PREVENTION OF TRANSMISSION

OF TUBERCULOSIS

IN

CONNECTICUT ACUTE CARE HOSPITALS

Results of a Study

and

Recommendations of the

Connecticut Tuberculosis Elimination

Advisory Committee

1996

PREVENTION OF TRANSMISSION OF TUBERCULOSIS IN CONNECTICUT ACUTE CARE HOSPITALS: RESULTS FROM A STUDY* AND RECOMMENDATIONS OF THE CONNECTICUT TUBERCULOSIS ELIMINATION ADVISORY COMMITTEE**

INTRODUCTION

In October 1993, the Centers for Disease Control (CDC) released draft guidelines regarding the prevention of tuberculosis (TB) transmission in health care settings (1). These guidelines have since been finalized (2). The recommendations they contain were developed in the wake of a number of documented outbreaks of nosocomial transmission of multidrug-resistant tuberculosis (MDR-TB) from patients to other patients and staff in hospitals in the United States between 1990-92 (3-9). A critical recommendation in the guidelines was that each hospital administration evaluate the potential for transmission of tuberculosis in their hospital by reviewing how recently hospitalized cases of tuberculosis were actually managed from the perspective of isolation, treatment and discharge planning.

Because of the proximity of Connecticut to New York City, where the majority of nosocomial MDR-TB outbreaks had been described, and the relatively high incidence of acquired immunodeficiency syndrome (AIDS) and human immunodeficiency virus type 1 (HIV) related tuberculosis in Connecticut, we felt it important to assess the potential for nosocomial transmission in hospitals located in the areas of highest AIDS incidence. This study was carried out during March - April 1994 with the help of a group of Yale MPH students. The results were presented to the state Tuberculosis Elimination Advisory Committee for their review and recommendations. Recommendations of the Committee are presented in the discussion in juxtaposition to the relevant findings of concern.

METHODS

The study had two components: a review of relevant hospital-specific policies and capacity and a chart review of all smear positive cases to determine actual practices. The study focused on the 14 hospitals located in the 8 towns with the highest AIDS incidence rates. These towns included Bridgeport, Danbury, Hartford, New Britain, New Haven, Norwalk, Stamford and Waterbury.

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* The persons who carried out the study include: James L. Hadler, M.D., M.P.H., Marjan Javanbakht, M.P.H., Vandana Kane, M.P.H., Azin Shahryarinejad, M.P.H., and Katherine Wolski, M.P.H.

** The Advisory Committee membership who participated in the development and review of this document is as follows: Dr. John Brackett, Dr. Richard Castriotta, Chairman, Dr. Brian Cooper, Dr. Lloyd Friedman, Ms. Rita Grygus, Dr. Walter Hierholzer, Dr. Richard Melchreit, Ms. Debra Rosen, Dr. Ulder Tillman, Dr. Stephen Updegrove; Staff: Dr. James Hadler, Ms. Ann Levison, Mr. Joseph Marino.

Hospital infection control staff at each hospital were interviewed regarding TB-specific infection control practices and the number of isolation and negative pressure isolation rooms using a standard questionnaire. Policy aspects examined included policies on initiation and termination of isolation, availability of laboratory smear and culture services, and staff training related to TB isolation. Where written policies had been developed, these were collected and reviewed.

To examine TB control practices, the hospital records of all smear positive TB cases diagnosed at these hospitals in 1990 and 1993 were audited. Since the first CDC guidelines for prevention of transmission in hospitals were published in 1990 (10), it was reasoned that comparison of 1990 with 1993 might allow analysis of whether significant changes in practices had occurred since then. Aspects of practices examined included: time intervals from admission to isolation and to when a smear for acid fast bacilli (AFB) was ordered or TB was mentioned in the chart, from initiation to termination of isolation, from when a sputum smear was ordered to when it was collected and the results reported, from sputum collection to when *M.tuberculosis* was identified and to when susceptibility was reported. In addition, the initial treatment regimen was reviewed and an assessment was made of completeness of reporting of selected TB case characteristics and timeliness of reporting. For the latter assessment, selected case characteristics were abstracted from each chart and compared to the comparable information reported to the state. Date of report to the state was compared with the date therapy was started and to when the patient was discharged from the hospital.

RESULTS

Thirteen of the 14 hospitals participated. The one that did not participate had only one smear positive case admitted in 1990 and 1993 combined. Of the participating hospitals, three treated $\geq$6 smear positive cases per year ("high risk"); four treated 3-5 cases per year ("medium risk"); and six treated $\leq$2 cases per year ("low-risk").

There were 74 smear positive cases admitted to the 14 hospitals in 1990 and 1993, representing 25% of all cases reported in CT during these two years. Of these 74 cases, charts were found and reviewed on 63 or 85% - 18 from 1990 and 45 from 1993. Case features included: age range of 18-94 years; 79% male; 65% minority; 32% foreign-born; 33% HIV positive and 46% unemployed.

HOSPITAL POLICIES

The following outlines important descriptive findings by policy area. Results flagged with "**" and/or in ***bold italics*** are findings of particular concern.

<u>Negative-pressure Isolation Rooms</u>

* There was a marked increase in negative pressure rooms in all hospitals between 1990 and 1993. This increase averaged xx rooms per hospital. By 1993, there were an average of 31 rooms per high-risk hospital; 18 rooms per medium-risk hospital; and 15 rooms per low-risk

hospital.

* Overall, 31% of hospitals use continuous-pressure monitoring devices. The others use intermittent monitoring of room pressure ranging from daily to every 3 months.

Policies on Use of Negative-pressure Rooms

** ***Only 85% (11/13) of hospitals have written criteria for who should be isolated for suspected TB***. Among the eleven hospitals with written policies: 91% require isolation if an AFB smear is positive; ***64% require isolation based on symptoms only; and 73% require isolation based on symptoms of cough in combination with either HIV positivity or a previous history of TB.***

** ***The same 85% (11/13) of hospitals have written criteria for when TB isolation can be terminated. Of these eleven: 64% require 3 negative smears for discontinuation of isolation; 45% require at least preliminary drug susceptibility results; 45% require at least 2 weeks of therapy to be completed; and 18% require sign-off by infection control.***

* The responsibility to initiate or terminate isolation most often rests with the attending or resident physician. Among the thirteen hospitals, isolation is the physician's responsibility in 92%. Termination of isolation is the physician's responsibility in 85%. Infection control personnel had authority to initiate or terminate isolation in 54% of the hospitals. In spite of attending physicians having the main responsibility for determining whether a patient gets put in negative pressure isolation, training in isolation policy and procedure did not reflect this. ***Training in isolation policy and procedures was required*** of infection control staff in 100% of hospitals, of nurses in 77% of hospitals, and ***of physicians in only 39% of hospitals.***

Policy Updates Since October 1993

The 1993 CDC draft guidelines recommended implementation of several policies regarding isolation, training, and involvement of public health officials in patient discharge planning. In response to this, 46%of the 13 hospital modified policies on clinical criteria for isolation; 39% changed policies regarding termination of isolation; 23% updated policies on infection control training; but **only 15% changed policies to incorporate the local health department in discharge planning.**

AFB Laboratory Services

** ***Of the 13 hospitals, only 39% have routine AFB smear services 7 days per week.***

* Nearly all, 92%, do AFB cultures on site and 58% use Bactec systems for isolation, including all 3 high-risk hospitals. However, most laboratories use the state laboratory for species identification and drug susceptibility testing. Only 8% (one hospital) does its own species identification and susceptibility tests.

HOSPITAL PRACTICES

The following outlines important findings identified by the investigation of how the 63 cases of TB were actually managed by policy area. Results flagged with "**" and/or in ***bold italics*** are findings of particular concern.

Isolation Practices

* Of the 63 cases whose charts were reviewed, 83% (52) had TB mentioned in the differential diagnosis in their admission note. AFB smears were ordered within 24 hours of admission for 89% (56).

** ***Only 70% of cases (44) were placed in a designated isolation room at time of admission.*** However, the use of negative pressure isolation improved dramatically from 1990 to 1993, from 7% to 56%.

** ***Of fifteen 1993 cases not initially isolated, 9 had symptoms (cough and either fever or weight loss) and 6 of these also had TB risk factors (homelessness, HIV positive, substance abuser, past history TB or positive tuberculin skin test).*** The six other cases did not have classic symptoms of tuberculosis on admission, but 4 of them had TB risk factors.

Laboratory Practices

* Sputum collection once specimens were ordered was prompt. Of the 56 cases for whom a sputum was ordered within 24 hours of admission, 55 (99%) had them collected the same day.

** ***Return of smear results was not always timely. Smear results as determined from review of physician and nursing notes and laboratory reports were first recorded or noted in the chart within 24 hours of collection for only 54% (34/63) of initial specimens collected.*** This did not improve over time: 62% of 1990 cases but only 51% of 1993 cases had results noted within the recommended time interval.

The preliminary and final results of laboratory cultures were also generally slow to return to the chart.

* Culture growth within 3 weeks of collection was noted in the chart for 44% (28/63) of initially positive specimens.

* Identification of *M.tuberculosis* was made within 3 weeks of specimen collection for 51% of patients. The percentage of initial specimens in which a timely identification was made improved dramatically between 1990 and 1993, from 30% to 59%. Much of this was due to the introduction and use of genetic probes.

** ***Only 40% (25/63) of cases ever had drug susceptibility results returned to the medical chart.*** However, this, too, showed improvement over time, from 6% in 1990 to 53% in 1993. Timeliness of drug susceptibility testing was also examined. ***Only 10% had drug susceptibility results returned to the medical chart within 3 weeks of initial sputum collection.*** Although the median number of days from identification of *M.tuberculosis* to having antibiotic susceptibility results was 10 days in 1993, down from 31 days in 1990, in only 13% of 1993 charts were drug susceptibility results noted within 3 weeks of sputum collection.

Treatment Regimens

Choice of initial drug treatment regimen was also reviewed.

* Of 56 cases for whom treatment was started in hospital, 88% were started on regimens containing at least isoniazid, rifampicin and pyrazinamide as recommended by the American Thoracic Society (13).

* Use of a four drug regimen increased from 1990 to 1993 from 20% to 46%.

** ***Of nineteen 1993 cases with risk factors for drug resistance (foreign-born, previous TB therapy, HIV positivity), only 11(58%) were started on a 4-drug regimen.***

Reporting Practices

Connecticut state law requires reporting of tuberculosis within 24 hours of strong suspicion. In addition, the 1993 CDC draft guidelines recommend that public health officials participate in discharge planning before a person on anti-tuberculosis therapy is discharged.

** ***Of 54 cases for whom treatment was started in hospital and full data was otherwise available, only 16 (30%) were reported to the state before discharge from hospital.*** There was no association of delayed reporting with particular hospitals. Because delayed reporting could have been due to patients being discharged just after diagnosis, the mean length of stay (LOS) in hospital between starting therapy and discharge was examined. The mean LOS was 19.7 days with a range of 2 to 88 days.

** ***There was significant undereporting of important epidemiologic information on the state TB report form compared to that obtained from chart review on 1993 cases, as outlined in Table 1 (next page).*** In particular, injection drug use, alcohol use, homelessness and whether an HIV test had been done were grossly undereported. Only positive HIV test results were fully reported.

Table 1. Actual and Reported Occurrence and Incidence Rates of Selected Risk Factors for Tuberculosis Among 45 TB Cases Hospitalized in Connecticut, 1993.

	Actual	No. Cases	Prevalence of Factor	
Risk Factor	Total	Reported	Actual	Based on Reporting only
Injection Drug Use	18	8	40%	18%
Alcohol Abuse	25	10	56%	22%
Homelessness	12	8	27%	18%
HIV tested	41	26	91%	59%
HIV positive	15	15	33%	33%
HIV negative	26	11	59%	24%

DISCUSSION AND RECOMMENDATIONS

The findings of this study show that there has been a conscientious effort among many hospitals in Connecticut to respond to the 1993 CDC guidelines for prevention of tuberculosis in health care settings. Considerable policy changes have been made and isolation capacity has greatly increased since 1990, particularly in those hospitals with the highest admission rates of smear positive tuberculosis. Infection control policies in the majority of hospitals surveyed reflect the attempt to address the 1993 CDC guidelines.

However, the results of the study of actual practices show that there is still substantial potential for transmission of TB from AFB smear positive patients admitted to Connecticut hospitals. A considerable number of patients are not put into isolation in spite of clear indications. Many patients with potential for drug resistance are not being started on appropriate therapy, and most patients are being discharged from the hospital without either drug susceptibility results or consultation with local health authorities. Contributing to this is that there is considerable variation between hospitals in isolation policies and training requirements and in availability of critical supporting laboratory services. The following outlines the main concerns raised by this study and the specific recommendations of the CT TB Elimination Advisory Committee to address them.

PATIENT ISOLATION CONCERNS

1. ***Thirty percent of smear positive TB patients admitted to Connecticut hospitals are not being isolated on admission.***

Most of these patients have symptoms consistent with active tuberculosis and recognizable risk factors for it. Failure to initiate isolation is due to a number of factors: a lack of standard policies for initiation and termination of isolation, inconsistent application of policies which do exist, and lack of systematic training in indications for isolation for the staff charged with ordering it. In many hospitals individual physicians are charged with the responsibility for initiating and terminating isolation, yet few hospitals require any specific training for these physicians.

Recommendations

(a) ***Isolation in a negative pressure room should be presumptively initiated on ALL individuals meeting standard clinical criteria. It should be terminated as soon as infectious tuberculosis is no longer suspected using standard criteria for termination of isolation.***

To assure that all patients with tuberculosis are initially isolated, hospitals must err on the side of caution, analogously to the manner in which persons with chest pain are admitted to coronary care units. Similarly, no one should be kept in designated negative pressure isolation rooms longer than necessary so that the rooms can be available for those who truly need them.

(b) ***All Connecticut hospitals should adopt a written list of specific clinical criteria for initiation and termination of isolation in a negative pressure room until infectious tuberculosis has been ruled out.***

The 1994 CDC final guidelines (2) recommend general clinical criteria for initiation of isolation. In addition, several Connecticut hospitals have developed detailed, standard, objective criteria for initiation and termination of isolation based on smear and/or culture results, drug susceptibility results, and the presence of medical or social risk factors for tuberculosis. The TEAC reviewed these criteria and developed consensus lists from them. ***Tables 2 and 3 present a set of reasonable, prudent criteria that can be used for initiation and termination of isolation for infectious tuberculosis***.

(c) ***All clinical staff with authority to order use of negative pressure isolation, including all housestaff, floor nurses and physicians with attending and/or admitting privileges, should receive a copy of the clinical criteria for isolation and its termination. A copy should also be available at each nursing station on all hospital clinical services.***

For consistent application of policy, it is essential that all staff be aware of it and have ready access to isolation guidelines. As required by the Joint Commission for Accreditation of Hospitals, it should be standard policy that the hospital epidemiology/infection control committee have the final authority regarding use of isolation. Any disagreements between clinical staff about its initiation or termination should be resolved by the hospital epidemiology/infection control staff.

CONCERNS ABOUT LABORATORY PRACTICES

2. ***AFB smears are not routinely done on weekends in most hospitals, delaying decisions about when to initiate isolation.***

For decisions about when to initiate or terminate isolation and what treatment regimen to ultimately use, it is important that the laboratory provide responsive support services. The 1994 CDC final guidelines specifically state that results of AFB sputum smears should be available within 24 hours of specimen collection (11).

Recommendation

All acute care hospitals in parts of the state which have relatively high AIDS incidence

rates*, should make arrangements for simple screening AFB smears (e.g., Ziehl-Nielsen on an unconcentrated specimen) each day including weekends and holidays for all sputum specimens on which smear for AFB is requested.
The results should be reported back to the relevant floor of the hospital by telephone daily and no later than 24 hours after the specimen was taken.

3. ***Drug susceptibility results were not filed in the chart or noted in the physician or nursing notes in nearly half of all recent smear positive TB cases reviewed.***
Drug susceptibility results are critical to decisions about when to terminate isolation, discharge a patient and for ultimate choice of drug regimens.

Recommendation
Before a patient with a positive AFB smear is discharged on anti-tuberculosis therapy, the status and, if available, preliminary results of drug susceptibility testing should be noted in the chart by the attending physician.

Rapid techniques for preliminary determination of drug susceptibility results for *M. tuberculosis* are now available at the state laboratory and some hospitals. Copies of preliminary and final drug susceptibility results should be filed in the patient's hospital record. Hospital infection control staff should review records of recent admissions for tuberculosis to see if this is happening. If not, a review of the hospital-specific Medical Records procedures for filing lab results that return after a patient is discharged should be undertaken.

CONCERNS ABOUT PATIENT TREATMENT REGIMENS

4. ***More than 40% of persons with clear risk factors for drug resistance are being started on sub-optimal treatment regimens (less than 4 drugs).***
This is of even more concern considering that most patients are discharged from the hospital before final susceptibility results are back and that at the time of this study, only a third of cases were reported before discharge from the hospital to local health departments who can provide follow-up and assurance of therapy.

Recommendation
Initial therapy of all new and recurrent tuberculosis cases in Connecticut should include at least 4 anti-tuberculosis drugs until the results of susceptibility testing are known.

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* Bridgeport, Danbury, Hartford, New Britain, New Haven, Norwalk, Stamford and Waterbury.

It has been nationally recommended that initial therapy for tuberculosis in any group in which the prevalence of resistance to isoniazid is $\geq$ 4% include at least 4 antituberculosis drugs (12,13). The following groups in Connecticut consistently meet this criterion: born outside the US, history of previous treatment for TB, or HIV-infected. Cases of MDR-TB have recently occurred in each of these groups, as well. Overall, the prevalence of resistance to at least isoniazid is 5.5% in Connecticut, based on 1993-1994 data. When persons in the above risk groups are excluded, the prevalence of INH resistance is 3%(14). More than 60% of Connecticut cases fall into these risk categories. Correspondingly, the TEAC recommends that an initial regimen of 4 anti-tuberculosis drugs be used in any case diagnosed in the state.

CONCERNS ABOUT REPORTING OF TB CASES

5. ***Only 30% of smear positive TB cases are being reported to the state and local health departments before discharge from the hospital.***

The average length of stay in hospital once therapy has been started is 20 days in Connecticut, giving plenty of time for reporting and discharge planning. Delayed reporting has a number of potentially harmful effects on TB control efforts, especially as it relates to the prevention of drug-resistant tuberculosis. It eliminates a ready opportunity for outreach workers to interview the patient, reinforce therapeutic messages, become familiar with his/her lifestyle and participate in discharge planning. This further greatly reduces the potential to fully consider directly observed therapy from the outset, thereby increasing the likelihood that recognition of problems with adherence to therapy will be delayed. Furthermore, initiation of contact investigations by the local health department will not occur until a case has been reported.

Recommendations

(a) Hospitals must fully comply with CDC guidelines and Connecticut state law and report any suspect or confirmed case of tuberculosis who has been started on therapy to the local and state health departments before discharge from the hospital. No patient on therapy for probable tuberculosis should be discharged before a treatment plan has been made with and agreed to by the local director of health in the town in which the patient resides.

The 1994 CDC guidelines (15) recommend that before a TB patient is discharged, there should be collaboration with public health officials to ensure continuation of therapy, including placement into case management or outreach programs of the public health department. Connecticut state law now requires predischarge collaborative planning with public health officials (16). Furthermore, documented or strongly suspect tuberculosis is reportable to the state and local health department in which a case resides within 24 hours of diagnosis or strong suspicion of it. Failure to report hospitalized TB cases before discharge could result in a state Department of Public Health Hospital Medical Care Division investigation and citation.

(b) All TB cases admitted to the hospital should be discharged on directly observed therapy.

Directly observed therapy (DOT) has become the standard for outpatient treatment of tuberculosis. The inability to predict which patients will be non-adherent to self-administered therapy (17,18), the risk of development of MDR-TB in those who are not adherent and the proven success of DOT (19,20) have all lead to the recommendation that all TB cases receive DOT(12).

6. ***There is significant undereporting of important TB information that is available on patient charts.***

In particular, homelessness, substance abuse (both injection use and alcohol abuse), and HIV negativity were undereported on 33-60% of cases. Since such information is used to plan TB control efforts, undereporting may result in failure to fully appreciate the importance of any given factor in contributing to the TB problem and thus cause less attention to be given to corresponding prevention initiatives that might be appropriate.

Recommendation

The infection control staff who report TB cases in hospitals should be informed of the results of this study by the state TB control program. They should be encouraged to accurately complete case report forms using the patient's medical chart.

They should be given periodic feedback on the results of their disease reporting efforts. State TB Program staff should periodically audit randomly selected records to ensure that case reporting is complete.

TABLE 2

MODEL CRITERIA FOR USING NEGATIVE PRESSURE ISOLATION FOR A PATIENT SUSPECTED OR CONFIRMED TO HAVE PULMONARY MYCOBACTERIUM TUBERCULOSIS (MTB)

PLACEMENT IN A NEGATIVE PRESSURE ROOM SHOULD BE REQUIRED FOR:

1. Persons with a **positive direct AFB smear of sputum**.
   Exception: recently documented atypical mycobacterial *pulmonary* infection, confirmed by previous laboratory testing and accompanied by an attending physician's note which indicates confirmed or strongly suspected alternative diagnosis.

2. Persons with a **chest x-ray with classic findings of MTB.** (i.e., upper lobe infiltrate or infiltrate in any lobe with cavities)

3. Persons with **undiagnosed pulmonary disease [with cough] [in whom an alternative diagnosis is not strongly suspected] AND any one of the following:**

   A. known recent exposure to MTB
   B. known history of MTB or +PPD
   C. known or suspected immunosuppressive state (e.g., HIV infection, immunosuppressive therapy)
   D. alcohol abuse or injection drug use
   E. past or current homelessness or incarceration
   F. born in a high incidence area of the world (Africa, Asia-Pacific Islands, South or Central America, Eastern Europe)
   G. recent fever, wight loss AND night sweats

4. Persons with a **history or clinical suspicion of multidrug-resistant TB** (MDR-TB).

ANY UNCERTAINTY OR DISAGREEMENT AMONG THE CLINICAL STAFF CONCERNING THE APPROPRIATE PLACEMENT OR USE OF NEGATIVE PRESSURE RESPIRATORY ISOLATION DEMANDS AN IMMEDIATE CONSULTATION WITH THE HOSPITAL EPIDEMIOLOGY DEPARTMENT. THE HOSPITAL EPIDEMIOLOGY DEPARTMENT AND THE INFECTION CONTROL COMMITTEE HAVE FINAL AUTHORITY IN THESE MATTERS.

TABLE 3

MODEL CRITERIA FOR DISCONTINUING
NEGATIVE PRESSURE ISOLATION FOR A PATIENT
SUSPECTED OR CONFIRMED TO HAVE
PULMONARY MYCOBACTERIUM TUBERCULOSIS (MTB)

In general, the safest place for any clinically stable drug sensitive tuberculosis patient is at home on ***directly observed therapy*** *with the appropriate contacts receiving preventive therapy.*

I. SPUTUM SMEAR NEGATIVE (MDR-TB NOT SUSPECTED)

A. If tuberculosis is considered unlikely, may be released from isolation if ANY of the following apply:

1. direct smears on 3 consecutive sputum samples are negative AND the attending physician thinks the patient does not have clinical TB and writes a note approving discontinuance.
2. a single bronchoscopic specimen is direct smear negative AND the attending physician thinks the patient does not have clinical TB and writes a note approving discontinuance.
3. at least one negative sputum smear and a confirmed alternative diagnosis.

B. If tuberculosis has already been confirmed by culture or cultures are pending and tuberculosis is considered a reasonable possibility, may be released from isolation if ALL of the following apply:

1. the patient is clinically improving;
2. drugs chosen for treatment are appropriate[1];
3. the patient has been able to consistently take and retain medication; and
4. at least one week (7 days) of therapy have been completed.

II. DIRECT SMEAR POSITIVE, CULTURE RESULTS POSITIVE OR PENDING (MDR-TB not suspected)

A. May be released from isolation if ALL of the following apply:

1. the patient is clinically improving (less cough and fever);
2. direct smears are improving;
3. drugs chosen for treatment are appropriate[1];
4. the patient has been able to consistently take and retain medication;
5. at least two weeks (14 days) of therapy have been completed.

B. If final culture results are pending and preliminary identification suggests MAI alone without concurrent MTB, the patient may be removed from isolation.

III. MDR-TB CONFIRMED (MTB resistant to at least INH and RIF) or **STRONGLY SUSPECTED**[2]

May be released from isolation if ALL of the following apply:[3]

1. the patient is clinically improving;
2. 3 consecutive sputum *cultures* are negative for MTB;
3. the patient has been able to consistently take and retain appropriate medication; and
4. the patient is taking at least two antituberculosis medications to which the organism is sensitive.

1 Appropriate initial therapy for persons with HIV infection or who were born outside the United States or who have a history of previous TB treatment should consist of at least 4 anti-TB drugs until sensitivity results are available. All other persons should have at least 3 anti-TB drugs and, ideally, 4 anti-TB drugs.

2 MDR-TB should be strongly suspected in persons who are HIV positive and who have an epidemiologic link to an MDR-TB case or who have recently been living in New York City or who have previously been under treatment for TB.

3 Patients with pulmonary MDR-TB should usually remain in negative pressure respiratory isolation for the duration of their hospitalization. On readmission, they must be placed in negative pressure respiratory isolation immediately and remain in isolation until their status for disease activity and potential transmission has been clarified.

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