

Case Management

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Introduction

Purpose

Tuberculosis (TB) case management describes the activities undertaken by the jurisdictional public health agency and its partners to ensure successful completion of TB treatment and cure of the patient.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 Ohio 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).
- 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 failure to complete standard treatment is that patients frequently fail to adhere to the lengthy course of treatment. Poor adherence to treatment regimens might result from difficulties with access to the healthcare system, cultural factors, homelessness, substance abuse, lack of social support, rapid clearing of symptoms, or forgetfulness.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 TB clinic or public health agency, in Ohio, the county TB control unit is responsible for monitoring and ensuring the quality of all TB-related activities 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 county TB programs in Ohio differ in their TB expertise, staffing, 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.

State Laws and Regulations

Ohio laws and rules on tuberculosis are located in the Ohio Revised Code 339.71 thru 339.89 and Ohio Administrative Code

Ohio Revised Code

339.71 TB Control unit definitions
339.72 Designation of TB control unit
339.73 Treatment to be available to all persons with TB
339.74 TB record bureau
339.75 County Commissioners may contract for treatment
339.76 TB clinics established by county commissioners
339.79 Reporting case of TB that is resistant to one or more drugs
339.80 Investigations
339.81 Confidential information
339.82 Duties of individual diagnosed with active or communicable TB
339.83 Notice to individual diagnosed with active or communicable TB
339.84 Order compelling compliance with duties
339.85 Injunctions
339.86 Detaining noncomplying individual
339.87 Emergency detention order
339.88 Expenses of detaining noncomplying individual
339.89 Spiritual treatment in lieu of medical treatment for TB
5705.20 Special levy for tuberculosis treatment or clinics

Program Standards

Ohio Administrative Code

Definitions, Acceptable Programs, Standards

3701-15-01 thru 03

Reporting & Isolation Requirements

3701-3-01 Reportable disease definitions

3701-3-02 Reportable diseases

3701-3-03 Reportable disease notification

3701-3-04 Lab reporting

3701-3-05 Time of report

3701-3-06 Reporting to ODH

3701-3-08 Release of medical records

3701-3-13 Isolation requirements

Quarantine

3701-13 Powers of Health Department

3701-34 Health Commissioner Authority

3701-56 Enforcement of Quarantine

3707-04 Quarantine regulations

Forms

Local public health agencies are required to complete and submit the reports listed in the table below to the Ohio Department of Health TB program:

REQUIRED REPORTS

Report Title	When Due
Report of Verified Case of Tuberculosis	By close of next business day
Initial Drug Susceptibility Report (Follow-up 1)	When results are available
Case Completion Report (Follow-up 2)	When patient completes treatment for active TB disease or when a suspect is determined not to have TB



To download forms for the above required reports, go to section three of the Infectious Disease Reporting Manual (IDCM). The IDCM can be downloaded from Ohio Department of Health at

<http://www.odh.ohio.gov/healthResources/infectiousDiseaseManual.aspx>

The Report of Verified Case of Tuberculosis (RVCT) forms are designed to collect information on cases of TB. Data obtained from RVCT forms are entered into the Ohio Disease Reporting System (ODRS) by the local TB control unit and the ODH TB Program, and then transferred electronically to the CDC. While a case of TB is required to be reported to the CDC only if active disease is verified and the case is to be part of the annual morbidity count, the CDC encourages the use of the RVCT forms and ODRS for the collection of data on suspected cases of TB.

Acknowledgments

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

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

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

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 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

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; 2011) at this hyperlink:

http://www.currytbcenter.ucsf.edu/sites/default/files/DOT_introduction.pdf.



For assistance with language issues, see the National Health Law Program and The National Council on Interpreting Health Care's *Language Services Resource Guide for Health Care Providers* (National Health Law Program Web site; October 2006) at this hyperlink:

<http://www.healthlaw.org/component/jsfsubmit/showAttachment?tmpl=raw&id=00Pd00000077hZVEAY> . Please note that this download is very slow.



For more information on using interpreters, see the *Interpretation Services* lesson in Module 9: "Patient Adherence to Tuberculosis Treatment" of the CDC's *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site) at this hyperlink: .

<http://www.cdc.gov/tb/education/ssmodules/module9/ss9contents.htm>

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 copies 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

The case manager (or designee) should make an initial hospital visit within 72 hours 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

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, infectiousness or potential infectiousness.
- Obtain and review the patient's health history.
- 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 Several home visits may be needed because usually not all of the necessary information is gathered from the patient and family at one time.

Obtain or review demographic information, including the name, address, telephone number(s), birth date, Social Security number, and health insurance provider's name, address, and identifying information.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 physician and/or program medical consultant should be consulted at the earliest opportunity following the receipt of a suspect report. A chest radiograph should be taken and interpreted. Also, 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 five years of age, posterior-anterior and lateral chest radiographs are important in the initial diagnosis.¹⁸ Adults who are suspected of TB or who are active cases usually need only an initial posterior-anterior chest radiograph.

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



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

Determine infectiousness or potential infectiousness. To determine 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 tuberculin skin test for contacts that were initially negative, can then be determined.²⁰



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. 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 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.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 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.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 as soon as notice of positive acid-fast bacilli (AFB) sputum smear results are received (unless there is evidence that the AFB is not *Mycobacterium tuberculosis* complex, e.g., by direct test of sputum) or another diagnosis is made. A

clinician should then complete the medical evaluation, contact the TB control unit in which the patient resides, write medical orders which document repeat sputum collection (if appropriate), drugs, dose, route, frequency, and duration, and if not planning to treat the patient until completion of therapy, refer the patient to an appropriate physician or nurse practitioner. The case manager then should then contact the patient to schedule the initial visit and initiate treatment.

Monitor the TB medication regimen. The case manager should ensure that medications and dosages are prescribed according to current American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC) guidelines. If the initial assessment occurs during the patient's hospitalization, the case manager should ensure that the ingestion of the TB medication is observed by a nurse. It is important to ensure that hospitals order and give the right doses, and are observing patients taking medications. Since the outpatient phase of treatment will involve giving TB medications at one time, **hospitals should be discouraged from splitting dosages** for two reasons: (1) taking medications more than once a day creates an expectation for the patient that will have to change after discharge from the hospital, and (2) tolerance to the full dosage cannot be assessed while in the hospital. The patient's tolerance to TB medications should be noted, and interactions with other medications should be determined prior to the patient starting TB medications.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 healthcare provider. It may be necessary to teach people how to take pills, or it may be necessary to crush the pills and put them in food, such as pudding or applesauce. In addition, the case manager should determine the need for enablers and identify incentives that will be most valuable to the patient. ODH TB staff can facilitate enrollment in the incentive/enabler program.

Review psychosocial status to identify unmet needs, the use of alcohol and/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 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 patients with TB, it is necessary to have an understanding of the patient's social and recreational activities and how he/she spends leisure time. This includes time spent at bars, floating card games, circuit parties, faith-based functions, and other venues.

Gather information for a possible contact investigation. A contact investigation should begin within 72 hours of a case/suspect report.



For more information, see the Contact Investigation section.

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 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 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.²⁶

In the initial management strategy, regardless of the source of supervision, always include an adherence plan that emphasizes 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 once per month during reviews of clinical progress.²⁹

Treatment Plan Components

The components of a treatment plan include the following:

- Patient's verified address and contact information
- Assignment of responsibilities: case manager, clinical supervisor (nurse, physician, or physician assistant), DOT workers, other caregivers (outreach workers, nurses), and person managing the contact investigation
- Patient educator's name and dates of education sessions
- Method for prevention of transmission: no isolation, airborne infection isolation, home isolation, legal order for isolation
- Planned course of antituberculosis drug therapy
- Estimated date of completion of treatment
- Test results from initial medical evaluation
- Medical history
- Diagnosis
- Monitoring activities and schedule to assess response to therapy
- Baseline tests, monitoring activities, and schedule to detect potential side effects and adverse reactions
- Potential drug interactions
- Potential treatment adherence obstacles
- Personal service needs
- Referrals for social services
- Means of ensuring successful completion of treatment (DOT, incentives, enablers)
- Location(s) where DOT will be administered
- Approvals and signatures of the attending physician, local public health agency representative, and the patient
- Intermediate and expected outcomes³⁰



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/productlist.htm>.

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.³¹ DOT should be the standard of care for all TB cases and suspects.

Establish time frames in the treatment plan to monitor the plan and patient response. Monitoring should be done 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.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 healthcare providers, social service agencies, or community organizations as needed.
- Broker and locate needed services relating to TB treatment.
- Negotiate a plan for DOT or self-administration evaluation.
- Coordinate strategies to improve adherence.

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

Broker and locate needed services relating to the TB treatment. This may include laboratory, auditory, or visual acuity testing; additional radiographs; or other tests required specifically for the patient. It is important to schedule or assist the patient in scheduling appointments and to monitor the patient's adherence. An understanding of the patient's financial resources and health insurance coverage is important. Lack of financial resources or health insurance will affect the patient's willingness to keep appointments, which may be critical to his or her health. The case manager may need to discuss essential services with insurance companies or other healthcare providers to obtain the most cost-effective, quality service.³⁵ 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 should be the standard of care for all patients. The case manager should ensure the plan is suitable for the patient's needs and achievable by the healthcare provider(s) and then have the patient sign a DOT agreement. Due to the length of TB treatment, the patient's circumstances may change. The case manager needs to verify that the time and place for DOT administration originally agreed upon is still agreeable to the patient and provider. It also may be necessary to coordinate the arrangements for DOT with outside organizations, such as school nurses or drug treatment center nurses.³⁶



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 8, and the “Incentives and Enablers” topic in this section.

Ongoing Assessment and Monitoring

Conduct ongoing assessments and monitor patients at least every *once per 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 TB treatment, or for those patients who are nonadherent to 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

Ongoing Assessment Activities

To complete an ongoing assessment, perform the following activities:

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

Monitor the clinical response to treatment by reviewing vital signs, weight, 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. The case manager should collect sputa for acid-fast bacilli (AFB) sputum smear and culture every week until sputum smear conversion. Thereafter, sputa should be collected every two weeks until there are two negative cultures. If a patient is on DOT, no further specimen collected is indicated unless the patient becomes

symptomatic. 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. 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 Ohio Department of Health TB Program.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

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.⁴⁵

Ensure that medications are ordered and given at the correct time, and in the correct dosage. Do not split doses. 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.⁴⁶ The patient should be monitored by a registered nurse and/or clinician at each clinic visit 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.

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.⁴⁷

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 not involved in providing DOT, a notification system should alert him or her if the patient misses a DOT dose or if there is suspicion of nonadherence if the case is on self-administered therapy. 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 to the case manager's supervisor. It is important not to send a mixed message to a patient by not promptly responding to missed DOT doses.

If the patient is self-administering TB medications, make a weekly visit to the patient's residence to assess adherence and monitor for side effects and adverse reactions. Also, regularly monitor the effectiveness of enhancement methods (i.e., incentives, enablers, behavioral contracting, or behavior modification).⁴⁸

Policies and procedures must be in place to establish the expected monthly rate of DOT adherence. The case manager should review the monthly adherence rate to ensure that patients achieve the expected adherence rate. DOT should be initiated if adherence is compromised, as evidenced by missed pill pick-up appointments, inaccurate pill counts, etc., in persons at high risk of developing TB disease. Drug levels should be ordered when non-adherence is suspected. The case manager should ensure that the patient is informed about the consequences of nonadherence, including legal interventions. Changes in the patient's attitude toward the healthcare worker should be noted and verified with the patient.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 healthcare beliefs that are in conflict with educational information. The case manager should ensure that education is provided in the patient's primary language and that it is culturally appropriate.⁵¹ The case manager should provide patient and family education at every opportunity 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 72 hours of a case/suspect report and is ongoing. The investigation should be repeated if for any reason the index patient becomes AFB sputum smear positive again during treatment and there has been sufficient exposure for the skin-test-negative persons to become infected.

Monitoring Side Effects and Adverse Reactions

Assess and document side effects and adverse reactions to antituberculosis medications and monitor toxicity. The patient should be monitored by a registered nurse and/or clinician or case manager weekly 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.

See Table 8: **Monitoring and Interventions for Side Effects and Adverse Reactions** in the Treatment of Tuberculosis Disease section.

As is true with all medications, combination chemotherapy for 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 the side effects and adverse reactions listed in the “Side Effects and Adverse Reactions” topic in the Treatment of Tuberculosis Disease section.

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.⁵⁷



For more information, see the Patient Education section.

Assess the patient for adverse reactions and side effects. For patients on self-administered therapy, the case manager ensures that patients are assessed for adverse effects to TB medications at least every month and at each visit. If the patient is on DOT or pill counts, staff should assess patients for side effects and adverse reactions on each visit by performing a symptom review. If indicated, order liver function tests and monitor their results. The case manager should be aware of complications in patients on medications by maintaining close communication with outreach staff.⁵⁸

Monitoring Bacteriologic Improvement

Assess and document response to treatment. The case manager should collect sputa for AFB sputum smear and culture every week until sputum smear conversion. Thereafter, sputa should be collected every few weeks until there are two negative cultures. If a patient is on DOT, no further specimen collected is indicated unless the patient becomes symptomatic.⁵⁹



Document bacteriologic reports and clinical improvement in the patient's Ohio Disease reporting System (ODRS) record.

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 chart and enter into ODRS. If previous AFB sputum smears were positive and now AFB sputum smears are negative on three separate consecutive days, consider discontinuing isolation.⁶⁰

Acid-Fast Bacilli Sputum Smear Positive

If a patient is AFB sputum smear positive **and**

- **Prior positive:** Place a report in the patient's chart. Repeat sputa smears weekly until three consecutive negative sputa smears have been documented.
- **Has new AFB sputum smear positive results and is diagnosed with pulmonary TB:** Notify the county TB control unit if not yet reported, notify the provider, initiate isolation, and enter report into ODRS. Repeat sputa smears at appropriate intervals, at least weekly, until three consecutive negative sputa smears have been documented from different days.⁶¹

Culture-Positive Pulmonary Tuberculosis

For patients with culture-positive pulmonary TB, collect two or more sputa specimens every two weeks for smears and cultures until persistently negative cultures are documented.⁶²

Continued Positive Sputum Smears or Positive Cultures



If sputum smears are positive after two months, call Ohio Department of Health TB Program at (614) 466-2381.

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

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

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

Culture Negative or No Specimens

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

1. Review the medications that the patient was on at the time TB medications were started, particularly other antibiotics.
2. If applicable, obtain follow-up chest radiograph reports to determine improvement.
3. Review the patient's symptoms for improvement, if applicable.
4. Review the patient's tuberculin skin testing information (retesting may be appropriate if initially negative or test if not initially done) and discuss this with the patient's provider.
5. Review information with the provider regarding his or her reasons for continuing TB medications.
6. Discuss the above findings with at Ohio Department of Health TB Program at (614) 466-2381 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. Confirm the appropriateness of regimen within 48 hours of provider notification.
 - c. If the regimen is inappropriate, immediately notify the clinician and the Ohio Department of Health TB Program at (614) 466-2381.
 - d. Initiate DOT.



3. If isoniazid-resistant or multidrug-resistant TB (MDR-TB):
 - a. Place contacts on appropriate TB infection (TBI) treatment regimens. Treatment of TBI 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 Ohio Department of Health TB Program at (614) 466-2381 for consultation regarding the treatment of drug-resistant TB.



Multidrug-Resistant Tuberculosis

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. Confirm initiation of an appropriate regimen **within 72 hours**. If the provider is unwilling to institute an appropriate regimen, notify the case manager's supervisor and the Ohio Department of Health TB Program on the same day so they can intervene with the provider.
3. For consultation regarding the treatment of drug-resistant TB, contact the Ohio Department of Health TB Program at (614) 466-2381.
4. Initiate transfer of patient care to a more appropriate provider, if necessary. The case manager, with TB clinician/Ohio Department of Health TB Program 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.
5. Obtain appropriate medications from suppliers.
6. 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.
7. 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



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:

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.⁶⁴



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

Closing a Case

If the patient is not to be reported as a case, notify the provider that the patient is closed to TB control program services. The patient can be closed to TB Registry in ODRS.



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 Ohio Department of Health TB Program 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.



Document verification and closure information in the ODRS record.

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 and treatment adjusted/prolonged.
- **For TB involving the bones or joints or tuberculous meningitis:** These are exceptions to the standard six-month course. See “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in the Treatment of Tuberculosis Disease section.
- **HIV-negative, culture-negative patients:** See “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in the Treatment of Tuberculosis Disease section.
- **Relapse of TB following treatment for TB with pan-susceptible organisms:** Treatment may be prolonged to nine months or more. (Current drug susceptibility testing must be performed and the regimen adjusted if resistance has developed.)⁶⁵

Calculating Completion of Therapy

So that doses missed due to nonadherence or other treatment interruptions are still given after treatment is resumed, **base the completion of treatment on the number of doses of DOT received rather than on the chronological passage of time** (e.g., six months).⁶⁶



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 Ohio Department of Health 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” only if a new address is obtained.



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

- **Not TB:** If the completed diagnostic evaluation determined that the diagnosis of TB is not substantiated and another diagnosis is established, the case is closed as “Not TB.”
- **Lost:** If all attempts to locate the patient fail, the case should be closed as “Lost.” Document each attempt to locate patient in the ODRS record; date and method (e.g., home visit, telephone call, letter, etc.).
- **Died:** If the patient expired prior to completion of therapy, the case is closed as “Died.”⁶⁷ NOTE: all bacteriologic tests must have final results before closing record in ODRS, and pulmonary disease must be investigated for community transmission.



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

Evaluation

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

Evaluation activities answer the following questions:

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

Evaluation Activities

To evaluate case management, perform the following activities:

- Monitor the multidisciplinary care plan at least every monthly
- Identify strengths or weaknesses in the healthcare system.
- Conduct a cohort analysis at least every quarterly, if appropriate.

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 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.⁶⁸

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

Conduct quarterly cohort analysis 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.”⁶⁹ With the information learned from the evaluation, the case manager can make changes to improve patient care outcomes.⁷⁰ **NOTE:** Very low morbidity counties in Ohio lack dedicated TB staff and report TB cases infrequently. Consequently, monthly case review will positively impact outcomes for cases and their contacts, where the cohort review process will have little effect.

Directly Observed Therapy

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

DOT is a component of case management that helps to ensure that patients receive effective treatment and adhere to it. The American Thoracic Society, the Centers for Disease Control and Prevention, and the Ohio Department of Health TB Program recommend that every TB patient be considered for DOT.⁷¹ DOT is implemented for the following reasons:

- DOT is the most effective strategy for making sure that patients take their medicines.
- DOT can lead to reductions in relapse and acquired drug resistance.⁷²
- Directly observing each dose provides immediate information on poor adherence and adverse effects, information that cannot readily be obtained from patients treated with SAT.

Candidates for Directly Observed Therapy

DOT *should be* the standard of care for all TB cases and suspects. In Ohio, DOT *is* the standard of care. 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.⁷³ Consider DOT for all patients with TB disease, and *ensure* that medications are delivered by DOT for the following patients:

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

How to Deliver Directly Observed Therapy

Who Can Deliver Directly Observed Therapy?

- Usually TB clinic personnel, such as a nurse or other healthcare worker
- Staff at other healthcare settings, such as outpatient treatment centers
- Other responsible persons, such as school personnel, employers, others trained by the local health jurisdiction
- *Not* family members⁷⁴

Principles of Directly Observed Therapy

- The healthcare worker should watch the patient swallow each dose of medication.
- Use DOT with other measures to promote adherence.
- DOT can be given anywhere the patient and healthcare worker agree upon, provided the time and location are convenient and safe.^{75,76}

Directly Observed Therapy Tasks

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



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

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



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

If it is necessary to make sure that the patient swallows the pills, the healthcare worker may have to check the patient’s mouth, or ask the patient to wait for a half hour before leaving the clinic so the medication can dissolve in the patient’s stomach.⁷⁷

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.⁷⁸



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.⁷⁹



For more information, see the Patient Education section. For points to use to explain to the patient why DOT is important, refer to the CDC's *Questions and Answers About TB 2005. Active TB Disease: What is directly observed therapy?* (Division of Tuberculosis Elimination Web site; 2011) at this hyperlink:

http://www.cdc.gov/tb/education/patient_edmaterials.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 this hyperlink:

[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 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.⁸⁰ ODH TB Program staff are available to provide guidance upon request.

Incentives and Enablers

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



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

Missed Directly Observed Therapy Dose



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

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

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

Incentives and Enablers

Use incentives and enablers to enhance adherence to therapy.⁸¹ Incentives and enablers are used to improve patient attitudes and to foster good health behaviors.⁸² They help patients stay with and complete treatment.⁸³

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.⁸⁴ **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/or enablers:

- Persons with active disease
- Close contacts to an active case of TB diagnosed with LTIB
- Special situations that are evaluated on a case by case basis

The following incentives and enablers are currently available in Ohio.

Table 1: **AVAILABLE INCENTIVES AND ENABLERS**

Incentives	Enablers
Gift cards (\$10) <ul style="list-style-type: none">▪ Speedway▪ Kroger▪ Meijer▪ McDonalds▪ CVS▪ Wendy's▪ Dave's Supermarket▪ Marc's▪ Fisher Foods▪ Target▪ Wal-Mart▪ Rural counties may contact ODH for special purchases	<ul style="list-style-type: none">▪ RTA Bus Passes▪ Patients residing in communities where local bus survive is not available may receive special consideration



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

Legal Orders

Understand when and how to use legal orders, if necessary, for adherence to therapy. Nonadherent adults with pulmonary TB pose the greatest threat to the health of a community. It is the local public health agency's responsibility to ensure that compliance is maintained, treatment is completed, and the risk of transmission to others is eliminated. These responsibilities require that TB staff members be innovative and always "go the extra mile" to see that patients take their medicine as prescribed. The public health mandate and good judgment dictate that program staff should go to every extent possible to fulfill the job responsibilities outlined above before resorting to legal action.⁸⁵

Ohio laws and rules on tuberculosis pertaining to compliance see: <http://codes.ohio.gov/>

Ohio Revised Code

- 339.82 Duties of individual diagnosed with active or communicable TB
- 339.83 Notice to individual diagnosed with active or communicable TB
- 339.84 Order compelling compliance with duties
- 339.85 Injunctions
- 339.86 Detaining noncomplying individual
- 339.87 Emergency detention order
- 339.88 Expenses of detaining noncomplying individual
- 339.89 Spiritual treatment in lieu of medical treatment for TB

Ohio Administrative Code

- 3701-3-13 Isolation requirements
- 3701-13 Powers of Health Department
- 3701-34 Health Commissioner Authority
- 3701-56 Enforcement of Quarantine
- 3707-04 Quarantine regulations

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), 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.⁸⁶

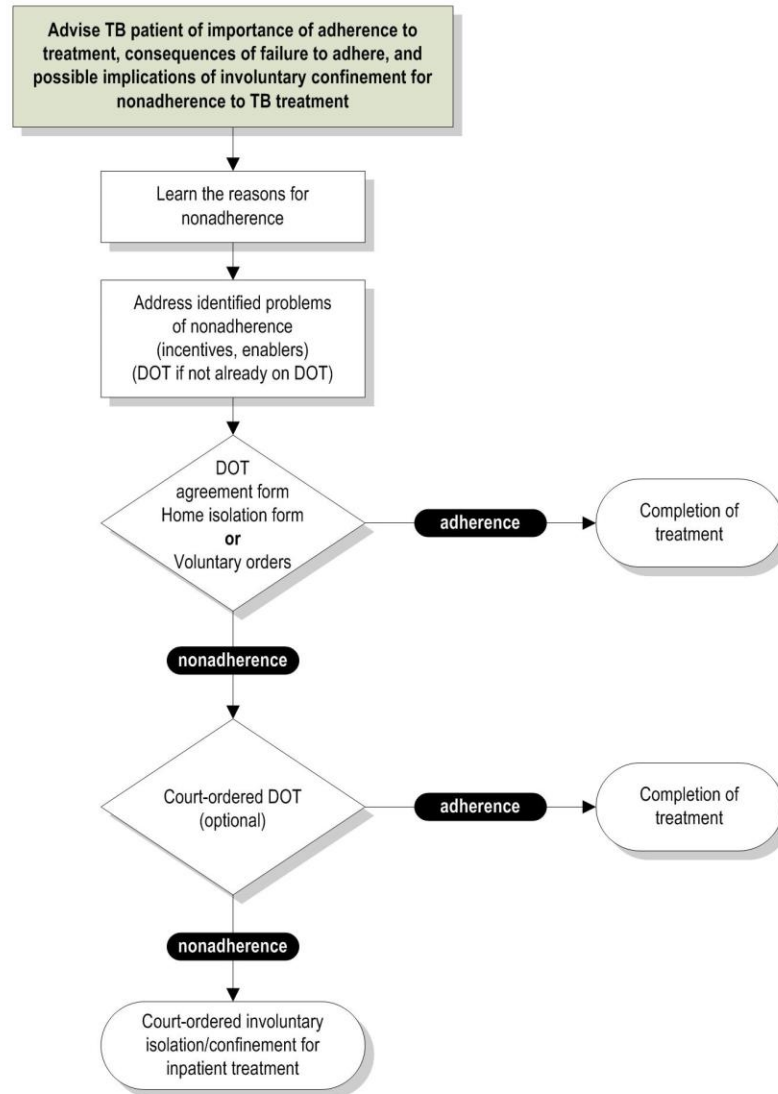
Before legal measures are taken against a patient who has been taking TB drugs on a self-administered basis, DOT should be offered to the patient.⁸⁷

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

If the patient does not adhere to DOT voluntarily, the next step may be court-ordered DOT. An optional step toward other legal orders, court-ordered DOT can be successful in convincing a patient that his or her TB treatment is an important public health priority. Involuntary confinement or isolation for inpatient treatment should be viewed as the step of last resort, to be used only when all other options fail. However, when a patient with infectious TB refuses treatment and voluntary isolation, emergency detention to isolate the person is appropriate.⁸⁸ For a list of legal orders and instructions on when and how to obtain and serve them, see Table 2: **Types of Legal Orders and How to Process Them.**

Under normal circumstances, patients with extrapulmonary TB do not transmit the disease to others, and, therefore, these persons usually cannot be legally ordered to take their medications. However, their personal health is endangered if they choose not to be treated. They should be educated regarding the possibility of their disease spreading to the lungs and becoming infectious to others.

Figure 1: **PROGRESSIVE INTERVENTIONS FOR NONADHERENT PATIENTS**⁸⁹



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

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



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

Types of Legal Orders and How to Process Them

When necessary, use the legal orders listed in the table below.

Table 2: **TYPES OF LEGAL ORDERS AND HOW TO PROCESS THEM**⁹⁰

Legal Order	Criteria for an Order	Authority/Responsibility	Action
ORC 339.82 (A) (1) (2) (B) Order to Complete a Course of Directly Observed Therapy	Patient informed of responsibility to complete treatment <i>and</i> documented as non-adherent	County TB Control Unit Authority or Health Commissioner issues order to submit to Directly Observed Therapy	Letter to individual informing their responsibility to complete treatment and prevent the spread of TB in the community
ORC 339.83 Notice to Individual diagnosed with active or communicable TB	Individual failed to comply with section 339.82 of the Ohio Revised Code	County TB Control Unit Authority or Health Commissioner	Informs individual verbally or in writing that failure to comply will result actions outlined in ORC 339.84
ORC 339.84 Order compelling compliance	Patient informed of responsibility to completed treatment	County TB Control Unit Authority or Health Commissioner issue	Letter to patient informing him or her of their responsibility to comply with treatment
ORC 339.85 Injunctions	Individual failed to comply with section 339.84 of the Ohio Revised Code	County TB Control Unit Authority or Health Commissioner petitions Probate Court	If immediate threat to public, prior hearing is waved or expedited and order is issued and patient is detained
ORC 339.86 Detaining noncomplying individual	Individual failed to comply with section 339.85 of the Ohio Revised Code	County TB Control Unit Authority or Health Commissioner petitions Probate Court	Detention; cannot extend more than 180 days without review. Renewal orders will not exceed 90 day increments

ORC 339.87 (A) Emergency Detention Order	When TB control unit has reasonable belief an individual poses a public health threat	County TB Control Unit Authority or Health Commissioner issues order	Sheriff or other law enforcement officer removes individual to a hospital or other place to be examined and treated
ORC 339.87 (B) Emergency Detention Order	Individual is detained under section 339.87 (A) of the Ohio revised Code	County TB Control Unit Authority or Health Commissioner	County TB Control Unit Authority or Health Commissioner petitions Probate Court for within 3 business days after detention or the individual is released
ORC 339.88 Expenses of detaining noncomplying individual	Detention under 339.86 or 339.87 of the Ohio revised Code	Detainee is responsible for payment, or if indigent, by the board of county commissioners of the county from which the individual was removed	Not applicable
ORC 339.89 Spiritual treatment in lieu of medical treatment for tuberculosis	Individual relies exclusively on spiritual treatment through prayer	County TB Control Unit Authority or Health Commissioner	Individual may be quarantined or safely isolated in home or other place that is suitable to county TB Control Unit

Resources and References

General Case Management Resources

- CDC. Module 4: “Treatment of Tuberculosis Infection and Disease” (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 2011). Available at: <http://www.cdc.gov/tb/education/ssmodules/pdfs/Module4.pdf>
- CDC. Module 9: “Patient Adherence to Tuberculosis Treatment” (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 2011). Available at: <http://www.cdc.gov/tb/education/ssmodules/module9/ss9contents.htm> .
- California Department of Health Services (CDHS)/California Tuberculosis Controllers Association (CTCA). “TB Case Management—Core Components” (*CDHS/CTCA Joint Guidelines* [CTCA Web site]; November, 2011). Available at: http://www.ctca.org/fileLibrary/file_238.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). Accessed March 2017. Available at: <http://globaltb.njms.rutgers.edu/educationalmaterials/productlist.html> .

Directly Observed Therapy Resources

- CDC. Chapter 7: “Treatment of TB Disease” (*Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]; Updated May 2016). Available at: <http://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]; 2011). Available at: <http://www.cdc.gov/tb/education/ssmodules/module9/ss9contents.htm> .
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Incentives and Enablers Resources

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