Recommendations of the Michigan Advisory Committee for Elimination of Tuberculosis, 2012

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EXECUTIVE SUMMARY

Although TB cases continue to decline in Michigan and across the nation, there are still many challenges to face. The Michigan Advisory Committee for Elimination of Tuberculosis (MI-ACET), a group of representatives from private and public agencies, has revised its 2003 Recommendations. The MI-ACET was formed in 1992 with the goal of developing strategies and recommendations for the elimination of tuberculosis (TB) in Michigan. This document represents the group’s efforts to provide the latest TB prevention and control strategies and contains a revised set of recommendations and strategies for a statewide coordinated approach to TB prevention, control, and elimination. It is targeted at a broad audience of private and public health care professionals, and has been prepared by representatives from those groups. Links to more detailed information, available online, have been provided throughout the body of this document as well as in the reference pages. Electronic copies of this document can be obtained by calling the Michigan Department of Community Health (MDCH) TB Program at (517) 335-8165.

ESSENTIAL ELEMENTS FOR TB CONTROL

- **Directly Observed Therapy (DOT)** is the standard of care for the treatment of all active cases of TB and selected high-risk individuals with LTBI.
- **Inpatient treatment for tuberculosis** should conform to national and state guidelines, and should be performed in consultation with the appropriate local health department. Inpatient treatment for tuberculosis should be directly-observed whenever possible, either by hospital or local health department staff.
- **Discharge planning** should occur in consultation with the appropriate local health department, with at least 48 hours advance notification to the local health department before patients are discharged to the community from an airborne isolation environment. A discharge planning checklist is included in Appendix A.
- **Outpatient treatment and community control of tuberculosis** should be accomplished through collaboration between the appropriate local health department and private providers. The American Thoracic Society, CDC and the Infectious Diseases Society of America, have identified the following four core strategies for TB control in the U.S.:
  1. Early and accurate detection, diagnosis, and reporting of TB cases leading to initiation and completion of treatment.
  2. Identification of contacts of patients with infectious TB and treatment of those at risk with an effective drug regimen.
  3. Identification of other persons with LTBI at risk for progression to TB disease and treatment of those persons with an effective drug regimen.
  4. Identification of settings in which a high risk exists for transmission of TB and application of effective infection-control measures.
Physicians, laboratories and other providers shall report all confirmed and suspected cases of tuberculosis as required under Michigan’s Public Health Code (MCL 333.5111) and Communicable Disease Rules (R 325.172 - 173). Local public health departments should utilize their authority and mandates for investigation, evaluation and treatment of tuberculosis as specified in the Public Health Code (MCL 333.2451, 5111, 5117, 5203, 5205, 5207) and Communicable Disease Rules (R 325.174). Occupational or employee testing for tuberculosis infection should follow Michigan Occupational Safety and Health Administration (MIOSHA) policies (http://www.michigan.gov/tb).

EPIDEMIOLOGY IN MICHIGAN

The incident case rate of TB in Michigan has declined steadily during the past 10 years, having dropped from 3.3 per 100,000 in 2001 to 1.7 in 2011. However, the incident case rate was 2.2 in 2006, indicating that the decline in incidence has slowed during the past five years. Trends in reported TB cases indicate an increasing proportion of cases among foreign-born persons, and an increase in homelessness and substance abuse. Additional data and analyses are available at www.michigan.gov/tb.

The CDC case definition for tuberculosis allows for cases to be defined on the basis of clinical indications (e.g. positive test for TB infection, signs/symptoms consistent with TB disease) or laboratory results (e.g. isolation or demonstration of M. tuberculosis complex from a clinical specimen). The CDC also recognizes cases that are reported based on a provider diagnosis, but do not meet the clinical or laboratory case definitions. Detailed descriptions of the case definitions are available in “Reported Tuberculosis in the United States”, published annually by the CDC (http://www.cdc.gov/tb/statistics/default.htm).

MICHIGAN TUBERCULOSIS STANDARDS OF CARE

Directly Observed Therapy

Directly observed therapy is the standard of care for treating all cases of active or suspected tuberculosis and for selected high-risk patients with LTBI. DOT is a strategy to assure and improve treatment adherence, in which a health care worker or another designated person watches the TB patient swallow each dose of the anti-TB drugs. The location and schedule for administering DOT should be established collaboratively between the health department and the patient. It is important to establish a plan for providing DOT that is amenable to the patient’s needs and schedule, as well as the health department’s operational capacity to have staff in the field. Avoid using the patient’s family members or other close personal associates to administer DOT, as these individuals are likely to encounter conflicts of interest in promoting or enforcing
the patient’s treatment plan. Moreover, frequent face-to-face contact during DOT visits gives the trained health care worker an opportunity to assess the patient for medication side effects. Doses given by DOT should be recorded. The record should include at minimum the drug(s) used, doses, date given and initials of health care worker and patient.

- Guidelines for the use of DOT
  - *Michigan TB Program Manual.* Chapter 9; Case Management (www.michigan.gov/tb)

**Targeted TB Testing for TB Infection**

Targeted testing for TB is done to identify persons at high risk of being infected with TB or developing TB disease if infected. The determination of risk level is based upon many factors including country of birth, recent exposure or likelihood of exposure to TB, immune status and medical conditions that may be immune-compromising. Clinicians should identify persons at high risk and test for TB infection as part of their routine evaluation. A key MI-ACET recommendation is that foreign-born persons who come to the United States with a non-resident visa status (international students, temporary professional workers, and vocational workers), shall receive testing for TB infection upon arrival at their Michigan destination as a condition for participation in the program or activity for which they are sponsored. The Tuberculin Skin Test (TST or Mantoux) and two blood tests that measure the release of interferon gamma are FDA-approved for testing for TB infection. The interferon gamma release assays (IGRAs) include the QuantiFERON TB Gold In-Tube (QFT-GIT, Cellestis Ltd.) and the T.SPOT-TB (Oxford Immunotec Ltd.). Recommendations for the use of these tests in high-risk persons or populations, and the interpretation of results, have been established by the CDC. Interferon gamma release assays are preferred in BCG-vaccinated individuals and in groups that typically have a poor return rate for skin-test reading. Institutional testing in settings such as health care, correctional or long-term care facilities should be based upon an assessment of risk for TB exposure and/or transmission, as described in CDC and Michigan Occupational Safety and Health Administration (MIOSHA) guidelines. Hospitals that routinely diagnose or provide care for TB patients are encouraged to identify and evaluate patients at high risk for TB.

- Guidelines for targeted testing and the determination of risk

- Guidelines for interpretation of TB test results and use in high-risk persons/settings
MIACET recommends TST certification. The Mantoux TST will be applied and read by designated staff that have received training and achieved certification by completion of the TST Workshop. This training includes, but is not limited to: how to apply a TST using 5 tuberculin units of purified protein derivative (PPD), how to read a TST, how to interpret a TST result, and supervised training in application and measuring of the skin test results. For more information on TST certification, contact the MDCH TB Program at (517) 335-8165 or visit www.michigan.gov/tb.

The Michigan Department of Human Services requires that caregivers and assistants in adult foster care and child care settings be screened as a condition of employment. These requirements are available through the Department of Human Services website at http://www.michigan.gov/dhs/0,1607,7-124-5455_27716--,00.html. Additional information is also available by phone at 866-685-0006.

MIOSHA also has requirements (GISHD-COM-05-2R2) for testing of employees as part of a TB control program in health care settings, drug treatment centers, homeless shelters, and correctional facilities (http://www.michigan.gov/tb).

**Diagnosis and Treatment of TB Disease**

Evaluation for TB includes a medical history, physical examination, test for TB infection (TST or IGRA), chest x-ray, and bacteriologic exam. Histological examination may be useful for diagnosis when bacteriologic studies have not or could not be obtained. Treatment of drug-susceptible TB disease for most patients consists of an initial 2-month phase of four drugs: isoniazid, rifampin, pyrazinamide, and ethambutol followed by a 4-month continuation phase of isoniazid and rifampin. Treatment regimens must be based upon known drug susceptibilities. A coordinated case management involving local health departments and other service providers is necessary to promote compliance and achieve treatment completion.

Treatment of drug-resistant tuberculosis should only be undertaken by or in close consultation with an expert. Expert medical consultation for TB diagnosis, treatment and case management is
Recommendations for HIV Testing

HIV is a leading risk factor for progression from LTBI to active TB disease, and is also a significant complicating factor in patients with active disease. Likewise, tuberculosis disease is a significant risk factor for HIV-positive patients, and is a major cause of death in patients with AIDS. In accordance with CDC guidelines, MIACET recommends that all TB or LTBI patients receive counseling and education on the risks of HIV/TB co-infection, and be offered testing for HIV infection. All HIV-positive patients should also be tested for TB infection, and any with positive TB tests (TST or IGRA) should be evaluated to rule out active TB disease. The evaluation and diagnosis of TB disease in HIV-positive patients, especially those with low CD4 levels, should be undertaken in consultation with an expert in managing HIV/TB co-infection. Expert medical consultation is available through the MDCH TB Program at (517) 335-8165.

- Clinical consulting is available through the MDCH TB Program at (517) 335-8165.
- Guidelines for TB testing in HIV patients
- Guidelines for HIV testing in TB patients
Recommendations for Microbiological Testing

Routine monitoring of specimens for bacteriologic clearing is crucial to assure successful treatment and determine completion of therapy. In patients with pulmonary disease, achieving AFB-negative sputum smears reduces the risk of transmission and is a major determinant for releasing a patient from isolation.

- For sputum smear positive patients receiving outpatient treatment, collect three serial specimens every two weeks until conversion to three serial negative smears. For sputum smear positive patients in isolation (e.g. inpatient airborne infection or home isolation), consider collecting specimens more frequently to document conversion to three serial negative smears.
- Regardless of sputum smear status, all patients should have sputum specimens collected for culture at 60 days post treatment initiation, unless culture-negativity has already been documented. Documentation of culture-negativity by 60 days post treatment initiation is crucial to determine success and length of therapy.

The MDCH Bureau of Laboratories Mycobacteriology Unit provides complete and full-extent mycobacterial testing services. The staff is available for questions and consultation Monday through Friday during the hours of 7:30 AM – 5:00 PM, 517-335-9636. All specimens are processed for acid-fast staining within 24 hours of receipt and a slide result is reported the same day. The Mycobacteriology Unit also performs the Gen-Probe Amplified Mycobacterium Tuberculosis Direct Test (MTD), which is a genetic probe technique capable of identifying \textit{M. tuberculosis} complex rRNA within 24 hours. MTD testing is performed on respiratory specimens that are non-bloody and are collected from patients without prior history of \textit{M. tuberculosis}, and on processed specimens from private submitters with prior approval from the Mycobacteriology lab. Susceptibility testing for first-line anti-tuberculosis drugs is done on all new isolates of \textit{M. tuberculosis}, with repeat testing every 90 days. Secondary susceptibility testing is done when there is resistance to any of the first-line antibiotics. The Mycobacteriology unit also performs identification of Mycobacteria from outside submitters by the use of HPLC and biochemical testing. The Mycobacteriology lab is under contract with CDC to perform molecular typing (aka genotyping) on all new \textit{M. tuberculosis} isolates from the eastern United States.

Michigan’s Communicable Disease Rules R325.179 (promulgated under the authority of the Public Health Code, Act 368, P.A. 1978, as amended) stipulate:

- A laboratory that initially receives any clinical specimen which yields Mycobacterium tuberculosis complex, or yields a preliminary result indicative of Mycobacterium tuberculosis complex, is responsible for ensuring that the following are submitted:
  - (a) All preliminary results and any interpretation of those results to the appropriate local health department.
  - (b) The first Mycobacterium tuberculosis complex isolate, or subculture thereof, from the patient being tested for tuberculosis, to the department.
  - (c) Any Mycobacterium tuberculosis complex isolate, or subculture thereof, from a follow-up specimen, collected 90 days or more after the collection of the first Mycobacterium tuberculosis complex positive specimen.

**Diagnosis and Treatment of TB Infection**

Diagnosing and treating TB infection (aka latent tuberculosis infection or LTBI) is essential to eliminate TB in the United States. Immune-competent individuals with untreated LTBI face a 10% chance of developing TB disease during their lifetime, but for immune-suppressed individuals the probability is 7 – 10% per year. Evaluation for TB infection includes a medical history, physical examination and test for TB infection (TST or IGRA). Individuals with positive TST or IGRA results should receive a chest x-ray or other radiologic evaluation to rule out pulmonary disease.

Several treatment regimens are approved for treating TB infection. Baseline laboratory testing is not indicated for all patients at the start of treatment for LTBI. Rather, hepatic measurement of serum AST or ALT and bilirubin are indicated for patients whose initial evaluation suggests an increased risk for liver disease. If TB infection is known or suspected to have arisen through exposure to a drug-resistant index case, expert consultation should be sought to determine the most appropriate treatment strategy. Expert medical consultation for the diagnosis, treatment and case management of TB infection is available through the MDCH TB Program at (517) 335-8165. Clinicians are also encouraged to reference the MDCH/MIACET Michigan Tuberculosis Control Manual, CDC’s Core Curriculum on Tuberculosis and the Self-Study Modules on Tuberculosis. Severe adverse reactions to anti-tuberculosis medications are rare, but should be identified and reported immediately. Report any suspected or confirmed severe adverse reactions to the MDCH TB Program at (517) 335-8165.

- Clinical consulting available through the MDCH TB Program at (517) 335-8165.
- Guidelines for diagnosing and treating TB infection
  - *Michigan Tuberculosis Control Manual* ([http://www.michigan.gov/mdch/0,4612,7-132-2945_5104_5281_46528_59092--.00.html](http://www.michigan.gov/mdch/0,4612,7-132-2945_5104_5281_46528_59092--.00.html))
Infection Control in Health Care Settings

The main goal of an infection control program is to identify TB disease early, isolate individuals who are suspect, and promptly treat persons who have TB. Infection control programs should include three types of controls: administrative controls, engineering controls, and personal respiratory protection, and should be based on a risk assessment of the setting. Patients with known or suspected infectious pulmonary TB should be placed in respiratory isolation immediately. Release from isolation should only occur when a patient meets all the following criteria: three consecutive negative sputum smears; documented clinical improvement; compliant with an adequate treatment regimen for at least 2 weeks.

- Guidelines for infection control and evaluating occupational exposure to TB

- Guidelines for release from respiratory isolation
  - Core Curriculum on Tuberculosis: What the Clinician Should Know (http://www.cdc.gov/tb/education/corecurr/index.htm)

BCG Vaccination

Interferon gamma release assays are highly specific for *M. tuberculosis* and do not react to antigens of the Bacillus of Calmette and Guerin (BCG) strain. Therefore, IGRAAs are recommended for testing patients with known history of BCG vaccination. If IGRA testing is unavailable, a TST should be placed and interpreted regardless of BCG history. BCG vaccination is not a contraindication to the TST nor does a history of BCG vaccination change the definition of a positive TST.

- Guidelines for tuberculosis testing among BCG-vaccinated patients
Evaluation of Immigrants and Refugees with Class B Tuberculosis Status

Federal law requires all individuals seeking to enter the U.S. as immigrants or refugees to undergo a medical exam prior to entry into the U.S. Children being adopted into the U.S. are considered as immigrants in this context. Overseas medical examinations are performed by panel physicians, who are selected by the U.S. Department of State, following Technical Instructions established by the CDC. The current Technical Instructions were released in 2007, and provide the following classifications pertaining to TB status (CDC Immigration Requirements, Technical Instructions for Tuberculosis Screening and Treatment. Oct. 1, 2009):

- No TB Classification: Applicants with normal tuberculosis screening examinations.
- Class A TB with waiver: All applicants who have tuberculosis disease and have been granted a waiver.
- Class B1 TB, Pulmonary
  - No treatment: Applicants who have medical history, physical exam, or CXR findings suggestive of pulmonary tuberculosis but have negative AFB sputum smears and cultures and are not diagnosed with tuberculosis or can wait to have tuberculosis treatment started after immigration.
  - Completed treatment: Applicants who were diagnosed with pulmonary tuberculosis and successfully completed directly observed therapy prior to immigration.
- Class B1 TB, Extrapulmonary: Applicants with evidence of extrapulmonary tuberculosis.
- Class B2 TB, LTBI Evaluation: Applicants who have a tuberculin skin test ≥10 mm or positive IGRA but otherwise have a negative evaluation for tuberculosis. Contacts with TST ≥5 mm or positive IGRA should receive this classification (if they are not already Class B1 TB, Pulmonary).
- Class B3 TB, Contact Evaluation: Applicants who are a recent contact of a known tuberculosis case.

Upon clearance for travel, all examination results and records are assembled and given in hard copy to the individual to carry with them when they enter the U.S. Digital copies of chest x-rays may be stored on a CD and given to the applicant. Upon the individual’s entry to the U.S., their medical information is entered by CDC staff into a secure database (Electronic Disease Notification or EDN). This information is provided to state and local public health departments through secure connection to the EDN. The MDCH TB program has worked with CDC to create jurisdiction-specific access to EDN for local health
departments that typically receive large numbers of immigrants or refugees. These health departments access EDN directly to obtain overseas medical information. For local health departments that do not have direct access to EDN, the MDCH TB program forwards overseas information for recent Class B arrivals. The CDC requests that all individuals with Class B status for TB should have an evaluation initiated through the local health department within 30 days of arrival, and the evaluation should be completed within 90 days of arrival. Follow-up forms are included with all Class B TB medical packets, and follow-up data should be entered into the EDN as quickly as possible. Local health departments with access to EDN should enter follow-up data directly, and MDCH will monitor submission of this data in a timely manner. Local health departments that receive packets from the MDCH TB program should return the follow-up forms with initial medical evaluation specified, to the MDCH TB program and the TB program will submit this information into EDN. The CDC has established guidelines for the domestic evaluation of newly-arrived refugees for TB.

- Overseas medical evaluation of immigrants and refugees and technical instructions
  - [Medical Examination of Immigrants and Refugees](http://www.cdc.gov/immigrantrefugeehealth/exams/medical-examination.html)
  - Domestic evaluation of refugees for TB
    - [Guidelines for Screening for Tuberculosis Infection and Disease during the Domestic Medical Examination for Newly-Arrived Refugees](http://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/tuberculosis-guidelines.html)

### Surveillance and Reporting Requirements

Michigan Communicable Disease Rules stipulate the legal requirements for reporting cases or suspected cases of TB. Tuberculosis cases or suspect cases must be reported within 24 hours of diagnosis to the appropriate local health department. Cases should be reported through the Michigan Disease Surveillance System (MDSS).

- Guidance and requirements for case reporting and surveillance data gathering
  - [MDCH TB Program](http://www.michigan.gov/tb)

### Public Health Legal Authority

The State of Michigan Public Health Code and Communicable Disease Rules provide the authority for investigation, treatment and control of hazardous communicable diseases. Model legal tools and templates are available through the MDCH TB Program website.

- Public Health Code, Communicable Disease Rules, and model legal tools.
Appendices

Appendix A (Hospital Discharge Planning Checklist)-
See next page.
Continuity of care is essential to successful TB treatment. Because of the complexity of treatment and the public health concerns involved, the TB patient’s local public health department must be involved in all aspects of discharge planning.

If a hospitalized patient who has suspected or confirmed TB disease is deemed medically stable (including those with positive AFB sputum smear results), the patient can be discharged from the hospital before converting to negative AFB sputum smears, unless MDR TB is suspected or confirmed, if the following conditions are met:

- **Coordinate discharge plan and arrange Directly-Observed Therapy (DOT):**
  - Coordinate follow-up care between the patient and their Local Health Department (LHD) to ensure that treatment continues and infection control precautions are followed. LHD home visits are likely for DOT and case management.
  - Assess potential barriers (e.g. access to care, unstable housing, co-morbidities including HIV and mental health) that could interfere with treatment and collaborate with LHD to address them.
  - LHD will manage and dispense all medication.

- **Verify patient’s local health department (LHD)* has been contacted.**

- **Consider isolation needs (If MDR TB is suspected or confirmed, LHD will determine discharge parameters):**
  - Discharge potentially infectious TB patients only to settings where no new persons, immunocompromised persons or children < 4 will be exposed. Children ≤5 should be on window prophylaxis.
  - Reinforce the need to stay home (except for healthcare visits, where masks should be worn) until the physician and health department determine that isolation is no longer needed.
  - Do not discharge infectious patients to congregate settings (e.g. long-term care facility, shelter, correctional facility) unless they will be in an airborne infection isolation room.

- **Ensure that patient is tolerating daily dosing of TB medications:**
  - The standard 4-drug therapy (INH, RIF, EMB, PZA) has been started (unless susceptibility results show resistance). All TB medications should be given at the same time of day in a single daily dose.
  - Address any adverse effects prior to discharge.

- **Educate the patient:**
  - Educate the patient about the length of therapy, the importance of careful adherence to treatment and follow-up appointments, and the consequences of untreated TB.
  - Review potential medication side effects and when to report them.
  - Emphasize the benefits of DOT as the most effective way to complete therapy as quickly as possible and prevent drug resistance. DOT is recommended for all patients with TB.
  - Reinforce infection control measures to patients with infectious TB (i.e. wearing a mask, staying home, covering mouth when coughing or sneezing, avoiding contact with previously unexposed persons).
  - Use a professional medical interpreter/language line when indicated.

- **Verify patient information:**
  - Obtain correct address (e.g. apartment number [not P.O.box], address where patient will be staying if different from home). If homeless, identify shelter or facility most frequented.
  - Obtain patient’s phone numbers (home, work, cell) and emergency/alternate phone numbers.

- **Schedule a follow-up outpatient appointment.**
  - Set up a specific appointment within one month of discharge with the provider responsible for patient’s ongoing TB care. Give the appointment to the patient. If patient is not on DOT, the appointment should be scheduled within two weeks of discharge.

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**References**

1. Centers for Disease Control and Prevention. Guidelines for Preventing and Transmission of Mycobacterium tuberculosis in Health-Care Settings. MMWR 2005, 54(No.RR-17).[38,45]

*For a list of local health departments visit [www.maph.org](http://www.maph.org)*

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