PURPOSE:

To achieve early detection, isolation, and treatment of persons with active TB and to minimize the risk of TB transmission.

POLICY:

Responsibility:

It is a collaborative effort consisting of Administration, Facilities Management, Employee Health and Infection Control or designees.

Risk Assessment:

1. An annual risk assessment to evaluate the risk of TB transmission will be done by the Infection Control Department and Employee Health Services. This will include all parts of the facility. All clinics where TB patients may receive care, active cases of TB in the hospital and community as well as Tuberculin Skin Testing (TST) conversions.

2. Data on the number of active TB cases among patients and health care workers will be collected, reviewed and used to:
   - Identify the number of negative pressure isolation rooms required.
   - Recognize clusters of hospital acquired transmission.
   - Assess the level of potential occupational risk.
   - Monitor drug susceptibility characteristics of M. tuberculosis isolates.

3. The hospital and clinics will be classified as high, intermediate or low risk based on the number of active or infectious TB patients seen and treated at MMSC or its clinics over the past 12 months and other risk factors.

4. Representatives of the Infection Control Department and Employee Health Services will inspect the facility, review data, and make recommendations regarding changes in the TB Exposure Control Plan at least annually or as necessary to update the plan in response to documented hospital acquired transmission of TB. This review and recommendations will be provided to the Infection Control Committee.

Tuberculosis Exposure Control Plan and Protocol
5. Following each risk assessment, the Infection Control Department and Employee Health Services, in conjunction with other appropriate health care workers will review all TB Control policies to assure that they are effective and meet current needs.

6. All TST results of employees will be kept in Employee Health Services. All TST results of volunteers will be kept in the Volunteer Services Department.

Observation of Infection Control Practices:
1. Compliance is considered to be a standard of performance and will be included in the annual performance evaluation for all employees with potential for exposure.

2. Strategies for monitoring of compliance:
   a. Follow-up on the report of an employee's failure to comply with the required protective measures will be the responsibility of the employee's department director.
   b. Follow-up of problems identified through informal reports, complaints from staff, safety reports, minutes from committees, and comments received during evaluation of education and training programs will be the responsibility of the department director in coordination with the Infection Control Director and Employee Health Services (if necessary).
   c. Noncompliance will be reported to an employee's Department Director for evaluation and follow-up.

Tuberculin Skin Testing:
1. Administration of tuberculin skin test (Mantoux):
   a) 0.1 ml of PPD will be injected into either the volar or dorsal surface of the arm.
   b) Tuberculin is injected just beneath the surface of the skin.
   c) Discrete, pale elevation of the skin or a (wheel) 6-10 mm should be produced.

2. Reading of the skin test:
   a) Trained personnel will read the test between 48-72 hours and record results on the appropriate form which will then be placed in the patient's chart.
   b) Presence or absence of induration is to be assessed, (not redness or erythema), and should be recorded in millimeters.

Identification, evaluation and treatment of patients with known or suspected Tuberculosis in the hospital setting:
1. TB Suspect Guidelines (Attach. 1) will be followed to identify such patients.
2. Adult and Pediatric patients with suspected or confirmed TB should be evaluated for potential infectiousness on the basis of symptoms: sputum AFB smears, radiological findings, and other criteria. Those with cavitary pulmonary or laryngeal TB should be placed in Airborne Precautions until they are determined to be non-infectious. If a Negative Pressure room is not available place the patient in a procedure mask until the time a room is ready. Notify the Infection Control Director upon placing a patient in Airborne Precautions.
3. Public Health should be contacted as soon as possible to begin assessment and investigation of patient’s contacts.
4. Close contacts of adult or pediatric patients suspected of having TB should be assessed as soon as possible for the presence of TB and should be asked to wear a mask at all times when in the facility until their status is known.
5. An injury/illness report is to be completed if there are co-workers that have had an exposure to a patient with suspected or confirmed TB and were not wearing the appropriate Personal Protective Equipment.
6. The medical record of active cases of TB admitted to MMSC shall be reviewed concurrently. Documentation will contain information regarding infection control practices and engineering control measures.
7. TB suspect or confirmed patients should wear a procedure mask if transportation out of the room is required for a test or procedure.
8. Visitors to Airborne Precautions rooms may be offered a (PAPR) Powered Air Purifying Respirator and would be instructed by a healthcare worker on the use of the respirator before entering the patient’s room. The PAPR would then be decontaminated after use using current recommendations from the manufacturer and CDC.

**Identification, evaluation and treatment of patients with known or suspected Tuberculosis in the ambulatory setting:**

1. Triage of patients in the Emergency Department, Diagnostic Imaging or other areas should identify patients who may potentially have TB. If patient is suspected of having active TB, they should be taken expeditiously to a room to minimize exposure. These patients should either wear a surgical mask or be given tissues to contain sneezes or cough.

**Treatment Guidelines:**

1. 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.

   A. Patient(s) in the following groups at high risk should be administered treatment for Latent Tuberculosis Infection (LTBI) if their Tuberculin Skin Test (TST) result is >5 mm, regardless of age:
      - Persons infected with HIV
      - Recent contact with a person with TB disease
      - Persons with fibrotic changes on chest radiograph consistent with previous TB disease
      - Organ transplant recipients
      - Other immunosuppressed persons (e.g., persons receiving >15 mg/day of prednisone for >1 month)

   B. Patient(s) in the following groups at high risk should be considered for treatment of LTBI if their TST result is >10 mm:
      - Recent immigrants (<5 years) from high TB prevalence counties.
      - Persons who inject illicit drugs
      - Residents and employees in congregate settings that are at high risk (i.e., correctional facilities and Long Term Care Facilities, hospitals and other health-care facilities, residential settings for persons with HIV/AIDS or other immunocompromising conditions, and homeless shelters
      - Personnel from mycobacteriology laboratories
      - Persons with any of the following clinical conditions or other immunocompromising conditions that place them at high risk for TB disease:
         1. Silicosis
         2. Diabetes Mellitus
         3. Chronic Renal Failure
         4. Certain hematologic disorders (e.g., leukemias and lymphomas)
         5. Other specific malignancies (e.g., carcinoma of the head, neck, or lung)
         6. Unexplained weight loss of >10% of ideal body weight
         7. Gastrectomy
         8. Jejunoileal bypass
      - Children aged less than 5 years
      - Infants, children, and adolescents exposed to adults at high risk for developing TB disease.
C. Patient(s) with no known risk factor for TB disease can be considered for treatment of LTBI if their TST result is >15 mm.

D. Prior to beginning treatment for LTBI, the diagnosis of TB disease will be excluded by history, medical examination, chest radiography, and, when indicated, bacteriologic studies. In addition, before offering treatment of LTBI, it will be ensured that the patient has not experienced adverse reactions with previous isoniazid (INH) treatment.

E. Treatment for patient(s) who have previous positive TST results and who completed treatment for LTBI previously is not necessary. Documentation of completed therapy for LTBI is critical. Instead of participating in serial skin testing, the patient should receive a medical evaluation and a symptom screen annually. A symptom screen is a procedure used during a clinical evaluation in which patients are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g. cough). Serial chest x-rays are not necessary unless the symptom screen that is done annually would show symptoms of active Tuberculosis.

F. Patient(s) who might not be good candidates for treatment of LTBI include those with a previous history of liver injury or a history of excessive alcohol consumption. Active Hepatitis is a contraindication to the use of Isoniazid (INH) for treatment of LTBI. If the decision is made to treat, baseline and follow-up monitoring of serum aminotransaminases should be considered.

G. Patients with a previously negative TST result who are contacts of a person with drug-susceptible TB disease and who subsequently have a positive TST result (≥5 mm) should be evaluated for treatment of LTBI, regardless of age. The majority of persons who are infected with M. tuberculosis will have a positive TST result within 6 weeks of exposure. Therefore, contacts of persons with drug-susceptible TB disease with negative TST results should be retested 8-10 weeks after the end of exposure to a patient with suspected or confirmed TB disease. Persons infected with M. tuberculosis should be advised that they possibly can be re-infected with M. tuberculosis if exposed again. Persons infected with HIV, persons receiving immunosuppressive therapy, regardless of TST result, and persons with a previous positive TST result who are close contacts of a person with suspected or confirmed TB disease should be considered for treatment of LTBI.

H. Treatment for LTBI caused by drug-resistant or MDR (Multi-Drug Resistant) TB disease is complex and will be conducted in consultation with the local or state health department’s infection control program and experts in the medical management of drug-resistant TB. In certain instances, medical decision making for the person with LTBI will benefit from the results of drug susceptibility testing of the isolate of the index TB case. Treatment would be guided by susceptibility test results from the isolate to which the patient was exposed and presumed to be infected.

I. Generally, pregnant women who are found to be tuberculin positive upon routine screening should not be given preventive therapy until two to three months post partum unless they are at higher risk (e.g. HIV infected, recent contact). Tuberculin skin testing is both safe and reliable throughout the course of pregnancy.

J. Standard Treatment Regimen
Isoniazid (INH) 5mg/kg or maximum dose 300 mg daily for nine (9) months
Rifampin may be used per physician order if employee cannot tolerate Isoniazid.

K. Baseline laboratory testing (measurements of serum AST, ALT, and Bilirubin) at the start of LTBI therapy is recommended for patient(s) with any of the following factors:
- Liver disorders
- History of liver disease (e.g. Hepatitis B or C, Alcoholic Hepatitis, or cirrhosis)
- Regular use of alcohol
- Risks for chronic liver disease
- HIV infection
- Pregnancy or the immediate postpartum period (i.e., within three months of delivery)

Testing can be considered on an individual basis, especially for patient(s) taking other medications for chronic medical conditions.

(Note) - AST or ALT elevations up to five times normal can be accepted if the patient is free of Hepatitis symptoms, and up to three times normal if there are signs or symptoms of liver toxicity.

L. Monitoring

Patients receiving preventive therapy will be monitored monthly by their family physician or by Public Health for the county in which the patient resides for the following:

- Adherence to prescribed regimen
- Symptoms of hepatitis, such as nausea, loss of appetite, vomiting, dark urine, yellow skin, malaise, unexplained elevated temperature for > three days, abdominal tenderness
- Symptom of neurotoxicity, such as paresthesis of hands or feet
- AST or ALT are to be measured prior to therapy if indicated and repeated if baseline results are abnormal, the employee/volunteer is pregnant, in the immediate postpartum period, or at high risk for adverse reactions or has symptoms of an adverse reaction.

M. Education

The patient(s) will receive education on the disease process and the rationale for the medication in absence of symptoms or radiographic abnormalities, the importance of completing the treatment for LTBI, the possible side effects of the medications, and the management of the common side effects and the need to report to EHS if needed.

PROCEDURE:

1. TB skin test will be given per protocol.
2. Induration >5mm will be evaluated according to the above policy.
3. Chest x-ray will be done per policy to rule out active TB disease.
4. Patients with positive chest x-rays will not be allowed to return to their regular work until active disease has been evaluated and treatments were discussed.
5. Patients with negative chest x-rays will be offered INH and have lab testing completed as outlined above (if applicable).
6. Infection Control in coordination with the Marshall County Public Health Department will finalize ordering and dispensing of the medication.

Cough - Inducing Procedures:

1. Cough-inducing procedures should not be performed on patients who may have infectious TB unless absolutely necessary. These cough-inducing procedures include endotracheal intubation and suctioning, diagnostic sputum induction, aerosol treatments and bronchoscopy. Other procedures that may generate aerosols, e.g. irrigation of TB abscesses, homogenizing or lyophilizing tissue, are also included in these recommendations.
2. All cough inducing procedures performed on patients who may have infectious TB should be performed while negative pressure in activated.
3. Health care workers should wear a hospital-approved respirator or mask when present in rooms where cough-inducing procedures are being performed on patients who have, or are at high risk of having infectious TB.
4. After completion of cough-inducing procedures, patients with known or suspected TB should remain in the isolation room or enclosure. They should be given tissues and instructed to cover their mouth and nose when coughing. If they must recover from their sedatives or anesthesia following procedures such as bronchoscopy, they should be monitored in a separate isolation room and not in recovery rooms with other patients.
5. Before the room is used for another patient, adequate time should be allowed to pass so that any droplet nuclei that have been expelled into the air are removed. This time will vary according to the efficiency of the ventilation of filtration used, but is generally 20 minutes.

6. If performing bronchoscopy in positive pressure rooms, such as operating rooms, if unavoidable, TB infection should be ruled out before the procedure. If bronchoscopy is being performed for diagnosis of pulmonary disease on patients that may have infectious TB, it should be performed in a room that meets TB isolation ventilation requirements.

Other Infection Control Measures:
Any required infection control measures must be followed to ensure compliance with the OSHA standards and/or current CDC guidelines for preventing the transmission of \textit{M. tuberculosis}.

Engineering Controls
Prevention of hospital acquired transmission. Patient rooms and areas where patients with suspected or confirmed TB are treated should be at negative pressure to adjacent areas, have at least 6 air changes per hour, be directly exhausted to the outside or have air recirculated through a HEPA filtration system with 99.7% filtration.

Monitoring of isolation rooms for negative pressure when used for Airborne Precautions will be done daily (when in use) by the Facilities Management Staff. When not in use, the rooms will be tested monthly as per Facilities Management policy.

Discharge Planning:
1. Collaborations must occur to ensure continuation of therapy. Collaboration includes the Nursing Staff, Patient & Family Services, the nursing agency to which the patient is discharged and the Marshall County Public Health Department.
2. While the patient is in the hospital, anti-tuberculosis drugs will be administered by directly observed therapy, in which a health care worker observes the patient ingesting the medications. All patients should be discharged on outpatient directly observed therapy. Arrangements for this will be made in collaboration with the Marshall County Public Health Department at 641-754-5022.
3. The patient shall be discharged with a follow up appointment, sufficient medication until the next appointment or a supply is available.
4. If the patient is still infectious, they shall be discharged home or to a facility with Airborne Precaution isolation capabilities.

Respiratory Protection:
2. In the following circumstances, health care workers should wear a NIOSH approved high efficiency particulate air (HEPA) respirator or an approved N-95 respirator (Tecnol):
   A. when entering patient rooms with suspected or confirmed infectious TB or in Airborne Precautions.
   B. when performing cough inducing, aerosol generating or other high risk procedures on patients who have suspected or confirmed infectious TB. Examples of these include administration of aerosolized medications, bronchoscopy, sputum induction, endotracheal intubation, suctioning, operative or autopsy procedures.
   C. emergency medical response personnel or others who must transport, in a closed vehicle, an individual with suspected or confirmed infectious TB.
3. Qualitative or quantitative fit testing must be performed for each respirator wearer. The results of such fit testing are kept in Employee Health, on the Airborne Precautions Cart and in the individual departments.
4. Medical surveillance will be performed on all potential HEPA respirator wearers.
5. Multi-use reusable HEPA respirators should be cleaned and filters checked and/or changed per hospital policy or current guidelines.
6. Designated user reusable HEPA respirators should be cleaned and filters checked and/or changed per hospital policy or current guidelines.
7. HEPA respiratory wearers should perform check to insure proper fit prior to each use.
8. Facial hair that interferes with the seal of the n-95 respirator must be removed or (PAPR) must be worn.
9. Medical Staff are accountable to protocols established by the Medical Staff.
10. Volunteers-
   a. TST testing will be provided by MMSC according to volunteer policy.
   b. Health records will be maintained by the Volunteer Office for volunteers.
11. Students- are accountable to protocols established by the school and by the hospital.

**Health Care Workers Tuberculosis Screening Program:**

1. Health care workers will have current 2-step TST (Mantoux) on employment and at appropriate intervals as determined by Employee Health Services and as determined by the annual risk assessment. Iowa State Law requires a health assessment and Tuberculosis status of an employee at least every 4 years. TST's will be completed to fulfill state law.
2. Individuals with a previous history of a positive TST should not continue to undergo skin testing. However, a baseline chest x-ray will be on file in the employee's health record.
3. TST is not contraindicated for pregnant employees.
4. Health care workers who previously received BCG vaccine as a child should receive a baseline TST. If positive, the employee should have a chest x-ray.

**Exposure Management**

1. Unprotected exposures to Active Tuberculosis will be documented using the injury/accident report. This report will serve as documentation of the exposure and allow follow up to be completed and recorded in the Employee/Volunteer health record.
2. Co-workers, physicians and volunteers exposed will be skin tested as soon as possible for a baseline PPD. This baseline will not be performed on those who have a negative TST on record 2 months prior to exposure. Co-workers who have a negative baseline TST will be retested in three months if the case is active and considered communicable.
3. Co-workers with positive TST who are exposed will have a chest x-ray (PA and lateral) three months after the exposure if the patient is active and considered communicable. If no active disease is found, follow up will be done per risk assessment.
4. Co-workers who convert to a positive TST will be treated with preventative therapy as recommended by personal physician or company doctor.
5. Co-workers with a positive or questionable chest x-ray will not be allowed to return to work until they have been evaluated for TB to include a medical history, physical exam, and appropriate bacteriologic or histologic tests have been completed. Co-workers must have therapy as directed by their physician and be culture negative.
6. Patient to patient transmission will be investigated in the same manner as co-workers.

**Health Care Workers with TB Infection or Active Disease:**

1. Health care workers with a positive TST, a current negative chest x-ray and no symptoms of active diseases will be able to continue work as usual. They should notify Employee Health Services immediately if symptoms develop.
2. Health care workers with infectious TB should notify Employee Health Services and be excluded from work until documented to be noninfectious and substantial improvement in symptoms. Clearance from Employee Health Services is required to return to work. Employee Health Services and Marshall County Public Health will monitor compliance with medications. Noncompliant health-care workers should be excluded from work until therapy is re-instituted and the individual assessed to be noninfectious.
3. Health care workers with TB at sites other than the lung or larynx usually do not need to be excluded from work if concurrent pulmonary TB has been excluded. (except exuding skin lesions).
4. All information provided by health care workers regarding their health status will be treated confidentially.
5. Refer to the Health and Safety Manual, Section 2, Employee Health, Policy No. HS.2.3.3, Positive Tuberculosis (TB) skin test reactor follow-up for additional details.

**Education and Training:**
All health care workers will receive initial employment and annual education about TB that is appropriate to their job category.

The following is an outline of the materials to be covered:
1. The basic concepts of TB transmission, pathogenesis, and diagnosis, including the difference between latent TB infection and active TB disease and the signs and symptoms of TB.
2. The potential for occupational exposure to patients with infectious TB.
3. Appropriate Airborne Precaution measures (negative pressure rooms, N-95 respirators, etc.)
4. The principles and practices of infection control that reduce the risk of transmission of TB, including the hierarchy of TB infection control measures, and exposure control plan. Include Airborne Precautions, transportation of TB patients, and required Personal Protective Equipment.
5. The purpose of TST, the significance of a positive result and the importance of participation in the skin test program.
6. The principles of preventive therapy of latent TB infection, indications, use and effectiveness, including the potential adverse effects of the drugs.
7. The responsibility of the employee to seek medical evaluation promptly if symptoms develop that may be due to TB or if TST conversion occurs in order to receive appropriate evaluation and therapy and to prevent transmission of TB to patients and other employees.
8. The principles of drug therapy for active TB. This should include the practice of direct observed therapy in the hospital and community.
9. The importance of notifying the appropriate individuals (Employee Health and Infection Control) if diagnosed with active TB so appropriate contact investigation can be instituted.
10. The responsibilities of the institution to maintain the confidentiality of the employee while assuring that the employee with TB receives appropriate therapy and is non-infectious before returning to duty.
11. The higher risk posed by TB to individuals with HIV infection or other causes of severely impaired cell-mediated immunity including:
   a. the more frequent and rapid development of clinical TB after infection with *Mycobacterium tuberculosis* (MTB).
   b. the differences in the clinical presentation of disease.
   c. the high mortality rate associated with MDR-TB (Multi Drug Resistant Tuberculosis M. tuberculosis organisms that are resistant to more than one anti-TB drug) disease in such individuals.

**Respiratory Training to include:**
1. Initial health history questionnaire and Air-Mate (PAPR) Instruction and/or fit-testing upon new employment if appropriate for their job category.
2. Annual health questionnaire for any changes which may indicate the need for medical testing or further medical review.
3. During fit testing the following is included in the training:
   a. define HEPA respirator and why OSHA requires its use.
   b. when to use a respirator (in room care of TB patient, bronchoscopy etc).
   c. recognize that respirators used for TB.
   d. describe how to clean and inspect the respirator.
   e. describe how long to use respirator.
   f. describe how to fit a respirator.
g. demonstrate a respirator fit-check.

h. medical surveillance requirement of respirator program.

I. describe the OSHA requirements for the program

4. There is an annual (train-the-trainer) course for co-workers who will be fit-testing other co-workers.

**POINTS TO REMEMBER:**

Epidemiology, Transmission, and Pathogenesis of TB

*M. tuberculosis* is carried in airborne particles called droplet nuclei that can be generated when persons who have pulmonary or laryngeal TB disease cough, sneeze, shout, or sing. The particles are approximately 1--5 μm; normal air currents can keep them airborne for prolonged periods and spread them throughout a room or building.

*M. tuberculosis* is usually transmitted only through air, not by surface contact. After the droplet nuclei are in the alveoli, local infection might be established, followed by dissemination to draining lymphatics and hematogenous spread throughout the body. Infection occurs when a susceptible person inhales droplet nuclei containing *M. tuberculosis*, and the droplet nuclei traverse the mouth or nasal passages, upper respiratory tract, and bronchi to reach the alveoli. Persons with TB pleural effusions might also have concurrent unsuspected pulmonary or laryngeal TB disease.

Usually within 2--12 weeks after initial infection with *M. tuberculosis*, the immune response limits additional multiplication of the tubercle bacilli, and immunologic test results for *M. tuberculosis* infection become positive. However, certain bacilli remain in the body and are viable for multiple years. This condition is referred to as latent tuberculosis infection (LTBI). Persons with LTBI are asymptomatic (they have no symptoms of TB disease) and are not infectious.

References:

*Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005* **MMWR** December 30, 2005 / 54(RR17);1-141

Questions and Answers about TB Booklet provided by the Iowa Department of Public Health Tuberculosis Control Program 2007.

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