



THE UNIVERSITY OF TOLEDO  
**MEDICAL CENTER**

# TUBERCULOSIS EXPOSURE CONTROL PLAN

FY 2009 Annual Review

## Background/Purpose

Transmission of TB (tuberculosis) is a recognized risk in health-care facilities. Transmission is most likely to occur from patients with unrecognized pulmonary or laryngeal TB who are not on effective anti-tuberculosis therapy and have not been placed in TB isolation. Recent outbreaks of multi-drug resistant tuberculosis (MDR-TB) have heightened concern about nosocomial transmission (mortality 43% - 93%). Increases in TB have been related to the high risk of TB among immunosuppressed persons, particularly those with HIV infection. If exposed, an immunosuppressed person is at higher risk to develop active TB disease.

On October 28, 1994, the Centers for Disease Control (CDC) published its draft rule on "Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities." This standard was enforceable under Federal Law until the final document was published. Its purpose is to require each employer to furnish employees a place of employment which is free from recognized hazards that are causing or are likely to cause death or serious harm, by eliminating or minimizing occupational exposure to tuberculosis. In response to this Federal Law, the University of Toledo Medical Center Tuberculosis Exposure Plan was written and implemented. This plan, and the original text as found in the Federal Register, is available to all UTMC employees in the Infection Control Manual.

**About the disease:** The bacteria that causes TB is called *Mycobacterium tuberculosis*. It is carried in airborne particles known as droplet nuclei, that can be generated when persons with pulmonary or laryngeal TB sneeze, cough, speak or sing. The particles are estimated to be one to five microns in size, and will travel and stay suspended in the air supported by air currents. Infection occurs when a susceptible person inhales droplet nuclei containing *Mycobacterium tuberculosis* that reaches the alveoli of the lungs. The organism may then spread to the rest of the body. Usually within two to ten weeks after initial infection the immune response limits further spread, however, some of the organisms may remain dormant for years. This is known as latent TB infection. These persons generally will have a positive Tuberculin Skin Test (TST) skin test, but are not infectious. There is up to a 10% chance during their lifetime that this will develop into active disease. The risk is greatest during the first two years after infection. HIV infection is currently the highest known risk factor for the progression from latent TB infection to active TB disease. The probability that a susceptible person will become infected depends primarily upon the concentration of infectious droplet nuclei in the air and the duration of the exposure.

Characteristics of the TB patient that increase transmission risk include:

1. Disease in the lungs, airways or larynx
2. Presence of cough or other forceful expiratory measures
3. Presence of acid-fast bacilli (AFB) in the sputum
4. Failure of the patient to cover the nose and mouth when coughing
5. Presence of cavitation on chest radiograph
6. Anti-tuberculous chemotherapy treatment failure/non-compliance
7. Administration of procedures that can induce coughing or cause aerosolization of *Mycobacterium tuberculosis* (e.g. sputum induction)

## POLICY

### ASSIGNMENT OF RESPONSIBILITY

#### **A. Infection Prevention and Control Department**

1. Maintains authority over the Plan.
2. Updates the Plan annually and as necessary.
3. Monitors the Plan continuously through rounds, feedback and reports.
4. Reviews reports submitted from departments that document compliance to the Plan and recommends corrective action for non-compliance of the Plan.
5. Reviews and revises as necessary, the safety test bank questions.

#### **B. Department Director/Manager**

1. Ensures that employees are following the Plan.
2. Ensures that non-compliance to the Plan is responded to adequately.

#### **C. All Employees**

1. Conduct activities in accordance with the Plan.
2. Report any non-compliance to the Plan to their respective department manager/director/supervisor, or to the Infection Prevention and Control or Health & Safety Departments.

### PROCEDURE

The Tuberculosis Exposure Control Plan is divided into the following sections:

1. Goals
2. Risk Assessment
3. Periodic Re-assessment of the Program
4. Early Detection of Patients with TB
5. Management of Patients in Outpatient Facilities with TB
6. Management of Hospitalized Patients with TB
7. Respiratory Protection
8. Education and Training
9. Health Care Worker Counseling, Screening, and Evaluation
10. Additional Considerations for Selected Areas
11. Supplement One - Protocol for Conducting a Risk Assessment
12. Supplement Two - Periodic Re-assessment of the Plan
13. Supplement Three - First Point of Contact Questions to Detect TB
14. Supplement Four - The TB Isolation Room
15. Supplement Five - Time Required to Remove Airborne Contaminants
16. Supplement Six - Interpreting Skin Tests
17. Supplement Seven - TB Treatment Regimens
18. Supplement Eight - Instructions on the PFR N95 Respirator

#### **D. Goals**

The Tuberculosis Exposure Control Plan has three goals: early detection, isolation, and treatment of persons with active TB. To achieve this, the following hierarchy of controls must be used:

- ♦ First Level - administrative (to reduce the risk of exposure): Written policy and procedures to ensure rapid detection, isolation, diagnostic evaluation, and treatment of persons likely to have TB.
- ♦ Second Level - engineering controls (to prevent the spread and reduce the concentration of infectious droplet nuclei): direct source control using local exhaust ventilation (e.g. hoods, tents), controlling direction of airflow to prevent contamination of air in areas adjacent to the infectious source, dilution and removal of contaminated air via general ventilation, and air cleaning via filtration or ultraviolet germicidal irradiation.

- ◆ Third Level - PPE respiratory protection, effective work practice controls.

Although completely eliminating the risk of TB transmission may be impossible, adherence to these guidelines will greatly reduce the risk.

**E. Risk Assessment** - (to evaluate the risk of TB transmission in all parts of the institution and to base the Plan on this risk assessment.)

- ◆ The algorithm from Supplement One will be used to assess employees for risk.
- ◆ TST results of employees will be recorded in the individual's employee health records. Results will also be recorded by University Health Services in a retrievable aggregated database. Identifying information will be handled confidentially.

**F. Periodic Reassessment of the Tuberculosis Exposure Control Plan**

The Tuberculosis Exposure Control Plan will be reviewed biannually and as needed to evaluate its effectiveness and to define actions necessary to minimize the risk of TB transmission (Supplement Two).

- ◆ Infection Prevention and Control will conduct a risk assessment bi-annually or more frequently if increased cases are identified.
- ◆ Facilities Maintenance, and the Safety and Health Department will meet annually to review ventilation and will report findings to the Infection Prevention and Control Committee.
- ◆ Annual reports from Facilities Maintenance will be reported to the Infection Prevention and Control Committee on the status of hospital ventilation.

**G. Early Detection of Patients with TB**

A diagnosis of TB should be considered for any patient with any of the following symptoms:

- ◆ Persistent cough >2 weeks duration.
- ◆ Complaints of bloody sputum, unexplained weight loss, or anorexia.
- ◆ Chest X-ray exam with pulmonary cavitation or hilar/mediastinal adenopathy, with or without pleural/pericardial effusion.
- ◆ Finding of apical/upper lobe infiltrates.
- ◆ Cough and fever, if the patient also has a significant reaction to a tuberculin skin test (see Supplement Six), a history of a significant reaction to a tuberculin skin test, a history of previous tuberculosis, or a history of exposure to infectious tuberculosis.
- ◆ A co-existing TB infection should be evaluated for in a patient that is immunosuppressed (e.g. HIV+) with pulmonary signs or symptoms that are initially ascribed to other etiologies. The evaluation should be repeated if the patient does not respond to appropriate therapy for the presumed etiology of the pulmonary abnormalities.

Diagnostic measures for identifying TB should be instituted among such patients. These measures may include:

- ◆ History and physical examination
- ◆ TST<sup>1</sup> test
- ◆ Chest radiograph, microscopic examination and culture of sputum or other appropriate specimens. Biopsy and/or bronchoscopy may be indicated for some patients.
- ◆ Consider Quantiferon TB Gold Test (QFT-G)<sup>2</sup> which measures the patient's immune system reaction to M.Tb.

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<sup>1</sup> TST tests are to be read between 48 and 72 hours after placement.

<sup>2</sup> Blood samples for QFT-G must be processed within 12 hours. QFT-G is an alternative to TST.

- ◆ Results of AFB smears of sputum will be available within 48 hours of specimen collection. Stat smears will also be available depending on circumstances.
- ◆ Patients with high suspicion of or confirmed TB will be reported to the appropriate health department immediately by the Infection Prevention and Control Department to assure identification and evaluation of contacts can be initiated.

## **H. Management of Patients in Outpatient Facilities with TB**

1. Triage of patients must include vigorous efforts to detect patients with active TB promptly.
  - ◆ Employees who are the first points of contact will be trained to ask appropriate questions which will help recognize and detect patients with signs and symptoms suggestive of TB (see Supplement Three).
2. A patient having signs or symptoms of TB should be evaluated promptly to minimize time spent in the outpatient areas.
  - ◆ When possible, the patient should be scheduled for the end of the day or when the least number of patients are present to avoid exposing other patients.
  - ◆ If there is a delay, or if the procedure is lengthy, the procedure should be postponed until the patient is deemed non-contagious by his/her physician.
3. Airborne Precautions must be started. This includes:
  - ◆ Promptly removing patient from waiting room.
  - ◆ Placing patient in Airborne Infection Isolation (AII) room (if available), or in a private room with the door shut and HEPA filter on.
  - ◆ Placing isolation mask on patient and instruct the patient to keep the mask on.
  - ◆ Giving the patient tissues and instruct the patient to cover their nose and mouth when coughing or sneezing if mask must be removed to facilitate respiratory clearance.
4. Ventilation in general use (waiting rooms) and special areas (treatment or isolation rooms) should be as described for similar patient areas (see Supplement Four).
5. Cough inducing procedures must be done in a room meeting TB isolation requirements (see Supplement Four).

## **I. Management of Hospitalized Patients with TB**

1. Admitting Physicians
  - ◆ Physician offices must alert the appropriate departments (e.g. Admitting, Emergency Room) to the fact that their patient is suspected of having TB.
2. Early Detection of TB
  - ◆ Employees who are the first points of contact should be trained to ask appropriate questions which will help recognize and detect patients with signs and symptoms suggestive of TB (see Supplement Three).
3. Admitting a patient with infectious or potentially infectious TB
  - ◆ The department where the patient first enters the facility (i.e. Admitting, Clinic or Emergency Room) must mask the patient immediately with an isolation mask, and the patient must be taken immediately to an isolation room.
  - ◆ If a patient is admitted through Admitting or as a direct admit and there is a delay in the availability of negative pressure rooms, the patient will be placed in a private room with the door shut.
  - ◆ Admitting personnel are not trained in respirator use; therefore, may not be put at risk to gather information from a potentially infectious patient. Admitting will first provide the patient with a mask or tissue with instructions to cover mouth and nose.

- ◆ The patient should be taken to a private room, preferably with negative pressure but may be placed in a private room with instructions to keep the mouth and nose covered with the tissue or mask
  - ◆ Admitting will then gather information over the phone to the isolation room and will request assistance with signatures from the patient's care provider trained in respirator use.
4. Readmitting patients with previously diagnosed TB
- ◆ When patients with previously diagnosed TB are readmitted before confirmation of complete cure, they should be placed in Airborne Precautions until infectiousness has been ruled-out.
5. Transporting a patient in Airborne Precautions
- ◆ Patient must wear a mask.
  - ◆ The transporter does not need to wear a respirator outside of the isolation room as long as the patient wears a mask.
6. Patient Room Placement
- Any patient suspected or known to have active TB should be placed in an AII Room (see Supplement Four for specifications). The purpose of an isolation room is to:
- ◆ Isolate patients who are likely to have infectious TB, from other people
  - ◆ Prevent escape of droplet nuclei from the room
  - ◆ Provide an environment that will allow a reduction of the concentration of droplet nuclei through engineering controls
  - ◆ If Negative Pressure Isolation Rooms are not available, patients may have to be placed into a room with a portable HEPA Filter.
7. Initiation of Airborne Precautions:
- ◆ The patient has signs and symptoms suggestive of TB
  - ◆ AFB smear is positive
  - ◆ Airborne Precautions can be initiated by the Medical Director of Infection Control, Infection Control Department, the attending physician, physician consultants, medical residents or primary care nurse.
8. Termination of Airborne Precautions
- Airborne Precautions may only be terminated by the physician if the following criteria are met:
- For patients known to have TB or known to have TB in the past with new symptoms:
- ◆ Infectious TB is unlikely and another diagnosis is made that explains the syndrome
  - ◆ Patient has three consecutive negative AFT sputum smear results, and
  - ◆ Patient has received standard antituberculosis treatment (minimum of two weeks), and
  - ◆ Patient has demonstrated clinical improvement.
- The patient is on effective treatment (TB American Thoracic Society Guidelines)
- ◆ Clinically, the patient is responding to treatment, or
  - ◆ Mycobacterial culture shows AFB other than TB.
- For patients admitted to rule out disease:
- ◆ Three negative smears
    - ◆ At least 8 hours apart
    - ◆ At least one collected during early morning.
  - ◆ In most cases, patients with negative sputum smear results may be released from AII in two days.

9. Labeling
  - ◆ The room must be labeled by placing the Airborne Precautions sign on the door.
  - ◆ An isolation sticker must be placed on the front of the chart.
  - ◆ The card and sticker are available in the isolation file at the nurse station of each unit.
  
10. Maintaining Appropriate Ventilation (see Supplement Four)
  - ◆ Door to the isolation room must remain closed. If the isolation room has an anteroom the doors to both rooms must be kept closed.
  - ◆ Isolation room pressure must be monitored daily.
    - a) For rooms with electronic monitors, check each time the room is entered.
    - b) For rooms without electronic monitors, call Facilities Management to daily smoke test the room.
  - ◆ "Airing" the Isolation Room
    - a) Upon discharge of patient or termination of AII (Airborne with Respirator) Precautions, the isolation room must be allowed to "air" to achieve a 99.9% removal efficiency prior to entering the room without a respirator or admitting another patient. This "airing" time can be found in Supplement Five.
  
11. Diagnostic and treatment procedures
  - ◆ Must be performed in the isolation room or appropriate negative pressure room.
  - ◆ Tests that cannot be performed in the patient's room should be delayed until the patient is out of isolation.
    - a) Only under an unusual medical urgency should the patient be transported outside of the isolation room.  
 Contact the Infection Control Practitioner, or designate, before any decision to break isolation is made outside of a medical emergency.  
 The procedure must be scheduled if possible at a time when the receiving department is least crowded, weighing the risk of transmission to other patients, visitors, and staff.
  
12. Visitors
  - ◆ Are to be kept to a minimum, should keep their visits short, and leave the room if the patient begins coughing.
  - ◆ Should wear a mask while in the room.
  - ◆ May voluntarily wear an N-95 respiratory but must have instructions on how to wear it.
  
13. HIV+ or immunosuppressed patients
  - ◆ Must be kept in Airborne Precautions for pulmonary or laryngeal infections with any mycobacterial species due to the potential for mixed infection with TB.
  - ◆ Isolation may be terminated by the physician if the following criteria are met:
    - ◆ Infectious TB is unlikely and another diagnosis is made that explains the syndrome
    - ◆ Patient has three consecutive negative AFT sputum smear results, and
    - ◆ Patient has received standard antituberculosis treatment (minimum of two weeks), and
    - ◆ Patient has demonstrated clinical improvement.
  - ◆ The patient is on effective treatment (TB American Thoracic Society Guidelines) and
    - ◆ Clinically, the patient is responding to treatment, or
    - ◆ Mycobacterial culture shows AFB other than TB.

For patients admitted to rule out disease or suspected:

  - ◆ Three negative smears are needed to discontinue isolation or one bronchoscopy/lung biopsy.
  
14. Pediatric patients
 

With suspected or confirmed TB should be evaluated for potential infectiousness no differently than adults, based on symptoms, AFB smears, and radiologic findings.

15. **Culturing Patients with Active TB**
  - ◆ Hospitalized patients with active TB who are on effective treatment as per American Thoracic Society Guidelines should be monitored for relapse with sputum smears every two weeks.
    - a) Failure to take medications and the presence of drug resistant TB are the two most common reasons for the patient remaining infectious.
  
16. **Multi-drug Resistant TB**
  - ◆ Patients with multi-drug resistant TB should be maintained in AII (Airborne with Respirator) Precautions throughout their hospital stay because of the tendency for treatment failure and relapse.
  
17. **Patient Education**
  - ◆ Patients in Airborne Precautions should be educated about the transmission of TB and the reasons for isolation precautions.
  - ◆ Patients should be taught to cover their mouths and noses with a tissue when coughing or sneezing, even while in the isolation room, to contain droplets.
  
18. **Initiation of Treatment**
  - ◆ Patients who have confirmed active TB or are considered highly likely to have active TB should be started on appropriate treatment promptly according to current guidelines (see Supplement Seven).
  - ◆ Anti-tuberculosis drugs should be administered by directly observed therapy (DOT) in which a health care worker observes the patient ingesting the medications.
  
19. **Discharge Planning**
  - ◆ Before a patient is discharged, the Outcome Management Department should:
    - a) Collaborate with public health authorities to ensure continuation of therapy.
    - b) Confirm appointment with a provider who will follow the patient until treatment is completed.
    - c) Confirm sufficient medication to take until the outpatient appointment.
    - d) Place into case management, such as outreach program of the health department.
  
20. Patients that are infectious at discharge should only be discharged to facilities with Airborne Precautions capabilities, or to home. They should not be discharged to a home with immunocompromised persons.
  
21. **Respiratory Protection**
  - ◆ Respirators will be used for respiratory protection. NIOSH has determined that the following categories of respirators are effective against TB (Type 100, Type 99, Type 95). The minimally accepted level of respiratory protection for TB is Type 95 (N95).
  - ◆ Respirators must be worn in all settings where there are patients with TB or suspected to have TB. Such settings would include Airborne Isolation rooms or exam rooms, bronchoscopy or thoracic surgery on a known or suspected TB patient, etc.
  - ◆ **A safe alternative to the N-95 respirator is the PAPR (Powered Air Protective Respirator) . These may be worn by any person, especially those with a beard or have not been able to be fit tested with the N-95 or N-100 respirator for other reasons. One time training is required prior to wearing the PAPR.**

All employees required to wear a respirator must be qualified. This must include:

- ◆ A confidential medical evaluation (medical questionnaire filled-out by employee and evaluated by University Health) **and fit tested.**
- ◆ Fit testing will be conducted by either University Health, by the Nursing Educators in Nursing Orientation or Health & Safety Departments (in accordance with stated procedure in the Federal Register) (29 CFR 1910.134). (Refer to UT respiratory protection program.
  - **Other trained individuals may assist these departments when needed.**
  - Qualified employees will have their certification kept in their employee health file.

- Employees who fail to be qualified for the N-95, may not wear an N-95 respirator and may not be put at risk of exposure to TB. An alternate choice would be the powered air respirator.
- The current choice of respirator for UTMC is the N-95 (see instructions, Supplement Eight) or the powered air respirator.
- Hoods and respirators are governed under the Respiratory Protection Program of UT.

Cleaning after patient discharge.

- ♦ Nursing will leave the isolation sign on the door and the HEPA device running until after the room is cleaned
- ♦ Environmental Services Staff will wait one hour before entering room without respiratory protection
- ♦ Environmental Services Staff may enter prior to one hour if the N-95 mask is worn and the door is kept shut.
- ♦ Staff will use the approved hospital disinfectant for cleaning the room

## **J. Cough Inducing Procedures**

1. Procedures that involve instrumentation of the lower respiratory tract or induce cough may increase the probability of droplet nuclei being expelled into the air (e.g. endotracheal intubation, aerosol treatments including pentamidine, bronchoscopy).

Aerosolized Pentamidine (AP)

- ♦ All patients should be screened for active TB before prophylactic AP therapy is initiated.
- ♦ Screen should include medical history, TST, and chest radiograph.
- ♦ For each subsequent treatment, patients should be screened for symptoms suggestive of TB. If such symptoms are elicited, a diagnostic evaluation for TB should be initiated.
- ♦ For patients with suspected or confirmed TB, it is preferable to use oral prophylaxis for PCP if clinically practical.

Bronchoscopy

- ♦ If bronchoscopy is used for diagnosis of pulmonary TB, it must be performed in a room that meets AII ventilation requirements.
- ♦ If only positive pressure rooms are available, TB should be ruled-out before the procedure.
- ♦ All patients having a bronchoscopy should be treated as if they have TB except where doing so would be overly prohibitive to patient care (i.e., all bronchoscopies which can be performed in negative pressure room should be). ICU patients would not fall into this category and would be considered in the overly prohibitive to patient care category, and based on this ,may choose to perform the bronchoscopy in a patient room, under negative pressure. Cough inducing procedures should not be performed on patients who may have infectious TB unless absolutely necessary.

2. All cough-inducing procedures must be done in a negative pressure isolation room or under local exhaust (booth or special enclosure).
3. After completion of procedure, patient must remain in Airborne Precautions Isolation Room or under local exhaust until coughing subsides.
4. Before the next patient is allowed into this area, sufficient time must be allotted to allow the ventilation to expel droplet nuclei from the air (see Supplement Four).

## **K. Education and Training**

1. All employees of UTMC will receive education about TB annually that is relevant to their occupational group.

2. Training will be conducted before initial assignment during new employee orientation.
3. Training may include the following elements:
  - ♦ The basic concepts of *M. tuberculosis* transmission, pathogenesis, and diagnosis, including information concerning the difference between latent TB infection and active TB disease, the signs and symptoms of TB, and the possibility of reinfection.
  - ♦ The potential for occupational exposure to persons who have infectious TB, including information concerning the prevalence of TB in the community and facility, the ability of the facility to properly isolate patients who have active TB, and situations with increased risk of exposure to *M. tuberculosis*.
  - ♦ The principles and practice of Infection Control that reduce the risk for transmission of *M. tuberculosis*, including information concerning the hierarchy of TB Infection Control measures and the written policy and procedures of the facility. Site-specific control measures should be provided to HCW's working in areas that require measures in addition to those of the basic TB Infection Control program.
  - ♦ The purpose of TST skin testing, the significance of a positive TST test result, and the importance of participating in the skin-test program.
  - ♦ The principles of preventative therapy for latent TB infection.
  - ♦ The HCW's responsibility to report positive TST (performed elsewhere) or signs and symptoms suggestive of TB to University Health Services.
  - ♦ The responsibility of UTMC to maintain the confidentiality of the HCW who has TB while ensuring the HCW is free of TB before returning to duty.
  - ♦ The higher risks associated with TB infection in persons with HIV infection or other severely impaired cell-mediated immunity.
  - ♦ UTMC's policy on voluntary work reassignment options for immunocompromised HCW'S.

#### **L. Health Care Workers Counseling, Screening, and Evaluation**

1. Counseling the HCW regarding TB
  - ♦ Because of the increased risk of rapid progression from latent to active TB in HIV positive or other severely compromised persons, University Health Services will evaluate each employee during their annual review to determine if they have a medical condition or are receiving medical treatment that may lead to severe cell-mediated immunity. This is done with a medical surveillance questionnaire.
  - ♦ Employees at risk for HIV infection should know their status and will be encouraged to seek voluntary testing. This will allow the employee to seek appropriate preventative measures and to consider voluntary work reassignments. This should be a personal decision. Human Resources will make reasonable attempts to offer alternative job assignments, i.e. a work setting with the lowest possible risk of occupational exposure to TB.
  - ♦ Immune status and voluntary job reassignment will be treated confidentially.
2. Screening HCW's for active TB
  - ♦ Any HCW with persistent cough (greater than two weeks), especially in the presence of other signs and symptoms compatible with TB, such as weight loss, night sweats, bloody sputum, anorexia, or fever, should be evaluated promptly for TB and may not return to work until TB is excluded or rendered non-infectious.
3. Screening HCW's for latent TB infection
  - ♦ At the time of employment, all HCW'S, including those with a history of BCG vaccination will receive a two-step Mantoux TST (a single step Mantoux TST will be provided if there is documentation from the employee of a negative TST within the last year).
  - ♦ HCW's with a documented history of a positive TST will be exempt from further testing unless they develop signs or symptoms suggestive of TB. An annual screening tool will be sent to each positive responder.

- ◆ All TST negative HCW's, based on their job assignment may undergo repeat TST testing as stated in Supplement Two.
4. Evaluation and management of HCW's with positive TST tests (see Supplement Six)
- ◆ All HCW's with newly recognized positive TST tests must be evaluated promptly for active TB with a chest radiograph and clinical evaluation.
  - ◆ IF a HCW's TST test converts to positive, a history of possible exposure must be taken in an attempt to determine the potential source of TB.
  - ◆ Routine chest radiographs are not required for asymptomatic TST converters, except for initial evaluation, or unless symptoms develop that may be due to TB.
  - ◆ HCW's with active TB may not return to work until on effective therapy, coughing is resolved, and three consecutive first morning AFB smears are negative. University Health Services must ensure that the HCW is maintained on adequate therapy and remains AFB smear negative. If treated by a private physician, Employee Health Services must communicate with the physician to ensure appropriateness of treatment, and to monitor symptoms and job duties. HCW's with active TB will be reported to the Public Health Department according to local laws.
  - ◆ HCW's with positive TST tests will be evaluated by University Health Services or through their PCP. If preventive therapy is advised, the recommended duration of therapy is 12 months for persons with HIV infection and persons with abnormal chest radiographs consistent with old TB; other persons should receive therapy for 9 months or as per most current American Thoracic Society recommendations. The usual preventative treatment regimen is oral isoniazid 300 mg daily for adults and 10 mg/kg/day up to 300 mg/day for children.

## **M. Additional Considerations for Selected Areas**

1. Operating Rooms
  - ◆ Elective operative procedures on patients with TB should be delayed until the patient is no longer infectious.
  - ◆ Procedures should be performed in operating rooms with anterooms. If there are no anterooms, the doors to the operating room must be kept closed and traffic in and out minimized. The procedure should be performed at the time when other patients are not present (i.e. end of day) and when a minimal number of personnel are present.
  - ◆ A bacterial filter should be placed on the patient endotracheal tube or at the expiratory side of the breathing circuit of the anesthesia machine.
  - ◆ The patient must be recovered in the operating room. When ready to transport, the patient must wear an isolation mask, or if intubated, the endotracheal tube must have a bacterial filter.
2. Morgue
 

If autopsies/dissections are being done:

  - ◆ The morgue must be under negative pressure, with the air vented to the outside of the hospital.

In addition, there must be at least 12 total air exchanges per hour.

  - ◆ Respirators must be worn during autopsies on patients who may have had TB.
3. Emergency Department
  - ◆ As part of the triage process, all patients must be assessed for clinical and historical signs or symptoms for TB.
4. Clinical Laboratory
  - ◆ The laboratory should conform to criteria specified by CDC and NIH. In accordance with local and state laws and regulations, a system is in place to report any positive results from any positive specimen to clinicians within 24 hours of receipt of the specimen.
5. Kobacker Center
  - ◆ Patients determined to have active TB infection will be transferred to a facility with negative ventilation capabilities until they meet the criteria for discontinuing Airborne isolation.

- 6. Endoscopy
  - ◆ Employees must wear a respiratory mask during all bronchoscopy procedures. All bronchoscopies must take place in a negative pressure room.
- 7. Rehab Hospital
  - ◆ Patients determined to have active TB infection will be transferred to a facility with negative ventilation capabilities until they meet the criteria for discontinuing Airborne isolation.

Prepared by: Sandra J. Hensley, Infection Control Practitioner

Reference:

- (1) Federal Register/vol.59, No. 208/Friday, October 28, 1994/Notices
- (2) MMWR November 4, 2005/Vol.54/No RR-12
- (3) MMWR Guidelines for Preventing the Transmission of Mycobacterium in Health Care Settings, 2005, MMWR December 30, 2005/Vol 54/No. RR17

Additional information and specifics can be found in Safety and Health procedure Airborne Pathogens Control Plan, and in Infection Control policy #31:DIS-206, TB Isolation.

Approved by:

Infection Control Committee Chairperson	9/2/2008
	Date

Director, Safety & Health	9/2/2008
	Date

## Supplement 1

### Protocol for Conducting a TB Risk Assessment

#### TB Risk Classifications (3)

Inpatient Settings	Low	Medium	Potential Ongoing Transmission
<200 beds	<3 TB patients/yr	≥3 TB patients/yr	Evidence of ongoing transmission, regardless of setting
≥200 beds	<6 TB patients/yr	≥6 TB patients/yr	

#### TB Risk Classifications (4)

Outpatient Settings	Low	Medium	Potential Ongoing Transmission
TB treatment facilities, medical offices, ambulatory care settings	<3 TB patients/yr	≥3 TB patients/yr	Evidence of ongoing transmission, regardless of setting

#### TB Risk Classifications (5)

Nontraditional Facility-based Settings	Low	Medium	Potential Ongoing Transmission
Emergency medical service (EMS), medical settings in correctional facilities, outreach care, long-term care facilities	Only patients with LTBI treated No cough-inducing procedures are performed in setting System to detect/triage persons with TB symptoms	Settings where TB patients are expected to be encountered	Evidence of ongoing transmission regardless of setting

## Supplement 2

### Periodic Reassessment Of The Tuberculosis Prevention Program (every six months and as necessary)

#### Infection Control

1. Review the number of TB patients seen, by area (inpatient and outpatient). This is to be used to:
  - ◆ Estimate the need for additional isolation rooms.
  - ◆ Recognize clusters of nosocomial transmission.
  - ◆ Assess level of potential occupational risk.
2. Review the drug-susceptibility patterns of TB patients seen at the facility.
3. Review a sample of TB patients seen at the facility to evaluate infection control parameters.
  - ◆ Were appropriate criteria used for discontinuing isolation?
  - ◆ Was there a delay in isolating the patient?
  - ◆ Was an appropriate isolation room used?
  - ◆ Was the patient's door and chart labeled appropriately?
  - ◆ Was patient transported out of isolation room except for medical emergencies?

#### University Health Services

Analyze HCW TST test data, by area (or by occupational group for persons not assigned to a specific area, such as respiratory therapists.)

TST test conversion rates should be calculated at 6 month intervals to estimate the risk of TST test conversion for each area in the facility and for each occupational group not assigned to a specific area. This rate should be compared to past history and to areas without occupational exposure.

Health Care Workers who fall into any of the following categories may also be included in the annual TB screening program, based on the results of the facility wide risk assessment which includes the number of cases of TB seen, along with the number of TST conversions over the previous six months"

- Those participating in aerosol-generating or aerosol-producing procedures (i.e., bronchoscopy, sputum induction, dental procedures, and administration of aerosolized medications).
- Employees participating in suspected or confirmed M. tuberculosis specimen processing
- Employees who report close contact with persons who share the same household or enclosed environment for prolonged periods with a person with pulmonary TB disease.

#### Engineering and Maintenance

Perform a review of ventilation (see Supplement four) to include:

- ◆ Direction of air flow in areas where TB transmission is a potential problem (waiting rooms, Admitting, procedure rooms, etc.). This should be accomplished with smoke tubes.
- ◆ Assessment of the ventilation system used in Negative Pressure Isolation rooms to include pressure readings, air exchanges, venting time and inspection of system and fans.
- ◆ Rooms passing inspection should be labeled with a sticker as certified. The label should contain the date certified, air exchanges per hour, and time required to vent the room.

### Supplement 3

#### First Point of Contact

#### Questions to Ask Patients to Detect Tuberculosis

Exposure	Symptoms
1. Have you ever been told by a doctor that you had TB?	1. Do you have night sweats?
2. Have you ever lived with or worked with anyone with TB?	2. Have you lost weight that wasn't from dieting?
3. Have you ever had a <b>skin</b> test that your doctor said shows that you had TB? The test may have been called a <b>TST</b> or <b>Tine Test</b> .	3. Do you cough up blood?
	4. Have you coughed for more than two weeks?

If the patient answers "yes" to

1) at least **one** question in **both** the **Exposure** and **Symptoms** columns,

or

2) at least **two** questions in the **Symptoms** column,

mask the patient immediately. This patient may have tuberculosis.

## Supplement 4

### THE TB ISOLATION ROOM

1. TB isolation rooms should be single patient rooms.
2. The room must be maintained under negative pressure (a pressure differential of 0.001 inch of water and an inward velocity of 100 feet per minute are minimum acceptable levels)

Doors must be kept closed to maintain negative pressure.

- ◆ Negative pressure should be checked daily on rooms in use for Negative Pressure Isolation by means of a smoke tube or air velocity measurement device as follows:

Rooms with electronic monitors

- ◆ Prior to patient being admitted or shortly after admission, the primary nurse will activate the monitor by turning the key.
- ◆ With room door closed, monitor should have a green light on.
- ◆ Primary care nurse is responsible to ensure this light is on.
- ◆ If light displays red, maintenance must be called immediately (Please allow 1-2 minutes for room pressure to balance after opening and closing door).
- ◆ All employees entering this room should also be made aware of the monitor and to report to the primary care nurse any problems.
- ◆ Negative pressure rooms are under the influence of a single dedicated exhaust fan, which is monitored by the Facilities Maintenance department.
- ◆ Failures are reported immediately, by Facilities Maintenance, to Safety & Health, the unit involved and to Infection Control.
  - ◆ Follow up to failure will be to remove any patient with TB or rule out TB to another area capable of HEPA filtration or dedicated exhaust with negative pressure capacity.

3. There must be a minimum of 12 ACH for isolation and treatment rooms constructed after 10/28/94. Rooms before this time must be at a minimum of 6 ACH, but should be increased to 12 ACH when feasible.
  - ◆ Air Changes per Hour (ACH) is calculated as follows:  $ACH = \frac{QN}{V} \times 60$ , where Q=cubic feet per minute, and V=room volume.
  - ◆ However, the air will not usually be changed the indicated number of times per hour, as the air flow patterns in the room may not permit complete mixing of the supply and room air in all parts of the room. A "mixing factor" is required to account for this. The factor is applied as an actual multiplier to determine the actual supply air flow ( $ACH \times \text{mixing factor} = \text{actual required supply ACH}$ ). Rooms should be designed to achieve the lowest mixing factor. A qualitative measure can be made with smoke tubes at various places in the room. (ASHRAE Journal, July 1968:pp 33-41).
4. Air from the TB isolation room must be:
  - ◆ exhausted to the outside, or
  - ◆ recirculated into the general ventilation using HEPA filters in the exhaust ducts before the air is returned to the general ventilation.
  - ◆ When HEPA filters are used in the general ventilation, a regularly scheduled maintenance program is necessary.
    - a. A quantitative leakage and filter performance test using the dioctyl phthalate (DOP) penetration test should be performed at the initial installation, when the filter is changed, and annually.
    - b. A manometer or pressure sensing device should be installed in the filter system to provide an accurate means of objectively determining the need for filter replacement.
5. Rooms with an anteroom are preferred since they increase the effectiveness of the isolation room by serving as an airlock. The anteroom must have positive pressure in relation to the isolation room.

6. After a patient is discharged from Airborne Precautions, the isolation room must be vented a set amount of time to achieve a 99.9% reduction in airborne contaminants (see Supplement five). This time is specific to each isolation room and should be calculated by the Facilities Management Department.

#### Additional Ventilation Concerns

1. General use areas (e.g. waiting rooms, radiology suites)
  - ◆ A single pass, non-recirculating system with air exhausted to the outside or a recirculation system with the air passed through HEPA filters before recirculation to the general ventilation system may be used.
2. HEPA filtration
  - ◆ HEPA filters must be carefully installed and meticulously maintained to ensure adequate function.
  - ◆ Such filters, when changed, must be regarded as infectious.
  - ◆ A respirator must be worn, and care must be taken so as not to aerosolize contents.
  - ◆ The filter must be red plastic bagged and sealed.
3. Portable HEPA filter (Private Room Only)
  - ◆ If monitored negative pressure rooms are not available, a portable HEPA filter unit is to be ordered from Central Service.
  - ◆ Unit should be positioned at the foot of the patient's bed, as close as possible to the center/middle of the room.
  - ◆ All negative pressure procedures also apply to those rooms.
4. Negative pressure must be verified daily when a patient with active pulmonary or laryngeal M.Tb. is occupying the room.
  - ◆ Verify and document the reading on the monitoring device at the door or
  - ◆ Verify and document that a tissue held at the gap at the bottom of the door is pulling in.

Nurse taking care of the patient should perform this assessment and document in patient chart in the isolation section of nursing record "Negative Pressure Operating".

## Supplement 5

### Air Changes Per Hour And Time In Minutes Required For Removal Efficiencies Of 90%, 99%, Or 99.9% Of Airborne Contaminants

[This table is prepared according to the formula\*  $t_1 = (C_2/C_1)/(Q/V) \times 60$ , which is an adaptation of the formula for the rate of purging airborne contaminants<sup>1</sup> with  $t_1=0$ , and  $C_2/C_1=1 - (\text{removal efficiency}/100)$ .]

Air Changes per Hour	Minutes required for a removal efficiency of:		
	90%	99%	99.9%
1	138	276	414
2	69	138	207
3	46	92	138
4	35	69	104
5	28	55	83
6	23	46	69
7	20	39	59
8	17	35	52
9	15	31	46
10	14	28	41
11	13	25	38
12	12	23	35
14	10	20	30

Air Changes per Hour	Minutes required for a removal efficiency of:		
	90%	99%	99.9%
15	9	18	28
16	9	17	26
17	8	16	24
18	8	15	23
19	7	15	22
20	7	14	21
25	6	11	17
30	5	9	14
35	4	8	12
40	3	7	10
45	3	6	9
50	3	6	8

\*Where  $t_1$ =initial time point  $t_2$ =time (minutes) required for removal efficiency  $C_1$ =initial concentration of contaminants  $C_2$ =final concentration of contaminants  $Q$ =air flow rate (cubic feet per hour)  $V$ =room volume (cubic feet)  $Q/V$ =air changes per hour.

The times given assume perfect mixing of the air within the space (i.e. mixing factor - 1) However, perfect mixing normally does not occur, and the mixing factor could be as high as 10 if air distribution is very poor. (A discussion of mixing is provided in reference Industrial Ventilation: A Manual of Recommended Practice 5. The required time is determined by multiplying the appropriate time from the table by the mixing factor determined for the booth or room. The factor and required time should be included by the manufacturer of the booth or enclosure as part of the operating instructions for the enclosure and these instructions should be followed.

<sup>1</sup> Mutchler, JE. Principles of ventilation. In: NIOSH. The industrial environment-its evaluation and control. Washington, D.C.: NIOSH, 1973.

<sup>2</sup> NIOSH: Guide to industrial respiratory protection, Cincinnati, Ohio: US DHHS, CDC, NIOSH. 1987: DHHS (NIOSH) publication No. 87-116.

## Supplement 6

### Summary of Interpretation Of Tuberculin Skin Tests (TST)

1. A reaction of  $\geq 5$  mm is classified as positive in:
  - ◆ Persons with HIV infection or risk factors for HIV infection with unknown HIV status.
  - ◆ Persons who have recent close contact\* with persons with active TB.
  - ◆ Persons who have abnormal chest radiographs consistent with old healed TB.
2. A reaction of  $\geq 10$  mm is classified as positive in all persons who do not meet any of the criteria above but who have other work risk factors for TB including:

#### High Risk Groups

- ◆ Intravenous drug users known to be HIV seronegative
- ◆ Persons with other medical conditions that have been reported to increase the risk of progressing from latent TB infection to active TB, including silicosis, gastrectomy, jejunum-ileal bypass surgery, being 10% or more below ideal body weight, chronic renal failure, diabetes mellitus, high dose corticosteroid and other immunosuppressive therapy, some hematologic disorders (e.g. leukemias and lymphomas), and other malignancies
- ◆ Locally identified high risk populations
- ◆ Children who are in one of the high risk groups listed above
- ◆ Health care workers who provide services to any of the high risk groups.

#### High-Prevalence Groups

- ◆ Foreign-born persons from high prevalence countries in Asia, Africa, and Latin America
- ◆ Persons from medically underserved low income populations
  - a) Residents of long-term care facilities (e.g. correctional institutions, nursing homes)
  - b) Persons from high risk populations in their communities, as determined by local public health authorities

3. Induration of  $\geq 15$  mm is classified as positive for persons who do not meet any of the above criteria
4. Recent converters are defined on the basis of induration:
  - ◆  $\geq 10$  mm increase within a 2-year period is classified as positive for persons
  - ◆  $\geq 5$  mm increases under certain circumstances (#1 above)
5. These guidelines are meant to be in compliance with, not supersede, the most recent recommendations of the American Thoracic Society.

\*Recent close contact implies household contact or unprotected occupational exposure similar in intensity and duration to household contact

## Supplement 7

### Regimen Options For The Treatment Of TB In Children And Adults

Option	Indication	Total Duration of Therapy	Initial Treatment Phase		Continuation Treatment Phase		Comments
			Drugs <sup>1</sup>	Interval and Duration	Drugs <sup>1</sup>	Interval and Duration	
1	Pulmonary and extrapulmonary TB in adults and children	6 months	INH RIF PZA EMB or SM	Daily for 8 weeks	INH RIF	Daily or two or three times weekly <sup>2</sup> for 16 weeks. <sup>3</sup>	EMB or SM should be continued until susceptibility to INH and RIF is demonstrated.  In areas where primary INH resistance is <4%, EMB or SM may not be necessary for patients with no individual risk factors for drug resistance.
2	Pulmonary and extrapulmonary TB in adults and children	6 months	INH RIF PZA EMB or SM	Daily for 2 weeks then two times weekly <sup>2</sup> for 6 weeks	INH RIF	Two times weekly <sup>2</sup> for 16 weeks. <sup>3</sup>	Regimen should be directly observed.  After the initial phase, EMB or SM should be continued until susceptibility to INH and RIF is demonstrated, unless drug resistance is unlikely.
3	Pulmonary and extrapulmonary TB in adults and children	6 months	INH RIF PZA EMB or SM	3 times weekly <sup>2</sup> for 6 months <sup>3</sup>			Regimen should be directly observed.  Continue all four drugs for 6 months <sup>4</sup> This regimen has been shown to be effective for INH resistant TB.
4	Smear and culture negative pulmonary TB in adults	4 months	INH RIF PZA EMB or SM	Follow options 1, 2, or 3 for 8 weeks.	INH RIF PZA EMB or SM	Daily or two or three times weekly <sup>2</sup> for 8 weeks.	Continue all four drugs for 4 months.  If drug resistance is unlikely (primary INH resistance <4% and patient has no individual risk factors for drug resistance), EMB or SM may not be necessary and PZA may be discontinued after 2 months.

<sup>1</sup> EMB = Ethambutol; INH = isoniazid; PZA = pyrazinamide; RIF = rifampin; SM = streptomycin

<sup>2</sup> All regimens administered intermittently should be directly observed.

<sup>3</sup> For infants and children with miliary TB, bone and joint TB, or TB meningitis, treatment should last 12 months. For adults with these forms of extrapulmonary TB, response to therapy should be monitored closely. If response is slow or suboptimal, treatment may be prolonged on a case-by-case basis.

<sup>4</sup> Some evidence suggests that SM may be discontinued after 4 months if the isolate is susceptible to all drugs.

<sup>5</sup> Avoid treating pregnant women with SM because of the risk of ototoxicity to the fetus.

Note: For all patients, if drug-susceptibility results show resistance to any of the first-line drugs, or if the patient remains symptomatic or smear or culture positive after 3 months, consult a TB medical expert.

Drugs	Dosage Schedule					
	Daily Dose (maximum dose)		2 times weekly dose (maximum dose)		3 times weekly dose (maximum dose)	
	Children*	Adult	Children*	Adult	Children*	Adult
Isoniazid	10-20 mg/kg (300 mg)	5 mg/kg (300 mg)	20-40 mg/kg (900 mg)	15 mg/kg (900 mg)	20-40 mg/kg (900 mg)	15 mg/kg (900 mg)
Rifampin	10-20 mg/kg (600 mg)	10 mg/kg (600 mg)	10-20 mg/kg (600 mg)	10 mg/kg (600 mg)	10-20 mg/kg (600 mg)	10 mg/kg (600 mg)
Pyrazinamide	15-30 mg/kg (2 gm)	15-30 mg/kg (2 gm)	50-70 mg/kg (4 gm)	50-70 mg/kg (4 gm)	50-70 mg/kg (3 gm)	50-70 mg/kg (3 gm)
Ethambutol	15-25 mg/kg	15-25 mg/kg	50 mg/kg	50 mg/kg	25-30 mg/kg	25-30 mg/kg
Streptomycin	20-40 mg/kg (1 gm)	15 mg/kg (1 gm)	20-40 mg/kg (1 gm)	20-40 mg/kg (1 gm)	20-40 mg/kg (1 gm)	20-40 mg/kg (1 gm)

\*12 years of age or under

## Supplement 8

### Instructions on the PFR N95 Respirator

1. You must qualify medically and pass fit-testing to wear this respirator.
2. Always wear the size that you were fitted to. You may not wear any other size. The size is located on the underside of the respirator.
3. The PFR N95 Respirator is disposable. You should dispose of this respirator when:
  - ◆ The respirator becomes soiled or damaged.
  - ◆ When the respirator becomes moist from your breath.
  - ◆ You are no longer able to achieve a good "fit".
  - ◆ After 8 hours of use.
4. The respirator is considered medical waste and must be disposed of in a red bag.
5. Each time you put on the respirator, you must:
  - ◆ Position it on the face
    - ◆ One band on upper neck, one band on top of head in front of ears.
    - ◆ No hair, scars, etc. that may break seal, especially at corners of respirator.
    - ◆ Nosepiece is centered and contoured.
  - ◆ Determine an acceptable fit
    - ◆ Chin is cupped in respirator.
    - ◆ Respirator spans from bridge of nose to chin.
    - ◆ Straps are not overly tight.
  - ◆ Check for "blow-by"
    - ◆ Exaggerate inhaling and exhaling with the chin down.
    - ◆ If air is felt escaping through the sides of the mask, reposition the mask and check again for "blow-by".

## Supplement 9

### Periodic Risk Assessment of the Tuberculosis Exposure Control Plan (Date indicates previous six month period)

<u>Date</u>	<u>Patients with Active TB</u>	<u>Employee TST Conversions</u>	<u>Risk Category</u>
Jan 99	0	2	Very Low
June 99	0	0	Very Low
Jan 00	1	3	Low
June 00	1	0	Low
Jan 01	1	0	Low
June 01	1	0	Low
Jan 02	1	0	Low
June 02	1	2	Low
Jan 03	1	0	Low
June 03	1	1	Low
Jan 04	0	1	Low
June 04	0	0	Very Low
Jan 05	1	0	Low
June 05	1	0	Low
Jan 06	2	1	Low
June 06	1	1	Low
Jan 07	0	4	Low
June 07	1	0	Low
Jan 08	0	0	Low
June 08	1	1	Low

Criteria: See Protocol for conducting a TB Risk Assessment, Supplement 1