

Chapter 7

Case Management

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Introduction

Purpose

Tuberculosis (TB) case management describes the activities undertaken by the local health authority (LHA) and its partners to ensure successful completion of TB treatment and cure of the patient.¹ Case management is a system in which a specific individual (case manager) or a group working together (case management team) is assigned primary responsibility for the care of a patient, systematic regular review of patient progress is conducted, and plans are made to address any barriers to adherence.²

Use this section to understand and follow national and Nevada State guidelines to do the following:

- 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), face-to-face or remotely.
- Use incentives and enablers to improve adherence to therapy.
- 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.³

One reason for incomplete standard treatment is 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, forgetfulness and adverse side effects from the medications.⁴

These adverse outcomes are preventable by case-management strategies provided by TB control programs, including use of DOT.⁵ It is strongly recommended that the initial treatment strategy utilize patient-centered case management with an adherence plan that emphasizes DOT.⁶ 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.⁷ 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.⁸

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.⁹

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



For roles and responsibilities, refer to Chapter 1, *Introduction*, section “Roles, Responsibilities, and Contact Information”, pages 1.14 to 1.20.

Reporting Requirements

Tuberculosis is a reportable disease in Nevada and in accordance with NRS 441A, healthcare professionals, laboratories and pharmacists shall notify the health authority within 24 hours of discovery of any case having active TB or any suspected case considered to have active TB.



A reportable disease form can be found at:

[http://dph.nv.gov/Programs/TB/dta/Forms/Tuberculosis \(TB\) - Forms/](http://dph.nv.gov/Programs/TB/dta/Forms/Tuberculosis (TB) - Forms/).

Check with your LHA prior to reporting as there may be an alternative format for reporting specific to that jurisdiction.

Effective January 13, 201, all Nevada registered or intern pharmacists practicing in the state of Nevada are required to notify the local and/or state health authorities whenever two or more TB medications are dispensed to an individual. Medications include: Ethambutol, Isoniazid, Pyrazinamide, Streptomycin, and any member of the Rifamycin group of drugs including, but not limited to, Rifabutin, Rifampin and Rifapentine, or any other newly developed TB medications.



A pharmacy reporting form can be found at:

[http://dph.nv.gov/Programs/TB/dta/Forms/Tuberculosis \(TB\) - Forms/](http://dph.nv.gov/Programs/TB/dta/Forms/Tuberculosis (TB) - Forms/).

Check with your LHA prior to reporting as there may be an alternative format for reporting specific to that jurisdiction.

Acknowledgments

The authors want to acknowledge the extensive use of two 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 were 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.

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.¹²



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



To document TB cases (both suspected and confirmed), LHA's utilize the NBS system which is a National Electronic Disease Surveillance System (NEDSS).

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) at this hyperlink:

<http://www.currytbcenter.ucsf.edu/node/165>.

For entire document, visit

<http://www.currytbcenter.ucsf.edu/products/view/directly-observed-therapy-training-curriculum-tb-control-programs> .



For assistance with language issues, rights, and responsibilities, see <https://www.kff.org/medicaid/report/ensuring-linguistic-access-in-health-care-settings-2/>. Also see, "Additional resources" in *Enhancing Skills for Cross-Cultural Patient Centered Care*, (Francis J. Curry National Tuberculosis Center Website, 2017) at

http://www.currytbcenter.ucsf.edu/sites/default/files/course-material/%5Bnid%5D/12_cross_cultural_skills_web.pdf .



Minnesota Department of Health's (MDH) Refugee Health and Tuberculosis Program is pleased to offer a show about tuberculosis (TB) for the public, which can be found at

<http://www.health.state.mn.us/divs/idepc/diseases/tb/ed/echo.html>



Another resource for information about cultural beliefs, medical issues and other related issues pertinent to health care can be found at:

<http://www.ethnomed.org/>



For more information on using interpreters, see the “*Working with an Interpreter*” 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) at:

http://www.heartlandntbc.org/assets/training/mini-fellowship/PediatricToolBox/CDC/ed_training/publications/ssmodules/pdfs/9.pdf

Patient’s Medical Records

The case manager, or case management team, needs all medical records in order to provide appropriate case management and recommend an effective case management plan. Prior to the visit with the patient, the case manager, or case management team, 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.¹⁴

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. Start the initial assessment within 1 business day of the case report for infectious or smear positive pulmonary cases; and <3 business days of the case report for others. See MMWR Guidelines for the Investigation of Contacts of Persons with Infectious TB. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm>.

Hospitalized patients: Hospital infection control programs are encouraged to keep patients suspected or confirmed to have TB disease in airborne isolation until at least 3 consecutive AFB negative smears have been collected on separate days with at least one specimen an early morning specimen; the client has been on effective therapy at least 2 weeks **and** is improving clinically.

A hospitalized patient who has suspected or confirmed **drug-susceptible** TB disease and who is deemed medically stable (including patients with positive AFB sputum smear results indicating pulmonary TB disease), may be discharged from the hospital before converting AFB sputum smear results if certain criteria are met:

A specific plan exists for follow-up care with the local tuberculosis (TB) control program.

AND

The patient has been started on a standard multidrug antituberculosis treatment regimen and directly observed therapy (DOT) has been arranged.

AND

No children aged <5 years or persons with immunocompromising conditions are present in the household.

AND

All immunocompetent household members have been previously exposed to the patient.

AND

The patient is willing to remain inside the home except for healthcare-associated visits until the patient has 3 consecutive negative acid-fast bacilli (AFB) sputum smear results.¹⁵

Multi-drug resistant TB Patients: Isolation requirements are extended until **cultures** are consistently negative (at least 3 consecutive negative cultures) if a person is suspected or confirmed to have multi-drug resistant TB.

Isolation requirements may be extended until cultures are consistently negative if there is drug resistance to one or more of the first line drugs. To be determined on a case by case basis.

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.¹⁶

Initial Assessment Activities

To complete an initial assessment, perform the following activities:

- Perform site visits to all sites of potential transmission, including the patient's home. See "Field Investigation", p. 8, *MMWR Guidelines for the Investigation of*

Contacts of Persons with Infectious TB.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm>

- Obtain and review demographic information.
- Ascertain the extent of TB illness.
- Obtain and review the patient's health history.
- Determine the infectious period. see *CDC. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis*, "Assigning Priorities to Contacts" and Figures 2-4. MMWR 2005;54, at:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm>
- Evaluate the patient's knowledge and beliefs about TB.
- Initiate treatment, if not initiated during the hospital stay.
- Monitor the TB medication regimen.
- Identify any barriers or obstacles to adherence.
- Review psychosocial status.
- Identify and document a thorough history of the patient's social network, to include but not limited to: home, social, work or school, and church site(s).
- Gather information for a contact investigation, if indicated.

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).¹⁷ Several home visits may be needed, because usually not all of the necessary information is gathered from the patient and family at one time. Determine other sites of potential exposure and make arrangements to assess those sites.

Obtain or review the client's demographic information, including the name, address, telephone number(s), birth date, and health insurance provider's name, address, and identifying information.¹⁸

Ascertain the extent of TB illness, including acuity and length of symptoms, bacteriologic and radiographic findings, laboratory analyses, tuberculin screening 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. Consult with the responsible physician and/or program medical consultant upon receipt of a suspect report. Ensure that a TB screening test has been completed, a chest radiograph has been performed and three consecutive sputa specimens have been collected on separate days with at least one being an early morning specimen.



In the case of pulmonary TB in children younger than five years of age, posterior-anterior **and** lateral chest radiographs are important in the initial diagnosis.¹⁹ 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, allergies, and current medications as some 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, as well as information regarding previous hospitalizations. It is important to know the patient’s history of treatment for TB infection and/or disease, especially for patients who have experienced treatment failure(s) or have a relapse of TB disease, as they are at a higher risk for developing multidrug-resistant TB (MDR-TB) or extensively drug-resistant TB (XDR-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.²⁰



Some antituberculosis medications are contraindicated when a patient is taking birth control pills. For more information, see Chapter 4, *Treatment of TB Disease*, section “Side Effects and Adverse Reactions.”

Determine infectiousness or potential infectiousness. To determine the need for and scope of the 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 (typically this means they have TB of the lungs or throat), the case manager should understand the period of infectiousness to focus the contact investigation on only those contacts most likely to be at risk for infection. The parameters of a contact investigation can then be determined, including the need for repeating the TB screening test 8 to 10 weeks from the last exposure or the initial negative TB screening test.²¹



In the case of a child with TB who is younger than five years, the contact investigation should focus on determining the source case of TB; since young children are not likely to transmit TB, they are usually infected by an adult referred to as the “source case.” If a source case is identified, dates of exposure and most recent information concerning the infectiousness of the source case should be documented.



For more information on the period of infectiousness and contact investigations, see Chapter 8, *Contact Investigation*.

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.²²



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.²³ Use age-appropriate educational materials and methods, especially when working with children. When working 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.²⁴

Initiate treatment, if not already initiated. The standard four-drug TB treatment regimen should be initiated promptly whenever a patient is seriously ill (history of cough, hemoptysis, night sweats, fever, weight loss, chest pain, abnormal radiographs, sputum smear positive) with a disorder that is thought to be TB. For patients in whom TB is suspected and who have a life-threatening condition, initiation of treatment should not be delayed because of negative AFB smear results. Disseminated (miliary) tuberculosis, for example, is often associated with negative sputum AFB smears. Likewise, for a patient with suspected TB and a high risk of transmitting *M. tuberculosis*, combination chemotherapy should be initiated in advance of microbiological confirmation of the diagnosis to minimize potential transmission (see MMWR; *Treatment of Tuberculosis*, 2003, specifically, "Deciding to Initiate Treatment," p. 40 at <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>).

The case manager should initiate treatment within one day of being notified that the clinician has completed the medical evaluation and has documented the drugs, dose, route, frequency and duration of the prescribed treatment regimen.

Monitor the TB medication regimen. The case manager ensures that medications and dosages are prescribed according to current American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC)/Infectious Diseases Society of America (IDSA). 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 confirm that hospitals order and give dosages according to current ATS/CDC/IDSA guidelines and are observing patients taking medications. In general, tuberculosis medications are administered together, at one dosing so as to achieve maximal peak serum concentrations and to facilitate DOT.²⁵ The case manager coordinates care with hospital staff to avoid split doses.



For more information on treatment regimens and dosages, see Chapter 4, *Treatment of TB Disease*, “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 (practicing with small candy can be helpful), 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. See “Incentives and Enablers” in this section of the manual.

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

Identify and document a thorough 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 social venues.

Gather information for a possible contact investigation.



For more information see, *Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis*. MMWR 2005;54 at <http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf>

Additional information can be found in this TB Manual, Chapter 8, *Contact Investigation*.

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 or longer), 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.²⁷

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.²⁸

DOT is significantly associated with improved treatment success (the sum of patients cured and patients completing treatment) and with increased sputum smear conversion during treatment, as compared to SAT (self-administered treatment). DOT is the standard of practice.²⁹

The case manager, or case management team, 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.³⁰ The treatment plan should be reviewed and updated at least monthly during reviews of clinical progress.³¹

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 the person managing the contact investigation (note: in small local health authorities, these roles may be performed by only one or two persons)

- Patient educator's name and dates of education sessions
- Method for prevention of transmission: airborne infection isolation, home isolation, legal order for isolation
- Contract Treatment Agreement -signatures of the local health jurisdiction representative and the patient (or patient's representative)
- 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, 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
- Process of ensuring successful completion of treatment (DOT, incentives, enablers)
- Location(s) where DOT will be administered (either in-person or via communication device)
- Intermediate and expected outcomes³²



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) at this hyperlink: <http://globaltb.njms.rutgers.edu/educationalmaterials/productfolder/tbcasenurse.php>

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.³³

Negotiate a plan for evaluation of directly observed therapy (DOT). DOT is the standard of care for all persons with TB and persons being evaluated for TB in Nevada. DOT and/or video DOT (V-DOT), coupled with individualized case management, leads to the best treatment outcomes.

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.³⁴

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.³⁵

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, video DOT or as a last resort, self-administration of medications.
- 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.³⁶ All patients with suspected or proven TB should be tested for HIV infection 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.

Refer patient for services relating to the TB treatment if not available at the local health authority (LHA). 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.

Broker and locate needed services relating to the TB treatment. 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.³⁷ Assistance 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 is the standard of care for TB 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.³⁸



Refer to the "Directly Observed Therapy" section in this chapter, pages 7.30 to 7.34.

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. Depending upon the identified obstacles to completion of therapy, the treatment plan also may include incentives and enablers. To

be effective, incentives and enablers should be meaningful and specific for a particular patient.³⁹ Incentives and enablers should be considered for use with all patients.



For more information on incentives and enablers, see *CDC. Treatment of Tuberculosis*. MMWR 2003;52: specifically, p.17, table 8, available at: <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>

Additionally, see the “Incentives and Enablers” section in this chapter, page 7.35.

Ongoing Assessment and Monitoring

Conduct ongoing assessments and monitor patients at least monthly, either in an ambulatory clinic setting, LHA, or private physician's office. Additional assessments may be needed for patients experiencing problems in their TB treatment, or for those patients who are nonadherent to directly observed therapy (DOT) or follow-up appointments.⁴⁰

There are countless stories from nurses and outreach workers reinforcing the fact that not all information is obtained from the patient or family during the initial visit. Therefore, the case manager must ensure that the list of contacts is updated during follow-up visits to determine the need for further testing. It is important to review the status of the contact investigation to ensure that timelines and standards are followed. Additionally, checking for the accuracy of previously gathered information should occur throughout the patient's TB treatment.⁴¹

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 and dosages are ordered and given as per current American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC) guidelines.
- 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, bacteriologic reports, and radiographic results, including drug susceptibility results and TB symptoms, and comparing them to previously 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 bacteriologic 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.⁴²

The case manager should collect one (1) sputum specimen for acid-fast bacilli (AFB) sputum smear and culture every one-to-two weeks (depending on the extent of the disease) until sputum smear conversion; then collect two additional sputa specimens to obtain three consecutive negative smears, enabling isolation orders to be rescinded. Thereafter, sputa should be collected every two weeks until there are two negative cultures. If a patient is on DOT, no further specimen collection is indicated unless the patient becomes symptomatic. A clinician should complete a medical review monthly until treatment is completed, and periodically based on patient condition or review of diagnostic information, patient chart, and chest radiographs.



Inconsistencies should trigger additional questions, such as the possibility of laboratory contamination. Bring these questions immediately to the attention of the patient's medical provider, LHA, the Nevada State Public Health Laboratory, and the Nevada DPBH TB Program.⁴³



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 and to weigh the child monthly.⁴⁴

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.⁴⁵ 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.⁴⁶

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.⁴⁷

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.⁴⁸ 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 immediately 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 orders. 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.⁴⁹

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 or virtual DOT, VDOT, (includes electronic DOT and Video 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 (i.e. via pill count or pharmacy checks). If a DOT or VDOT 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 (not recommended), 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).⁵⁰

The case manager should ensure that the patient is informed about the consequences of nonadherence, including legal interventions and has signed contracts of understanding with the health authority. Changes in the patient's attitude toward the healthcare worker should be documented and verified with the patient.⁵¹



For more information, see "Directly Observed Therapy" and "Legal Orders" sections in this chapter, page 7.30 and 7.36, respectively.

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.⁵²

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 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.⁵³ The case manager should provide patient and family education at every opportunity and at least monthly until satisfactory recall is obtained.



For more information, see the Chapter 13, *Patient Education*, in this TB Manual.

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 should 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 understand the team members, and mediate, negotiate, and resolve differences of opinion regarding the patient and interventions.⁵⁴

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.⁵⁵

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 Chapter 4, *Treatment of Tuberculosis Disease*, Table 8: **Monitoring and Interventions for Side Effects and Adverse Reactions**, pages 4.17 through 4.23.

As is true with all medications, combination chemotherapy for TB is associated with a predictable incidence of adverse effects, some mild, some serious.⁵⁶

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.⁵⁷ 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. In addition, proper management of more serious adverse reactions often requires expert consultation.⁵⁸



Instruct patients to report the side effects and adverse reactions listed in the “Side Effects and Adverse Reactions” section in Chapter 4, *Treatment of Tuberculosis Disease*.

Activities to Monitor for Side Effects and Adverse Reactions

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.⁵⁹



For more information, see Chapter 13, *Patient Education*.

Assess the patient for adverse reactions and side effects. For patients receiving DOT or video DOT, staff should assess them briefly for side effects and adverse reactions on each visit and thoroughly each month by reviewing medication side effects, in addition to 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 providing DOT. For patients on self-administered therapy, the case manager must ensure that patients are assessed for side effects and adverse reactions to TB medications at least monthly and at each clinic or office visit.⁶⁰

Monitoring Bacteriologic Improvement

Sputum Smears and Cultures

Assess and document response to treatment. 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. If a patient is on DOT, no further specimen collected is indicated unless the patient becomes symptomatic.⁶¹ 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) and extensively-drug-resistant TB (XDR) patients, monthly specimens are required. For patients with “Extrapulmonary TB,” the frequency and types of evaluation will depend on the site involved.

Activities to Monitor for Bacteriologic and Clinical Improvement

If the patient initially had positive AFB sputum smear results, 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 (see *CDC. Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings*; MMWR;2005, specifically, “Sputum Specimen Collection,” p. 51).
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e

If earlier AFB sputum smears were positive and now AFB sputum smears are negative on three separate, consecutive days, consider discontinuing isolation.⁶²



For more information on discontinuing isolation, see *Infection Control*, Chapter 2, in this TB Manual.



Additional information on using NAAT results for discontinuation of airborne isolation, see NTCA, APHL “Consensus statement on the use of Cepheid Xpert MTB/RIF assay in making decisions to discontinue airborne infection isolation I healthcare settings,” (National Tuberculosis Controllers Website) Available at:

http://www.tbcontrollers.org/docs/resources/NTCA_APHL_GeneXpert_Consensus_Statement_Final.pdf

For patients with AFB smear negative, culture-positive pulmonary TB, collect at least one sputum specimen per month for smear and culture until persistently negative cultures are documented.

Continuously or Recurrently Positive Cultures

Patients with persistently positive cultures after 3 months of treatment, with or without ongoing symptoms, require careful evaluation to identify the cause of delayed response.

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Potential reasons for poor treatment response or treatment failure include, but are not limited to:

- Nonadherence in patients not receiving DOT
- Cryptic nonadherence in patients receiving DOT
- Unrecognized drug resistance
- Mal-absorption
- Laboratory error

The case manager should initiate the evaluation of the patient and notify his or her supervisor immediately. 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. Consult with a provider experienced with TB relapse and/or failing regimens is highly recommended. The Curry International TB Center is the western region TB consultation center, warm-line 877-390-6682, or 415-502-4700.
5. 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.
Never Add a Single Drug to a Failing Regimen.
6. Consider performing serum drug level testing.
7. Repeat cultures and repeat drug susceptibility testing.⁶⁴

Culture Negative or No Specimens

Failure to isolate *M. tuberculosis* from sputa specimens in persons suspected of having pulmonary tuberculosis, due to radiographic or clinical findings, does not exclude a diagnosis of active pulmonary TB. Some reasons for failure to isolate *M. tb* include the recent use of antibiotics that have a bactericidal activity against *M. tb* (e.g., fluoroquinolones), paucibacillary load, inadequate sputa specimens, overgrowth of cultures with other microorganisms, or errors in specimen processing.⁶⁵

In some circumstances when extra-pulmonary TB disease is suspected a specimen may not be obtainable from the site of disease, such as ocular TB. In such instances, a diagnosis is made on clinical findings and response to treatment.

If a patient has negative cultures or no specimens were obtainable:

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 status, i.e. improving, worsening, or stable.
3. Review the patient's symptoms and weight for improvement, if applicable.
4. Review the patient's TB screening test information (retesting may be appropriate if initially negative or if a test was 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 LHA, the Nevada State TB Controller and/or the Health Officer 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:**
 - a. Notify the provider for adjustment of medications.
 - b. Consult a clinician experienced with treating drug-resistant TB. Confirm the appropriateness of the regimen.
 - c. Obtain expert opinion and guidance from The Curry International TB Center, the western region TB consultation center, warm-line 877-390-6682, or 415-502-4700.
3. **If isoniazid-resistant or multidrug-resistant TB (MDR-TB) or extensively drug resistant TB (XDR-TB):**
 - a. 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.
 - b. Contact the Curry International TB Center at 877-390-6682, or 415-502-4700 for consultation regarding the treatment of drug-resistant TB.

Multidrug-Resistant Tuberculosis (MDR-TB)

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

1. Notify his or her supervisor and the patient's provider the same day that MDR-TB findings are reported/known.

2. For consultation regarding the treatment of drug-resistant TB, contact the Curry International TB Center at 877-390-6682, or 415-502-4700 for consultation.
3. Initiate transfer of patient care to a more appropriate provider, if necessary. The case manager, with TB clinician and the Health Officer, should confer with the provider and arrange transfer of the case to a provider with experience/expertise in the management of MDR-TB. The case manager must document transfer of care and ongoing follow-up.
4. Obtain appropriate medications from suppliers.
5. Initiate DOT and maintain accurate DOT records. If the patient is nonadherent with DOT, the case manager must document attempts to correct the situation and notify his or her supervisor.
6. Provide the following for patients with MDR-TB:
 - a. Patient education, including information regarding second-line TB drugs
 - b. DOT at the patient's convenience
 - c. Incentives and enablers
 - d. Legal orders, if necessary



For more information, refer to topics in this section on “Directly Observed Therapy, Incentives and Enablers” and “Legal Orders.”

Clinical Response to Treatment

The case manager should monitor/evaluate a patient's clinical response to treatment. The following are indicators of a patient's clinical response to treatment:

1. Lessening or resolution of TB symptoms
2. Weight gain
3. Progressive improvement in the chest radiograph (if pulmonary TB disease is diagnosed and repeat radiographs are ordered)

Isolation

If a patient is isolated, ensure and document the patient's adherence to respiratory isolation.⁶⁶



For more information on isolation and quarantine, refer to Chapter 2, *Infection Control*.

Closing a Case

If the person evaluated for TB is not to be reported as a case (TB disease has been ruled-out), notify the provider that the patient is closed to TB control program services. The patient file can be closed in the TB Registry.



For more information on closing a case of TB, see the following topic below, “Completion of Therapy.”

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 Nevada and the Centers for Disease Control and Prevention (CDC) goal and an 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.



To record verification and closure information, use the National Electronic Disease Surveillance System (NEDSS) available to the LHA. Outside providers should contact their LHA or the Nevada DPBH TB Program at 775-684-5936.

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” section in Chapter 4, *Treatment of Tuberculosis Disease*, page 4.12.



For additional information see: CDC. *Treatment of Tuberculosis. MMWR; 2003*, at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>.

- **HIV-negative, culture-negative patients:** See “Duration of Treatment” in the “Treatment Regimens and Dosages” section in Chapter 4, *Treatment of Tuberculosis Disease*, page 4.12. **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).⁶⁷ See “Management of Relapse, Treatment Failure, and Drug Resistance” in CDC. *Treatment of Tuberculosis. MMWR; 2003*, at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>

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, CDC. *Treatment of Tuberculosis. MMWR; 2003;52[No. RR-11]* found at: <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>, 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).⁶⁸



For the total number of doses recommended for completion of regimens using first-line drugs, refer to the “Recommended Treatment Regimens,” specifically “Definition of Completion of Therapy” (pg.40) in the CDC. Treatment of Tuberculosis Disease. MMWR; 2003, at:

<https://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>

Additionally, see Chapter 4, Treatment of Tuberculosis Disease, section “Treatment Regimens and Dosages,” page 4.5.

Closures Other than Completion of Therapy

- **Moved:** The case manager should obtain the new or forwarding address. Complete and submit copy of the [Interjurisdictional Tuberculosis Notification](#) form, to both the receiving site and Nevada DPBH TB Program. If possible, this form should be submitted to both prior to the patient’s move. 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 State TB Control Offices link on the CDC website at:

<http://www.cdc.gov/tb/links/tboffices.htm>; or the National TB Controllers Association “Community” page at:

<http://www.tbcontrollers.org/community/statecityterritory/#.WsZAJbmGOUk>

- **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.”
- **Lost:** If all attempts to locate the patient fail, the case should be closed as “Lost.”
- **Died:** If the patient expired prior to completion of therapy, the case is closed as “Died.”⁶⁹ The LHA should provide the date of death on the completion of therapy report and also indicate if death was a “TB-related death” or “Non-TB-related death.”



Ensure that the contact investigation on the case is also completed. For more information, see *CDC. Guidelines for the investigation of Contacts of Persons with Infectious Tuberculosis*. MMWR 2005;54, at:

<http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf>

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

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:

- Review the patient's record (i.e., medications, bacteriology, radiographs, patient status, etc.) and update reports sent to Nevada DPBH TB Program
- Review Cohort Review Report
- Review the contact investigation

Review the treatment plan at least every month, 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.⁷⁰

Identify strengths or weaknesses that negatively or positively affected the expected outcome. A good evaluation will lead to positive changes for the patient and others.

Conduct a cohort analysis at least annually to identify variances or common elements among the group, perform more frequently (at least every 6 months) in larger jurisdictions. Cohort review is a "systematic review of the management of TB patients with TB disease and their contacts."⁷¹ With the information learned from the evaluation, the case manager can make changes to improve patient care outcomes.⁷²

Review reports to ensure that the TB case reports are accurate, updated and all data variables are complete. Ensure that the contact investigation is complete.⁷³

Directly Observed Therapy

Provide directly observed therapy (DOT) or virtual DOT (VDOT), 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 is left with a family member, friend, or acquaintance, is considered 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 Nevada Division of Public and Behavioral Health recommend that every tuberculosis (TB) patient have their TB medications administered via DOT.⁷⁴ DOT is the standard of care for TB patients in Nevada because:

- DOT is the most effective strategy for ensuring patients receive appropriate and adequate treatment to cure their TB;
- DOT can lead to reductions in relapse and acquired drug resistance;⁷⁵ and,
- Directly observing each dose provides information about a patient’s response to treatment and any 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 Nevada, and many other public health agencies, DOT *is* the standard of care. Because it has been shown to be such an important treatment tool, it is the goal to place all patients on DOT, which may include virtual DOT (VDOT), regardless of the patient’s circumstances.⁷⁶

Priority situations for the use of DOT include the following conditions/circumstances:

- Infectious pulmonary TB
- Patients who have experienced treatment failure or relapse
- Persons with current or prior substance abuse
- Persons with memory impairment or psychiatric illness
- Patients nonadherent to the prescribed regimen
- Pediatric patients with TB disease
- Patients with multidrug-resistant TB (MDR-TB) or extensively-drug resistant TB (XDR-TB)
- All patients being treated with regimens that use intermittent drug administration have all doses administered under DOT because of the potentially serious

consequences of missed doses, see *CDC. Treatment of Tuberculosis*, “Promoting Adherence.” *MMWR* 2003:52, p. 16. At:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>

- Persons with human immunodeficiency virus (HIV) coinfection and those with HIV on treatment for latent TB infection (LTBI)
- Immunocompromised persons on treatment for TB disease as well as LTBI
- Pediatric contacts on treatment for LTBI
- Household contacts on treatment for LTBI



See *Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis*, “Treatment for Contacts with LTBI.”

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm>

How to Deliver Directly Observed Therapy and Virtual DOT

Who Can Deliver Directly Observed Therapy (DOT) and Virtual-DOT?

- TB clinic personnel or other healthcare worker trained to provide DOT.
- Staff at other healthcare settings, such as outpatient treatment centers.
- Persons outside the LHA, such as school nurses, drug treatment center staff, pharmacists, fire department staff and employers.
- Other responsible persons trained and approved of by the local health authority TB clinic.
- Not family members.⁷⁷

Principles of Directly Observed Therapy and Virtual-DOT

- The healthcare worker, or whoever is providing the DOT, ensures the patient swallows each dose of medication.
- Use DOT with other measures to promote adherence, such as incentives and enablers.



See *CDC. Treatment of Tuberculosis*, “Promoting Adherence,” Table 8, *MMWR* 2003; 52, pg. 17, at:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>

- DOT can be given anywhere the patient and DOT administrator agree upon, provided the time and location are convenient and safe.^{78,79}

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 and dosage.
4. Watch the patient take pills.



DOT providers 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.

As 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.⁸⁰

5. Document the visit.
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.⁸¹



For more information, refer to the “Incentives and Enablers” section in this chapter, page 7.34.

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.⁸²



For more information, see *Patient Education*, Chapter 13. 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) at: http://www.cdc.gov/tb/publications/faqs/qa_TBdisease.htm

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) at: [http://globaltb.njms.rutgers.edu/downloads/products/PediatricGuidelines%20\(Screen\).pdf](http://globaltb.njms.rutgers.edu/downloads/products/PediatricGuidelines%20(Screen).pdf)

Agreements

It may be useful to develop a letter of agreement or acknowledgment between the patient and the LHA and/or the DOT worker. Some jurisdictions have successfully utilized virtual DOT (VDOT), including video DOT and electronic, eDOT, 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.⁸³



DOT Agreement Forms may be available through the Local Health Authority, or can be found in Chapter 18, *Forms, Supplies, and Services*. Additionally, template ideas can be found in New Jersey Medical School National Tuberculosis Center's *Guidelines for Collaborating with Community Physicians*, page 11, at: <http://globaltb.njms.rutgers.edu/downloads/products/collaborating.pdf>

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.

Virtual Directly Observed Therapy

Directly observed therapy (DOT) is the most effective strategy for ensuring that tuberculosis (TB) patients adhere to treatment, and it is the standard of care in Nevada. DOT means that a healthcare worker or another designated person watches the TB patient swallow each dose of the prescribed medication. However, because DOT can be time and resource intensive. Virtual DOT, including video DOT, electronic DOT, is an alternative method to in-person DOT in which a patient is remotely observed (e.g., over a smartphone, tablet) taking his or her TB medication.



For more information on the CDC Toolkit for virtual DOT, see “Implementing an Electronic Directly Observed Therapy (eDOT) Program: A Toolkit for TB Programs” (Division of Tuberculosis Elimination Web site; 2017) at <https://www.cdc.gov/tb/publications/guidestoolkits/tbedottoolkit.htm>

Local Health Department's Tuberculosis Programs should consider developing and implementing virtual DOT programs. A toolkit has been created by the Centers for Disease Control and Prevention to assist local and state programs develop virtual DOT programs. When implementing VDOT on an individual basis, attention must be paid to the patient's ability to utilize and access virtual technologies (eg., Smartphones), continued confidentiality of information transfer, and consent or agreements forms.



VDOT Agreement Forms may be available through the Local Health Authority, or can be found in Chapter 18, *Forms, Supplies, and Services*.

Incentive and Enablers

Use incentives and enablers to enhance adherence to therapy.⁸⁴ Incentives and enablers are used to improve patient attitudes and to foster good health behaviors.⁸⁵ They help patients stay with and complete treatment.⁸⁶

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.⁸⁷ **Enablers** are those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties.

Use of incentives and/or enablers should be considered for all persons with 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. 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"> ▪ Food and beverages ▪ Clothing ▪ Automotive supplies ▪ Hobby/craft items ▪ Household items ▪ Laundry services ▪ Seasonal/holiday treats ▪ Movie passes ▪ Restaurant/fast food vouchers ▪ Toys ▪ Personal care items 	<ul style="list-style-type: none"> ▪ Transportation <ul style="list-style-type: none"> • Bus pass • Cab fare • Battery for patient's car • Gas • Fee for driver's license ▪ Childcare ▪ Obtaining and transporting specimens for the patient ▪ Assisting the client to get medication refills ▪ Rent assistance ▪ Assisting the client to complete paperwork to get food/housing assistance ▪ Assisting the client to get substance treatment ▪ Phone or internet service in order to utilize virtual DOT

Legal Orders



For Nevada State laws and regulations on TB, see the following:

Nevada Revised Statutes, Chapter 441A – Infectious Diseases; Toxic Agents, at: <https://www.leg.state.nv.us/Nrs/NRS-441A.html>

And

Nevada Administrative Code, NAC 441A- Infectious Disease; Toxic Agents, at: <https://www.leg.state.nv.us/NAC/NAC-441A.html>

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 health authority'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.⁸⁸

Progressive Interventions

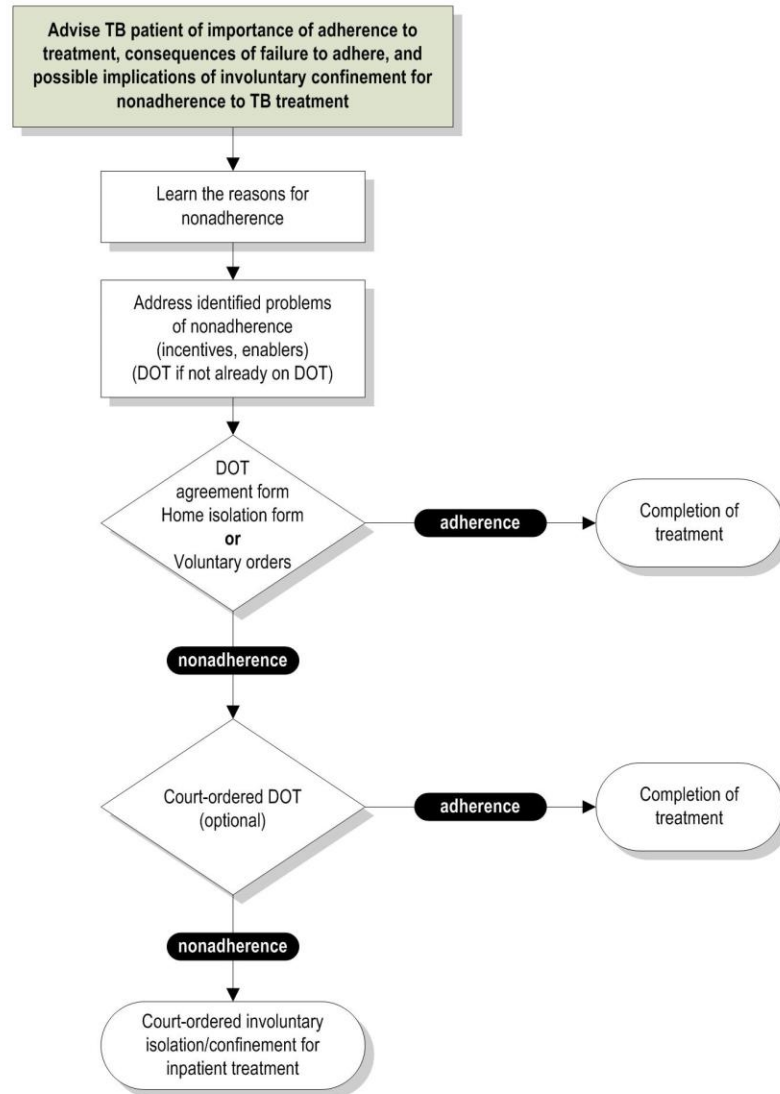
Have an intervention plan that goes step-by-step from voluntary participation to involuntary confinement as a last resort. Refer to Figure 1: **Progressive Interventions for Nonadherent Patients**. Progressive intervention should begin with learning the possible reasons for nonadherence and addressing the identified problems using methods such as directly observed therapy (DOT) and virtual DOT (VDOT), incentives, and enablers. Prior to initiating treatment, the patient should be told verbally, 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.⁸⁹ If necessary, an interpreter needs to be provided during this process.

Before legal measures are taken against a patient who has been taking TB drugs on a self-administered basis, DOT or VDOT should be offered to the patient.⁹⁰

Use a DOT/VDOT 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 and/or VDOT 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.⁹¹

Figure 1: PROGRESSIVE INTERVENTIONS FOR NONADHERENT PATIENTS⁹²



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.

Resources

General Case Management Resources

- CDC. Module 4: “Treatment of Tuberculosis Infection and Disease” (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 2016). Available at: <https://www.cdc.gov/tb/education/ssmodules/default.htm> .
- CDC. Module 9: “Patient Adherence to Tuberculosis Treatment” (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 2016). Available at: <https://www.cdc.gov/tb/education/ssmodules/default.htm>
- California Department of Health Services (CDHS)/California Tuberculosis Controllers Association (CTCA). “TB Case Management—Core Components” (*CDHS/CTCA Joint Guidelines* [CTCA Web site]; May 11, 1998). Available at: <http://www.ctca.org/guidelines/IIA6casemgmt.pdf> .
- New Jersey Medical School National Tuberculosis Center. *Tuberculosis Case Management for Nurses: Self-Study Modules* (New Jersey Medical School Global Tuberculosis Institute Web site). Available at: <http://www.umdnj.edu/globaltb/products/tbcasemgmtmodules.htm> .

Directly Observed Therapy Resources

- CDC. Chapter 6: “Treatment of TB Disease” (*Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]; Updated November 2016). Available at: <https://www.cdc.gov/tb/education/corecurr/index.htm>
- CDC. Module 9: “Patient Adherence to Tuberculosis Treatment” (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 2016). Available at: <https://www.cdc.gov/tb/education/ssmodules/default.htm>
- Francis J. Curry National Tuberculosis Center. *Directly Observed Therapy (DOT) Training Curriculum for TB Control Programs* (Francis J. Curry National Tuberculosis Center Web site; 2003). Available at: <http://www.nationaltbcenter.ucsf.edu/catalogue/epub/index.cfm?uniqueID=1&tableName=DOT> .

CDC. “Implementing an Electronic Directly Observed Therapy (eDOT) Program: A Toolkit for TB Programs” (Division of Tuberculosis Elimination Web site; 2017). Available at <https://www.cdc.gov/tb/publications/guidestoolkits/tbedottoolkit.htm>

Incentives and Enablers Resources

- CDC. Chapter 6: “Treatment of TB Disease” (*Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]; Updated November 2016). Available at: <https://www.cdc.gov/tb/education/corecurr/index.htm>

- CDC. Module 9: “Patient Adherence to Tuberculosis Treatment” (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 1999). Available at: <https://www.cdc.gov/tb/education/ssmodules/default.htm> Legal Orders Resources
- New Jersey Medical School National Tuberculosis Center. *Implementing Legal Interventions for the Control of Tuberculosis* (New Jersey Medical School Global Tuberculosis Institute Web site; 2005). Available at: <http://www.umdnj.edu/globaltb/products/legalinterventions.htm> .

Quick Start Check List

Suggested use of Time Frames and Task Assignments for diagnosis, treatment, and contact investigation of a patient with TB

(Roadmap): Use this table as a quick reference list of tasks or use it as a check list to track that tasks are completed for a specific patient. To read this table, start at the top row and read it from left to right. Continue to the next row below and read it from left to right. Note that this table shows the general sequence of tasks, and the sequence of tasks may differ for individual patients. Also note that not all tasks may be required for all patients. To use this table as a check list, place a copy in the patient's chart and initial in the box next to each task when it is completed. If a task is not needed, cross it off the table. Initial at the bottom of each page when the page is completed.

Table 2: TIME FRAMES & TASK ASSIGNMENTS FOR DIAGNOSIS, TREATMENT, AND CONTACT INVESTIGATION OF A PATIENT WITH TB

MONTH 1 – WEEK 1*				
Start of initial assessment	Receive the TB Suspect/case report and notify the appropriate health authority [_____]	Assign the case manager [_____] <ul style="list-style-type: none"> • Advise staff to don personal respiratory precautions, if necessary 	Implement isolation protocols, if necessary (positive AFB sputum smear and/or cavitary disease). [_____]	Start the initial assessment within ≤ 1 business day of notification of the case. [_____]
Initial interviews and consultations	Consult with the responsible physician and/or program medical consultant for medical examination/case review within ≤ 1 day of notification of the case [_____]	Interview the patient within ≤ 1 business day of the case report (begin patient education, collect patient data to determine infectious period, and gather contact investigation data if needed) [_____] <ul style="list-style-type: none"> • <input type="checkbox"/> Begin RVCT Form and TB contact report 		Visit the patient's residence within ≤ 3 business days after first interview (collect contact investigation data if needed) [_____] <ul style="list-style-type: none"> • Re-interview 1-2 weeks
Medical evaluation	Assure a medical evaluation of the patient takes place within 1 week of referral [_____]	Screen for HIV [_____]	Administer, measure, and interpret a Mantoux TST (or IGRA) [_____]	Collect and submit 3 sputum specimens for AFB smear and culture (if not done earlier). Obtain specimens 8 to 24 hours apart with at least one being an early morning specimen [_____]
	Gather Medical History [_____]	Conduct a physical Exam [_____]	Order Chest X-ray [_____]	

After AFB sputum smear testing completed	Receive results of AFB sputum smear tests (laboratory must report within 2 days of AFB smear result) [_____]	Assure that an NAA (Gene X-pert) test is ordered, if needed to quickly confirm diagnosis of TB for a patient with positive AFB sputum smear. [_____]	Send the written “Confirmed/Suspected Report of Tuberculosis Disease” to the NSHD TB Program within 7 days of the LHA receiving notification of suspect or confirmed case [_____]	Determine the index patient’s infectious period (count three months back from start of symptoms-cough, weight loss, fever, chest pain, night sweats) [_____]
After sufficient medical and laboratory assessment data gathered	For a hospitalized patient, clarify the hospital discharge arrangements and assure that they are communicated to the hospital’s outpatient coordinator and the treating physician(s) [_____]	Obtain baseline biochemistry tests [†] for toxicity monitoring (choose tests based on regimen and specific situations such as HIV infection, history of liver disease, alcoholism, and pregnancy): <ul style="list-style-type: none"> • Complete blood count • Platelets • Liver function tests • Uric acid measurements 	Perform baseline visual acuity and color discrimination tests [†] for toxicity monitoring if the patient is prescribed Ethambutol [_____]	Begin implementing the treatment plan [_____]
			Assure that a written treatment plan is developed [_____] Assure that education is provided to the patient and provider as needed when their signatures are obtained on the treatment plan [_____]	Initiating medical treatment is recommended with a positive AFB sputum smear results [_____]
Decision to investigate	Gather the index patient’s medical records (from hospital, clinic, and/or healthcare provider) (See patient interview and home visit above in the Initial Interviews row.) [_____]		Decide if a contact investigation is indicated (based on positive AFB sputum smear results and/or cavitary disease or pleural TB) [_____]	If an investigation is indicated, start the contact investigation within ≤1 business day of notification of the suspect or confirmed case [_____]
Contact list	During the index patient interview, start listing names and locating information of named contacts and continue listing them throughout the investigation [_____]		Assign an initial priority classification to each contact (and revise as needed when new information is received) [_____]	Review all documentation to ensure that the contact list is complete [_____]

* When a task needs to be completed before the end of the first week, its time frame is bolded.

† For more information on baseline testing, refer to Table 8 in the Treatment of TB Disease section.

MONTH 1 – WEEK 2*

<p>Case management of index patient</p>	<p>Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [_____]</p>	<p>If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported. This usually occurs within 2 months of treatment. If beyond 2 months then other tests may need to be ordered (e.g. blood level drug testing). [_____]</p>	<p>Reassess information about the index patient weekly until drug susceptibility results are available or for 2 months after the case report, whichever is longer</p> <p>Susceptibility reports are usually available within 28 days (first line drugs) if drug resistance then it may take 30 or more additional days to determine total drug resistance. [_____]</p>	<p>If the patient is isolated, determine whether isolation can be discontinued based on conversion of negative sputum smear and culture and if patient is sensitive to all first line drugs.</p> <p>[_____]</p>
	<p>Follow up missed appointments on the same day [_____]</p>	<p>If the patient initially had positive AFB sputum smear results quantified as 3+ to 4+ and/or cavitation, continue collecting one specimen each week until 3 consecutive negative smears and negative culture [_____]</p>	<p>Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs [_____]</p>	
<p>Field investigation and interviews</p>	<p>Complete the field investigation (visiting all potential transmission sites) within 5 days after starting the investigation [_____]</p>	<p>Re-interview the index patient in their home within 2 weeks after the first interview [_____]</p>		
<p>Contact evaluation</p>	<p>Assure that face-to-face initial encounters and a TB screening test (TST or IGRA) is conducted among high- and medium-priority contacts within 7 business days after their being listed in the investigation [_____]</p>	<p>Assure that medical evaluations[†] are conducted and treatment started for LTBI in high-priority contacts who are children and/or have high-risk factors within 5 business days after initial encounters [_____]</p>	<p>Assure that medical evaluations[†] are conducted of other high-priority contacts to index patients with positive AFB sputum smear results within 5 business days after initial encounters [_____]</p>	<p>Review and assess the completeness of contacts' medical follow-up and treatment plans within 5 business days after their medical evaluations [_____]</p>

Data review and reporting	Each week, review documentation to ensure that the contact list is complete [_____]	Each week, collect and analyze data on contacts and TSTs or IGRAs; reassess contact priorities [_____]	Decide whether to continue/expand the investigation based on analysis of TB screening test data [_____]	Report to the Nevada State TB Program all cases or suspect cases of TB are diagnosed and when any extra-ordinary circumstances are encountered. [_____]
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* Most tasks listed on this page should be started and completed during the second week. When a task's time frame may fall outside of the second week, its time frame is bolded.

† Medical evaluation for TST- or IGRA positive contacts includes history and chest radiography. For contacts with symptoms of TB disease, evaluate with history and bacteriology tests.

MONTH 1 – WEEKS 3 AND 4*				
Case management of index patient	Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [_____]	If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+; each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported [_____]	Reassess information about the index patient weekly until drug susceptibility results are available and then reassess at least monthly [_____]	If the patient is isolated, determine whether isolation can be discontinued based upon: <ul style="list-style-type: none"> • Resolution of symptoms upon current treatment. • 3 negative smears and/ or negative cultures. • Current treatment with antituberculosis regimen is appropriate (the strain is known to be susceptible to the regimen). [_____]
	Follow up missed appointments on the same day [_____]		Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs [_____]	
Contact evaluation and treatment	Assure that face-to-face initial encounters and skin (or IGRA) testing are conducted among high- and medium-priority contacts within 3 business days after their being listed in the investigation [_____]	Assure that medical evaluations† are conducted and treatment started for LTBI in high-priority contacts who are children and/or have high-risk factors within 5 business days after initial encounters [_____]	Assure that medical evaluations† are conducted of other high-priority contacts to index patients with positive AFB sputum smear results within 5 business days after initial encounters [_____]	Assure that medical evaluations† are conducted of high-priority contacts to AFB-sputum- smear-negative index patients and medium-priority contacts within 10 business days after initial encounters [_____]

	Assure that treatment is started for LTBI in adult high- and medium-priority contacts that do not have high-risk factors (not on window prophylaxis) within 10 business days of their medical evaluations [_____]	Review and assess the completeness of contacts' medical follow-up and treatment plans within 5 business days after their medical evaluations [_____]	Review and assess the timeliness of initiating the treatment plans for contacts within 10 business days after their medical evaluations [_____]	
Data review and reporting	Each week, review documentation to ensure that the contact list is complete [_____]	Each week, collect and analyze data on contacts and TSTs or IGRAs; reassess contact priorities [_____]	Decide whether to continue/expand the investigation based on analysis of TB screening test (TST or IGRA) data [_____]	Report to the Nevada State TB Program all cases or suspect cases of TB are diagnosed and when any extra-ordinary circumstances are encountered. [_____]

* Most tasks listed on this page should be started and completed during the third and fourth weeks. When a task's time frame may fall outside of the third and fourth weeks, its time frame is bolded.
† Medical evaluation for TST- or IGRA positive contacts includes history and chest radiography. For contacts with symptoms of TB disease, evaluate with history and bacteriology tests.

MONTH 2*				
Case management of index patient	Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [_____]	Conduct ongoing assessment and monitoring at least monthly (clinical response, adverse reactions, adherence) [_____]	If the patient has negative AFB sputum smear results, each month collect sputum specimens and submit them for testing until negative <u>culture</u> results are reported [_____]	If sputum smear results are positive after 2 months of treatment , call the local health officer, medical provider, or experienced TB medical consultant for medical consultation and recommendations. [_____]
	Follow up missed appointments on the same day [_____]	If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported [_____]	Call the local health officer, medical provider, or experienced TB medical consultant to determine how to monitor when the patient: <ul style="list-style-type: none"> • Is culture negative • Had AFB 3+ or 4+ results and/or cavitation on x-ray or • Had no sputum specimens collected [_____] 	

	<p>Repeat liver function tests (AST, ALT and serum bilirubin) † when the patient is taking isoniazid, a rifamycin, or pyrazinamide if</p> <ul style="list-style-type: none"> • Baseline results are abnormal • Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions • Patient has symptoms of adverse reactions <p>[_____]</p>	<p>Question patients taking ethambutol monthly regarding possible visual disturbances, including blurred vision or scotomata (loss of vision in a part of the visual field; blind spot) [_____]</p>	<p>Receive culture results [_____]</p>	<p>If the patient is isolated, determine whether isolation can be discontinued [_____]</p>
		<p>Test visual acuity and color discrimination monthly when the patient is taking ethambutol†</p> <ul style="list-style-type: none"> • In doses >15–25 mg/kg • For >2 months • With renal insufficiency <p>[_____]</p>	<p>Reassess information about the index patient weekly until drug susceptibility results are available or for 2 months after the case report, whichever is longer [_____]</p>	<p>Send updates with changes in treatment plan to Nevada Division of Public and Behavioral Health via the RVCT reporting system.</p> <p>[_____]</p>
			<p>Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs [_____]</p>	
evaluation and treatment	<p>Assure that contacts are assessed monthly for</p> <ul style="list-style-type: none"> • Clinical follow-up • Adherence to LTBI treatment • Adverse reactions to LTBI treatment <p>[_____]</p>	<p>On contacts whose results were initially negative, repeat TST or IGRA testing 8 to 10 weeks after each contact's last exposure to the index patient during the infectious period [_____]</p>	<p>After retesting, reevaluate contacts who were initially TST- or IGRA negative and started on LTBI treatment (window prophylaxis) to determine if treatment should be continued [_____]</p>	
Data review and reporting	<p>Each week, review documentation to ensure that the contact list is complete [_____]</p>	<p>Each week, collect and analyze data on contacts and TSTs or IGRAs; reassess contact priorities [_____]</p>	<p>Determine if transmission occurred and whether to expand the investigation [_____]</p>	<p>After retests are completed, prepare contact information for ARPE (Aggregate Report of Program Evaluation) report for NV reporting of TB Services to the CDC [_____]</p>

* Most tasks listed on this page should be started and completed during the second month. When a task's time frame may fall outside of the second month, its time frame is bolded.

† For more information on follow-up testing, refer to Table 8 in the Treatment of TB Disease section.

MONTHS 3 THROUGH 5*

<p>Case management of index patient</p>	<p>Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [_____]</p>	<p>Conduct ongoing assessment and monitoring at least monthly (clinical response, adverse reactions, adherence) [_____]</p>	<p>When the patient has negative AFB sputum smear results, each month collect sputum specimens and submit them for testing until negative <u>culture</u> results are reported [_____]</p>	<p>If sputum smear results are positive after 2 months of treatment, call the local health officer, medical provider, or experienced TB medical consultant for medical consultation and recommendations. [_____]</p>
	<p>Follow up missed appointments on the same day [_____]</p>	<p>If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported [_____]</p>	<p>Call the local health officer, medical provider, or experienced TB medical consultant to determine how to monitor when the patient:</p> <ul style="list-style-type: none"> • Is culture negative • Had AFB 3+ or 4+ results and/or cavitation on x-ray or • Had no sputum specimens collected <p>[_____]</p>	
	<p>Repeat liver function tests (AST, ALT and serum bilirubin) † when the patient is taking isoniazid, a rifamycin, or pyrazinamide if</p> <ul style="list-style-type: none"> • Baseline results are 	<p>Question patients taking ethambutol monthly regarding possible visual disturbances, including blurred vision or scotomata (loss of vision in a part of the visual field; blind spot) [_____]</p>	<p>Receive culture results [_____]</p>	<p>If the patient is isolated, determine whether isolation can be discontinued [_____]</p>

	<p>abnormal</p> <ul style="list-style-type: none"> • Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions • Patient has symptoms of adverse reactions <p>[_____]</p>	<p>Test visual acuity and color discrimination monthly when the patient is taking ethambutol†</p> <ul style="list-style-type: none"> • In doses >15–25 mg/kg • For >2 months • With renal insufficiency <p>[_____]</p>	<p>Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician’s orders and order drugs [_____]</p>	<p>Send updates with changes in treatment plan to Nevada Division of Public and Behavioral Health via the RVCT reporting system.</p> <p>[_____]</p>
Contact treatment and investigation	<p>Assure that contacts are assessed monthly for</p> <ul style="list-style-type: none"> • Clinical follow-up • Adherence to LTBI treatment • Adverse reactions to LTBI treatment [_____] 	<p>Each week, review documentation to ensure that the contact list is complete [_____]</p>		

* Most tasks listed on this page should be started and completed during the third to fifth months. When a task’s time frame may fall outside of this period, its time frame is bolded.
† For more information on follow-up testing, refer to Table 8 in the Treatment of TB Disease section.

MONTHS 6 THROUGH 9*				
Case management of index patient	<p>Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [_____]</p>	<p>Follow up missed appointments on the same day [_____]</p>	<p>Conduct ongoing assessment and monitoring at least monthly (clinical response, adverse reactions, adherence) [_____]</p>	<p>When the patient has negative AFB sputum smear results, each month collect sputum specimens and submit them for testing until negative <u>culture</u> results are reported [_____]</p>
	<p>Repeat liver function tests (AST, ALT and serum bilirubin) † when the patient is taking isoniazid, a rifamycin, or pyrazinamide if</p> <ul style="list-style-type: none"> • Baseline results are 	<p>Question patients taking ethambutol monthly regarding possible visual disturbances, including blurred vision or scotomata (loss of vision in a part of the visual field; blind spot) [_____]</p>	<p>Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician’s orders and order drugs [_____]</p>	<p>Send updates with changes in treatment plan to Nevada Division of Public and Behavioral Health via the RVCT reporting system.</p> <p>[_____]</p>

	<p>abnormal</p> <ul style="list-style-type: none"> • Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions • Patient has symptoms of adverse reactions <p>[_____]</p>	<p>Test visual acuity and color discrimination monthly when the patient is taking ethambutol†</p> <ul style="list-style-type: none"> • In doses >15–25 mg/kg • For >2 months • With renal insufficiency <p>[_____]</p>	<p>Verify completion of TB treatment 6 to 9 months after treatment was started (depending upon regimen, adherence, response to treatment, number of weeks on DOT, and number of doses required and taken) [_____]</p>	
Contact treatment and investigation	<p>Assure that contacts are assessed monthly for</p> <ul style="list-style-type: none"> • Clinical follow-up • Adherence to LTBI treatment • Adverse reactions to LTBI treatment [_____] 	<p>Verify completion of LTBI treatment 3 to 9 months after treatment was started (depending upon regimen, adherence, number of weeks on treatment and/or number of doses required and taken) [_____]</p>	<p>Each week, review documentation to ensure that the contact list is complete [_____]</p>	

* Most tasks listed on this page should be started and completed during the sixth to ninth months. When a task's time frame may fall outside of this period, its time frame is bolded.

† For more information on follow-up testing, refer to Table 8 in the Treatment of TB Disease section.

MONTHS 10 THROUGH 12*				
Case management of index patient	<p>Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [_____]</p>	<p>Follow up missed appointments on the same day [_____]</p>	<p>Conduct ongoing assessment and monitoring at least monthly (clinical response, adverse reactions, adherence) [_____]</p>	<p>When the patient has negative AFB sputum smear results, each month collect sputum specimens and submit them for testing until negative <u>culture</u> results are reported [_____]</p>
	<p>Repeat liver function tests (AST, ALT and serum bilirubin) † when the patient is taking isoniazid, a rifamycin, or pyrazinamide if</p> <ul style="list-style-type: none"> • Baseline results are 	<p>Question patients taking ethambutol monthly regarding possible visual disturbances, including blurred vision or scotomata (loss of vision in a part of the visual field; blind spot) [_____]</p>	<p>Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs [_____]</p>	<p>Send updates with changes in treatment plan to Nevada Division of Public and Behavioral Health via the RVCT reporting system. [_____]</p>

	<p>abnormal</p> <ul style="list-style-type: none"> • Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions • Patient has symptoms of adverse reactions <p>[_____]</p>	<p>Test visual acuity and color discrimination monthly when the patient is taking ethambutol†</p> <ul style="list-style-type: none"> • In doses >15–25 mg/kg • For >2 months • With renal insufficiency <p>[_____]</p>	<p>Verify completion of TB treatment 6 to 9 months after treatment was started (depending upon regimen, adherence, response to treatment, number of weeks on DOT, and number of doses required and taken) [_____]</p>	
<p>Contact treatment and investigation</p>	<p>Assure that contacts are assessed monthly for</p> <ul style="list-style-type: none"> • Clinical follow-up • Adherence to LTBI treatment • Adverse reactions to LTBI treatment [_____] 	<p>Verify completion of LTBI treatment 3 to 9 months after treatment was started (depending upon regimen, adherence, number of weeks on treatment and/or number of doses required and taken) [_____]</p>	<p>Each week, review documentation to ensure that the contact list evaluations are complete, and data has been documented [_____]</p>	<p>Prepare and send contact information (ARPE report) to DPBH TB Program for NV reporting of TB Services to the CDC [_____]</p>

* Most tasks listed on this page should be started and completed during the tenth to twelfth months. When a task's time frame may fall outside of this period, its time frame is bolded.

† For more information on follow-up testing, refer to Table 8 in the Treatment of TB Disease section.

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