Chater 9: Case Management for TB Disease

Contents

Introduction

Purpose

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

Use this section to understand and follow national and Wisconsin 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 or oversee delegation of directly observed therapy (DOT) or video directly observed therapy (vDOT), when appropriate
- Utilize TAP and local resources for 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 failure to complete standard treatment is that patients have difficulty adhering to the lengthy course of treatment. Poor adherence to treatment regimens might result from difficulties with access to the health care system, cultural factors, homelessness, substance abuse, lack of social support, rapid clearing of symptoms, or forgetfulness.[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] Wisconsin has aligned its practice with national standards, performing DOT or vDOT as the standard of practice for all patients with active TB disease.

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 local public health agencies differ in their staffing and organization and that no set of guidelines can cover all the situations that may arise relating to case management.[11]

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

Forms

Required and recommended forms are available on the Wisconsin Tuberculosis Program's website.

The Wisconsin Tuberculosis Program also offers a Nurse Case Management for Active Tuberculosis guide that has sample forms and letter templates that can be used, as well as other tools that may be useful in case management.

We also offer many resources and informational materials on our website, in the TB Nurse Care Management section.

Acknowledgments

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

The New Jersey Medical School National Tuberculosis Center's Tuberculosis Case Management for Nurses: Self-Study Modules course is a comprehensive and well-written overview of case management for a national audience. The text for large portions of the "Initial Assessment," "Treatment Plan," and "Ongoing Assessment and Monitoring" topics was taken 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 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 health care 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]

Required and recommended forms are available on the Wisconsin Tuberculosis Program's webpage.

Cultural sensitivity and language barriers

In the initial assessment, consider cultural sensitivity and language barriers. To improve the validity and quality of the assessment information, health care workers need to be culturally sensitive in approaching each patient. A medical interpreter should be made available for patients whose primary language is not English. Cultural liaisons or translators may also be valuable resources for programs with consistent cultural or non-English language speaking populations.

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.

For assistance with language barriers, see the National Health Law Program and The National Council on Interpreting Health Care's Language Services Resource Guide for Health Care Providers.

For more information on using interpreters, see the Interpretation Services lesson in Module 9: "Patient Adherence to Tuberculosis Treatment" of the CDC's Self-Study Modules on Tuberculosis.

Patient's medical records

All medical records are needed in order to provide case management and recommend a treatment plan. Prior to the visit with the patient, the case manager should ensure that a copy of all the patient's medical records (from hospitals, clinics, and other health care providers) and chest radiographs are available to the treating physician and nurse case manager. Without the medical records, the physician may not be able to make the correct judgments in medical management.[14]

Assessment site

The case manager (or designee) should make an initial hospital visit **within one business day of a referral or case report** to assess the condition of the patient and begin the contact investigation.

If the patient is hospitalized, conduct the initial assessment during the patient's hospitalization. If the patient is not hospitalized, conduct the initial assessment at the first clinic visit or during a home visit.

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.[15] The Wisconsin Tuberculosis Program offers a Discharge Checklist for Active/Suspect Tuberculosis Disease that can help ensure continuity of care for clients being discharged from the hospital setting.

Initial assessment activities

To complete an initial assessment, perform the following activities:

- Visit the patient's home
- Obtain or review demographic information
- Ascertain the extent of TB illness
- Obtain and review the patient's health history

- Determine infectiousness or potential infectiousness
- Evaluate the patient's knowledge and beliefs about TB
- Initiate treatment, if not initiated during 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
- Gather information for a possible contact investigation

Visit the patient's home. During the patient's TB treatment, at least one or more home visits are required. Home visits are useful for confirming the patient's address, particularly for patients at high risk for default from treatment. Information gathered at the patient's home is often more revealing than assessments performed in the clinical or health department settings and can lead to a more accurate understanding of the patient's lifestyle (for example, seeing a child's shoes or toys when a child was not named in the contact investigation).[16] It is also possible to glean areas of misunderstanding or miscommunication, for example, seeing things that suggest the person has had others in the location or has left the location. This can supply valuable insights into where more education is needed. Several home visits may be needed because usually not all the necessary information is gathered from the patient and family at one time. It may take weeks to gain trust and elicit contact information.

Obtain or review demographic information, including the name, address, telephone number(s), birth date, Social Security number, and health insurance provider's name, address, and identifying information.[17]

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

Diagnostic activities should be completed within specific time frames. The responsible provider should be consulted within one business day of receipt of a suspect report. If not already performed, a tuberculin skin test should be placed, measured, and interpreted or an IGRA blood test performed; and a chest radiograph should be taken and interpreted. Also, **as soon as feasible from notification of a suspected case, a minimum of three consecutive sputum specimens of good quality should be collected eight to 24 hours apart (with at least one being an early morning specimen) and submitted to the laboratory.**

In the case of pulmonary TB in children younger than 5 years of age, posterior-anterior and lateral chest radiographs ("2-view CXR") are important in the initial diagnosis.[18] Adults who are suspected to have TB or who are already diagnosed with TB disease, may only need an initial posterior-anterior chest radiograph, although the lateral view may increase the quality of the image.

Obtain and review the patient's health history to determine concurrent medical problems, including human immunodeficiency virus (HIV) disease or risk factors, country of birth, sexual history, allergies, or medications that may interfere with TB drugs. The case manager should obtain the names, addresses, and telephone numbers of the patient's primary care provider and any specialists involved in his or her medical care, previous hospitalizations, allergies, and current non-TB medications. It is important to know the patient's history of treatment for TB infection or disease, especially for those who have experienced past treatment failure or have a relapse of TB disease, as they are at a higher risk for developing multidrug-resistant TB (MDR-TB). It is also important to determine what the patient perceives as his or her most important medical or health problem. The date of the last menstrual period and contraceptive use should be obtained from female patients of childbearing age.[19]

Patient's able to get pregnant may need to use alternate forms of birth control while on TB medications (barrier methods). Remind patients to discuss all medications and interactions with their providers. For more information, see the "Side Effects and Adverse Reactions" topic in the Treatment of Tuberculosis Disease section.

Determine infectiousness or potential infectiousness. To determine 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, the case manager should have an understanding of the period of infectiousness. The parameters of a contact investigation, including the need for repeating the TB test (either TST or IGRA) for contacts that were initially negative, can then be determined.[20]

In the case of a child with TB who is younger than 5 years, the contact investigation should focus on determining the source case of TB, since young children are not likely to transmit TB. 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 the Contact Investigation section.

Evaluate the patient's knowledge and beliefs about TB, including a history of TB in family 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 verbal information.[21]

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 health care provider alone. Keep in mind that parents who have misinformation or cultural bias about TB may affect their children's understanding of the disease.[22] 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.[23]

Initiate treatment, if not initiated during the hospital stay. A clinician should initiate medical treatment within 48 hours of positive acid-fast bacilli (AFB) sputum smear results (unless there is evidence that the AFB is not *Mycobacterium tuberculosis* complex, for example, by direct test of sputum) or a presumptive diagnosis. A clinician should complete medical evaluations within one week of a referral. As soon as possible after receipt of medical orders which document drugs, dose, route, frequency, and duration, the case manager should submit the medication order to the TB dispensary. The case manager then should initiate treatment as soon as possible after receiving the drugs. The Wisconsin Tuberculosis Program's goal is that clients will start treatment within seven days of suspicion or diagnosis of TB.

Monitor the TB medication regimen. The case manager should ensure that medications and dosages are prescribed according to current American Thoracic Society (ATS) and CDC guidelines. If the initial assessment occurs during the patient's hospitalization, the case manager should ensure that the ingestion of the TB medication is observed by a nurse. It is important to ensure that hospitals order and give the right doses and are observing patients taking medications. Since the outpatient phase of treatment will involve giving TB medications at one time, hospitals should be discouraged from splitting dosages for:

- Taking medications more than once a day creates an expectation for the patient that will have to change after discharge from the hospital.
- Tolerance to the full dosage cannot be assessed while in the hospital.
- Splitting doses of individual medications decreases the serum concentration of the medications and can reduce the bactericidal efficacy of the regimen.

Nurse case managers should ensure that all oral TB medications are given at the same time during hospitalization and before discharge. All medications in the TB regimen are intended to be taken together. The patient's tolerance to TB medications should be noted, and interactions with other medications should be determined prior to the patient starting TB medications.[24]

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

If the medications will be given to a child in a school or daycare setting, parental authorization must be obtained.

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 health care provider. It may be necessary to teach people how to take pills, or it may be necessary to crush the pills and put them in food, such as pudding

or applesauce. In addition, the case manager should determine the need for enablers and identify incentives that will be most valuable to the patient.

Review psychosocial status to identify unmet needs, the use of alcohol or illegal drugs, and any pre-existing psychiatric diagnoses.[25]

Identify and document a thorough history of the patient's social network. This is important to identify and document if 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 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, or school should be noted. In order to identify those who have shared common air space with the infectious, untreated patients with TB, it is necessary to have an understanding of the patient's social and recreational activities and how they spend leisure time. This includes time spent at bars or restaurants, with friends and family, faith-based functions and worship, or sports or hobby groups.

Gather information for a possible contact investigation. A contact investigation should begin three or less business days after of a case/suspect report. Attempts should be made to elicit contacts and have people evaluated as soon as possible, but it is also possible it may take time to build patient trust and recall all events and contacts. As soon as contacts are identified however, they should be notified and educated about next steps for testing and evaluation.

For more information, see the Contact Investigation section.

Treatment plan

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

To ensure that therapy is completed, a treatment plan should be based on data collected by the health care 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.[26]

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.[27]

The case manager is responsible for the overall plan, including documentation, monitoring the patient response, interventions, intermediate and expected outcomes, and initiating changes in the plan to reflect changes in circumstances.[28] The treatment plan should be reviewed and updated at least monthly during reviews of clinical progress.[29]

To develop a treatment plan, see the "Treatment Plan" example included in the Nurse Case Management for Active Tuberculosis Disease guide. Also consider the elements identified in the next section "Treatment Plan Components."

Treatment plan components

The components of a treatment plan include:

- Patient's verified address and contact information.
- Assignment of responsibilities: case manager, clinical supervisor (nurse, physician, or physician assistant), DOT workers, other caregivers (outreach workers, nurses), and person managing the contact investigation.
- Patient educator's name and dates of education sessions.
- Method for prevention of transmission: no isolation, airborne infection isolation, home isolation, legal order for isolation.
- Planned course of antituberculosis drug therapy.
- Estimated date of completion of treatment.
- Test results from initial medical evaluation.
- Medical history.
- Diagnosis.
- Monitoring activities and schedule to assess response to therapy.
- Baseline tests, monitoring activities, and schedule to detect potential side effects and adverse reactions.
- Potential drug interactions.
- Potential treatment adherence obstacles.

- Personal service needs.
- Referrals for social services.
- Means of ensuring successful completion of treatment (DOT or vDOT, incentives, enablers).
- Location(s) where DOT will be administered.
- Approvals and signatures of the attending physician, local public health agency representative, and the patient.
- Intermediate and expected outcomes.[30]

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.

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 health care continuum and prevent duplication and fragmentation of services. The plan should be discussed and validated with all team members and the patient.[31] DOT should be the standard of care for anyone on a regimen for active TB disease.

Establish time frames in the treatment plan to monitor the plan and patient response. Monitoring should be done at least every month at the patient's home, ambulatory clinic, health department, private physician's office, or other mutually agreed upon location. 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.[32]

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.[33]

Implementation activities

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

- Refer the patient to other health care providers, social service agencies, or community organizations as needed.
- Broker and locate needed services relating to TB treatment.
- Negotiate a plan for DOT.
- Coordinate strategies to improve adherence.

Refer the patient to other health care 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.[34] All patients with suspected or proven TB should be assessed for HIV risk and offered counseling and voluntary testing for HIV, with referral for HIV treatment services when necessary. If HIV testing is not easily accessible at the client's clinic, health department, or lab, free at-home test kits may be available. Please request this service from the state TB program as needed. Referrals to medical specialists for conditions that would endanger the patient or affect the outcome of treatment should be made as soon as possible. The patient should be sent to an emergency department if the condition is serious when assessed by the case manager. The case manager should follow up a referral to obtain medical information and determine whether the necessary medical intervention has been completed.

Broker and locate needed services relating to the TB treatment. This may include laboratory, auditory, or visual acuity testing; additional radiographs; or other tests required specifically for the patient. It is important to schedule or assist the patient in scheduling appointments and to monitor the patient's adherence. An understanding of the patient's financial resources and health insurance coverage is important at the time of diagnosis/ medication order. Coverage for TB medications is available via the state dispensary pharmacy program. All medications must be requested and approved for fill via the state program to be eligible for payment assistance or coverage. Lack of financial resources or health insurance will affect the patient's willingness to keep appointments, which may be critical to their health. The case manager may need to discuss essential services with insurance companies or other health care providers to obtain the most cost-effective, quality service.[35] Billing departments may need to be reminded to bill at the Medicaid rate in the situation when no insurance is available, to make reimbursement via the state programs possible. 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. DOT is the standard of care for all patients. The case manager should ensure the plan is suitable for the patient's needs and achievable by the health care provider(s) and then have the patient sign a DOT agreement (as part of the Active TB Disease

Treatment Agreement found on page 22 of the Nurse Case Management publication. 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.[36] Video DOT may also be an option for the patient.

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

Coordinate strategies to improve adherence. The case manager must have knowledge of and proficiency in strategies to improve patient adherence, understand the importance of developing and maintaining a therapeutic relationship, and be familiar with the principles and practices of behavioral contracting and behavioral modification. Collaboration with team members is essential to obtain as much information as possible about strategies to improve adherence of individual patients and elicit opinions, attitudes, and feelings expressed by the patient. Incentives and enablers should be considered for use with all patients. Depending upon the obstacles to completion of therapy, the treatment plan also may include incentives and enablers, and to be effective, incentives and enablers should be meaningful and specific for a particular patient.[37]

For more information on incentives and enablers, see the "Treatment of Tuberculosis" topic, Table 15.6, and the "Incentives and Enablers" topic in this section.

Ongoing assessment and monitoring

Conduct ongoing assessments and monitor patients at least every month either in an ambulatory clinic setting, local public health agency, or private physician's office. Schedule additional assessments throughout the month for patients experiencing problems with their TB treatment, or for those patients who are nonadherent to directly observed therapy (DOT) or follow-up appointments.[38]

There are countless stories from nurses and outreach workers reinforcing the fact that not all information is obtained from the patient or family at one time. Therefore, the case manager must ensure that the list of contacts is updated from time to time and determine the need for further testing. It is also important to review the status of the contact investigation to ensure that timelines and standards are followed. Also, checking for the accuracy of previously gathered information should occur throughout the patient's TB treatment.[39]

For ongoing assessment and monitoring, document information and updates in the appropriate section(s) of the client's WEDSS record.

Wisconsin DHS has training for new staff on documenting TB, LTBI, and contact investigation information in WEDSS.

Ongoing assessment activities

To complete an ongoing assessment, perform the following activities:

- Monitor the clinical response to treatment.
- Determine human immunodeficiency virus (HIV) status and the risk factors for HIV disease, and refer the patient for treatment, if indicated.
- Review the treatment regimen.
- Ensure that medications are ordered and given at the correct time, and in the correct dosage.

Refer to American Thoracic Society/ Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis for dosing recommendations.

- Determine the unmet educational needs of the patient.
- Assess adherence daily and monthly and identify positive and negative motivational factors influencing adherence.
- 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, comparing them to previous documented findings. This review is an important measurement of clinical improvement, worsening, or stabilization of the patient's condition.

For patients with cavitation or who have sputum smears that are 3+ (moderate) or 4+ (many), wait two or more weeks after the start of treatment to collect the first follow-up sputum specimen. If that specimen is smear negative, obtain a second sputum specimen. If the second is smear negative, obtain a third sputum specimen. If any are smear positive, wait one week, and start the process over until you have three consecutive negative smear specimens.

For patients without cavitation, or who have sputum smears that are 1+ (rare) or 2+ (few), a single sputum specimen can be collected after one week of treatment. If the first sputum is smear negative, obtain a second, if the second is smear negative, obtain a third. If any are smear positive, wait one week, and start the process over until you have three consecutive negative smear specimens.

The case manager should collect three sputa specimens for acid-fast bacilli (AFB) sputum smear and culture every month until sputum smear conversion (established through two consecutive specimens that are negative by culture). A clinician should complete a medical evaluation every month until treatment is completed and periodically based on patient condition or review of diagnostic information, patient chart, and chest radiographs. If the patient's condition is worsening, interview the patient to determine the potential cause(s) for the worsening condition and report findings to the treating physician or provider. 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.[40]

Inconsistencies should trigger additional questions, such as the possibility of laboratory contamination. Bring these questions immediately to the attention of the physician and the Wisconsin Tuberculosis Program staff.[41]

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. [42]

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.[43] 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.[44]

The Wisconsin Tuberculosis Program has partnered with Simple HealthKit™ to offer at-home HIV testing to clients. If you have a client who is interested in this program, please contact the Wisconsin Tuberculosis Program at 608-261-6319 to request a test kit be sent to the client.

Additionally, the Wisconsin Department of Health Services' HIV Program offers many resources for use with clinician and patient education

Review the treatment regimen to verify that the provider's orders are clear and concise. One of the case manager's primary responsibilities is to ensure that the patient completes treatment, and that the treatment aligns with CDC guidance or is expert clinician guided. It is also important to ensure that the plan is specific for the individual patient and follows the principles of TB treatment.[45]

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 provider if abnormal results are obtained.[46] The patient should be monitored by a registered nurse or clinician or case manager at least every month for signs and symptoms of adverse reactions until treatment is completed. If a patient is symptomatic, the provider should be consulted, and the patient monitored more frequently. Chemistries and complete blood count (CBC), aspartate aminotransferase (AST)/alanine aminotransferase (ALT), or other tests based on specific drugs should be done periodically per orders from the patient's medical provider. See Table 6.9: **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 weekly with designated staff to determine whether the child is experiencing medication side effects or adverse reactions.[47] School nursing staff may also need education about DOT and side and adverse effects to monitor for on TB medications.

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. 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. If the case manager is delegating DOT to other trained staff, they should be notified if the patient misses a DOT dose or if there is suspicion of nonadherence so any issues can be addressed early. A preventable interruption in treatment can be avoided if the case manager is notified immediately, rather than when the monthly DOT rate is calculated. If a DOT dose is missed, the patient should be contacted the same day, or the next business day and the issue escalated. If treatment lapse is more than one week, please also notify the state TB program so troubleshooting can continue. The patient's provider may also need to be involved in getting the patient back on therapy, depending on the reasons DOT was not done.

Regularly monitor the effectiveness of enhancement methods (that is, incentives, enablers, behavioral contracting, or behavior modification).[48]

Policies and procedures must be in place to establish the expected weekly DOT schedule. The case manager should review the monthly adherence rate to ensure that patients achieve the expected adherence rate. DOT should be increased if adherence is compromised, as evidenced by missed pill pick-up appointments, inaccurate pill counts, other reasons to believe treatment is slow or failing, or inability to self-administer on weekends or holidays, in people at high risk of developing TB disease. The case manager should ensure that the patient is informed about the consequences of nonadherence, including legal interventions. Changes in the patient's attitude toward the health care worker should be noted and verified with the patient.[49]

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

Determine the unmet educational needs of the patient regarding transmission, diagnosis, and treatment of TB. Identify the concerns and anxieties regarding diagnosis and need for further education. The educational needs of the patient/family may vary throughout the course of treatment. Patient education also will vary depending on beliefs about TB treatment, acceptance of the diagnosis, coping mechanisms, cultural values, and the accuracy of the information they have already received. The case manager should explore the effect the diagnosis has on the patient’s relationships with other family members, coworkers, and social contacts so that appropriate, culturally sensitive information can be provided.[50]

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 health care beliefs that are in conflict with educational information. The case manager should ensure that education is provided in the patient’s primary language and that it is culturally appropriate.[51] The case manager should provide patient and family education every visit or at least monthly and until satisfactory recall is obtained.

For more information, see the Patient Education section.

Advocate for the patient with team members and other service providers when necessary. The case manager should demonstrate respect and understanding of the patient’s cultural beliefs and values and 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 have an understanding of the team members, and mediate, negotiate, and resolve differences of opinion regarding the patient and interventions.[52]

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.[53] A contact investigation should begin within three or fewer business days of a case/suspect report and all contacts should be reported to the Wisconsin Tuberculosis Program within two weeks by entering the contact information into the Wisconsin Electronic Disease Surveillance System (WEDSS). The investigation should be repeated or reopened depending on number of contacts who convert or new information about unknown or unidentified epi links now apparent from whole genome sequencing links.

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 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 per orders from the patient's medical provider. See Table 6.9**:** **Monitoring and Interventions for Side Effects and Adverse Reactions** in the Treatment of Tuberculosis Disease section. The Wisconsin Tuberculosis Program's Nurse Case Management for Active Tuberculosis Disease guide offers a helpful Timeline for the Management of Patients with drug susceptible TB that indicates when specific activities should be done.

As is true with all medications, combination chemotherapy for TB is associated with a predictable incidence of adverse effects, some mild, some serious.[54]

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.[55] 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. [56]

Instruct patients to report any side effects and adverse reactions periodically. See the list of more common reactions in the "Side Effects and Adverse Reactions" topic in the Treatment of Tuberculosis Disease section.

To record information from monitoring for side effects and adverse reactions, please update the appropriate sections of the TB-Clinical tab in the client's WEDSS record.

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 via DOT. Case managers should be familiar with all TB medications, their side effects, contraindications, and drug interactions.[57]

For more information, see the Patient Education section.

Assess the patient for adverse reactions and side effects. Staff should assess patients for side effects and adverse reactions on each visit by performing a symptom review. If indicated, alert the provider so they may order liver function tests and monitor the results. The case manager should be aware of complications in patients on medications by maintaining close

communication with DOT workers, cultural liaisons, or any other staff assisting with case management and contact investigation.[58]

Monitoring bacteriologic improvement

Assess and document response to treatment. The case manager should collect sputa for AFB smear and culture as indicated in the state TB program Case Management document and detailed below.

Activities to monitor for bacteriologic and clinical improvement

To monitor for response to treatment, perform the activities described below.

For more information on discontinuing isolation, see the Infection Control section.

Acid-fast bacilli sputum smear negative

If a patient is AFB sputum smear negative, place laboratory reports promptly in the patient's record in WEDSS. If previous AFB sputum smears were positive, follow the collection schedule outlined below based on the release from isolation guidance being used by your local jurisdiction.

Acid-fast bacilli sputum smear positive (if using sputum smear method for release from isolation).

For patients with cavitation or who have sputum smears that are 3+ (moderate) or 4+ (many), wait two or more weeks after the start of treatment to collect the first follow-up sputum specimen. If that specimen is smear negative, obtain a second sputum specimen. If the second is smear negative, obtain a third sputum specimen. If any are smear positive, wait one week, and start the process over until you have three consecutive negative smear specimens.

For patients without cavitation, or who have sputum smears that are 1+ (rare) or 2+ (few), a single sputum specimen can be collected after one week of treatment. If the first sputum is smear negative, obtain a second, if the second is smear negative, obtain a third. If any are smear positive, wait one week, and start the process over until you have three consecutive negative smear specimens.

The case manager should continue to collect three sputa specimens for acid-fast bacilli (AFB) sputum smear and culture every month until sputum culture conversion (established through two consecutive specimens that are negative by culture) is achieved.

Acid-fast bacilli sputum smear positive (and if using newer NTCA RIR guidance, 2024).

The Wisconsin Tuberculosis Program recommends obtaining sputum collection once weekly (in patients smear-positive at diagnosis) or once every other week (if smear-negative at diagnosis) until there are two consecutive AFB culture-negative results (constituting “culture conversion”) to guide assessment of response to TB therapy.

Culture-positive pulmonary tuberculosis

For patients with smear-negative, culture-positive pulmonary TB, collect two or more sputa specimens every month for smears and cultures until persistently negative cultures are documented, or until they are no longer able to produce testable specimens. [59]

Culture negative or no specimens

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

1. Review the medications that the patient was on at the time TB medications were started, particularly other antibiotics.
2. If applicable, obtain follow-up chest radiograph reports to determine improvement.
3. Review the patient’s symptoms for improvement, if applicable.
4. Review the patient’s IGRA or tuberculin skin testing information (retesting may be appropriate if initially negative or test if not initially done) and discuss this with the patient’s provider.
5. Review information with the provider regarding reasons for continuing or not continuing TB medications past eight weeks.
6. Discuss the above findings with the Wisconsin Tuberculosis Program staff at 608-261-6319 to determine if the patient is to be counted as a verified case and continued on therapy.

Continued positive sputum smears or positive cultures

If sputum smears continue to be positive after two months, call the Wisconsin Tuberculosis Program at 608-261-6319 for guidance.

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

The case manager should initiate the evaluation of the patient and notify his or her supervisor and the Wisconsin Tuberculosis Program as soon as possible. The case manager also should do the following:

1. Evaluate the client’s clinical improvement (ex. weight gain, resolution or improvement of symptoms, systemic and constitutional status).

2. Review and confirm the patient's medication compliance.
3. Place the patient on increased in-person DOT, depending on current schedule.
4. Reconfirm the appropriateness of the medication regimen, based on drug susceptibility results and other considerations. Offer to set up a consultation with the state medical consultant via the state TB program if the provider is not comfortable with assessment of the situation. If additional antituberculosis drugs are added to the treatment regimen, ensure that at least two new drugs that the patient has not been treated with previously are used.
5. Consider serum drug levels, request assistance with process via the state TB program.
6. Notify the state TB program so that they can recommend and request additional or repeat susceptibility testing, as applicable.[60]

Verification of isolate drug susceptibility results

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

- If a patient's TB organism is pan-susceptible, follow the recommended treatment regimen.
- If a patient's TB organism is newly identified as drug resistant:
    - Notify the provider for adjustment of medications.
    - Confirm the appropriateness of regimen within one business day of provider notification.

If the regimen is inappropriate, immediately notify the clinician and the Wisconsin Tuberculosis Program staff at 608-261-6319.

- Continue DOT or increase frequency of DOT.
- If rifampin-resistant, isoniazid-resistant, or multidrug-resistant TB (MDR-TB):
    - Place infected contacts on appropriate latent TB infection (LTBI) treatment regimens and those eligible for window prophylaxis on appropriate 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.

Contact the Wisconsin Tuberculosis Program staff at 608-261-6319 for consultation regarding the treatment of drug-resistant TB.

Multidrug-resistant tuberculosis

If a patient has Multi-Drug Resistant-TB (MDR-TB), the case manager should:

- Notify his or her supervisor, and the patient's provider the same day that MDR-TB findings are reported/known.
- Confirm initiation of an appropriate regimen **within** one business day. If the provider is unwilling to institute an appropriate regimen, notify the case manager's supervisor and the Wisconsin Tuberculosis Program staff on the same day so they can intervene with the provider. Providers may need assistance with setting up medical consultation with the state program or education about local availability and procurement of MDR regimens.

For consultation regarding the treatment of drug-resistant TB, contact the Wisconsin Tuberculosis Program staff at 608-261-6319.

- Initiate transfer of patient care to a more appropriate provider, if necessary. The case manager, with TB clinician and Wisconsin Tuberculosis Program staff 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. For those with limited experience, support is available via the state TB program medical consultant, and the CDC supported TB center of excellence (MCCT).
- Obtain appropriate medications in coordination with the state program. Procurement of some medications may be logistically challenging; direction is available through the state program.
- Initiate DOT and maintain accurate DOT records. If the patient is experiencing issues with DOT, the case manager must document attempts to correct the situation and notify his or her supervisor.
- Provide the following for patients with MDR-TB:
  - Patient education, including information regarding the MDR-TB regimen
  - DOT at the agreed upon interval, location, and times.
  - Incentives and enablers
  - Legal orders

For more information, refer to the Patient Education section and 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:

- Lessening or resolution of TB symptoms
- Weight gain

- 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 and restrictions (RIR).[61]

For more information on isolation and quarantine, refer to the Infection Control section.

Closing a Case

If the patient has another more likely explanation for TB like clinical picture and the client will not be starting or continuing TB therapy, notify the state TB program and document and close out accordingly in WEDSS. *Please note, there is no gold standard "rule out" test for TB and even in the presence of negative test results, it is possible to have TB*. Please seek medical consultation if the provider would like assistance with diagnostic recommendations.

For more information on closing a case, see the "Completion of Therapy" topic in this section.

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 goal of the Wisconsin TB Program and CDC and an important measurement of the effectiveness of TB control efforts. Verification of completion of therapy and a completed contact investigation are the responsibility of the case manager. Completion of therapy entails both minimum duration in number of weeks of DOT and meeting the individual DOT dose goal.

Use the Active Tuberculosis Disease Follow-up Report form to record verification and closure information if your department doesn't have a standard form or letter.

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.

Culture remains positive beyond two months of treatment: Reasons for persistent positive cultures should be examined, discussed with the stater TB program, and treatment adjusted/lengthened.

For TB involving the bones or joints or tuberculous meningitis: These are exceptions to the standard six-month course. See “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in the Treatment of Tuberculosis Disease section.

HIV-negative, culture-negative patients: See “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in the Treatment of Tuberculosis Disease section.

Relapse of TB following treatment for TB with pan-susceptible organisms: Discuss this situation with the state TB program as additional testing may be warranted and would need to be specifically requested by the state TB program. Treatment may be prolonged to nine months or more. (Current drug susceptibility testing must be repeated, and the regimen adjusted if resistance has developed.)[62]

Calculating completion of therapy

So that doses missed for any reason are still given after treatment is resumed, base the completion of treatment on the number of doses of directly observed therapy (DOT) received rather than on the chronological passage of time or self-administered doses (for example, 26 weeks).[63]

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

Closures other than completion of therapy

Moved: All attempts should be made by the case manager to obtain the new or forwarding address. If this new address is within the original jurisdiction, the case should be transferred, as per the local public health agency protocol. If the new address is in another jurisdiction, the Wisconsin TB Program and the new jurisdiction should be notified, and procedures followed as described in the Transfer Notifications section. Cases should be closed as moved or “forwarded out of state” only if a new address is obtained and receipt of Interjurisdictional Notification (IJN) has been verified.

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

Not TB: If the completed diagnostic evaluation determined that the diagnosis of TB is not substantiated and another diagnosis is established, the case is closed as “Not a case.”

Lost: If all attempts to locate the patient fail, the case should be closed as "Lost to follow up." Notify the Wisconsin Tuberculosis Program about any client records that are designated as lost to follow up.

Died: If the patient expired prior to completion of therapy, the case is closed as "Died."[64] Record the date of death in WEDSS and notify the state TB program.

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

Evaluation

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

Evaluation activities answer the following questions:

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

Use the program evaluation resources from the Centers for Disease Control and Prevention for evaluation activities.

Evaluation activities

To evaluate case management, perform the following activities:

- Monitor the multidisciplinary care plan at least every month
- Identify strengths or weaknesses in the health care system
- Conduct a cohort analysis at determined intervals
- Monitor reports

Monitor 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 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.[65]

Identify strengths or weaknesses in the health care system that negatively or positively affect the expected outcome. A good evaluation will lead to positive changes for the patient and others.

Conduct a cohort analysis at least every 6–12 months, depending on volume of cases within your jurisdiction, to identify variances or common elements among the group. Cohort review is a "systematic review of the management of TB patients with TB disease and their contacts."[66] With the information learned from the evaluation, the case manager can make changes to improve patient care outcomes.[67]

See CDC's Understanding the Cohort Review Process guide for more information how to carry out cohort reviews for your cases.

Monitor reports to ensure that the TB case reports are accurate and updated according to state standards and that the contact investigation is complete.[68] All documentation should be completed in WEDSS.

Directly observed therapy

Providing directly observed therapy (DOT) is required. DOT means that a health care worker or other designated individual trained by the local health jurisdiction watches the patient swallow every dose of the prescribed TB drugs and monitors for side effects, adverse effects, and barriers to therapy. A family member cannot be designated to observe therapy. A dose of medication that is delivered to a patient, an address, or a mailbox or left with a family member, friend, or acquaintance is a dose of self-administered therapy (SAT) and should be designated as such.

DOT is a component of case management that helps to ensure that patients receive effective treatment and tolerate it, avoiding developing additional drug resistance and relapse. The American Thoracic Society (ATS), CDC, and Wisconsin Tuberculosis Program recommend that every TB patient be considered for DOT.[69] DOT is implemented for the following reasons:

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

Candidates for directly observed therapy

In Wisconsin and for many other public health agencies, DOT *is* the standard of care for all people on active TB disease therapy. That is, it is the goal to place all patients on DOT regardless of the patient's circumstances because it has been shown to be such an important treatment tool.[71] Especially prioritize, that medications are delivered by DOT (and consider an increased DOT to SAT ratio) for the following patients:

- Patients on intermittent regimens.
- Pediatric patients with TB disease.
- Patients with multidrug-resistant TB (MDR-TB).
- People with human immunodeficiency virus (HIV) coinfection and on treatment for LTBI.
- People who are immunocompromised and on treatment for LTBI.
- Pediatric contacts on treatment for LTBI.
- Pediatric or immune compromised adult patients on window prophylaxis.

Video directly observed therapy

Video directly observed therapy can help people with TB complete treatment. Based on evidence presented in the Recommendations for Use of Video Directly Observed Therapy During Tuberculosis Treatment-United States, 2023. The CDC has updated the recommendation for DOT during TB treatment to include video directly observed therapy (vDOT) as an equivalent alternative to in-person DOT.

The Wisconsin Tuberculosis Program does not recommend any specific platform for vDOT. Individual jurisdictions should research available options that are compatible with their agency's security requirements and budgetary considerations. Consult with your agency's Corporation Counsel and Information Technology Department with questions about your agency's security requirements and whether or not a specific platform meets established requirements. Please keep in mind that whatever platform is used, vDOT procedures must be compliant with the Health Insurance Portability and Accountability Act (HIPAA).

Some things to consider when reviewing and selecting vDOT platforms:

- What languages can the software accommodate?
- Is the software able to store or forward videos? This may be useful if asynchronous vDOT is necessary. This option may also be useful in areas where internet access can be limited or intermittent.
- Is the software compatible with different types of devices and operating systems?

Preparing clients to use video directly observed therapy

The Wisconsin Tuberculosis Program recommends that in-person DOT occur for the first 14 days of treatment. This allows for the assessment for side effects and adverse reactions regularly in the early stages of treatment when these events are more likely to occur. It also allows for patient education about when and how to take the medications properly as well as side effects to monitor for and report and return demonstration of understanding of these by the client. Other considerations to assess:

- Does the client have the capacity to self-administer medications reliably?
- Does the client understand how to utilize the required technology for vDOT?
- Does the client have regular access to a video-enabled phone, tablet, or computer for vDOT? The Wisconsin Treatment Assistance Program may be used to assist with providing clients with the appropriate equipment or services necessary for vDOT.
- Does the client have regular, reliable access to Wi-Fi or internet services?

It is important to provide the client education about how to use the vDOT platform that has been selected and to establish boundaries about activities that will result in discontinuation of vDOT and switching to in-person DOT (for example, multiple missed vDOT sessions).

The Wisconsin Tuberculosis Program offers a Wisconsin Electronic Video Directly Observed Therapy publication regarding eDOT/vDOT.

How to deliver directly observed therapy

Who can deliver directly observed therapy?

Usually TB clinic personnel, such as a nurse or other health care worker

Staff at other health care settings, such as outpatient treatment centers

Other responsible people, such as school personnel, employers, others trained by the local health jurisdiction

Not family members[72]

Principles of directly observed therapy

The health care worker should watch the patient swallow each dose of medication.

Use DOT with other measures to promote adherence.

DOT can be given anywhere the patient and health care worker agrees upon, provided the time and location are convenient and safe.[73,74]

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 medications being taken are correct and appropriate.
4. Watch the patient ingest all of the TB medications.

Health care workers should watch for tricks or techniques some patients may use to avoid swallowing medication, such as hiding pills in the mouth and spitting them out later, hiding medicine in clothing, or vomiting (either intentional or unintentional) after the DOT session.

If it is necessary to make sure that the patient swallows the pills, the health care worker may have to check the patient's mouth or prolong the visit doing other relevant tasks and monitoring duties to ensure the medications were tolerated. Patients should be instructed to report any vomiting after the medication visit.[75]

5. Document the visit.

Use the Medication and Administration and DOT section of the TB Treatment tab in the client's record in WEDSS to document adherence to treatment regimen and DOT.

6. As necessary and appropriate, do the following:
   - **a.** Provide patient education.
   - **b.** Help the patient make and keep medical appointments.
   - **c.** Continue to assist with maintenance of insurance (if client is eligible) and keep track of reimbursable expenses.
   - **d.** Connect the patient with social services and transportation.
   - **e.** Draw upon familiarity with the patient's home environment to identify household contacts.
   - **f.** Offer incentives and enablers to encourage adherence.[76]

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

Adherence to directly observed therapy

Patient education

The case manager should ensure that education is provided in the patient's primary language and is culturally appropriate.[77]

For more information, see the Patient Education section. For points to use to explain to the patient why DOT is important, refer to the CDC's Questions and Answers About TB 2021. Active TB Disease: What is directly observed therapy?

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.

Agreements

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

See the Wisconsin Tuberculosis Program's Nurse Case Management for Active Tuberculosis Disease guidance document for examples of agreement documents.

Incentives and enablers

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

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

Missed directly observed therapy dose

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

It is important not to send a mixed message to patients by delaying the response to missed DOT doses. After telling patients that TB treatment is so important for their health and the health of the community, you cannot delay in responding to the failure to be available for DOT. Individual departments may consider creating a standard number of missed appointments without prior notice and the steps that will ensue if the individual is to violate this agreement.

A missed dose needs to be seen as an opportunity to identify barriers to adherence and work with patients to find ways to successfully complete treatment. The key to a successful DOT program is the use of immediate information on poor adherence, side effects, and adverse reactions in order to promptly identify and respond to potential barriers to adherence, missed doses, and potential adverse treatment effects. This approach has been referred to as enhanced DOT—the use of a patient-centered approach to promptly identify and address barriers to treatment completion through use of incentives, enablers, and education efforts appropriate to the individual patient.

Incentives and enablers

Use incentives and enablers to enhance adherence to therapy.[79] Incentives and enablers are used to improve patient and provider rapport and to foster adherence to the treatment plan.[80] They help patients stay with and complete treatment.[81]

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

Eligible patients

The following patients may receive incentives and enablers:

- Patients being treated for active Tuberculosis disease, who are receiving medications through the Wisconsin Tuberculosis Dispensary Program or are utilizing a contact set up with the state TB dispensary program.
- Patients being treated for latent TB infection, who are receiving care from the LTHD.

- Close contacts to patients with active infectious TB, who are being evaluated by the LTHD for suspected TB or LTBI or those on window prophylaxis.

Available incentives and enablers

The following incentives and enablers are available in Wisconsin:

Table 9.1: Available incentives and enablers

Incentives	Enablers

• Food and beverages
• Clothing
• Automotive supplies
• Hobby/craft items
• Household items (cleaning supplies, air purifier)
• Laundry services
• Seasonal/holiday treats
• Movie passes
• Restaurant/fast food vouchers
• Toys
• Personal care items
• Visits to gym or physical education class
	• Transportation
	  ○ Bus pass
	  ○ Cab fare
	  ○ Battery for patient's car
	  ○ Gas- in the form of gift cards for "gas only"
	  ○ Fee for driver's license
	• Cell phone, tablet, or technology to communicate with care managers and schedule and perform DOT
	• Childcare
	• Obtaining and transporting specimens for the patient
	• Pill boxes, lock boxes, or medication storage.
	• Rent assistance
	• Assisting the client to complete paperwork to get food/housing assistance
	• Assisting the client to enroll in or get to substance use treatment
	• Making appointments/calling provider offices

To obtain incentives and enablers, see the "Incentives and Enablers" topic in the Supplies, Materials, and Services section.

Legal orders

For Wisconsin laws and rules on TB, see chapters 250-252 of the Wisconsin Statutes & Annotations.

Understand when and how to use legal orders, if necessary, for adherence to therapy. Adults who are not on appropriate TB therapy who have respiratory tract TB pose the greatest risk to the health of a community. It is the local public health agency's responsibility to ensure that compliance with the treatment plan is maintained, treatment is completed, and the risk of transmission to others is minimized. These responsibilities may require that TB staff members be innovative to see that patients take their medicine as prescribed and get through therapy. DOT also acts to put the responsibility of completing therapy successfully on the health department and not on the individual patient. 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.[83]

Progressive interventions

Have an intervention plan that goes step-by-step from voluntary participation to involuntary confinement as a last resort. Refer to **Table 9.2**: **Progressive Interventions for Patients with Adherence Barriers**. Progressive intervention should begin with learning the possible reasons for nonadherence and addressing the identified problems using methods such as directly observed therapy (DOT), incentives, and enablers. The patient should be told orally and in writing of the importance of adhering to treatment, the consequences of failing to do so, and the legal actions that will have to be taken if the patient refuses to take medication.[84]

Before legal measures are taken against a patient who has been taking TB drugs on a self-administered basis, increased frequency/ ratio of DOT should be offered. Attempt to mitigate barriers early to avoid needing to escalate to the next step. Notify the state TB program of any indications that assistance may be needed. Team meetings may be necessary to brainstorm ideas and past successes. It is often necessary to involve the patient's provider(s) to educate the patient and/ or their family and friends. Remember, the patient may have the best rapport with someone not prescribing them TB therapy, and if that provider is willing to assist, may be a valuable resource.

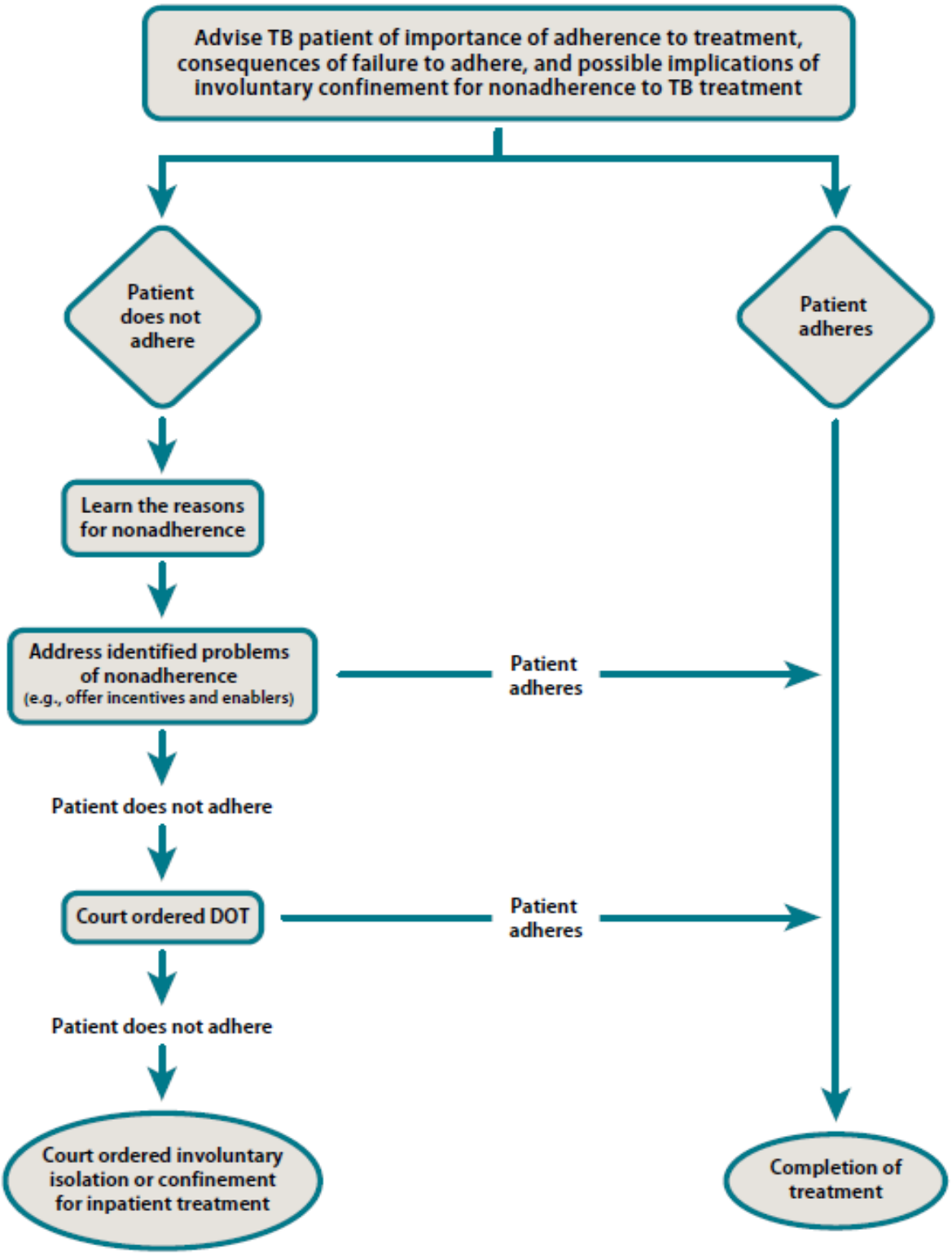
Use a DOT agreement form and home isolation form for all clients starting TB therapy. With a patient who may need more encouragement to adhere to treatment, complete a voluntary orders form. Voluntary orders are not legal orders but serve to clarify the mutual understanding between the patient and the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

The Wisconsin Tuberculosis Program offers a Home Isolation Agreement form and an Electronic Video Directly Observed Therapy form online. You can also find templates of an Active TB Disease Treatment Agreement and Coordination of Tuberculosis Care with Public Health in the Nurse Case Management for Active Tuberculosis Disease guidance document.

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

treatment and voluntary isolation, emergency detention to isolate the person is appropriate.[85] Please note that an affidavit from the treating physician detailing the client's infectiousness or potential for infectiousness is needed to pursue legal recourse.

Figure 9.1: Progressive Interventions for Nonadherent Patients



Definitions of abbr
Source: CDC. Mod
Tuberculosis Eli

Criteria for starting isolation and discontinuing isolation are provided in the Infection Control section.

Pursuing legal options

Before pursuing legal options to enforce isolation or adherence to treatment for tuberculosis disease, please consult with your health officer, agency's Corporation Counsel, and the Wisconsin Tuberculosis Program for recommendations.

Resources and references

Resources

General case management resources

CDC. Module 3: "Treatment of Latent Tuberculosis Infection and Tuberculosis Disease" (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 2021). Available at: Self-Study Modules on Tuberculosis | Tuberculosis (TB) | CDC

CDC. Module 6: "Managing Tuberculosis Patients and Improving Adherence *"Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 2021). Available at: Self-Study Modules on Tuberculosis | Tuberculosis (TB) | CDC

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