

Pennsylvania Department of Public Welfare

Office of Mental Health

Office of Mental Retardation

Tuberculosis Control Program

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PENNSYLVANIA DEPARTMENT OF PUBLIC WELFARE
OFFICES of MENTAL HEALTH and MENTAL RETARDATION

TUBERCULOSIS CONTROL POLICY

Tuberculosis is a bacterial disease communicated person-to-person through airborne droplets of infectious particles known as droplet nuclei. Persons infected with tuberculosis may develop disease within the first two years of infection, may have dormant infection for several years before developing disease, or may never develop disease. Tuberculosis disease can cause disability and death. The incidence of tuberculosis has increased in many geographic locations due to the increasing numbers of immunocompromised persons, particularly those infected with human immunodeficiency virus (HIV). The treatment of co-infected TB/HIV patients/individuals is complicated by several factors including: the presentation of active TB is different among the HIV/AIDS population, thus making it harder to recognize; the development of disease among the HIV/AIDS population is more rapid; and the comorbid conditions of HIV and TB result in a much poorer outcome.

Treatment of tuberculosis disease requires multiple drugs for an extended period of time, resulting in greater risks associated with the treatment of TB than most other infectious diseases. When therapy is not adhered to strictly, the tuberculosis bacteria develop resistance quickly to the medications employed. These resistant forms are then transmitted to other persons whose poor compliance with a medical regimen may result in bacteria that are resistant to multiple drugs. Such multi-drug resistant tuberculosis (MDR-TB) strains have resulted in great outbreaks in New York, Florida, and New Jersey. These outbreaks have had particularly devastating and fatal outcomes when they occurred among immunocompromised people such as the HIV/AIDS sub-population.

Therefore, the control of tuberculosis transmission has become a very important public health issue and the reason for this document, which addresses itself to measures for state mental health and mental retardation facilities in the Commonwealth of Pennsylvania.

Although eliminating the risk for transmission of *Mycobacterium tuberculosis* in all health-care facilities may not be possible, the Centers for Disease Control and Prevention (CDC) released guidelines for reducing this risk and preventing the morbidity and mortality, which has been associated with tuberculosis and multi-drug resistant tuberculosis. The CDC document is entitled, *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities, 1994*. The MH/MR policy, which follows, uses CDC's guideline as its framework.

A hierarchy of control measures will be employed to prevent the spread of tuberculosis at state MH and MR facilities. This hierarchy of controls includes: administrative measures to reduce the risk for exposing uninfected persons to persons who have infectious TB; engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei; and personal protective equipment for use in certain situations in which the other two controls will not completely prevent the spread of TB.

Tuberculosis Infection Control Program

I Responsibility for the Tuberculosis Control Program

Responsibility for the tuberculosis control program within a facility shall be assigned to the *Infection Control Committee*. This committee must have access to persons with expertise in infection control, occupational health, and engineering.

The chairperson of the infection control committee must select at least one medically trained individual (physician, registered nurse, or infection control coordinator) to be responsible for interpreting this policy. This individual(s) shall be known as the *Tuberculosis Control Program Coordinator*. The duties of the individual(s), specially trained in tuberculosis control practices, shall include: answering all questions that arise concerning tuberculosis transmission; review of the TB control program at least annually including all data which arises from purified protein derivative (PPD)-tuberculin skin test administration to patients/individuals, volunteers, students, and staff; and primary responsibility for investigating all cases of active TB within the facility.

Disciplinary action for staff noncompliance with the TB Control Program is directed by the facility's Personnel Director in compliance with DPW Personnel Manual Section 7173.

II Risk Assessment, Infection Control Plan, and Periodic Assessment

- A. General - To develop a risk assessment for each facility, the CDC suggests consideration of a number of parameters; see Table 1. Using Table 1 as a guide, the facility should conduct an initial baseline assessment. From this initial assessment, the facility establishes its "level of risk" category, upon which all future evaluations will be determined as seen in Table 2.
1. The community TB profile shall take into account all the counties of origin included in the patient/individual population. County of origin for each patient/individual shall be defined as the county(ies) of residence within the six months prior to the most recent admission. The definition and profile shall also include the county in which the patient/individual most recently was subject to residential services (e.g., state correctional facility, county jail, and other inpatient psychiatric facilities).
 2. Regardless of risk level for each facility, the management of a patient/individual with known or suspected TB should not vary. The index of suspicion must be held high. Treatment must be aggressive.
 3. The risk assessment shall be conducted by the individual(s) named by the infection control committee chairman as the Tuberculosis Control Program Coordinator.
 4. The risk assessment shall be conducted for the entire facility and for specific areas within the facility [e.g., forensic unit, admission unit(s), geriatric unit(s), drug treatment unit(s), and acute care unit(s)].

In addition, risk assessments shall be conducted for groups of employees who work throughout the facility rather than in a specific area (e.g., physicians, psychiatrists, "float" nursing personnel, environmental services, dietary, maintenance, students, and volunteers).

5. Classification of risk for a facility, unit, or occupational group will follow the same tenets proposed in Figure 1 which includes the community TB profile, the number of cases of active TB handled by the facility annually, and the number of employees with conversions.
6. The **minimal risk** category applies only when the entire facility does not admit TB patients/individuals to inpatient/residential areas and is located in a community without any TB cases in the previous year.
7. The **very low risk** category applies to a facility in which:
 - a) a patient/individual with known, active TB is not admitted to inpatient/residential status, but may develop the disease over the course of stay; or
 - b) a patient/individual suspected of having active TB is referred to a collaborating facility for treatment.

Very low risk is also assigned to facility without a case of active TB in the previous year, but which had active TB reported in the community.

8. The **low risk** category is assigned to areas or occupational groups which have shown: a) no increase in PPD test conversion rates; b) no clusters⁽¹⁾ of PPD conversion; c) no person-to-person transmission of TB; and d) fewer than six TB patients/individuals are treated per year.
 9. The **intermediate risk** category is assigned to areas or occupational groups which have: a) no increase in PPD test conversion rates; b) no clusters of PPD conversion; c) no person-to-person transmission of TB; and d) six or more patients/individuals with active TB are treated each year.
 10. The **high risk** category is assigned to areas or occupational groups which have: a) significantly greater PPD conversion rates than comparable groups or areas of other hospitals; or b) a cluster of PPD conversions have occurred; or c) other evidence that person-to-person transmission of *M. tuberculosis* has occurred.
- B. Community TB Profile - Each facility shall gather data from the Pennsylvania Department of Health concerning the incidence of tuberculosis disease in each county of origin as defined in Section II, A, 1. The drug susceptibility patterns shall also be considered a part of the risk assessment in addition to impacting the treatment modalities considered.

⁽¹⁾ A cluster is defined as two or more PPD conversions.

C. Case Surveillance

1. Data from all suspected and confirmed cases of active TB among patients/individuals and employees shall be collected, reviewed, and used to estimate the occupational risk to employees. State mental hospitals shall use this data to estimate the need for TB isolation rooms, as defined in Table 1; mental retardation centers should not use this data for this purpose since TB isolation rooms are not authorized for mental retardation centers.
2. Drug susceptibility patterns of *M. tuberculosis* isolates shall be gathered from the laboratory data on all TB patients/individuals/employees and shall be used to indicate the need for modification of initial treatment.

D. Analysis of Employee PPD Test Screening Data

1. Results of all employee PPD testing shall be recorded in the individual employee's health record and in a retrievable aggregated database. PPD test conversion rates should be calculated at appropriate intervals to estimate risk (Table 2).
2. To calculate PPD test conversion rates, the number of PPD test conversions among employees (the numerator) shall be divided by the total number of previously PPD negative employees tested (the denominator) in each area or group.
3. If PPD test conversions are noted, an epidemiologic investigation is to be undertaken to determine the likelihood of nosocomial transmission of *M. tuberculosis*.
4. The frequency and comprehensiveness of employee testing should be evaluated periodically to ensure that all employees who should be tested are included in the testing program. In state MH/MR facilities, all full-time and part-time employees (temporary and permanent), students, contract service provider(s), and volunteers (i.e., persons providing at least two hours per week or eight hours per month of unpaid service to the hospital/center with patient/individual contact) are to be tested serially with PPD by Mantoux skin tests in accordance with Table 1. PPD testing will be provided free of charge from the state MH/MR facility. If an employee, volunteer, contract service provider, or student has written proof of a PPD by Mantoux method within the last six months, the MH/MR facility may accept this documentation in lieu of administration of a repeat test. In addition, if provisions of a contract include evidence of administration of the PPD by Mantoux method to students/contract service providers, documented results of the test shall be accepted by the MH/MR facility.

E. Review of Medical Records of Patient/Individual with TB

1. The medical records of each patient/individual diagnosed with TB during inpatient / residential, status at a MH/MR facility shall be reviewed periodically to evaluate infection control parameters (Table 1).
2. Medical records should be reviewed for evidence other admissions may have resulted in person-to-person transmission of TB.

3. Data from the case review should determine the need to modify: a) protocols for identifying and isolating patients/individuals who may have active TB; b) laboratory procedures; c) administrative policies and practices; and d) protocols for patient/individual management.
- F. Observation of TB Infection Control Practices - A part of the evaluation process must be an assessment of adherence to the TB infection control policies of the state MH/MR facility. Work practices related to TB isolation must be observed to determine if the hospital/center is enforcing and employees are adhering to the policies. Education and other corrective action are indicated if adherence to the policies is not occurring. Every effort shall be made to ascertain patient/individual adherence to protocols.
- G. Engineering Evaluation - Results of physical plant management and maintenance measures should be reviewed at regular intervals (Table 3). Data from the most recent evaluation and from maintenance procedures and logs should be reviewed carefully as a part of the risk assessment.

Infection control plans developed at each state MH/MR facility shall integrate this document, with supporting information taken from the CDC's *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Facilities, 1994*, as minimum standards.

Periodic reassessment shall be performed at intervals no less often than those indicated in Table 2. Reassessments shall be reviewed by at least the staff responsible for TB control in each facility and findings shall be reported to the infection control committee.

III Identifying, Evaluating, and Initiating Treatment for Employees/Patients/Individuals Who May Have Active TB

The most important factors in preventing transmission of TB are early identification of persons who may have infectious TB, prompt initiation of treatment, and implementation of TB precautions.

A. Identification of Employees/Patients/Individuals Who May Have Active TB

1. All employees of a state MH/MR facility shall implement and enforce protocols for the early identification of patients/individuals who may have infectious TB. The criteria for these protocols should be based on such elements as the rate of tuberculosis at the MH/MR facility and the risk for TB in the surrounding community.
2. All patients/individuals shall be screened on admission and at the time of the annual assessment for TB through PPD skin test and/or through the review of symptoms and chest x-ray, if indicated. Any patient/individual will be suspected of having infectious TB if s/he has had a persistent cough of greater than three weeks duration and one or more of the following: a) night sweats; b) unexplained weight loss; c) increased frequency of cough; d) increased production of sputum; or e) hemoptysis.
3. Any employee with signs and symptoms as defined in III, A, 2 shall be excluded from work and evaluated promptly. The employee may not return to work until the diagnosis of

TB has been excluded or until determination has been made that the employee is no longer infectious. For evaluation and management, an employee shall be referred to the public health provider (State Health Center or county/municipal health department) or to his/her private physician in accordance with the policy of the MH/MR facility.

B. Diagnostic Evaluation for Active TB

1. Diagnostic measures such as medical history, physical examination, PPD skin test, chest x-ray, and microscopic and culture examination of the sputum should be performed on any person suspected of having active TB.
2. The most rapid methods of laboratory evaluation should be employed to expedite the diagnosis and treatment of TB.
3. Laboratory results of acid-fast bacilli (AFB) smears must be available to the state MH/MR facility within 48 hours.
4. The risk of TB is greater among employees/patients/individuals with a history of positive PPD test, previously known TB disease, known exposure to TB, or with risk factors for TB disease. Employees/patients/individuals with suggestive signs or symptoms of TB (AFB positive smear, abnormal x-ray, symptoms suggestive of TB) should be clinically managed as if TB were diagnosed until the disease is ruled out.
5. It is more difficult to diagnose TB among employees/patients/individuals co-infected with HIV. TB should be suspected regardless of the PPD results. The presence of *M. avium* does not rule out *M. tuberculosis* in this category of persons.
6. Immunocompromised employees/patients/individuals who have pulmonary signs or symptoms, which are ascribed initially to infections or conditions other than TB should be evaluated for coexisting TB.
7. Employees/patients/individuals with suspected or confirmed TB shall be reported immediately to the Pennsylvania Department of Health.

C. Initiation of Treatment for Suspected TB in Patients/Individuals

1. Patients/individuals with confirmed active TB or who are considered highly likely to have active TB should be started promptly on appropriate treatment (Supplement 2).
2. When an MH/MR facility without an appropriate TB isolation room suspects a patient/individual has active TB, the patient/individual shall be transferred promptly to an acute care setting. It is the responsibility of the state facility to develop an agreement with an appropriate inpatient facility, which can manage both active TB and the mental health/mental retardation needs of the patient/individual.

The state MH/MR facility may only readmit the patient/individual when s/he is not infectious; i.e., has had three negative smears on consecutive days. Any patient known or suspected of having active infectious TB will not be admitted to the state MH/MR facilities without appropriate TB isolation facilities until rendered non-infectious.

3. Administration of medication shall be directly observed during the entire length of treatment for TB of the patient/individual at the state MH/MR facility. Any patient/individual on a self-medication program must be observed while taking anti-tuberculosis medications.
4. In the event of resistance by a patient/individual to therapy, and in accordance with Communicable Disease Law, the following steps will be taken for any patient/individual being treated for suspected tuberculosis disease:
 - a) The patient/individual will receive a written plan of therapy for tuberculosis to include the treatment modalities, anticipated length of treatment, and information about the disease to include communicability and outcome without treatment. This plan is to be read and explained to the patient/individual when diagnosis is suspected and/or upon return from the acute care facility.
 - b) After starting treatment and being rendered non-infectious, any patient/individual who refuses to take his/her medication shall meet with the treatment team within three days of refusal. During this meeting, an in-depth explanation and written notice shall be given to the patient/individual on the need for the TB medication and the potential for court action if refusal continues. This will be known as a ***Level 1 refusal***.
 - c) If the patient/individual continues to refuse treatment, a second team meeting will be held when a total of five days of treatment has been missed. At this time, the patient/individual is considered infectious and shall be placed in TB isolation (including transfer to acute care facility, if necessary). The legal process for court ordered therapy will begin. This is a ***Level 2 refusal***.
 - d) Any variation from this format will depend on the policies and procedures of the MH/MR facility. All variant policies shall be submitted in writing for review by the Medical Director, Office of Mental Health, or the Bureau of Direct Program Operations, Office of Mental Retardation.

IV Managing Patients/Individuals Who Have Possible Infectious TB

When signs and symptoms of tuberculosis are present and TB is suspected, it is imperative that the patient/individual is placed in TB isolation. Identification of TB disease may be difficult in the person co-infected with HIV due to atypical presentations of TB. Maintain a high index of suspicion for active TB when a patient/individual presents with a history of risk factors such as chronic medical conditions, a history of alcohol or drug abuse, recent immigration to this country, homelessness, HIV infection or any other predisposing factors which may contribute to the development of the disease.

- A. Isolate any persons suspected of having active infectious disease in a TB isolation room as quickly as possible. Infectiousness is defined in Supplement 1.
1. If the facility has no TB isolation capacity, transfer to an acute care hospital capable of managing both TB and psychiatric illnesses/mental retardation as indicated. A pre-arranged cooperative agreement must be established. This will facilitate the rapid transfer on a 24 hours per day basis of any patient/individual suspected of having active TB. A mask/respiratory protective device (see VI, B) shall be placed on the patient/individual promptly and during transport to the acute care hospital.
 2. In the event a patient is maintained at the state MH facility for treatment of active TB, each TB isolation room(s) shall be maintained in compliance with the current CDC/ATS recommendations for ventilation.

When the patient/individual is considered not infectious and treatment at the MH/MR facility is resumed, frequent checks of sputum for AFB shall be performed to identify a need for TB isolation.

B. TB Isolation Practices

1. Any patient/individual placed in TB isolation shall be educated on the mechanism of transmission and instructed to cover mouth and nose with a tissue when coughing or sneezing.
2. A patient/individual will remain in a TB isolation room at all times, with the door closed. If s/he leaves the TB isolation room, the patient/individual is to wear an appropriate particulate respirator to cover his/her mouth and nose.
3. The number of persons entering a TB isolation room should be minimized. All persons who enter such a room must wear appropriate respiratory protection as defined in Section VI of this document.
4. Disposal of items contaminated with respiratory secretions of a patient/individual with *M. tuberculosis* does not pose an increased threat to employees, but should be handled in a manner that reduces the risk for transmitting other microorganisms and in accordance with facility policy.

C. TB Isolation Room - The primary purposes of the TB isolation room are to separate the patient/individual likely to have active TB from others; to reduce the concentration of droplet nuclei through engineering methods; and to prevent the escape of droplet nuclei into the corridor or other areas of the facility.

1. A TB isolation room is to be a single patient/individual bedroom with special ventilation characteristics defined in the CDC's Supplement 3 of the *Guidelines for Preventing the Transmission of M. tuberculosis in Health Care Facilities, 1994*.

2. The TB isolation room should be maintained under negative pressure (Supplement 3). Doors are to be kept closed unless a person is entering or exiting the room.⁽²⁾
 3. Negative pressure in the room shall be monitored daily in accordance with Supplement 3, and a record kept while the room is being used to provide TB isolation.
 4. A minimum of six air exchanges per hour shall be provided in any room maintained for TB isolation (patient/individual bedrooms and treatment rooms). If possible, this airflow rate may be increased to 12 or greater air exchanges per hour in existing facilities. All newly constructed or renovated facilities shall maintain airflow of greater than 12 air changes per hour for TB isolation rooms.
 5. Air from TB isolation rooms and treatment rooms shall be exhausted to the outside. This air must not be re-circulated into the general ventilation system. If this is unavoidable, HEPA filters must be installed to exhaust ducts leading from the room to the general ventilation system.
 6. Upper room air UVGI may be used as an adjunct to general ventilation in the TB isolation room (Section II, F; Supplement 3). Air in the TB isolation room may be re-circulated within the room through HEPA filters or UVGI devices.
 7. Estimating the number of TB isolation rooms necessary for each facility will be based on the results of the risk assessment of the hospital/center. Any facility with a risk greater than minimal and very low risk must have at least one TB isolation room or a contract in place for prompt patient/individual admission to an acute care hospital (see III, C, 2).
 8. If at all possible, TB isolation rooms in a facility should be grouped together geographically.
- D. Discontinuation of TB Isolation - TB isolation can be discontinued if the diagnosis of TB is ruled out. In the event that TB cannot be ruled out, the patient/individual must remain in TB isolation until a determination is made that the patient/individual is not infectious.
1. The length of time required to render a patient/individual non-infectious after beginning antituberculosis medication is variable. TB isolation may only be discontinued when the patient/individual is on effective therapy, is clinically improved, and has had three consecutive negative sputum AFB smears collected on different days.
 2. To monitor for relapse, sputum smears for AFB for any patient/individual with active TB in the state MH/MR facility shall be conducted regularly for the duration of time the patient/individual is actively treated for tuberculosis. Smears shall be collected and analyzed not less than every two weeks while the patient/individual has a productive cough.

² Alternatives to use of negative pressure are delineated in CDC's Supplement 3.

3. A patient/individual with known multi-drug resistant TB shall be kept in TB isolation for the duration of therapy due to the high risks associated with relapse and communicability among the state MH/MR facility population.
- E. Discharge Planning - Discharge from the state MH/MR facility of any patient/individual who has not completed a full course of therapy for tuberculosis shall require a referral to the public health provider for the county to which the patient/individual is being discharged. The public health provider will be the Pennsylvania State Health Center or the County/Municipal Health Department. The attending physician in the community shall also be notified.

V Engineering Control Recommendations

- A. General Ventilation - This applies to the engineering controls for general use areas of the state MH/MR facility. TB isolation room recommendations are contained in the CDC's Supplement 3 on this subject.
1. All state MH/MR facilities with TB isolation rooms shall have access to an engineer or other professional with expertise in ventilation. This person shall work closely with the infection control staff. An engineer may be obtained from the DPW Bureau of Facilities Management.
 2. Ventilation systems must meet all federal, state, and local requirements.
 3. The direction of airflow should be designed so that the air flows from clean areas to less clean areas.
 4. High prevalence facilities need to consider the use of UVGI and/or HEPA filtration systems to supplement the other engineering controls.
- B. Additional Engineering Control Approaches -
1. HEPA Filtration - Refer to Supplement 3 for complete information on this topic. However, the HEPA filters may be used in the following ways: a) in exhaust ducts discharging air from booths or enclosures into the surrounding room; b) in ducts or ceiling or wall mounted units for re-circulating air within the patient/individual room; c) in portable air cleaners; d) in exhaust ducts to remove droplet nuclei from air being discharged to the outside; e) in ducts discharging air from the TB isolation room into the general ventilation system. Maintenance must be performed in accordance with the manufacturer's suggestion.
 2. UVGI - In high risk areas for transmission of M. tuberculosis, UVGI may be used as an adjunct to ventilation for reducing the concentration of infectious droplet nuclei. Ultraviolet units can be installed in a room or corridor to irradiate the air in the upper portion of the room, or they can be installed in ducts to irradiate air passing through the ducts. UV can be used in ducts that re-circulate air back into the same room, but may not be used as a substitute for HEPA filters in ducts that discharge air from TB isolation rooms into the

general ventilation system. Maintenance on the UV lamps must be in accordance with the manufacturer's guidelines.

VI Respiratory Protection

- A. Personal respiratory protection should be used by any: 1) person entering a room in which a patient/individual is known or suspected of having infectious TB; 2) person present during cough-inducing or aerosol-generating procedures performed on such a patient/individual; 3) person in other settings where administrative and engineering controls are not likely to protect him/her from infectious airborne nuclei including settings such as transport vehicles and surgical or dental clinics. Fit testing for TB infection control respirators shall be performed in accordance with standards set by CDC.
- B. Respiratory protective devices should meet the following criteria: 1) the ability to filter particles 1 micrometer with a filter efficiency of $\geq 95\%$; 2) the ability to be qualitatively or quantitatively fit tested to prevent face seal leakage over 10%; 3) the ability to fit the different facial sizes and characteristics of patients/individuals/employees; 4) the ability to be checked for face piece fit in accordance with OSHA standards and good industrial hygiene. According to the *Federal Register* of June 8, 1995, all nine categories of non-powered air purifying particulate respirators meet this standard (N-95, N-99, N-100, P-95, P-99, P-100, R-95, R-99, R-100). Therefore, appropriately labeled respirators are acceptable.
- C. In settings where employees are at risk for exposure to respiratory pathogens, such as M. tuberculosis and mucous membrane exposure to fluids infected with blood borne pathogens, employees should be protected from both.
- D. State facilities shall adhere to the standards set forth in the Safety and Occupational Health Manual, Communicable Disease Guidelines Policy (see DPW Administrative Manual Section 7067, Chapter 9, Section 2).
- E. When a patient suspected of having infectious M. tuberculosis is not in an TB isolation room, s/he must be encouraged to use a particulate respirator (see VI, B) to reduce the expulsion of droplet nuclei into the air.

VII Employee TB Training and Education

All employees, including physicians, should receive education regarding TB that is relevant to persons in their particular occupational group or setting. Training should occur before initial assignment and annually thereafter. The program should include the following elements:

- 1. The basic concepts of transmission of M. tuberculosis, its pathogenesis, and diagnosis. This should include information concerning the difference between infection and disease, the signs and symptoms of active disease, and the possibility of reinfection.

2. The potential for occupational exposure to persons who have infectious TB in the facility including information about the prevalence of TB in the community and at the facility.
3. The principles and practices of infection control which reduce the risk for transmission of *M. tuberculosis*. Site-specific control measures should be provided to employees in areas that require additional control measures, such as in laboratory and dental settings. All appropriate employees shall be trained about the proper fit and use of respiratory protection devices.
4. The purpose of PPD skin testing, the significance of a positive PPD test result, and the importance of participating in the skin test program. Also discussed shall be the need for a review of signs/symptoms of TB among persons known to have a positive reaction to PPD, persons refusing the PPD skin test and/or persons known to be allergic to the PPD Mantoux skin test.
5. The principles of preventive therapy for latent TB infection, including indications, use, effectiveness, and the potential for adverse effects (Supplement 2).
6. The employee's responsibility to seek prompt medical evaluation if a PPD test conversion occurs or if symptoms develop that could be caused by TB. Prompt evaluation thus enables employees with active TB to receive appropriate therapy and will help to prevent transmission of *M. tuberculosis*.
7. The principles of drug therapy for active TB.
8. The importance of notifying the facility if the employee is diagnosed with active TB so that appropriate contact investigation can be performed.
9. The responsibility of the facility to maintain the confidentiality of the employee who has TB while ensuring that s/he receives appropriate therapy and is non-infectious before returning to work.
10. The higher risks associated with TB infection in persons who have impaired cell mediated immunity (such as HIV infection) including: a) the more frequent and rapid development of clinical TB after infection with *M. tuberculosis*; b) the differences in the clinical presentation of disease; and c) the high mortality rate associated with MDR-TB in such persons.
11. The potential development of cutaneous anergy as immune function declines.
12. Information regarding the efficacy and safety of BCG vaccination and the principles of PPD screening among BCG recipients.

*VIII Counseling, Screening and Evaluation For Latent TB among Patients/Individuals/
Employees/Volunteers/Students*

A TB counseling, screening, and prevention program must be established to protect both patients/individuals and employees at MH/MR facilities. Because some patients/individuals of MH/MR

facilities remain in care for extended periods of time, a serial program of evaluation for latent TB infection and disease is indicated. All employees and all patients/individuals of MH/MR facilities with a history of positive PPD should be evaluated initially for prophylactic antibiotics and reviewed annually for signs and symptoms of disease. All employees/patients/individuals of MH/MR facilities with PPD test conversions or symptoms suggestive of TB should be identified, evaluated to rule out a diagnosis of active TB, and started on treatment or prophylactic therapy as indicated.

A. Counseling Employees/Patients/Individuals regarding TB in the Presence of HIV co-infection.

1. Because of the risk of rapid progression from latent infection to active disease with *M. tuberculosis*, all employees/patients/individuals at risk for HIV infection should be encouraged to be tested for HIV infection. Any employee who is considered immunocompromised due to immunosuppressive disease or therapy should consider reassignment away from any high risk setting in which the exposure to *M. tuberculosis* may be great.
2. All employees should be informed of the need to follow existing recommendations for infection control to minimize the risk for exposure of immunocompromised employees to infectious agent. All employees should be informed about the potential risks to severely immunocompromised patients/individuals who might be exposed to the infectious diseases of their caregivers, including TB.
3. The hospital/center shall make reasonable accommodations (e.g., alternative job assignments) for employees who have a health condition that compromises cell mediated immunity and who work in settings where they may be exposed to *M. tuberculosis*. Evaluation of all such situations should include consideration of the Americans with Disabilities Act of 1990 provisions and any other applicable federal, state and local laws.
4. Immunocompromised employees/patients/individuals/volunteers/students should have appropriate follow-up and screening for infectious diseases. It is recommended that immunocompromised employees/patients/individuals be given anergy³ panel with PPD testing at least every six months while the PPD remains negative. This shall be provided for patients/individuals. Employees/volunteers/students shall be encouraged to be followed by their private medical practitioner.
5. Information provided by employees/patients/individuals/volunteers/students regarding their health status shall be treated confidentially.

B. Screening Employees/Patients/Individuals/Volunteers/Students for Latent TB Infection

1. During the pre-employment physical, when applying for a volunteer position, or during admission to the MH/MR facility, all persons shall receive a PPD skin test. Persons with a history of BCG vaccination should have a baseline PPD performed in accordance with Supplement 2. The only exception to offering PPD testing would be individuals with a documented, known positive test in the past. All individuals who have not had a previous

³ Refer to CDC Supplement 3 for anergy panel recommendations.

negative PPD within the preceding 24 months must have a two step PPD performed to detect boosting phenomenon. Booster testing is unnecessary for persons under the age of 18.

2. Employees/patients/individuals who have a documented history of: a) a positive PPD test; b) adequate treatment for disease; or c) adequate preventive therapy for infection, shall be submitted to annual review of signs and symptoms of disease as well as a review of risk factors for disease (example: Figure 4). All such employees shall be administered an initial chest x-ray upon hire, unless they have a documented normal chest x-ray within the previous year.
3. It is the responsibility of the facility's personnel department to insure that all students, full and part-time employees,⁴ contract,⁵ and temporary employees⁶ be tested for TB through PPD skin testing by Mantoux method or completion of the PPD questionnaire at a minimum of once a year and in accordance with Table 2. The facility shall provide free testing for all the above. Persons not complying with the policy requirements will be subject to disciplinary or administrative action, as applicable and appropriate.
4. The testing of volunteers (i.e., persons providing at least two hours per week or eight hours per month of unpaid service to the hospital/center with patient/individual contact) shall be provided by the facility. Volunteers without this level of exposure, and/or groups of volunteers that visit only once or twice per year, need not be tested. Persons not complying with this mandate shall be asked not to return to the facility until the testing is completed.
5. Any PPD negative employees/patients/individuals known to be exposed to an infectious TB patient/individual shall submit to PPD testing when contact is discovered and three months after the last possible exposure to infectious TB.
6. All PPD tests on employees/patients/individuals shall be administered, read, and interpreted in accordance with current guidelines by specially trained personnel. At the time the test results are read, the person tested should be informed of the interpretation of results. Positive test results for employees/patients/individuals in the state MH/MR facility shall be 10 mm, unless known to be HIV positive, exposed to an infectious case of TB, and/or immunocompromised. In the latter situations, a 5 mm response or greater shall be considered positive.
7. All employees/patients/individuals with PPD conversions found on serial testing shall require investigation to determine the possibility of exposure at the MH/MR facility. Investigation sites shall include primary ward and any other areas of the MH/MR facility in which the person with PPD conversion would have had extensive exposure.

⁴ Part-time employee is anyone who provides at least two hours per week or eight hours per month of service and who usually has contact with patients/individuals.

⁵ Same criteria as for part-time employees; two hours/week, eight hours/month with patient/individual contact.

⁶ Same criteria as for part-time employees; two hours/week, eight hours/month with patient/individual contact.

8. In any area of a facility where transmission of *M. tuberculosis* is known to have occurred, a problem evaluation should be conducted and the frequency of skin testing should be upgraded in accordance with the applicable risk category.
 9. PPD test results should be recorded confidentially in the individual employee's health record or the patient's/individual's chart and in an aggregate data base of all employee/patient/individual PPD test results. The database shall be analyzed periodically as a part of the risk assessment.
- C. Evaluation and Management of Employees/Patients/Individuals Who Have Positive PPD Test Results or Active TB
1. Evaluation of Patients/Individuals of MH/MR Facilities with Positive PPDs
 - a) Evaluation of any patient/individual admitted to the MH/MR facility with a documented history of a positive PPD shall be through the use of a review of symptoms (as shown in Figure 4), a chest x-ray (within the three months prior to admission), and evaluation for need of prophylactic treatment for latent TB infection, if indicated.
 - b) Evaluation of a patient/individual who converts on PPD testing during serial monitoring shall submit to all of the processes listed in VIII, C, 1, a, as well as an evaluation of potential source(s) of exposure, both on and off grounds.
 - c) Any patient/individual with a positive PPD and signs and symptoms of active disease shall be treated in accordance with Section III.
 2. Post Exposure Evaluation of Employees
 - a) Evaluation of all employees with positive PPD test conversions shall be performed promptly by the county's public health provider; State Health Center or County/Municipal Health Department. If the history, physical, and chest x-ray are considered compatible with active TB, the employee shall be excluded from the work place until: 1) the diagnosis of active TB is ruled out; or 2) the employee with the diagnosis of active TB is treated and a determination is made that s/he is not infectious. Employees with conversions, but who are free of active disease, must be evaluated for prophylactic treatment.
 - b) If an employee's PPD test result converts to a positive, an extensive history shall be taken to determine all potential sources of exposure including work place and social life activities. Any potential source patient/individual identified shall have drug susceptibility patterns performed in an effort to identify the appropriate preventive therapy for the exposed employee.
 3. Routine and follow-up chest radiographs are not required for asymptomatic, PPD positive employees. A repeat chest x-ray need not be done unless symptoms develop, which could be attributed to TB.

4. Work Place Restrictions

a) Employees with Active TB

- 1) Employees with pulmonary or laryngeal TB pose a risk to patients/individuals and other employees while they are infectious. They shall be excluded from the work place until they are non-infectious. All work place exclusion shall be charged to the employee as sick leave, unless a determination is made the disease is a result of work place exposure, at which point Workman's Compensation provisions will be implemented.
- 2) Before the employee (who has active TB disease) can return to the work place, the facility shall receive documentation from his/her health care provider that the employee is receiving adequate therapy, is free from cough, and has had three consecutive negative sputum smears collected on different days. While the employee remains on anti-TB therapy, the facility shall require monthly documentation from the health care provider that the employee remains non-infectious.
- 3) An employee with active laryngeal or pulmonary TB who discontinues treatment before being cured shall be excluded from the work place until treatment is resumed and the employee is found to be free of symptoms and signs of infectiousness as defined above.
- 4) Employees who have TB at sites other than the lungs or larynx do not need to be excluded from the work place if a diagnosis of concurrent pulmonary TB has been ruled out.

- b) Latent TB Infection - Employees receiving preventive treatment for latent TB infection should not be restricted from their usual work activities. If an employee with latent TB infection refuses to take or cannot tolerate preventive therapy, s/he should be counseled about the risk for developing active TB.

5. Management - Any employee found to have a positive PPD, with or without signs and symptoms of disease, shall be offered access to the public health care provider as defined above for management of latent infection and disease. This service is provided free to all state residents by the Pennsylvania Department of Health.

D. Employee Compliance

1. All employees are required to participate in the TB screening program.
 - a) If an employee refuses the PPD skin test, has a previous positive PPD test or is allergic to PPD, the employee shall complete a PPD questionnaire (Figure 4).
 - b) The PPD questionnaire is completed by the employee and reviewed by the TB coordinator/health care provider who asks further questions, when indicated, and reviews the signs and symptoms of disease with each employee.

- c) If the PPD questionnaire responses are predominately positive, the employee should be counseled by the TB coordinator/health care provider on the importance of PPD skin testing (if s/he is refusing the PPD test) and the need for further evaluation (i.e., physical examination, chest x-ray, sputum evaluation).

If an employee with predominately positive answers on the PPD questionnaire, still refuses to submit to medical testing, the employee shall not be permitted to return to his/her job until a medical evaluation is completed.

- d) If the PPD questionnaire responses are negative, and the questionnaire has been reviewed by the TB coordinator/health care provider, no further evaluation is needed. If the TB coordinator/health care provider suspects that the employee is withholding information, the employee shall be subjected to further evaluation (chest x-ray, physical examination, sputum evaluation). When the questionnaire is completed and the employee is felt to be free of disease, the employee should then be counseled about signs and symptoms of disease and the importance of reporting same should they occur.
- e) If the employee refuses to comply with screening for TB; i.e., the PPD skin test or the PPD questionnaire (Figure 4), s/he must complete the Refusal Form, Tuberculosis Control Program (Figure 5). The Noncompliance Notification (Figure 6) shall be issued informing him/her that s/he must provide written medical documentation (Figure 7) from a physician stating the employee is free from TB disease before returning to work.
 - 1) The medical document must be completed and returned by the employee no later than two weeks from receipt of the Noncompliance Notification letter. This medical documentation shall include the determination, date, and physician's signature.
 - 2) This outside evaluation shall be done at the employee's expense and using employee's approved leave.
- f) Disciplinary action may be administered for refusal to complete the Refusal Form (Figure 5) or comply with the Noncompliance Notification (Figure 6) requirements. As in any such matter, it is the responsibility of management to implement appropriate disciplinary measures. This disciplinary action must be decided in collaboration with the Department's Division of Labor Relations.

If an employee continues to refuse to comply with the requirements outlined above after disciplinary action, the facility must contact the Division of Labor Relations for recommendations for additional disciplinary action, up to and including discharge.

IX Problem Evaluation

The state MH/MR facility must evaluate its policies, procedures, practices, and performance as soon as possible if certain events occur. Such events include: a) the occurrence of PPD test conversions or active TB in employees or patients/individuals; b) the occurrence of possible

person-to-person transmission of *M. tuberculosis*; and c) situations in which patients/individuals or employees with active TB are not promptly identified and isolated resulting in the potential for exposure of staff and patients/individuals.

Investigation of PPD test conversions among employees or patients/individuals is essential.

If a skin-test conversion in a patient/individual or employee is identified as a part of routine screening, the protocol previously described in Section VIII shall be followed.

1. If the history suggests the patient/individual or employee was exposed to and infected with *M. tuberculosis* outside the facility, then no further epidemiologic investigation is necessary.
2. In the epidemiologic investigation of any conversion, the assistance of the public health provider is encouraged.
3. If the history does not suggest the employee or patient/individual was exposed outside the facility, contacts of the suspected source patient/individual must be identified and evaluated. Possible reasons for the exposure and transmission should be evaluated (Table 4), interventions should be implemented to correct these causes, and PPD testing on PPD negative patients / individuals / employee contacts must be performed immediately and at three months. If there are conversions among this group, the Medical Director, Office of Mental Health or the Bureau of Direct Program Operations, Office of Mental Retardation, and the state Department of Health must be notified. Further investigations will be implemented.
4. If the history does not suggest the patient/individual/employee was exposed outside of the facility and a source patient/individual is not identified, further investigation within the facility is warranted. In this situation, the Medical Director, Office of Mental Health or the Bureau of Direct Program Operations, Office of Mental Retardation, and state Department of Health are to be notified to assist with a determination of the risk of an undetected active case within the staff or patients/individuals of the hospital/center.

X. Coordination with the Department of Health

- A. As soon as a patient/individual or employee is known or suspected of having active TB, the state Department of Health is to be notified. Concurrently, the Medical Director, Office of Mental Health, or the local MR Medical Officer and the Bureau of Direct Program Operations, Office of Mental Retardation, is/are to be notified by the MH/MR facility, respectively. Additionally, in the event that it is a employee, the DPW Bureau of Personnel (Occupational Health Nurse) is to be informed.
- B. The Department of Health will assist with contact investigation, may participate in management of disease in the case of the employee, will be involved with all cases of refusal to comply with medication, and will be involved with discharge planning for any patient/individual who leaves the hospital/center prior to completion of chemotherapy for TB.

XI Additional Considerations for Selected Areas

Special areas and types of clinics require special consideration and are defined as such below.

- A. Laboratory - A laboratory in which specimens for mycobacteriological studies are processed, should be designed to conform with criteria specified by CDC and the National Institutes of Health.
- B. Long Term Care Facility or Hospice - Any such setting operated by the state MH/MR facility is to conform to the criteria set forth in this document. If such a setting exists on the grounds but is not under the direction of the MH/MR facility, every effort shall be made to keep the populations of the two facilities separate.
- C. Dental Setting - Some procedures performed in a dental setting can be considered "cough" producing although this is not the intent of the procedure.
 - 1. A risk assessment should be done annually, and TB infection control policies reviewed in the dental care setting.
 - 2. While taking a patient's/individual's medical history, initially and periodically, questions should be asked pertaining to the possibility of active TB; e.g., cough of greater than three weeks duration, unexplained weight loss, and hemoptysis.
 - 3. Any patient with a history suggestive of active TB should be referred back for appropriate evaluation by the medical physician.
 - 4. Elective dental treatment should be deferred until a physician confirms the patient/individual does not have infectious TB or is appropriately rendered non-infectious with chemotherapeutics.
 - 5. If urgent dental care must be provided for a patient/individual who has or is strongly suspected of having infectious active TB, such procedures must be provided in an environment that can provide appropriate TB isolation.
- D. Specialty medical office/clinic in the state MH/MR facility shall be subject to the same policy as defined above under dental setting.

Table 1

Elements of a Risk Assessment for Tuberculosis in Health-care Facilities

1. Review the community TB profile (from public health department data).
2. Review the number of TB patients who were treated in each area of the facility. (This information can be obtained by analyzing laboratory surveillance data and by reviewing discharge diagnoses or medical and infection control records.)
3. Review the drug-susceptibility patterns of TB isolates of patients who were treated at the facility.
4. Analyze purified protein derivative (PPD) tuberculin skin test results of employees, by area or by occupational group for employees not assigned to a specific area (e.g., respiratory therapists).
5. To evaluate infection control parameters, review medical records of a sample of TB patients seen at the facility.

Calculate intervals from:

- ✓ admission until TB suspected;
- ✓ admission until TB evaluation performed;
- ✓ admission until acid-fast bacilli (AFB) specimens ordered;
- ✓ AFB specimens ordered until AFB specimens collected;
- ✓ AFB specimens collected until AFB smears performed and reported;
- ✓ AFB specimens collected until cultures performed and reported;
- ✓ AFB specimens collected until species identification conducted and reported;
- ✓ AFB specimens collected until drug-susceptibility tests performed and reported;
- ✓ admission until TB isolation initiated;
- ✓ admission until TB treatment initiated; and
- ✓ duration of TB isolation.

Obtain the following additional information:

- ✓ Were appropriate criteria used for discontinuing TB isolation?
- ✓ Did the patient have a history of prior admission to the facility?
- ✓ Was the TB treatment regimen adequate?
- ✓ Were follow-up sputum specimens collected properly?
- ✓ Was appropriate discharge planning conducted?

6. Perform an observational review of TB infection control practices.
7. Review the most recent environmental evaluation and maintenance procedures.

Table 2⁷

Elements of a Tuberculosis Infection Control Program

Element	Minimal	Very low	Low	Intermediate	High
Designate TB Control Coordinator	R	R	R	R	R
Baseline risk assessment	R	R	R	R	R
Community TB Profile – incidence, prevalence, drug susceptibility	Y	Y	Y	Y	Y
Facility case surveillance	C	C	C	C	C
Analysis of PPD test employees	Y	Y	Y	6-12 M	3 M
Review of medical records of a patient/individual with TB	Y	Y	Y	6-12 M	3 M
Observation of infection control practices	Y	Y	Y	6-12 M	3 M
Evaluation of engineering control practices	Y	Y	Y	6-12 M	3 M
Written TB infection control plan	R	R	R	R	R
Reassessment of risk	Y	Y	Y	6-12 M	3 M
Protocol for identifying patients who may have active TB	R	R	R	R	R
Protocol for diagnostic evaluation of patients who may have active TB ⁸	R	R	R	R	R

⁷ R = recommended Y = yearly C = continual N/A = not applicable

⁸ Does not include patients identified in triage system and referred to a collaborating facility or patients/individuals being managed in outpatient areas.

Element	Minimal	Very low	Low	Intermediate	High
Protocol for reporting lab results to clinicians, infection control committee, referral facilities, Department of Health	R	R	R	R	R
Protocol for initiating treatment for active TB disease ⁹	R	R	R	R	R
Appropriate number of TB isolation rooms	N/A	N/A	R	R	R
Protocol for initiating TB isolation	R	R	R	R	R
Protocol for TB isolation practices	R	R	R	R	R
Protocol for discontinuing TB isolation	R	R	R	R	R
Protocol for discharge planning	R	R	R	R	R
Protocol for maintenance of engineering controls	R	R	R	R	R
Respiratory protection program	R	R	R	R	R
Education and training of employees regarding TB	R	R	R	R	R
Counseling employees regarding TB	R	R	R	R	R

R= recommended Y = yearly C = continual N/A = not applicable

⁹ Does not include patients identified in triage system and referred to a collaborating facility or patients/individuals being managed in outpatient areas.

Element	Minimal	Very low	Low	Intermediate	High
Protocol for identifying signs/symptoms of active TB among employees/individuals/patients	R	R	R	R	R
Baseline PPD screening of employees and individuals/patients	R	R	R	R	R
Routine periodic PPD screening of employees and individuals/patients	Y	Y	Y	6-12 M	3 M
Protocol for evaluating and managing employees and patients/individuals with positive PPDs	R	R	R	R	R
Protocol for managing employees and individuals/patients with active TB	R	R	R	R	R
Protocol for investigating PPD conversions and active TB in employees/individuals/patients	R	R	R	R	R
Protocol for investigating possible person-to-person transmission of TB	R	R	R	R	R
Protocol for investigating possible contacts of individuals / patients with TB	R	R	R	R	R
Effective system of reporting patients who have a suspected or confirmed case of TB	R	R	R	R	R

R = recommended

Y = yearly

C = continual

N/A = not applicable

Figure 4

PPD Questionnaire

Name _____ Date _____

Employee#/SS# _____ Department _____

I. This form is being used because of:

- _____ Positive Reaction
- _____ Date of (+) PPD / / Reaction _____ mm
- _____ Treated with INH yes _____ no _____ Date: / /
- _____ Known Allergic
- _____ Refuses test

II. Complete the following:

SIGNS/SYMPTOMS

- Cough of greater than 3 weeks duration Yes _____ No _____
- Unexplained weight loss Yes _____ No _____
- Change in cough- frequency or production Yes _____ No _____
- Coughing up blood Yes _____ No _____
- Night sweats Yes _____ No _____
- Increasing lethargy/fatigue Yes _____ No _____

RISK FACTORS

- History of Diabetes Yes _____ No _____
- Foreign born Yes _____ No _____
- Country _____
- Emphysema/Asthma Yes _____ No _____
- Cigarette smoker Yes _____ No _____
- If so, pack(s)/day _____ years _____
- Treated for CA Yes _____ No _____
- If so, when _____ site _____

III. Based upon the response of questions, it is recommended that the employee:

- _____ Counseled/informed of importance of TB detection and can be returned to the work site. No further evaluation needed.
- _____ Needs further evaluation: chest x-ray, review of symptoms and/or physical exam. May return to work at the present time.
- _____ Needs further evaluation. The employee cannot return to the work site. If refuses to comply at this point, counsel employee and refer for disciplinary action.

Completed by: _____ Date: _____
TB Coordinator/Health Care Provider

Comments:

Figure 5

**Refusal Form
Tuberculosis Control Program**

Date: _____ Name: _____ Phone: _____

The purpose of the PPD skin test is to determine whether you have ever been exposed to the bacteria that causes tuberculosis. A positive reaction does not mean that you have the disease. It means only that at some time in your lifetime you were exposed to the organism that causes tuberculosis. If you have a positive reaction, further studies, such as a chest x-ray and an evaluation by a physician may be necessary.

The test consists of a small amount of the test material being injected into the skin. The results of the test will be read 2-3 days later.

I have read the information on this form about the tuberculosis skin test. I have had the opportunity to ask questions which have been answered to my satisfaction. However, I am still refusing the test.

_____ I am refusing the test because:

The purpose of the PPD Questionnaire is to discover the presence of signs, symptoms and risk factors associated with the pulmonary disease of tuberculosis. In the event that you have a positive reaction to PPD, are allergic to PPD, or refuse to submit to the PPD skin test, you must complete the questionnaire to be in compliance with the TB Control Program of this facility.

_____ I am refusing the PPD Questionnaire because:

I understand that if I refuse to submit to both of these tests, that I must provide written medical documentation by a physician stating that I am free of TB within two weeks of the date of this notification.

Signature: _____ Date: _____
SS#: _____ Ward: _____
Department: _____ Shift: _____

Figure 6

NONCOMPLIANCE NOTIFICATION

Date: _____

Dear _____:

SS#: _____

Work site: _____

The policy of this facility is to have an annual evaluation for tuberculosis. This means you should have a purified protein derivative (PPD)-tuberculin skin test and/or be assessed for signs and symptoms of disease annually. This office has no evidence that you have been evaluated within the past year.

If you have had an evaluation for TB, please bring proof to the Employee Health Services Office. If not, please report to _____ for administration of the appropriate evaluation.

If you refuse to have the PPD test or TB questionnaire done, it will be necessary for you to contact _____ so that we can ensure compliance of all personnel with the TB Control Program.

You must respond within two weeks of the date of this letter or disciplinary action may be imposed upon you. Thank you for your cooperation.

Sincerely,

Health Services Office

cc: Supervisor
Personnel Office

Figure 7

Medical Documentation

I certify to the best of my knowledge that _____
(employee's name)

is/ is not free of tuberculosis disease.

I discussed the signs and symptoms of TB disease with this employee.

I made my determination of this individual's status based upon the following:

Physician's Signature

Print Physician's Name

Telephone Number

Date

If this employee is not free of Tuberculosis Disease, please explain:

THIS FORM MUST BE RETURNED TO THE EMPLOYER NO LATER THAN _____