

# Case Management

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# Quick Start Check List: Case Management

This check list is designed to assist public health nurses when managing a case. The tasks below should be performed by licensed nursing, medical, and laboratory staff. This check list requires understanding the instructions in the manual and familiarity with local protocols and standing orders. Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273.

Tasks for Case Management	Instructions and Forms
<p>When a suspected or confirmed case of tuberculosis (TB) disease is reported to the local public health agency:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Receive the case report</li> <li><input type="checkbox"/> Assign the case manager</li> <li><input type="checkbox"/> Notify the Montana TB Program at 406-444-0275</li> </ul>	
<p>Take infection control precautions:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Isolate the patient, if necessary (if the patient has positive acid-fast bacilli [AFB] sputum smear results and/or cavitary disease)</li> <li><input type="checkbox"/> Advise staff to take personal respiratory precautions, if necessary</li> </ul>	<p>Instructions:</p> <p>Section 16: Infection Control</p> <p>Topics: Isolation, Who Should Use a Mask or Respirator, Airborne Infection Isolation in a Healthcare Facility, Residential Settings</p> <p>Recommended Form:</p> <ul style="list-style-type: none"> <li>▪ "Home Isolation Agreement" (if the patient is isolated at home)</li> </ul>
<p>Perform the initial assessment of the patient:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Start the initial assessment within ≤1 business day of the case report</li> <li><input type="checkbox"/> Consult with the responsible physician and/or program medical consultant for medical examination/case review within ≤1 business day of the case report</li> <li><input type="checkbox"/> Conduct an initial interview of the patient and visit the patient's home: <ul style="list-style-type: none"> <li>▪ Interview the patient within ≤1 business day of the case report. If the patient is hospitalized, conduct the initial assessment during the patient's hospitalization.* If the patient is not hospitalized, conduct the initial assessment at the first clinic visit or during a home visit</li> <li>▪ Visit the patient's home (if initial visit occurred in the hospital) within ≤3 business days after the first interview</li> <li>▪ Reinterview the patient within 1 to 2 weeks after the first interview</li> </ul> </li> </ul> <p>If the patient is hospitalized outside of his or her county</p>	<p>Instructions:</p> <p>Section 9: Case Management</p> <p>Topic: Initial Assessment</p> <p>Section 10: Contact Investigation</p> <p>Topics: Quick Start Check List, Decision to Initiate a Contact Investigation, Infectious Period, Index Patient Interviews</p> <p>Recommended Forms:</p> <ul style="list-style-type: none"> <li>▪ "Treatment Plan"</li> <li>▪ "Treatment of Active TB Education Form"</li> <li>▪ "TB Home Evaluation"</li> <li>▪ "Bacteriology Data Sheet"</li> <li>▪ "Biochemistry Data Sheet"</li> <li>▪ "TB Contact Investigation Report"</li> </ul>

Tasks for Case Management	Instructions and Forms
<p>of residence, coordinate with the other county or hospital's infection control staff to conduct the assessment.</p>	
<p>Perform the initial assessment of the patient (continued):</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Use the data collected from the physician consultation(s), record review, and patient interviews to complete the following tasks: <ul style="list-style-type: none"> <li>▪ Review demographic information</li> <li>▪ Ascertain the extent of TB illness (See below for diagnosis of TB disease.)</li> <li>▪ Review the patient's health history</li> <li>▪ Determine infectiousness or potential infectiousness</li> <li>▪ Evaluate the patient's knowledge and beliefs about TB</li> <li>▪ Initiate treatment (if not initiated during hospital stay)</li> <li>▪ Monitor the TB medication regimen</li> <li>▪ Identify any barriers or obstacles to adherence</li> <li>▪ Review psychosocial status</li> <li>▪ Identify and document a good history of the patient's social network</li> <li>▪ Prepare for a possible contact investigation</li> </ul> </li> </ul>	
<p>Assist in diagnosing TB disease:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Assure that a medical evaluation of the patient is completed within 1 week of referral</li> <li><input type="checkbox"/> Assure that the necessary diagnostic tasks are done to diagnose TB disease or to rule out TB disease</li> <li><input type="checkbox"/> Receive initial culture results</li> </ul>	<p>Instructions:</p> <p>Section 5: Diagnosis of Tuberculosis Disease Topic: Quick Start Check List</p> <p>Section 7: Diagnosis of Latent Tuberculosis Infection Topics: Administration, Measurement, and Interpretation of the Tuberculin Skin Test</p>
<p>Communicate to state TB program staff:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Send the written "Confirmed/Suspected Report of TB Disease" to the Montana TB Program within 7 days of the case report</li> </ul>	<p>Instructions:</p> <p>Section 2: Surveillance Topic: Required Reports from Local Health Agencies</p> <p>Required Form:</p> <ul style="list-style-type: none"> <li>▪ "Confirmed/Suspected Report of TB Disease"</li> </ul>
<p>Assure that a treatment plan is developed and promptly initiated:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Initiate medical treatment within 3 days of positive AFB sputum smear results</li> <li><input type="checkbox"/> Assure that a written treatment plan is developed</li> <li><input type="checkbox"/> Assure that the patient and provider are aware of and educated about the treatment plan</li> </ul>	<p>Instructions:</p> <p>Section 9: Case Management Topic: Treatment Plan</p> <p>Recommended Forms:</p> <ul style="list-style-type: none"> <li>▪ "Treatment Plan"</li> <li>▪ "Directly Observed Therapy Agreement"</li> </ul>

Tasks for Case Management	Instructions and Forms
<p>Assure that a treatment plan is developed and promptly initiated (continued):</p> <ul style="list-style-type: none"> <li>□ Begin implementing the treatment plan: <ul style="list-style-type: none"> <li>▪ Refer the patient to other healthcare providers, social service agencies, or community organizations as needed (case manager works as a liaison between the patient and other providers)</li> <li>▪ Broker and locate needed services relating to TB treatment</li> <li>▪ Negotiate a plan for directly observed therapy (DOT) or self-administration evaluation</li> <li>▪ Coordinate strategies to improve adherence</li> </ul> </li> <li>□ If the patient is hospitalized, clarify the hospital discharge arrangements and assure that they are communicated to the hospital's outpatient coordinator and the treating physician(s)</li> </ul>	
<p>Gather baseline data for toxicity monitoring:</p> <ul style="list-style-type: none"> <li>□ Obtain baseline biochemistry tests for toxicity monitoring (choose tests based on regimen and for special situations such as human immunodeficiency virus [HIV] infection, history of liver disease, alcoholism, and pregnancy): <ul style="list-style-type: none"> <li>▪ Complete blood count</li> <li>▪ Platelets</li> <li>▪ Liver function tests</li> <li>▪ Uric acid measurements</li> </ul> </li> <li>□ Perform baseline visual acuity and color discrimination tests for toxicity monitoring if the patient is prescribed ethambutol</li> </ul>	<p>Instructions:</p> <p>Section 6: Treatment of Tuberculosis Disease Topics: Quick Start Check List, Side Effects and Adverse Reactions (Table 8)</p> <p>Recommended Forms:</p> <ul style="list-style-type: none"> <li>▪ "Treatment Plan"</li> <li>▪ "Bacteriology Data Sheet"</li> <li>▪ "Biochemistry Data Sheet"</li> </ul>
<p>Provide DOT:</p> <ul style="list-style-type: none"> <li>□ Provide DOT and assess adherence and drug toxicity at each visit</li> <li>□ Follow up missed appointments on the same day</li> </ul>	<p>Instructions:</p> <p>Section 9: Case Management Topic: Directly Observed Therapy</p> <p>Recommended Forms:</p> <ul style="list-style-type: none"> <li>▪ "Treatment Plan"</li> <li>▪ "Directly Observed Therapy Agreement"</li> <li>▪ "Directly Observed Therapy Form 1 - Treatment Record"</li> <li>▪ "Directly Observed Therapy Form 2 - Side Effects and Adverse Reactions"</li> </ul>

Tasks for Case Management	Instructions and Forms
<p><b>Monitor the patient regularly:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Conduct ongoing assessment and monitoring at least monthly for clinical response, drug toxicity, and adherence (See below for more details.)</li> <li><input type="checkbox"/> Call the Montana TB Program at 406-444-0275 to determine how to monitor when the patient <ul style="list-style-type: none"> <li>▪ Is initially culture negative, or</li> <li>▪ Has AFB 3+ or 4+ results, or</li> <li>▪ Has cavitation on chest radiograph, or</li> <li>▪ Has no sputum specimens collected</li> </ul> </li> <li><input type="checkbox"/> Determine HIV status and the risk factors for HIV disease, and refer the patient for treatment, if indicated</li> <li><input type="checkbox"/> Receive and review drug susceptibility results 1 to 2 months after the patient's initial sputum collection date</li> <li><input type="checkbox"/> Reassess treatment and, if concerned about response or drug toxicity, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs</li> <li><input type="checkbox"/> Ensure that medications are ordered and given at the correct time, and in the correct dosage</li> <li><input type="checkbox"/> If the patient is isolated, determine whether isolation can be discontinued</li> <li><input type="checkbox"/> Review the status of the contact investigation, if one was started</li> <li><input type="checkbox"/> Send a written update monthly to the Montana TB Program on the "TB Case Monthly Report"</li> </ul>	<p><b>Instructions:</b></p> <p>Section 16: Infection Control  Topics: Isolation, Airborne Infection Isolation in a Healthcare Facility, Residential Settings</p> <p>Section 2: Surveillance  Topic: Required Reports from Local Health Agencies</p> <p><b>Forms:</b></p> <ul style="list-style-type: none"> <li>▪ "TB Case Monthly Report" (required)</li> <li>▪ "Treatment Plan" (revise original plan if new orders are given)</li> </ul>
<p><b>Monitor the clinical response to treatment:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Reassess information about the index patient weekly until drug susceptibility results are available or for 2 months after the case report, whichever is longer</li> <li><input type="checkbox"/> If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, then each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported</li> <li><input type="checkbox"/> If sputum smear results are positive after 2 months of treatment, call the Montana TB Program at 406-444-0275</li> </ul>	<p><b>Instructions:</b></p> <p>Section 9: Case Management  Topic: Ongoing Assessment and Monitoring</p> <p><b>Recommended Forms:</b></p> <ul style="list-style-type: none"> <li>▪ "Treatment Plan"</li> <li>▪ "Bacteriology Data Sheet"</li> <li>▪ "Biochemistry Data Sheet"</li> <li>▪ "Treatment of Active TB Education Form"</li> <li>▪ "Monthly TB Patient Assessment"</li> <li>▪ "Directly Observed Therapy Form 1 - Treatment Record"</li> <li>▪ "Directly Observed Therapy Form 2 - Side Effects and Adverse Reactions"</li> <li>▪ "TB Contact Investigation Report"</li> </ul>

Tasks for Case Management	Instructions and Forms
<p><b>Monitor the clinical response to treatment (continued):</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> When the patient has negative AFB sputum smear results, then each month collect sputum specimens and submit them for testing until 2 consecutive negative culture results are reported <ul style="list-style-type: none"> <li>▪ For multidrug-resistant TB (MDR-TB) patients, monthly specimens are required</li> <li>▪ For non-MDR-TB patients who can produce sputum, monthly specimens are recommended</li> </ul> </li> <li><input type="checkbox"/> If sputum smear results or culture results are positive after 3 months of treatment, consult with the Montana TB Program at 406-444-0275</li> </ul>	
<p><b>Monitor the patient for drug toxicity:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Assess drug toxicity at each DOT visit</li> <li><input type="checkbox"/> Repeat liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and serum bilirubin) when the patient is taking isoniazid, a rifamycin, or pyrazinamide if <ul style="list-style-type: none"> <li>▪ Baseline results are abnormal</li> <li>▪ The patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions</li> <li>▪ The patient has symptoms of adverse reactions</li> </ul> </li> <li><input type="checkbox"/> If the patient is taking ethambutol, question the patient monthly regarding possible visual disturbances, including blurred vision or scotomata</li> <li><input type="checkbox"/> Test visual acuity and color discrimination monthly when the patient is taking ethambutol <ul style="list-style-type: none"> <li>▪ In doses &gt;15–25 mg/kg</li> <li>▪ For &gt;2 months</li> <li>▪ With renal insufficiency</li> </ul> </li> </ul>	<p><b>Instructions:</b> Section 6: Treatment of Tuberculosis Disease Topics: Quick Start Check List, Side Effects and Adverse Reactions (Table 8)</p> <p><b>Recommended Forms:</b></p> <ul style="list-style-type: none"> <li>▪ “Treatment Plan”</li> <li>▪ “Biochemistry Data Sheet”</li> <li>▪ “Directly Observed Therapy Form 2 - Side Effects and Adverse Reactions”</li> </ul>
<p><b>Assess adherence and address obstacles to adherence:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Assess adherence daily and monthly and identify positive and negative motivational factors influencing adherence</li> <li><input type="checkbox"/> Determine the unmet educational needs of the patient</li> <li><input type="checkbox"/> Educate the patient about the TB disease process</li> <li><input type="checkbox"/> Advocate for the patient with team members and other service providers</li> </ul>	<p><b>Instructions:</b> Section 9: Case Management Topic: Adherence to Directly Observed Therapy, Incentives and Enablers, Legal Orders</p> <p><b>Recommended Forms:</b></p> <ul style="list-style-type: none"> <li>▪ “Treatment Plan”</li> <li>▪ “Directly Observed Therapy Agreement”</li> <li>▪ “Treatment of Active TB Education Form”</li> </ul>

Tasks for Case Management	Instructions and Forms
<p><b>Assess adherence and address obstacles to adherence (continued):</b></p> <ul style="list-style-type: none"> <li>□ Address nonadherence, if necessary: <ul style="list-style-type: none"> <li>▪ Review with the patient the treatment agreements and directly observed therapy arrangements</li> <li>▪ Educate the patient about TB and its treatment</li> <li>▪ Refers the patient to social services, if necessary</li> <li>▪ Provide incentives and enablers</li> <li>▪ Initiate legal orders, if other measures do not improve adherence</li> </ul> </li> </ul>	
<p><b>Determine the completion of treatment:</b></p> <ul style="list-style-type: none"> <li>□ Verify completion of treatment 6 to 9 months after treatment was started based on: <ul style="list-style-type: none"> <li>▪ Regimen</li> <li>▪ Adherence</li> <li>▪ Response to treatment</li> <li>▪ Number of weeks on DOT</li> <li>▪ Number of doses taken</li> </ul> </li> <li>□ If treatment is not completed within the recommended time frame, contact the Montana TB Program at 406-444-0275 and assess the patient with a physician to determine continuation of longer therapy</li> </ul>	<p><b>Instructions:</b></p> <p>Section 9: Case Management Topic: Completion of Therapy</p> <p>Section 6: Treatment of Tuberculosis Disease Topics: Completion of Therapy, Regimens (Table 3)</p> <p><b>Recommended Forms:</b></p> <ul style="list-style-type: none"> <li>▪ "Treatment Plan"</li> <li>▪ "Monthly TB Patient Assessment"</li> <li>▪ "Directly Observed Therapy Form 1 - Treatment Record"</li> <li>▪ "Bacteriology Data Sheet"</li> </ul>
<p><b>Evaluate case management activities:</b></p> <ul style="list-style-type: none"> <li>□ Monitor the activities against the treatment plan monthly (or more frequently if needed)</li> <li>□ Report data monthly on the "TB Case Monthly Report"</li> </ul>	<p><b>Instructions:</b></p> <p>Section 9: Case Management Topic: Evaluation</p> <p><b>Forms:</b></p> <ul style="list-style-type: none"> <li>▪ "Treatment Plan" (recommended)</li> <li>▪ "TB Case Monthly Report" (required)</li> </ul>

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# Introduction

## Purpose

*Tuberculosis (TB) case management* describes the activities undertaken by the jurisdictional public health agency and its partners to ensure successful completion of TB treatment and cure of the patient.<sup>1</sup> Case management is a system in which a specific health department employee is assigned primary responsibility for the patient, systematic regular review of patient progress is conducted, and plans are made to address any barriers to adherence.<sup>2</sup>

Use this section to understand and follow national and Montana state guidance to

- conduct initial assessments;
- develop treatment plans for case management activities;
- conduct monthly ongoing assessments;
- monitor adverse reactions to antituberculosis medications and monitor toxicity;
- monitor bacteriologic and clinical improvement;
- verify completion of therapy;
- evaluate case management activities;
- provide directly observed therapy (DOT);
- use incentives and enablers to improve adherence to therapy; and
- understand when and how to use legal orders, if necessary, for adherence to therapy.

One of the four fundamental strategies to achieve the goal of TB control in the United States is the early and accurate detection, diagnosis, and reporting of TB cases, leading to initiation and completion of treatment. Completion of a full course of standard therapy is essential to prevent treatment failure, relapse, and the development of drug resistance.<sup>3</sup>

One reason for failure to complete standard treatment is that patients frequently fail to adhere to the lengthy course of treatment. Poor adherence to treatment regimens might result from difficulties with access to the healthcare system, cultural factors, homelessness, substance abuse, lack of social support, rapid clearing of symptoms, or forgetfulness.<sup>4</sup>

These adverse outcomes are preventable by case-management strategies provided by TB control programs, including use of DOT.<sup>5</sup> It is strongly recommended that the initial treatment strategy utilize patient-centered case management with an adherence plan that emphasizes DOT.<sup>6</sup> It is essential to provide patient-centered case management in which treatment is tailored and supervision is based on each patient's clinical and social



circumstances.<sup>7</sup> Programs utilizing DOT as the central element in a comprehensive, patient-centered approach to case management (enhanced DOT) have higher rates of treatment completion than less intensive strategies.<sup>8</sup>

## Policy

Although some patients may undergo most of their evaluation and treatment in settings other than a local public health agency, a local public health agency should undertake the major responsibility for monitoring and ensuring the quality of all TB-related activities in the community as part of its duties to protect the public health.<sup>9</sup>

Effective TB case management requires administrative commitment and support. This includes education, staff training, and ensuring adequate funding to maintain program activities.<sup>10</sup> It is recognized that local public health agencies differ in their staffing and organization and that no set of guidelines can cover all the situations that may arise relating to case management.<sup>11</sup>



For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the Introduction.

## Forms



Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273.

## Acknowledgments

The authors want to acknowledge the extensive use of two non–Centers for Disease Control and Prevention (CDC) sources for the content in this section.

The New Jersey Medical School National Tuberculosis Center’s *Tuberculosis Case Management for Nurses: Self-Study Modules* course is a comprehensive and well-written overview of case management for a national audience. The text for large portions of the “Initial Assessment,” “Treatment Plan,” and “Ongoing Assessment and Monitoring” topics was taken and/or adapted from the second module of this self-study course.

The California Department of Health Services (CDHS)/California Tuberculosis Controllers Association (CTCA) “TB Case Management—Core Components” guideline provides another comprehensive source of recommendations on case management practices. This guideline is one in the series of *CDHS/CTCA Joint Guidelines* and is used throughout urban and rural areas in California. Some content in the “Ongoing

Assessment and Monitoring” topic was taken from the “TB Case Management—Core Components” guideline.

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# Initial Assessment

Conduct initial assessments of tuberculosis (TB) patients to gather data that will form the basis for TB treatment and care. It is essential to gather data to determine the clinical and social issues and circumstances of relevance to the patient and to assess each situation objectively to determine the appropriateness of the planned intervention. Many professionals involved in the patient's care contribute to the assessment data, and the case manager gathers assessment data from many sources, including community agencies, primary care providers, schools, and other healthcare facilities.<sup>12</sup>



When the patient with TB is a child, the case manager should involve both the child and family in the assessment process.<sup>13</sup>



To document and report on suspected/confirmed TB cases, use the "Confirmed/Suspected Report of TB Disease" form. Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273.

## Cultural Sensitivity and Language Issues

In the initial assessment, consider cultural sensitivity and language issues. To improve the validity and quality of the assessment information, healthcare workers need to be culturally sensitive in approaching each patient. A medical interpreter may be needed for patients whose primary language is not English.



For more information on cultural sensitivity, refer to the *Participant's Workbook* for Session 4: "Working with Culturally Diverse Populations" in *DOT Essentials: The DOT Trainer's Curriculum* (Francis J. Curry National Tuberculosis Center Web site; 2003). This content is no longer available online.



For assistance with language issues, see the National Health Law Program and The National Council on Interpreting Health Care's *Language Services Resource Guide for Health Care Providers* (National Health Law Program Web site; October 2006) This content is no longer available online.



For more information on using interpreters, see the *Interpretation Services* lesson in Module 9: “Patient Adherence to Tuberculosis Treatment” of the CDC’s *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 1999). This content is no longer available online.

## Patient’s Medical Records

The case manager needs all medical records in order to provide case management and recommend a treatment plan. Prior to the visit with the patient, the case manager should ensure that a copy of all of the patient’s medical records (from hospitals, clinics, and other healthcare providers) and chest radiographs are available to the treating physician. Without the medical records, the physician may not be able to make the correct judgments in medical management.<sup>14</sup>

## Assessment Site

If the patient is hospitalized, conduct the initial assessment during the patient’s hospitalization. If the patient is hospitalized outside of his or her county of residence, coordinate with the other county or hospital’s infection control staff to conduct the assessment. If the patient is not hospitalized, conduct the initial assessment at the first clinic visit or during a home visit.

## Discharge Planning



Patients who are diagnosed with TB during a hospitalization will require discharge planning. The case managers should ensure that appropriate discharge planning occurs for all patients with TB, to prevent transmission in the community and interruption in treatment.<sup>15</sup>

## Initial Assessment Activities

To complete an initial assessment, perform the following activities:

- Visit the patient’s home
- Obtain or review demographic information
- Ascertain the extent of TB illness
- Obtain and review the patient’s health history
- Determine infectiousness or potential infectiousness
- Evaluate the patient’s knowledge and beliefs about TB

- Initiate treatment, if not initiated during hospital stay
- Monitor the TB medication regimen
- Identify any barriers or obstacles to adherence
- Review psychosocial status
- Identify and document a good history of the patient's social network
- Gather information for a possible contact investigation

**Visit the patient's home.** During the patient's TB treatment, at least one or more home visits are required. Home visits are useful for confirming the patient's address, particularly for patients at high risk for default from treatment. Information gathered at the patient's home is often more revealing than assessments performed in the clinical or health department settings and can lead to a more accurate understanding of the patient's lifestyle (for example, seeing a child's shoes or toys when a child was not named in the contact investigation).<sup>16</sup> Several home visits may be needed, because usually not all of the necessary information is gathered from the patient and his or her family at one time.

**Obtain or review demographic information,** including the name, address, telephone number(s), birth date, Social Security number, and health insurance provider's name, address, and identifying information.<sup>17</sup>

**Ascertain the extent of TB illness,** including acuity and length of symptoms, bacteriology and radiographic findings, laboratory analyses, tuberculin skin test results, nutritional status, vital signs, and baseline weight (without shoes or excess clothing). Assess temperature, pulse, and respiration if the patient appears ill or the history suggests illness. Blood pressure evaluations are valuable, especially if the patient has no primary care provider.

The responsible physician and/or program medical consultant should be consulted within one business day of receipt of a suspect report. Within one week of a case report, a tuberculin skin test should be placed, measured, and interpreted; and a chest radiograph should be taken and interpreted. Also within one week of a case report, a minimum of three consecutive sputum specimens of good quality should be collected 8–24 hours apart (with at least one being an early morning specimen) and submitted to the laboratory.



In the case of pulmonary TB in children younger than 5 years of age, posterior-anterior and lateral chest radiographs are important in the initial diagnosis.<sup>18</sup> Adults who are suspected of TB or who are active cases usually need only an initial posterior-anterior chest radiograph.

**Obtain and review the patient's health history** to determine concurrent medical problems, including human immunodeficiency virus (HIV) disease or risk factors, country of birth, sexual history, allergies, or medications that may interfere with TB drugs. The case manager should obtain the names, addresses, and telephone numbers of the

patient's primary care provider and any specialists involved in his or her medical care, previous hospitalizations, allergies, and current medications. It is important to know the history of treatment for TB infection and/or disease, especially for patients who are treatment failures or have a relapse of TB disease, as they are at a higher risk for developing multidrug-resistant TB (MDR-TB). It is also important to determine what the patient perceives as his or her most important medical/health problem. The date of the last menstrual period and contraceptive use should be obtained from female patients.<sup>19</sup>



Some antituberculosis medications are contraindicated when a patient is taking birth control pills. For more information, see the “Side Effects and Adverse Reactions” topic in the Treatment of Tuberculosis Disease section.

**Determine infectiousness or potential infectiousness.** To determine where and whom to initiate contact investigation, the initial assessment should gather information to define the start and end dates of the period of infectiousness. This assessment should include the duration and frequency of symptoms, especially cough, and a review of the radiographic findings. If the patient is infectious or potentially infectious, the case manager should have an understanding of the period of infectiousness. The parameters of a contact investigation, including the need for repeating the tuberculin skin test for contacts that were initially negative, can then be determined.<sup>20</sup>



A source-case investigation seeks the source of recent *Mycobacterium tuberculosis* infection, perhaps newly diagnosed TB disease. TB disease in children younger than 5 years typically indicates that the infection is recent. The yield of source-case investigations for children who have TB disease varies, typically less than 50%. A younger age cut-off might be advisable, because the focus would be on more recent transmission.



For more information on the period of infectiousness and contact investigations, see the Contact Investigation section.

**Evaluate the patient's knowledge and beliefs about TB,** including a history of TB in family and/or friends and the response to treatment. The case manager can assess TB knowledge by interviewing the patient regarding TB transmission, pathogenesis, and symptoms. Patient education should be based on current knowledge and ability to comprehend written, visual, and/or verbal information.<sup>21</sup>



It is important to interview both the child and parent or guardian in their own language when assessing TB knowledge; however, adolescents should be given the opportunity to speak to a healthcare provider alone. Keep in mind that parents who have misinformation or cultural bias about TB may affect their children's understanding of the disease.<sup>22</sup> Use age-appropriate educational materials and methods, especially in working with children. When dealing with a school-aged child, it is important to explain

that TB is treatable, and with the adolescent, it may be necessary to constantly reaffirm confidentiality.<sup>23</sup>

**Initiate treatment.** A clinician should initiate medical treatment within three days of positive acid-fast bacilli (AFB) sputum smear results (unless there is evidence that the AFB is not *M. tuberculosis* complex, e.g., by direct test of sputum) or a presumptive diagnosis. A clinician should complete medical evaluations within one week of a referral. Immediately upon receipt of medical orders which document drugs, dose, route, frequency, and duration, the case manager should order drugs. The case manager then should initiate treatment within one business day of receiving the drugs.

**Monitor the TB medication regimen.** The case manager should ensure that medications and dosages are prescribed according to current American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC) guidelines. If the initial assessment occurs during the patient's hospitalization, the case manager should ensure that the ingestion of the TB medication is observed by a nurse. It is important to ensure that hospitals order and give the right doses and are observing patients taking medications. Since the outpatient phase of treatment will involve giving TB medications at one time, hospitals should be discouraged from splitting dosages for two reasons: (1) taking medications more than once a day creates an expectation for the patient that will have to change after discharge from the hospital, and (2) tolerance to the full dosage cannot be assessed while in the hospital. The patient's tolerance to TB medications should be noted, and interactions with other medications should be determined prior to the patient starting TB medications.<sup>24</sup>



For more information on treatment regimens and dosages, see the Treatment of Tuberculosis Disease section.

**Identify any barriers or obstacles to adherence** in taking TB medications and keeping physician or clinic appointments. This includes such issues as language, availability of transportation, the patient's preference for place and time of directly observed therapy (DOT), and the ability to swallow pills. Many adolescents and adults who have difficulty swallowing pills are embarrassed to report this to the healthcare provider. It may be necessary to teach people how to take pills, or it may be necessary to crush the pills and put them in food, such as pudding or applesauce. In addition, the case manager should determine the need for enablers and identify incentives that will be most valuable to the patient.<sup>25</sup>

**Review psychosocial status** to identify unmet needs, the use of alcohol and/or illegal drugs, and any pre-existing psychiatric diagnoses.<sup>26</sup>

**Identify and document a good history of the patient's social network.** This is important to identify and document in the event that the patient does not return for follow-up. The case manager needs to verify the patient/family's address, evaluate residential stability, and assess potential for homelessness. Determine the patient's residence(s) during the past year, particularly any congregate living situations, such as

prison, jail, homeless shelter, nursing home, boarding home, or foster care. Establish the patient's occupation and/or student status, and document the name and address of business or school. The name and location of a child's babysitter, other caretakers, daycare center, and/or school should be noted. In order to identify those who have shared common air space with the infectious, untreated patient with TB, it is necessary to have an understanding of the patient's social and recreational activities and how he/she spends leisure time. This includes time spent at bars, floating card games, circuit parties, faith-based functions, and other venues.

**Gather information for a possible contact investigation.**



For more information, see the Contact Investigation section.



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# Treatment Plan

When sufficient information has been gathered by members of the healthcare team to assess a patient's needs and problems, the case manager should develop a treatment plan for each patient with confirmed or suspected tuberculosis (TB). The plan should combine both medical management of the patient and nursing interventions. Due to the length of TB treatment (from 6 to 24 months), the plan must include intermediate and expected outcomes.

To ensure that therapy is completed, a treatment plan should be based on data collected by the healthcare team and must be designed to meet the patient's medical and personal needs. Treatment of a patient with TB is most successful within a comprehensive framework that addresses both clinical and social issues of relevance to the patient. Patient-centered care is essential to provide because it tailors treatment and bases supervision on each patient's clinical and social circumstances.

Each patient's management plan should be individualized to incorporate measures that facilitate adherence to the drug regimen, such as social service support, treatment incentives and enablers, housing assistance, referral for treatment of substance abuse, and coordination of TB services with those of other providers.<sup>27</sup>

In the initial management strategy, regardless of the source of supervision, always include an adherence plan that emphasizes directly observed therapy (DOT), in which patients are observed as they ingest each dose of antituberculosis medications, to maximize the likelihood of completion of therapy.<sup>28</sup>

The case manager is responsible for the overall plan, including documentation, monitoring the patient response, interventions, intermediate and expected outcomes, and initiating changes in the plan to reflect changes in circumstances.<sup>29</sup> The treatment plan should be reviewed and updated at least monthly during reviews of clinical progress.<sup>30</sup>

## Treatment Plan Components

Recommended components of a treatment plan include the following:

- Patient's verified address and contact information
- Assignment of responsibilities: case manager, clinical supervisor (nurse, physician, or physician assistant), DOT workers, other caregivers (outreach workers, nurses), and person managing the contact investigation
- Patient educator's name and dates of education sessions
- Method for prevention of transmission: no isolation, airborne infection isolation, home isolation, legal order for isolation
- Planned course of antituberculosis drug therapy
- Estimated date of completion of treatment
- Test results from initial medical evaluation
- Medical history
- Diagnosis
- Monitoring activities and schedule to assess response to therapy
- Baseline tests and monitoring activities and schedule to detect potential side effects and adverse reactions
- Potential drug interactions
- Potential treatment adherence obstacles
- Personal service needs
- Referrals for social services
- Means of ensuring successful completion of treatment (DOT, incentives, enablers)
- Location(s) where DOT will be administered
- Intermediate and expected outcomes<sup>31</sup>



For a list of intermediate and expected outcomes, see *Module 2: "Fundamentals of TB Case Management,"* pages 23–25 in the New Jersey Medical School National Tuberculosis Center's *Tuberculosis Case Management for Nurses: Self-Study Modules* (New Jersey Medical School Global Tuberculosis Institute Web site).

## Planning Activities

To complete planning, perform the following activities:

- Establish the treatment plan
- Establish time frames in the treatment plan to monitor the plan and patient response
- Negotiate and adjust the treatment plan

**Establish the treatment plan**, ensuring that all the components are included. The case manager should ensure that the treatment plan is useful and meaningful. It becomes the internal standard of care for the patient as well as the performance standard for the case manager. Good planning will allow the patient to experience TB care and treatment along the healthcare continuum and prevent duplication and fragmentation of services. The plan should be discussed and validated with all team members and the patient.<sup>32</sup> DOT should be the standard of care for all TB cases and suspects.

**Establish time frames in the treatment plan to monitor the plan and patient response.** Monitoring should be done at least monthly at the patient's home, ambulatory clinic, health department, or private physician's office. Each component of the plan should be reviewed to ensure that it is an accurate accounting of the patient's problems, required tests, and interventions. To track progress toward outcomes, document all treatment activities and their dates: medications taken, tests and results, patient visits, monitoring activities, side effects, adverse reactions, education sessions, social service referrals, incentives, enablers, isolation status changes, and patient problems.<sup>33</sup>

**Negotiate and adjust the treatment plan** as needed, to meet new realities. Since patient circumstances are usually fluid and personnel resources often change over time, it is essential that the plan be negotiated with the patient and changed to adjust to new situations. The adjusted plan should be discussed with the team members, as well as the patient.<sup>34</sup>

## Implementation Activities

To begin implementation of the treatment plan, perform the following activities:

- Refer the patient to other healthcare providers, social service agencies, or community organizations, as needed, with the case manager functioning as a liaison
- Broker and locate needed services relating to TB treatment
- Negotiate a plan for DOT or self-administration evaluation
- Coordinate strategies to improve adherence

**Refer the patient to other healthcare providers, social service agencies, or community organizations, as needed.** The referral process requires the case manager to locate and coordinate accessible, available, and affordable resources for the patient. After the referral is made, the case manager should monitor the patient's adherence to the referral and obtain the consultation or follow-up report in writing. Immediate intervention may be necessary if the patient or the referring agency experiences difficulty.<sup>35</sup> All patients with suspected or proven TB should be assessed for HIV risk and offered counseling and voluntary testing for HIV, with referral for HIV treatment services when necessary. Referrals to medical specialists for conditions that would endanger the patient and/or affect the outcome of treatment should be made as soon as possible. The patient should be sent to an emergency department if the condition is serious when assessed by the case manager. The case manager should follow up a referral to obtain medical information and determine whether the necessary medical intervention has been completed.

**Broker and locate needed services relating to the TB treatment.** This may include laboratory, auditory, or visual acuity testing; additional radiographs; or other tests required specifically for the patient. It is important to schedule or assist the patient in scheduling appointments and to monitor the patient's adherence to the appointment and the results. An understanding of the patient's financial resources and health insurance coverage is important. Lack of financial resources or health insurance will affect the patient's willingness to keep appointments, which may be critical to his or her health. The case manager may need to discuss essential services with insurance companies or other healthcare providers to obtain the most cost-effective, quality service.<sup>36</sup> Help should be provided to reinforce a patient's efforts to receive financial assistance and treatment for psychosocial, alcohol-related, and drug-related conditions.

**Negotiate a plan for DOT or self-administration evaluation.** DOT should be the standard of care for all patients. The case manager should ensure the plan is suitable for the patient's needs and achievable by the healthcare provider(s) and then have the patient sign a DOT agreement. Due to the length of TB treatment, the patient's circumstances may change. The case manager needs to verify that the time and place for DOT administration originally agreed upon is still agreeable to the patient and provider. It also may be necessary to coordinate the arrangements for DOT with outside organizations, such as school nurses or drug treatment center nurses.<sup>37</sup>



Refer to the "Directly Observed Therapy" topic in this section.

**Coordinate strategies to improve adherence.** The case manager must have knowledge of and proficiency in strategies to improve patient adherence, understand the importance of developing and maintaining a therapeutic relationship, and be familiar with the principles and practices of behavioral contracting and behavioral modification. Collaboration with team members is essential to obtain as much information as possible about strategies to improve adherence of individual patients and elicit opinions, attitudes,

and feelings expressed by the patient. To be effective, incentives and enablers should be meaningful and specific for a particular patient.<sup>38</sup> Incentives and enablers should be considered for use with all patients.

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## Ongoing Assessment and Monitoring

Conduct ongoing assessments and monitor patients at least monthly, either in an ambulatory clinic setting, local public health agency, or private physician's office. Schedule additional assessments throughout the month for patients experiencing problems in their tuberculosis (TB) treatment, or for those patients who are nonadherent to directly observed therapy (DOT) or follow-up appointments.<sup>39</sup>

There are countless stories from nurses and outreach workers reinforcing the fact that not all information is obtained from the patient or family at one time. Therefore, the case manager must ensure that the list of contacts is updated from time to time and determine the need for further testing. It is also important to review the status of the contact investigation to ensure that timelines and standards are followed. Also, checking for the accuracy of previously gathered information should occur throughout the patient's TB treatment.<sup>40</sup>



For ongoing assessment and monitoring, use the "TB Case Monthly Report." Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273..

## Ongoing Assessment Activities

To complete an ongoing assessment, perform the following activities:

- Monitor the clinical response to treatment
- Determine human immunodeficiency virus (HIV) status and the risk factors for HIV disease, and refer the patient for treatment, if indicated
- Review the treatment regimen
- Ensure that medications are ordered and given at the correct time, and in the correct dosage
- Monitor the side effects of and adverse reactions to medication
- Assess adherence daily and monthly, and identify positive and negative motivational factors influencing adherence
- Determine the unmet educational needs of the patient
- Educate the patient about the TB disease process
- Advocate for the patient with team members and other service providers
- Review the status of the contact investigation, if one was started

**Monitor the clinical response to treatment** by reviewing vital signs, weight, bacteriology reports, and radiographic results, including drug susceptibility results and TB symptoms, and comparing them to previous documented findings. This review is an important measurement of clinical improvement, worsening, or stabilization of the patient's condition. If the patient's condition is worsening, interview the patient to determine the potential cause(s) for the worsening condition. List all bacteriological reports in chronological order, and correlate them with the patient's current symptoms history and chest radiograph report to ensure accuracy. Also, conduct this review at conversion as evidence for the improving condition of the patient.<sup>41</sup>



Inconsistencies should trigger additional questions, such as the possibility of laboratory contamination. Bring these questions immediately to the attention of the physician and the Montana TB Program manager.<sup>42</sup>



A child's clinical response to treatment may not be as significant as that of an adult. Therefore, it is important to reinforce what the expected response to treatment should be for the individual child during the course of treatment.<sup>43</sup>

**Determine HIV status and the risk factors for HIV disease, and refer the patient for treatment, if indicated.** It is important for patients to understand the correlation between TB and HIV disease. The case manager should ensure that HIV counseling and testing are done at the beginning of TB treatment, if the HIV status is not previously known. If the patient refuses HIV testing, an assessment of the risk factors for HIV should be completed.<sup>44</sup> If a patient refuses, voluntary HIV testing and counseling should continue to be offered periodically throughout treatment.

If the parents of a young child with TB refuse to permit the child to be HIV tested, the parents should be interviewed regarding the child's risk of HIV disease, including neonatal transmission.<sup>45</sup>

**Review the treatment regimen** to verify that the physician's orders are clear and concise. One of the case manager's primary responsibilities is to ensure that the patient completes treatment according to the physician's orders. It is also important to ensure that the plan is specific for the individual patient and follows the principles of TB treatment.<sup>46</sup>

**Ensure that medications are ordered and given at the correct time, and in the correct dosage.** Review the patient's treatment plan and chart, and correct the medications as necessary.

**Monitor the side effects of and adverse reactions to medication.** Review laboratory findings and contact the treating physician if abnormal results are obtained.<sup>47</sup> The patient should be monitored by a registered nurse and/or clinician or case manager at least monthly for signs and symptoms of adverse reactions until treatment is completed. If a patient is symptomatic, the provider should be consulted and the patient monitored

more frequently. Chemistries and complete blood count (CBC), aspartate aminotransferase (AST)/alanine aminotransferase (ALT), or other tests based on specific drugs should be done periodically per physician's order. See Table 8: **Monitoring and Interventions for Side Effects and Adverse Reactions** in the Treatment of Tuberculosis Disease section.



If a child is taking TB medications at school, communicate at a minimum on a monthly basis with designated staff to determine whether the child is experiencing medication side effects or adverse reactions.<sup>48</sup>

**Assess adherence daily and monthly, and identify positive and negative motivational factors influencing adherence.** An assessment of adherence needs to occur at each patient encounter. If the case manager is not involved in providing DOT, a notification system should alert him or her if the patient misses a DOT dose or if there is suspicion of nonadherence if the case is on self-administered therapy. If a DOT dose is missed, the patient should be contacted the same day or the next business day and the issue escalated to the case manager's supervisor. Direct observation provides immediate information on poor adherence and adverse effects. The key to a successful DOT program is the timely use of this information in order to promptly identify and respond to potential barriers to adherence, missed doses, and potential adverse treatment effects. It is important not to send a mixed message to a patient by not promptly responding to missed DOT doses. If the patient is self-administering TB medications, make a weekly visit to the patient's residence to assess adherence and monitor for side effects and adverse reactions. Also, regularly monitor the effectiveness of enhancement methods (i.e., incentives, enablers, behavioral contracting, or behavior modification).<sup>49</sup> DOT should be initiated if adherence is compromised.

The case manager should ensure that the patient is informed about the consequences of nonadherence, including legal interventions. Changes in the patient's attitude toward the healthcare worker should be noted and verified with the patient.<sup>50</sup>



For more information, see the "Directly Observed Therapy" and "Legal Orders" topics in this section.

**Determine the unmet educational needs of the patient** regarding transmission, diagnosis, and treatment of TB. Identify the concerns and anxieties regarding diagnosis, and need for further education. The educational needs of the patient/family may vary throughout the course of treatment. Patient education also will vary depending on beliefs about TB treatment, acceptance of the diagnosis, coping mechanisms, cultural values, and the accuracy of the information they have already received. The case manager should explore the effect the diagnosis has on the patient's relationships with other family members, coworkers, and social contacts so that appropriate, culturally sensitive information can be provided.<sup>51</sup>



**Educate the patient about the TB disease process** during the course of TB treatment. Provide instruction relevant for the patient's level of education or ability to learn, and address healthcare beliefs that are in conflict with educational information. The case manager should ensure that education is provided in the patient's primary language and that it is culturally appropriate.<sup>52</sup> The case manager should provide patient and family education monthly, until satisfactory recall is obtained.



For more information, see the Patient Education section.

**Advocate for the patient with team members and other service providers** when necessary. The case manager should demonstrate respect and understanding of the patient's cultural beliefs and values, and prevent team members from imposing their own values or belief systems on the patient. The case manager should be able to communicate the patient's fears/anxieties, likes/dislikes, and needs/wants to the team members in a nonjudgmental manner. The case manager must also have an understanding of the team members, and mediate, negotiate, and resolve differences of opinion regarding the patient and interventions.<sup>53</sup>

**Review the status of the contact investigation**, if one was initiated. It has been found that patients may not initially reveal the names of all close contacts. Over time, many more individuals are often identified.<sup>54</sup> The investigation should be repeated if for any reason the index patient becomes AFB sputum smear positive again during treatment and there has been sufficient exposure for the skin-test-negative persons to become infected.

## Monitoring Side Effects and Adverse Reactions

Assess and document side effects and adverse reactions to antituberculosis medications and monitor toxicity. The patient should be monitored by a registered nurse and/or clinician or case manager at least monthly for signs and symptoms of adverse reactions until treatment is completed. If a patient is symptomatic, the provider should be consulted and the patient monitored more frequently. Chemistries and CBC, AST/ALT, or other tests based on specific drugs should be done periodically. See Table 8: **Monitoring and Interventions for Side Effects and Adverse Reactions** in the Treatment of Tuberculosis Disease section.

As is true with all medications, combination chemotherapy for tuberculosis is associated with a predictable incidence of adverse effects, some mild, some serious.<sup>55</sup>

Adverse effects are fairly common and often manageable. Although it is important to be attuned to the potential for adverse effects, it is at least equally important that first-line drugs not be stopped without adequate justification.<sup>56</sup> However, adverse reactions can be severe, and thus, it is important to recognize adverse reactions that indicate when a drug should not be used. Mild adverse effects can generally be managed with symptomatic therapy, whereas with more severe effects, the offending drug or drugs must be discontinued.<sup>57</sup> In addition, proper management of more serious adverse reactions often requires expert consultation.<sup>58</sup>



Instruct patients to report the side effects and adverse reactions listed in the “Side Effects and Adverse Reactions” topic in the Treatment of Tuberculosis Disease section.

To monitor for side effects and adverse reactions, perform the following activities:

- Educate the patient and family to report side effects and adverse reactions
- Assess the patient for side effects and adverse reactions

**Educate the patient and family** to report side effects and adverse reactions. The case manager reinforces prior patient teaching and continues to educate the patient and family about TB medications, signs and symptoms of adverse effects, and the importance of continued treatment and uninterrupted drug therapy. Case managers should be familiar with all TB medications, their side effects, contraindications, and drug interactions.<sup>59</sup>



For more information, see the Patient Education section.

**Assess the patient for adverse reactions and side effects.** For patients on self-administered therapy, the case manager ensures that patients are assessed for adverse effects to TB medications at least monthly and at each visit. If the patient is on DOT or pill counts, staff should assess patients for side effects and adverse reactions on each visit by performing a symptom review. If indicated, order liver function tests and monitor their results. The case manager should be aware of complications in patients on medications by maintaining close communication with outreach staff.<sup>60</sup>

## Monitoring Bacteriologic Improvement

### Sputum Smears and Cultures

During treatment of patients with pulmonary TB, a sputum specimen for microscopic examination and culture should be obtained at a minimum of monthly intervals until two consecutive specimens are negative on culture. More frequent acid-fast bacilli (AFB) smears may be useful to assess the early response to treatment and to provide an indication of infectiousness. For multidrug-resistant TB (MDR-TB) patients, monthly specimens are required. For patients with extrapulmonary TB, the frequency and kinds of evaluation will depend on the site involved.



Call the Montana TB Program at 406-444-0273 to determine how to monitor when the patient

- Is initially culture negative, or
- Has AFB 3+ or 4+ results, or
- Has cavitation on chest radiograph, or
- Has no sputum specimens collected.

If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, collect one sputum specimen per week and submit it for testing until one specimen tests negative. After the specimen tests negative, then obtain two more consecutive sputum specimens collected 8 to 24 hours apart (with at least one being an early morning specimen).

If earlier AFB sputum smears were positive and now AFB sputum smears are negative on three separate, consecutive days, consider discontinuing isolation.<sup>61</sup>

For patients with culture-positive pulmonary TB, collect two or more sputum specimens at least monthly for smears and cultures until persistently negative cultures are documented.<sup>62</sup>

## Continued Positive Sputum Smears or Positive Cultures



If sputum smears are positive after two months, call the Montana TB Program at 406-444-0273.

A patient with continued AFB sputum smear positive results or positive cultures should be evaluated for treatment failure if sputum specimen(s) remain bacteriologically positive (i.e., culture positive and/or AFB sputum smear positive) after three months of treatment or become bacteriologically positive after initially converting to negative.

The case manager should initiate the evaluation of the patient and notify his or her supervisor within one business day. The case manager should also do the following:

1. Review and confirm the patient's medication compliance.
2. Place the patient on DOT, if not already on DOT.
3. Reconfirm the appropriateness of the medication regimen, based on drug susceptibility results and other considerations.
4. If additional antituberculosis drugs are added to the treatment regimen, ensure that at least two new drugs that the patient has not been treated with previously are used.
5. Consider serum drug levels.
6. Repeat cultures and repeat drug susceptibility testing.<sup>63</sup>

## Culture Negative or No Specimens

If a patient is culture negative or no specimens were collected:

1. Review the medications that the patient was on at the time TB medications were started, particularly other antibiotics.
2. If applicable, obtain follow-up chest radiograph reports to determine improvement.
3. Review the patient's symptoms for improvement, if applicable.
4. Review the patient's tuberculin skin testing information (retesting may be appropriate if initially negative or test if not initially done), and discuss this with the patient's provider.
5. Review information with the provider regarding his or her reasons for continuing TB medications.
6. Discuss the above findings with the Montana TB program at 406-444-0273 to determine if the patient is to be reported as a case.



## Verification of Isolate Drug Susceptibility Results

The case manager should obtain and promptly document all positive cultures and respective drug susceptibility results.

- 1. If a patient's TB organism is pan-susceptible:** Follow the recommended treatment regimen.
- 2. If a patient's TB organism is drug resistant:** The Montana TB Program will contact the local health jurisdiction with the drug susceptibility results.
- 3. If isoniazid-resistant or multidrug-resistant TB (MDR-TB):** Place contacts on appropriate latent TB infection (LTBI) treatment regimens. Treatment of LTBI caused by drug-resistant organisms should be provided by, or in close consultation with, an expert in the management of these difficult situations. For patients with MDR-TB, refer to the instructions on Multidrug-Resistant Tuberculosis, provided below.

## Multidrug-Resistant Tuberculosis

If a patient has MDR-TB, the case manager immediately should:

1. Notify his or her supervisor, and
2. Notify the Montana TB Program at 406-444-0273.



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## Completion of Therapy

The case manager should verify completion of therapy. Completion of therapy is essential to ensure that the patient is cured. It is also a State of Montana and Centers for Disease Control and Prevention (CDC) goal and important measurement of the effectiveness of tuberculosis (TB) control efforts. Verification of completion of therapy and a completed contact investigation are the responsibility of the case manager.



Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273.

## Verifying Adequate Course of Treatment

Most cases of active TB can be successfully treated using the standard short course (six months) of therapy. The case manager is responsible for considering the following conditions to ensure that the patient has received an adequate course of therapy.

- **If culture remains positive beyond two months of treatment**, reasons for persistent positive cultures should be examined and treatment adjusted/prolonged.
- **For TB involving the bones or joints or tuberculous meningitis:** These are exceptions to the standard six-month course. See “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in the Treatment of Tuberculosis Disease section.
- **HIV-negative, culture-negative patients:** See “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in the Treatment of Tuberculosis Disease section.
- **Relapse of TB following treatment for TB with pan-susceptible organisms.** Treatment may be prolonged to nine months or more. (Current drug susceptibility testing must be performed and the regimen adjusted if resistance has developed.)<sup>64</sup>

## Calculating Completion of Therapy

So that doses missed due to nonadherence or other treatment interruptions are still given after treatment is resumed, the 2003 revised TB treatment guidelines “Treatment of Tuberculosis” (*MMWR* 2003;52[No. RR-11]) recommend basing the completion of treatment on the number of doses of directly observed therapy (DOT) received rather than on the chronological passage of time (e.g., six months).<sup>65</sup>



For the total number of doses recommended for completion of regimens using first-line drugs, refer to the “Treatment Regimens and Dosages” topic in the Treatment of Tuberculosis Disease section.

## Closures Other than Completion of Therapy

- **Moved:** All attempts should be made by the case manager to obtain the new or forwarding address. If this new address is within the original jurisdiction, the case should be transferred, as per the local public health agency protocol. If the new address is in another jurisdiction, the Montana TB Program should be notified and procedures followed as described in the Transfer Notifications section. Cases should be closed as “moved” only if a new address is obtained.



For information on whom to alert when a case will move or has moved, refer to the Transfer Notifications section.

- **Not TB:** If the completed diagnostic evaluation determined that the diagnosis of TB is not substantiated and another diagnosis is established, the case is closed as “Not TB.”
- **Died:** If the patient expired prior to completion of therapy, the case is closed as “Died.”<sup>66</sup> The local health jurisdiction should provide the date of death on the completion of therapy report and send the form to the Montana TB Program.



Ensure that the contact investigation on the case is also completed. For more information, see the Contact Investigation section.

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# Evaluation

Evaluate case management activities. Patient care is never complete without the evaluation component. In tuberculosis (TB) case management, the achievement of desired outcomes must be evaluated so that services and activities can be improved and TB treatment goals achieved. Evaluation is the outcome of the case management process and should be continuous and ongoing.

Evaluation activities answer the following questions:

- Were the TB treatment plan and control activities implemented in a timely manner?
- Were intermediate and expected outcomes achieved?
- Was the patient satisfied with services or care?
- Were the case manager and the team members satisfied with the plan and outcomes?

To evaluate case management, perform the following activities:

- Monitor monthly, using the “TB Case Monthly Report”
- Monitor reports and the contact investigation

**Monitor the treatment plan at least monthly**, or more frequently, depending on the complexity of treatment and patient variables. Review the appropriateness of interventions, as well as dates when intermediate and/or expected outcomes were achieved. Pay attention to how rapidly the treatment plan was changed when the need was identified. If the treatment plan has remained unchanged, determine the reason why.<sup>67</sup>

**Monitor reports and the contact investigation** to ensure that the TB case reports are accurate and updated according to state standards and that the contact investigation is complete.<sup>68</sup>



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## Directly Observed Therapy

Provide directly observed therapy (DOT), as required. DOT means that a healthcare worker or other designated individual trained by the local health jurisdiction watches the patient swallow every dose of the prescribed TB drugs (“supervised swallowing”). A family member should not be designated to observe therapy. A dose of medication that is delivered to a patient, an address, or a mailbox or left with a family member, friend, or acquaintance is a dose of self-administered therapy (SAT) and should be designated as such.

DOT is a component of case management that helps to ensure that patients receive effective treatment and adhere to it. The American Thoracic Society (ATS), the Centers for Disease Control and Prevention (CDC), and the State of Montana recommend that every tuberculosis (TB) patient be considered for DOT.<sup>69</sup> DOT is implemented because

- DOT is the most effective strategy for making sure that patients take their medicines;
- DOT can lead to reductions in relapse and acquired drug resistance;<sup>70</sup> and
- Directly observing each dose provides immediate information on poor adherence and adverse effects, information that cannot readily be obtained from patients treated with SAT.

## Candidates for Directly Observed Therapy

DOT *should be* the standard of care for all TB cases and suspects. In Montana, DOT *is* the standard of care, that is, it is our goal to place all patients on DOT regardless of the patient’s circumstances, because it has been shown to be such an important treatment tool.<sup>71</sup> The following groups of patients should be given priority for receiving medications by DOT:

- Patients on intermittent regimens
- Pediatric patients with TB disease
- Patients with multidrug-resistant TB (MDR-TB)
- Persons with human immunodeficiency virus (HIV) coinfection and on treatment for latent TB infection (LTBI)
- Immunocompromised persons on treatment for LTBI
- Pediatric contacts on treatment for LTBI
- Household contacts on treatment for LTBI

# How to Deliver Directly Observed Therapy

## Who Can Deliver Directly Observed Therapy?

- Usually TB clinic personnel, such as a nurse or other healthcare worker
- Staff at other healthcare settings, such as outpatient treatment centers
- Other responsible persons, such as school personnel, employers, others trained by the local health jurisdiction
- *Not* family members<sup>72</sup>

## Principles of Directly Observed Therapy

- The healthcare worker should watch the patient swallow each dose of medication.
- Use DOT with other measures to promote adherence.
- DOT can be given anywhere the patient and healthcare worker agree upon, provided the time and location are convenient and safe.<sup>73,74</sup>

## Directly Observed Therapy Tasks

1. Deliver medication.
2. Check for side effects and adverse reactions.



For more information, see the “Ongoing Assessment and Monitoring” topic in this section and the “Side Effects and Adverse Reactions” topic in the Treatment of Tuberculosis Disease section.

3. Verify medication.
4. Watch the patient take pills.



Healthcare workers should watch for tricks or techniques some patients may use to avoid swallowing medication, such as hiding pills in the mouth and spitting them out later, hiding medicine in clothing, or vomiting the pills after leaving the clinic.

If it is necessary to make sure that the patient swallows the pills, the healthcare worker may have to check the patient’s mouth, or ask the patient to wait for a half hour before leaving the clinic so the medication can dissolve in the patient’s stomach.<sup>75</sup>

5. Document the visit.



Use the “Directly Observed Therapy Form 1 - Treatment Record” and “Directly Observed Therapy Form 2 - Side Effects and Adverse Reactions” forms from the “Montana Tuberculosis Forms.” Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273.

6. As necessary and appropriate, do the following:

- a. Provide patient education
- b. Help the patient keep appointments
- c. Connect the patient with social services and transportation
- d. Draw upon familiarity with the patient’s home environment to identify household contacts
- e. Offer incentives and/or enablers to encourage adherence<sup>76</sup>



For more information, refer to the Patient Education section and the “Incentives and Enablers” topic in this section.

## Adherence to Directly Observed Therapy

### Patient Education

The case manager should ensure that education is provided in the patient’s primary language and is culturally appropriate.<sup>77</sup>



For more information, see the Patient Education section. For points to use to explain to the patient why DOT is important, refer to the CDC’s *Questions and Answers About TB 2005. Active TB Disease: What is directly observed therapy?* (Division of Tuberculosis Elimination Web site; 2005).

### Children with Tuberculosis

To facilitate DOT adherence of children with TB, the case manager needs to be familiar with the childhood developmental stages, including important events, and utilize strategies in consideration of these stages.



For more information on adherence strategies for different developmental stages, see Appendix C in the New Jersey Medical School National Tuberculosis Center's *Management of Latent Tuberculosis Infection in Children and Adolescents: A Guide for the Primary Care Provider* (New Jersey Medical School Global Tuberculosis Institute Web site; 2004). This content is no longer available online.

## Agreements

It may be useful to develop a letter of agreement or acknowledgment between the patient and the DOT worker. Some jurisdictions have successfully used these as a method of ensuring adherence to therapy. The DOT worker and the patient negotiate dates, places, and times for DOT services to be provided, and both sign a document stating such agreements. Included in the agreement could be language specifying what consequences may result in the event that the client violates the terms of the contract.<sup>78</sup>



Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273.

## Incentives and Enablers

Incentives and enablers may be appropriate to help patients adhere to DOT.



For more information, see the "Incentives and Enablers" topic in this section.

## Missed Directly Observed Therapy Dose



If a DOT dose is missed, the patient should be contacted on the same day or on the next business day and the issue escalated to the case manager's supervisor.

It is important not to send a mixed message to patients by delaying the response to missed DOT doses. After telling patients that TB treatment is so important for their health and the health of the community, you cannot delay in responding to the failure to be available for DOT.

A missed dose needs to be seen as an opportunity to identify barriers to adherence and work with patients to find ways to successfully complete treatment. The key to a successful DOT program is the use of immediate information on poor adherence, side effects, and adverse reactions in order to promptly identify and respond to potential barriers to adherence, missed doses, and potential adverse treatment effects. This

approach has been referred to as enhanced DOT—the use of a patient-centered approach to promptly identify and address barriers to treatment completion through use of incentives, enablers, and education efforts appropriate to the individual patient.

# Incentives and Enablers

Use incentives and enablers to enhance adherence to therapy.<sup>79</sup> Incentives and enablers are used to improve patient attitudes and to foster good health behaviors.<sup>80</sup> They help patients stay with and complete treatment.<sup>81</sup>

**Incentives** are small rewards given to patients to encourage them to either take their own medicines or keep their clinic or field directly observed therapy (DOT) appointments.<sup>82</sup> **Enablers** are those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties.<sup>83</sup>

Use of incentives and/or enablers should be considered for all cases of tuberculosis (TB) as an adherence-improving measure. The local TB case manager should determine the most appropriate incentive and/or enabler on a case-by-case basis. Payment for incentives and enablers is available on a limited basis through the Montana TB Program. Contact the Montana TB Program for availability of funds.

Some **examples** of incentives and enablers used previously are listed below.

TABLE 1: AVAILABLE INCENTIVES AND ENABLERS

Incentives	Enablers
<ul style="list-style-type: none"> <li>▪ Food and beverages</li> <li>▪ Clothing</li> <li>▪ Automotive supplies</li> <li>▪ Hobby/craft items</li> <li>▪ Household items</li> <li>▪ Laundry services</li> <li>▪ Seasonal/holiday treats</li> <li>▪ Movie passes</li> <li>▪ Restaurant/fast food vouchers</li> <li>▪ Toys</li> <li>▪ Personal care items</li> </ul>	<ul style="list-style-type: none"> <li>▪ Transportation               <ul style="list-style-type: none"> <li>• Bus pass</li> <li>• Cab fare</li> <li>• Battery for patient's car</li> <li>• Gas</li> <li>• Fee for driver's license</li> </ul> </li> <li>▪ Childcare</li> <li>▪ Obtaining and transporting specimens for the patient</li> <li>▪ Assisting the client to get medication refills</li> <li>▪ Rent assistance</li> <li>▪ Assisting the client to complete paperwork to get food/housing assistance</li> <li>▪ Assisting the client to get substance treatment</li> </ul>

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# Legal Orders



For Montana laws and rules on tuberculosis (TB), see the following:

- Chapter 17 (Tuberculosis Control) in Title 50 (Health and Safety) of the Montana Code Annotated (MCA).
- Subchapter 10 (Tuberculosis Control) 37.114.1001–37.114.1016 in the Administrative Rules of Montana (ARM)

Understand when and how to use legal orders, if necessary, for adherence to therapy. Nonadherent adults with pulmonary TB pose the greatest threat to the health of a community. It is the local public health agency's responsibility to ensure that compliance is maintained, treatment is completed, and the risk of transmission to others is eliminated. These responsibilities require that TB staff members be innovative and always "go the extra mile" to see that patients take their medicine as prescribed. The public health mandate and good judgment dictate that program staff should go to every extent possible to fulfill the job responsibilities outlined above before resorting to legal action.<sup>84</sup>

Have an intervention plan that goes step-by-step from voluntary participation to involuntary confinement as a last resort. Refer to Figure 1: **Progressive Interventions for Nonadherent Patients**. Progressive intervention should begin with learning the possible reasons for nonadherence and addressing the identified problems using methods such as directly observed therapy (DOT), incentives, and enablers. The patient should be told orally and in writing of the importance of adhering to treatment, the consequences of failing to do so, and the legal actions that will have to be taken if the patient refuses to take medication.<sup>85</sup>

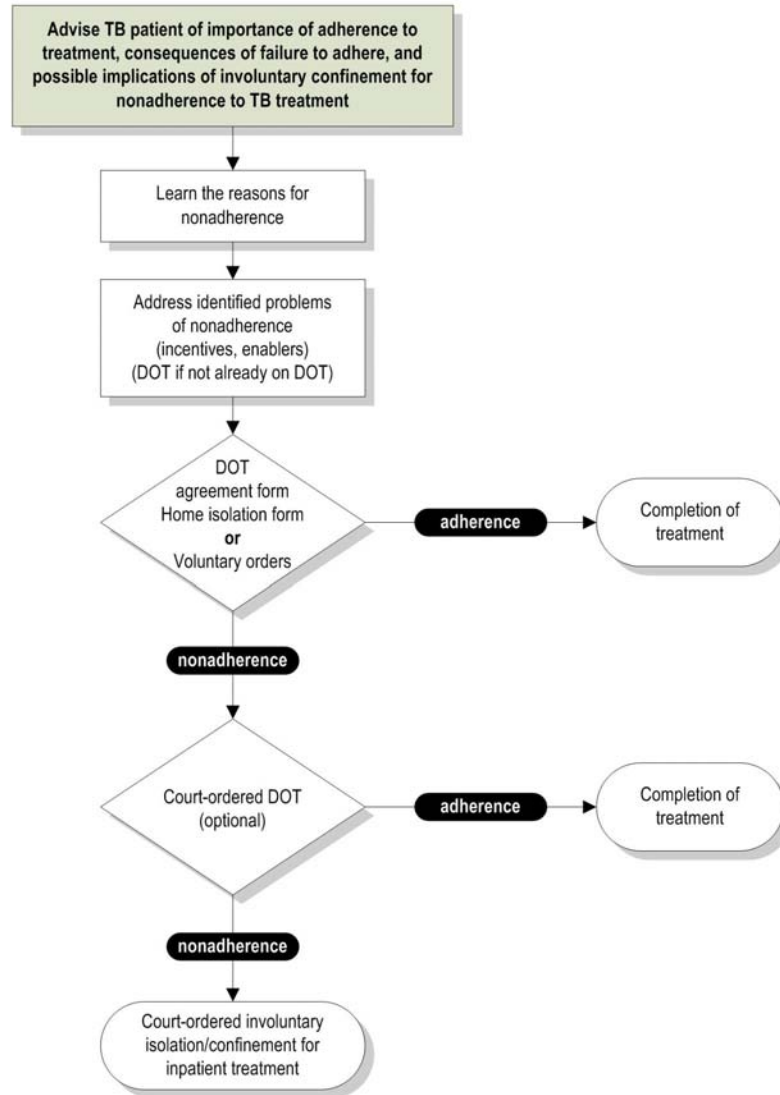
Before legal measures are taken against a patient who has been taking TB drugs on a self-administered basis, DOT should be offered to the patient.<sup>86</sup>

Use a DOT agreement form and home isolation form with a patient who is likely to comply with treatment requirements. With a patient who may need more encouragement to adhere to treatment, complete a voluntary orders form. Voluntary orders are not legal orders but serve to clarify the mutual understanding between the patient and the local public health agency and provide written proof that treatment requirements were communicated to the patient and that the patient agreed to them.

If the patient does not adhere to DOT voluntarily, the next step may be court-ordered DOT. An optional step toward other legal orders, court-ordered DOT can be successful in convincing a patient that his or her TB treatment is an important public health priority. Involuntary confinement or isolation for inpatient treatment should be viewed as the step of last resort, to be used only when all other options fail. However, when a patient with

infectious TB refuses treatment and voluntary isolation, emergency detention to isolate the person is appropriate.<sup>87</sup>

FIGURE 1: PROGRESSIVE INTERVENTIONS FOR NONADHERENT PATIENTS<sup>88</sup>



Definitions of abbreviations: DOT = directly observed therapy; TB = tuberculosis.

Source: CDC. Module 9: Patient Adherence to Tuberculosis Treatment. *Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]. 1999:28.



Criteria for starting isolation and discontinuing isolation will be provided in the Infection Control section of this manual.



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## Resources and References

### General Case Management Resources

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- New Jersey Medical School National Tuberculosis Center. *Tuberculosis Case Management for Nurses: Self-Study Modules* (New Jersey Medical School Global Tuberculosis Institute Web site).

### Directly Observed Therapy Resources

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