

EIP ARRA PCV13 ABSTRACT

The 13-valent conjugate pneumococcal vaccine (PCV13) is expected to be licensed and distributed in the fall of 2009. This vaccine will replace the current 7-valent vaccine (PCV7). Since the PCV13 vaccine will be licensed based on immunogenicity data, an efficacy study is necessary to understand the impact of this vaccine on invasive pneumococcal disease.

In partnership with the CDC and participating EIP sites, the Connecticut Department of Public Health plans to perform the proposal development and case-control work for the vaccine efficacy study in Connecticut. Connecticut has a diverse population of 3.5 million people. The catchment area for the study will be the entire state of Connecticut. In 2007, the last full year for which serotyping data is available, there were a total of 39 cases who were less than 5 years of age, of whom 23 were less than 2 years, and 16 between 2-4 years. Of the 23 cases less than 5, 17 had serotypes covered by PCV13, and none had serotypes included in PCV7. In cases 2-4 years of age, 10 had serotypes covered by PCV13, and none had serotypes included in PCV7. Currently, more than 90% of 2 year olds in Connecticut are fully vaccinated using PCV7. Thus, depending on efficacy of PCV13 and how quickly it replaces PCV7, we could have anywhere from 6-23 cases in <2 year olds to enroll during the first year of the case-control study.

The Connecticut DPH will also conduct a parallel study of efficacy using controls matched by date of birth and zip code selected from the Connecticut Immunization Registry and Tracking System.

Project activities will involve obtaining consent, interviewing parents of case and control infants, and obtaining information on vaccination status from the infant's primary care provider, data entry, and analysis. ARRA funds will be used to hire one durational worker to assist with study activities.

13-Valent Pneumococcal Conjugate Vaccine

The State of Connecticut Department of Public Health (DPH) Emerging Infections Program ARRA Funding Request

The State of Connecticut Department of Public Health is soliciting funding for the budget period of August 30, 2009 through December 29, 2011.

Line Item	Total
Personnel	\$100,000
Fringe	\$56,710
Supplies	
Equipment	
Travel	
Other	
Contractual	
Indirect Cost	\$36,200
Total	\$192,910

Background and Current Activities/Capacities

Connecticut Emerging Infections Program (EIP)

The Connecticut EIP, established in 1995, is a collaborative effort of the Department of Public Health (DPH) and the Yale School of Public Health. This partnership gives the Connecticut EIP substantial capacity and flexibility to take on labor-intensive projects that often fall outside the realm of routine surveillance, some of which can only be done in county-based or smaller catchment areas. DPH, having authority and responsibility to protect the public health, assumes most EIP projects that tie into reportable disease surveillance, outbreak investigation and response, or investigation of new acute emerging infections demanding an immediate public health response. The Yale office of the Connecticut EIP (Yale EIP), being much more flexible to hire personnel, utilize students, and involve other interested investigators at both the School of Public Health and the Medical School, assumes most elective and labor-intensive EIP projects. Funds are transferred from DPH to the Yale EIP via a contract mechanism.

The Connecticut DPH has the authority to add or delete diseases from the reportable disease list on an annual basis, eliminating one major constraint to initiation of new surveillance efforts. In Connecticut, invasive pneumococcal disease (IPD) is a laboratory and physician reportable condition. Routine audits are conducted of all clinical laboratories in the state to ensure completeness of reporting. All reports of IPD are investigated through the Active Bacterial Core Surveillance (ABCs) Project using a structured case report form to obtain demographic and clinical data for eligible cases. Previously, the Connecticut DPH utilized case-control studies for outbreak investigations, the meningococcal conjugate vaccine effectiveness study, and collaborated with Yale on the PCV7 vaccine effectiveness study and both pediatric and adult

vaccine effectiveness evaluation. This experience, coupled with the routine IPD surveillance system will allow CT DPH to identify and enroll the majority of eligible cases for this study.

OPERATIONAL PLAN

The Connecticut EIP participated in the efficacy study of the PCV7 vaccine. At that time, in part due to scope of the project, we decided to contract with Dr. Marietta Vasquez at the Yale University School of Medicine. For the proposed efficacy study of PCV13, we plan to do the proposal development and case-control work at the Connecticut DPH using ABC staff supplemented by a durational worker. With a diverse population of 3.5 million people and a relatively small geographic size, Connecticut is uniquely suited for such a study. The catchment area for the study will be the State of Connecticut.

In 2007, the last full year for which serotyping data is available, there were a total of 39 cases who were less than 5 years of age, of whom 23 were less than 2 years, and 16 between 2-4 years. Of the 23 cases less than 5, 17 had serotypes covered by PCV13, and none had serotypes included in PCV7. In cases 2-4 years of age, 10 had serotypes covered by PCV13, and none had serotypes included in PCV7. Currently, more than 90% of 2 year olds in Connecticut are fully vaccinated using PCV7. Thus, depending on efficacy of PCV13 and how quickly it replaces PCV7, we could have anywhere from 6-23 cases in <2 year olds to enroll during the first year of the case-control study.

In addition to enrolling controls according to whatever protocol is developed, the Connecticut DPH is also interested in conducting a parallel study of efficacy using controls matched by date of birth and zip code selected from the Connecticut Immunization Registry and Tracking System.

Human Subjects

All Connecticut ABCs pathogens are reportable by laboratories and physicians, with data kept confidential under Connecticut General Statutes and the Connecticut Public Health Code. Core surveillance activities are considered HIC-exempt by the CDC and DPH HIC approval in deferred to the CDC. The DPH is also a HIPAA exempt agency. Studies considered research do require DPH HIC approval and there is a process in place at DPH to submit protocols to the DPH HIC for review and approval.

ROLES AND RESPONSIBILITIES

The DPH is the lead agency for this project. Matthew L. Cartter, M.D., M.P.H., State Epidemiologist and EIP Principal Investigator, will have overall responsibility for overseeing the activities of this project. The lead for hiring staff and day-to-day oversight of the project will be Susan Petit, M.P.H., Connecticut EIP ABCs Coordinator. Dr. James Hadler, M.D., M.P.H., former Connecticut EIP Principal Investigator, will assist Ms. Petit with the protocol development and obtaining the required human subjects approvals as necessary. Carmen Marquez, the health program assistant for the ABCs project will identify eligible cases from routine surveillance data. Collection of data on case and control infants including obtaining consent, interviewing parents of case and control infants, and obtaining information on vaccination status from the infant's primary care provider will be conducted by Heather Altier, health program assistant for the ABCs project, and an additional epidemiologist who will be

hired as a durational worker for this project. Heather Altier was recently recruited to replace Kristen Desy. Kristen has taken another position with the program.

Specific positions that due to this funding will be created or retained.

ARRA funds will be used to support one new durational position at DPH.

Epidemiologist 1 – budgeted for 24 months for the period January 1, 2010 – December 29, 2011.

PERFORMANCE MEASURES AND EVALUATION PLAN

The DPH ABCs staff will work with CDC to develop methods to track and report on specific project milestones and performance measures as required under the ARRA reporting requirements.

The following activities will also be measured: 1) the number of monthly conference call and percent of ABCs staff who participate in these calls; 2) development and pilot testing of study instruments within study deadlines; 3) transmission of data to CDC at required deadlines; 4) percent of enrolled cases with isolates shipped to CDC; 5) percent of eligible cases enrolled; 6) percent of enrolled cases with matched controls; 7) percent of enrolled cases and controls with collected vaccine history; 8) percent of enrolled cases and controls with completed parent interviews; 9) number of presentations or publications using study data.

BUDGET JUSTIFICATION – 13-Valent Pneumococcal Conjugate Vaccine

The Connecticut state Department of Public Health (DPH) is requesting federal ARRA funds to support the Connecticut Emerging Infections Program (EIP). The Connecticut Emerging Infections Program is a collaborative effort involving the DPH and the Yale University School of Public Health. The DPH currently uses CORE-CT, Connecticut state government's financial, human resources and payroll system. CORE-CT will allow DPH to track ARRA funds separately from the base EIP funds and also has reporting functions that will allow program staff to track and monitor the expenditure of ARRA funds. The DPH also utilizes the CORE-CT human resources/payroll functions; so all personnel expenditures charged to ARRA funds are tracked and approved by Supervisors/Managers at DPH.

The total ARRA assistance requested for DPH 13-Valent Pneumococcal Conjugate Vaccine activities are \$192,910. These funds are for the time period August 30, 2009 – December 29, 2011.

Personnel

Total \$100,000

1. To be Determined, Epidemiologist 1 (100% effort for 24 months) (\$100,000)

This person works in the Epidemiology and Emerging Infections Program of the DPH, under the direct supervision of Susan Petit, M.P.H. The DPH is anticipating hiring the position as of January 1, 2010 as it usually takes a few months to establish the position, post the announcement and interview qualified candidates. The responsibilities of this position include: identifying eligible cases and controls, performing medical chart review, obtaining consent from study participants, conducting structured telephone interviews with parents of enrolled cases and controls, coordinating isolate shipment with laboratory personnel, data analysis, and developing reports of study findings.

Fringe

Total \$56,710

The estimated fringe benefit rate for state fiscal year 2009 for the DPH is 56.71%.

Indirect Cost

Total \$36,200

The indirect cost rate for the DPH for SFY 2009 is 36.2%, applied to salary only