLE 7
PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2017	FY 2018	FY 2019
Revenue from Operations*	$4,750,000	$4,911,295	$4,970,474
Total Operating Expenses**	$5,208,730	$5,470,996	$5,676,231
Gain/Loss from Operations	($457,817)	($559,701)	($705,757)

* Net revenue per case remains flat and assumes no increase in payer reimbursement
** 2.68% inflation rate applied over five resulting in increasing expenses; 2.6 new FTE cardiology staff, on-call payment and call back pay to staff, 24/7 on call physician expenses at $125/hr. Exhibit A, p. 1409; Ex. BB, Transcript, Ms. Janette Edwards, Backus Hospital, p. 128.

39. Backus would need to perform 385 PCI procedures in year five of the program to break even financially. The Applicants project they would perform 233 procedures in the year 2020. Ex. A, pp. 68, 70.

40. Estimated capital expenditures associated with the proposal are almost $5 million. Capital costs would support an additional catheterization lab, new software and equipment upgrades. An additional 3% of net patient revenues would be committed to ongoing capital needs. The Applicants' proposed capital expenditures are as follows:

TABLE 8
TOTAL PROPOSAL CAPITAL EXPENDITURES

Purchase/Lease	**Cost**
Equipment (Medical, Non-medical Imaging)	$344,000
Construction/Renovation	$4,500,000
Other (specify) (*estimated 3% of operating revenue for additional capital needs*)	$138,053
Total Capital Expenditure (TCE)	**$4,982,053**
Total Capital Cost (TCO)	**$0**
Total Project Cost (TCE+TCO)	**$4,982,053**

Exhibit A, pp. 67, 77.

41. The Applicants would fund the proposal through Backus' income from operations. Exhibit A, p. 65.

42. The Applicants project overall gains from Backus' operations from FY17 through FY19.

TABLE 9
BACKUS HOSPITAL PROJECTED REVENUES AND EXPENSES WITH CON

	FY 2017	FY 2018	FY 2019
Revenue from Operations	$308,297,624	$317,799,924	$329,208,612
Total Operating Expenses	$270,537,970	$276,777,162	$285,116,496
Gain/Loss from Operations	$37,759,653	$41,1022,761	$44,062,116

Exhibit A, p. 1409.

43. The projected patient population mix for the proposed PCI program is as follows:

TABLE 10
BACKUS HOSPITAL'S PROJECTED PAYER MIX

Payer	Projected**					
	FY 2016		FY 2017		FY 2018	
	Volume	%	Volume	%	Volume	%
Medicare*	109	50%	110	50%	113	50%
Medicaid*	25	11%	25	11%	26	11%
CHAMPUS & TriCare	-	0%	-	0%	-	0%
Other Government	2	1%	2	1%	2	1%
Total Government	**135**	**62%**	**136**	**62%**	**140**	**62%**
Commercial Insurers	79	37%	80	37%	82	37%
Uninsured	2	1%	2	1%	2	1%
Workers Compensation	-	0%	-	0%	-	0%
Total Non-Government	**81**	**38%**	**82**	**38%**	**85**	**38%**
Total Payer Mix	**216**	**100%**	**218**	**100%**	**225**	**100%**

*Includes managed care activity
**Payor-weighted reimbursement by DRG based on the payor mix of all PCI patients originating from the proposed service area.
Ex. A, p. 1469

44. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations yet to be adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))

45. The CON application is inconsistent with the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))

46. The Applicants have not sufficiently demonstrated that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

47. The Applicants have satisfactorily demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))

48. The Applicants have not satisfactorily demonstrated that access to services, cost effectiveness and the quality of health care delivery would be maintained. (Conn. Gen. Stat. § 19a-639(a)(5))

49. The Applicants have satisfactorily shown that there will be no change in access to primary and elective PCI services to the relevant populations and payer mix, including Medicaid patients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6))

50. The Applicants have not satisfactorily identified the population to be served or that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7))

51. The Applicants' historical utilization in the area does not support this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))

52. The Applicants have not satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))

53. The Applicants have satisfactorily demonstrated that the proposal would not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10))

54. The Applicants have satisfactorily demonstrated that the proposal would not negatively impact the diversity of PCI providers in the area. (Conn. Gen. Stat. § 19a-639(a)(11))

55. The Applicants have satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or accessibility to care. (Conn. Gen. Stat. § 19a-639(a)(12))

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board, 309 Conn. 727 (2013).*

Backus is a 233-bed/bassinet acute care hospital, located at 326 Washington Street in Norwich, CT, and is affiliated with Hartford. *FF1.* Hartford is an 867-bed major teaching hospital affiliated with the University of Connecticut School of Medicine and a regional referral center serving New England. *FF2.* Backus currently offers inpatient and outpatient cardiac services including diagnostic cardiac catheterizations, cardiac imaging services, echocardiology, intra-aortic balloon pumping and vascular surgical services offered, such as peripheral angioplasty and stenting, by interventional radiology staff. *FF3.*

The Applicants are proposing to expand cardiac services at Backus to include a primary and an elective PCI program. *FF4.* Backus' 12-bed critical care unit would be the primary unit for all post-PCI patients. *FF4.* Hartford would provide off-site surgical back-up. *F8.* Hartford provides comprehensive cardiac services and performs more than 1,000 angioplasties annually and, in addition to tertiary back-up, would provide the necessary training and oversight of Backus' newly established PCI program. *FF8.*

<u>The Applicants have not satisfactorily identified the population to be served by the proposal</u>

Rather than basing the service area on Backus' inpatient discharges, the Applicants based the projected population to be served on a combination of a) towns within a 30-minute radius from Backus and b) towns for which Backus would be the closest PCI-provider by travel time. *FF14.* According to the Applicants, it selected drive time because of the "urgency of time, in order to access [PCI] service." The Applicants stated they selected 30 minutes as the perimeter of the drive time based on the DPH OEMS Guidelines. *FF16.*

The Applicants' proposed service area is inappropriate for three reasons. First, the Applicants failed to provide an adequate rationale for its selection of 30 minutes as the perimeter for the towns to be served. The stated goal of the DPH OEMS Guidelines is to "ensure that authorized EMS personnel obtain a 12-lead electrocardiogram in the field on all patients with suspected MI." It is intended to provide guidance to emergency transport vehicles as to what hospital patients who have a pre-hospital diagnosed STEMI should be directed. *FF17.* Although it is well established that the time to reperfusion correlates to the extent of heart muscle damage in a patient experiencing acute myocardial infarction ("AMI"), the Applicants provided no recognized standard that establishes that every town should be within 30 minutes of a PCI-

capable facility. The Applicants' basis for a 30 minute drive time standard misinterprets the standards and the purpose of the DPH OEMS Guidelines.

Second, for NSTEMI patients requiring an elective -- as opposed to primary -- angioplasty, timing is less critical. According to the Applicants, patients presenting with a one or more significant arterial blockages that are non-life threatening, or NSTEMI, should receive an elective angioplasty within 24 to 48 hours of being diagnosed. *FF7*. Therefore, the application of a travel time constraint of 30 minutes when identifying the projected population to be served by the elective angioplasty program is unfounded as patients may travel to existing elective PCI programs in the area within 24 to 48 hours.

Finally, the Applicants incorrectly state that several of the towns included in their proposed service area are closer to Backus than any other PCI-capable facility. Backus would not be the closest PCI-capable hospital for several of the towns it included in its proposed SA. For example, UMass would be the closest PCI facility for patients originating from Thompson, Putnam, Pomfret or Woodstock. *FF22*. Additionally, as the only acute care hospital in Northeast Connecticut, Day Kimball would likely be the hospital at which patients from that area (including Thompson, Putnam, Pomfret and Woodstock) showing signs of AMI would likely present. Day Kimball, as a hospital lacking PCI capabilities, has stated that it intends to transfer AMI patients to UMass. *FF23*. Due to Day Kimball's proximity to UMass and stated referral patterns, it is uncertain whether patients from multiple towns in the Applicant's proposed service area would seek treatment at Backus. Therefore, the Applicants have failed to adequately identify the population the proposed program may likely serve.

In order to assess whether there is a clear public need for the establishment of a new angioplasty program in a given region and a new program's anticipated impact on existing providers, it must be determined, in part, how many patients would likely receive treatment at the new program. Based on Backus' historic inpatient discharges, its service area, and projected population to be served, is: Canterbury, Colchester, Griswold, Lisbon, Ledyard, Montville, Norwich, Preston, Plainfield and Groton. *FF15*.

Based on declining utilization rates, the increasing use of non-surgical medications and alternate methods of treatment and diagnosis of cardiovascular events the Applicants have not demonstrated that there is a clear public need for a new angioplasty program in the service area.

The Applicants claim that towns in their service area experience elevated incidents of STEMI and NSTEMI compared to Connecticut overall and that this indicates an unmet need for PCI services exists in the proposed service area. While the proposed service area did have a 2010 incidence rate of 104.3 STEMIs per 100,000 people--higher than Connecticut's 83 -- its incidence rate of NSTEMI for the same period was lower than that of the state -- 237.2 compared to 242.3. *FF24*. This suggests that although there may be a need for primary PCI services to address STEMI patients in the area, the NSTEMI data provided by the Applicants does not support the need for an elective program. Additionally, according to Applicants-provided

inpatient elective PCI procedure volume, there is a declining trend in elective PCIs in the area -- consistent with the trend observed state-wide. *FF25.*

Furthermore, other indicators of the need for an elective PCI program in the area are also declining. The number and percentage of cardiac catheterization transfers from a non-PCI facility to a PCI-capable facility for elective angioplasties are two such indicators. The number of patient transfers for an elective PCI following a cardiac catheterization at Backus decreased from 90 in 2012 to 46 in 2015. The transfer rate similarly decreased, from 28.4% in 2012 to 19.4% in 2015. *FF26* This mirrors the state and national data indicating a declining need for elective PCIs.

According to the 2014 Guidelines, due to the increased use of non-surgical alternatives, the number of PCIs performed is likely to continue to decline. It states that drug-eluting stents, enhanced primary and secondary prevention efforts and a greater emphasis on medical therapy are increasingly replacing PCIs as the choice treatment in certain situations. *FF27.*

Additionally, as discussed above, the Applicants cite the DPH OEMS Guidelines as evidence of the need for a PCI program at Backus but misstate the standards and goals of the policy. The Applicants state that "[residents] to the north and east of Norwich do not have timely access to a Connecticut primary or elective PCI-equipped hospital within 30 minutes' drive time, as specified by DPH OEMS Guidelines." *Ex.A, p. 16.* However, the referred-to standard pertains to EMS transport of patients with pre-hospital-diagnosed STEMI and is intended to assess whether such patients should be transported to a PCI-capable hospital based on travel time, recommending STEMI patients be transferred to a PCI-capable hospital if one is less than 30 minutes away. *FF17.* The OEMS Guidelines make no indication as to the ideal location of PCI facilities and do not recommend that all towns be within a 30 minute drive time of a PCI facility.

The Applicants again cite DPH OEMS Guidelines regarding EMS transport, stating that STEMI patients should be identified in the field via an electrocardiogram (ECG) in effort to direct patients expeditiously to the appropriate level of care. The Applicants continue that there are only 15 emergency advanced life support vehicles with ECGs to cover 13 towns in the Backus region. The Applicants suggest that because there may be an insufficient number of ECG-equipped emergency transport vehicles, some patients may not be identified as STEMI prior to delivery at a hospital and therefore Backus requires PCI capabilities to treat these patients. *Ex. A, p. 34.* An insufficient number of ECG-equipped vehicles does not equate to the need for a PCI program at every hospital, but rather speaks to whether there is a need for additional appropriately-equipped emergency vehicles.

The Applicants-provided data shows that there may be elevated incidence of STEMIs in the Backus area, potentially warranting a primary PCI program. A shortage of ECG-capable emergency transport vehicles may also highlight the need for additional advanced life support vehicles in the region. However, the declining incidence of NSTEMIs in the region and declining number of cardiac catheterization patients transferred from Backus to an elective PCI-capable hospital do not demonstrate the need for an elective PCI program at Backus. As such, the

Applicants have not demonstrated a clear public need for the as-proposed PCI program at Backus.

The Application does not meet the ACCF/AHA/SCAI Guidelines for proposed PCI programs and, as such, is not consistent with the Statewide Health Care Facilities and Services Plan.

The Department of Public Health's *2012 Statewide Health Care Facilities and Services Plan* standards and guidelines for proposed primary and elective PCI programs draw from those set forth by ACCF/AHA/SCAI. The ACCF/AHA/SCAI Guidelines establish the appropriate minimum volume of PCIs that should be performed at both a facility and by the individual medical professionals administering the procedures. *FF13.*

A facility volume of fewer than 200 PCIs performed per year is, according to the 2014 update of the Guidelines, associated with worse patient outcomes. *FF29*. Therefore, it is recommended that a facility perform at least 200 PCIs per year, 36 of which should be primary PCIs. According to the Plan, "a facility with a volume of fewer than 200 procedures per year, unless located in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service." Geographic isolation exists if the emergency transport time from a non-PCI facility to a PCI capable facility is greater than 30 minutes. *FF29.*

In 2015, patients originating from Backus' service area received approximately 369 PCIs at existing PCI-capable hospitals. *FF32.* Based on a presumed 100% retention rate of patients who went to Hartford and 36% of those who went to the other six hospitals not affiliated with Backus, the Applicants projected Backus would initially perform 165 PCIs—55 of which were primary. *FF32,33,35*. This projection falls significantly short of the 200 procedures recommended by the Guidelines.

L+M, which provides both primary and elective PCIs, is a 21-minute drive from Backus. *FF30.* It can be expected that the emergency transport time would be potentially shorter. As such, Backus does not qualify as geographically isolated and, according to the Guidelines, should not establish a PCI facility due to the likelihood it would fall below the minimum volume recommended for even a low-volume operator.

The Guidelines also state that "[m]ultiple low-volume and partial service-PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access." *FF29.* Not only would Backus' PCI program be unlikely to meet the recommended minimum volume, it would likely have a negative impact on L+M patient volumes, creating precisely the multiple low-volume provider situation the Guidelines warn against. In 2015, L+M performed 216 angioplasty procedures. Sixty-three PCI patients originated from Backus' service area. *FF33.* Had those 63 patients gone to Backus, L+M would have performed only 153 PCI procedures, also falling below the recommended guidelines. *FF35.* L+M has stated that it has no backlog and can accept additional volume. *FF34.*

The Applicants have not satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of services or how the proposal is needed based on utilization at existing PCI providers.

As discussed above, maintaining a certain level of utilization at existing providers is considered necessary to upholding the competency of a hospital and its physicians in performing PCIs. According to the Applicants, residents from Backus' service area who receive PCI treatment currently do so at Hartford, Yale-New Haven Hospital, L+M, Saint Francis Hospital, John Dempsey Hospital, The Hospital of Central Connecticut or UMass Memorial. *FF32.*

The proposal will impact existing providers and the existing providers are not currently being fully utilized by the Applicants. L+M would likely be the existing PCI provider most impacted by the Applicants' proposal. L+M performed 216 PCIs in 2015, 63 of which originated from Backus' service area. *FF32,33.* The Applicants and L+M presented multiple estimates as to the number of patients from Backus' service area who would seek service at Backus rather than the existing hospitals. The proposed retention rate estimates varied from 36% to 80%. *FF36.* Regardless of the precise retention rate applied, either L+M or Backus would not reach the minimum 200 procedures recommended by the Guidelines if the proposal is approved.

Additionally, L+M established its elective PCI program subsequent to entering into an Agreed Settlement with OHCA in 2013. *FF37.* The agreement was based on the expectation that L+M would be able to perform the Guidelines-established minimum number of PCIs of 200 per year. L+M does not anticipate that it will be able to meet the Guidelines minimum and will not be able to comply with this term of the agreement if Backus establishes a program. *FF37.*

The Applicants state that Backus is currently unable to meet the 120 minute door-to-balloon guideline regarding transferring AMI patients to a primary PCI-capable hospital. *FF19.* From 2011 through 2015, Backus' median door-to-balloon time was 134 minutes and travel time to a PCI-capable hospital accounted for the largest portion of Backus' transfer times. *FF19.* However, according to the Applicants, Backus has only transferred three patients to L+M, which is 21 minutes away. According to the Applicants, due to referral patterns, Backus transfers the majority of patients in need of primary PCI to Hartford, 40 minutes away. *FF20,32.* As such, the Applicants have not provided sufficient evidence demonstrating a need for a PCI program. The majority of patients that would be treated at Backus are currently being treated by other providers and, therefore, this proposal represents merely a shift in patient volume due to siphoning patients from existing providers.

The Applicants would likely be able to absorb the financial losses of the program.

The Applicants estimate Backus would need to perform 385 PCI procedures for the program to break even financially, and do not anticipate performing the necessary number of procedures through 2020, at which point they project the program would perform approximately 233 procedures *FF39.* The Applicants also estimate the proposal would necessitate nearly $5 million of capital expenditures in the form of an additional catheterization lab, new software and

equipment upgrades, as well as 3% of net patient revenues for ongoing capital needs. *FF40.* The program would operate at a loss of $355,363 in FY16, increasing to $705,757 in FY19. *FF38.*

The Applicants' projections, however, were conservative and assumed no increase in payer reimbursement but included increased costs and accounted for inflation. *FF38.* Additionally, the Applicants project income gains from overall operations at Backus from FY17 through FY19, sufficient to compensate for the program's increasing year-to-year losses. *FF42.* Although the program in itself would not be financially feasible due to increasing losses, the Applicants would be able to absorb those losses. As such, the proposal is financially feasible.

The Applicants have not satisfactorily demonstrated how the proposal would improve quality, accessibility and cost effectiveness of health care delivery, including to indigent and Medicaid patients.

The presence of a PCI program on-site at Backus would obviate the need for revascularization following a cardiac catheterization diagnosis, allowing the diagnostic and elective procedure to be completed together. This would reduce patient exposure to radiation and intravenous contrast used during the procedure. *FF12.* Currently, when Backus performs a cardiac catheterization and discovers a partial blockage, a patient must schedule an elective PCI elsewhere and then have the catheterization re-performed at that time. With the proposal, Backus would be able to perform the elective PCI at the time of catheterization.

As discussed, there are indisputable benefits to minimizing the time between when a patient presents at the emergency department and when the colluded artery is reopened. *FF18.* AMI patients currently presenting at Backus must be transported to a PCI-capable hospital, delaying treatment. Although a primary PCI program at Backus would decrease transport time, the Guidelines state that the door-to-balloon time should be within 120 minutes. *FF11.* Currently PCI-capable hospitals exist in Backus' area to which Backus could transport patients and the 120 minute window could be met. *FF32.* Although the Applicants have demonstrated how the proposal would improve quality of care, it is unclear the extent of the improvement.

Despite these potential benefits of the proposal, the Guidelines state that the minimum number of PCIs a facility should perform is set to maintain the competency of the hospital and its physicians. *FF29.* Should Backus' proposed program not meet that minimum, it is possible competency may not be maintained. Furthermore, the proposed program risks syphoning enough patients from existing hospitals to also depress the number of procedures performed at other area hospitals. *FF32,33,35.* It is possible quality may be compromised not only at Backus, but surrounding PCI-providers, as well.

The proposal would, as the establishment of a new service, likely increase access to care for Medicaid and indigent patients as Applicants' projected payer mix is comprised of 11% Medicaid and 37% uninsured. *FF43.*

Based on the aforementioned findings of fact, the Applicants have failed to meet their burden of proof in satisfying the statutory requirements of Conn. Gen. Stat. §§ 19a-639. The Applicants have neither satisfactorily identified the patient population to be served with an elective and primary PCI program nor have they demonstrated, in light of decreasing utilization and the existence of other providers in the area, that there is a clear public need for the proposed service. Furthermore, the proposal is likely to have a detrimental effect on existing providers in the area and may negatively impact the quality of care afforded patients. Finally, the Applicants have not sufficiently shown that the proposal is consistent with the PCI standards in the ACCF/AHA/SCAI Guideline and Statewide Health Care Facilities and Services Plan. However, as the proposal is neither a termination nor consolidation of health care providers, the proposal would not negatively impact the diversity of providers or choice for patients in the area.

Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application of The William W. Backus and Hartford Hospital to establish a primary and elective PCI program without on-site surgical backup is hereby **DENIED**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Department of Public Health
Office of Health Care Access

9/16/16
Date

Yvonne Addo
Yvonne Addo, MBA
Deputy Commissioner

Olejarz, Barbara

From:	Olejarz, Barbara
Sent:	Friday, September 16, 2016 2:27 PM
To:	'Janette.Edwards@hhchealth.org'; Michele Volpe (mmv@bvmlaw.com); 'RAnthony@brownrudnick.com'
Cc:	Armah, Olga; Fernandes, David; Schaeffer-Helmecki, Jessica; Riggott, Kaila; Hansted, Kevin; Martone, Kim
Subject:	The William Backus Hospital Final Decision
Attachments:	32031-20.pdf

Tracking:

Recipient	Delivery
'Janette.Edwards@hhchealth.org'	
Michele Volpe (mmv@bvmlaw.com)	
'RAnthony@brownrudnick.com'	
Armah, Olga	Delivered: 9/16/2016 2:27 PM
Fernandes, David	Delivered: 9/16/2016 2:27 PM
Schaeffer-Helmecki, Jessica	Delivered: 9/16/2016 2:27 PM
Riggott, Kaila	Delivered: 9/16/2016 2:27 PM
Hansted, Kevin	Delivered: 9/16/2016 2:27 PM
Martone, Kim	Delivered: 9/16/2016 2:27 PM

9/16/16

Attached is the Final Decision for The William Backus Hospital

Barbara K. Olejarz
Administrative Assistant to Kimberly Martone
Office of Health Care Access
Department of Public Health
Phone: (860) 418-7005
Email: Barbara.Olejarz@ct.gov