Case Management

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] This section will focus on case management for persons being treated for TB disease. A new "Latent Tuberculosis Infection: A Quick Guide to Case Management" is included at the end of this section. Most PHNs in Alaska will provide services to persons being treated for LTBI; not all, however, will manage persons being treated for active TB disease. PHNs managing persons being treated for latent TB infection (LTBI) will find that many case management principles and activities are similar. Case management is a system in which a specific health department employee is assigned primary responsibility (case manager) 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 Alaska guidelines to:

- conduct initial assessments;
- develop treatment plans for case management activities;
- conduct monthly ongoing assessments;
- monitor adverse reactions to antituberculosis medications and monitor toxicity;
- monitor bacteriologic and clinical improvement;
- verify completion of therapy;
- evaluate case management activities;
- provide directly observed therapy (DOT);
- use incentives and enablers to improve adherence to therapy; and
- understand when and how to use medical 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 most patients will undergo their initial evaluation and treatment in settings other than a public health agency, a 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 **1.11**.

In Alaska, regional and local public health nurses (PHNs) function as case managers for each person with suspected or diagnosed active tuberculosis.

All persons suspected or diagnosed with active tuberculosis need a provider or medical home. The case manager should ensure that all patients have a clinical provider to manage their TB treatment and care.

Directly observed therapy (DOT) is the standard of care for all persons diagnosed with tuberculosis in Alaska. It is required for all persons being treated for pulmonary tuberculosis.

PHNs also provide oversight for all persons taking anti-tuberculosis medications for the treatment of LTBI. This may include health education; assessing adherence with the prescribed regimen; ordering medications; arranging and monitoring DOT for high risk individuals; assessing for adverse reactions; facilitating evaluation or diagnostic testing; and reporting status and completion of treatment, as needed, to the Alaska TB Program.

See “Latent Tuberculosis Infection: A Quick Guide to Case Management” for more information on LTBI case management in topic **A.1** of this section.

Forms

Required and recommended forms are available in the Forms section **18.1**.

Consent for Release of Medical Information

Contact Investigation Form

DOT Aide Job Description

DOT Aide Memorandum of Agreement

DOT Calendar

DOT Monthly Invoice for Payment

End of Treatment Letter and Summary

Referral and Authorization for TB Screening and Follow-up Services

TB and LTBI Prescription and Medication Request Form

TB Case Management Form

TB Case Management Information Request

TB Medication Drug Count Worksheet

Tuberculosis Discharge Planning Checklist

Tuberculosis Treatment Contract

Alaska TB Program: Timeline for the Case Management of Tuberculosis Treatment Rev. 1/17

Activity	Weeks 0	1	2	3	4	5	6	7	8	Months 3	4	5	6	9	5	End of treatment evaluation
	Initial Treatment Phase									Continuation Treatment Phase						
Clinical & lab evaluation (1) History & Physical CBC, platelets, creatinine, AST, bilirubin, alk. phosph. Visual acuity, color vision HIV test	X X X X X X				(2) →					→	→	→	→	→		Not recommended
Drugs Refer to CDC. Treatment of Tuberculosis. MMWR 203;52 (No. RR-11)	Isoniazid →									→				→		
	Rifampin →									→				→		
	Pyrazinamide →															
	Ethambutol →									(3)						
Treatment options (4)	All doses should be taken using directly observed therapy (DOT)															
1.) INH, RIF, PZA, EMB	Dose daily (7 days/wk) for 56 doses (8 wks) or 5 days/wk for 40 doses (8 wks). Preferred regimen for patients with newly diagnosed pulmonary TB.									7 days/wk for 126 doses (18 wks) 5 days/wk for 90 doses or twice wkly for 36 doses (18 wks) When appropriate, consider INH + RPT (5)				(6)		Count doses/complete weeks of treatment delivered by DOT to assure treatment completion (7)
2.) INH, RIF, PZA, EMB	Dose daily (7 days/wk) for 56 doses (8 wks) or 5 days/wk for 40 doses (8 wks). Preferred regimen when more frequest DOT during continuation phase is difficult to acheive.									3 days/week for 54 doses (18 wks) (5)				(6)		
3.) INH RIF, PZA, EMB	Dose three times wkly for 24 doses (8 wks.); use regimen with caution in patients with HIV and/or cavitary disease. Missed doses can lead to treatment failure, relapse and acquired drug resistance.									Three times wkly for 54 doses (18 wks)				(6)		
4.) INH, RIF,PZA, EMB	7 days/wk for 14 doses then twice weekly for 12 doses. Do not use twice-weekly regimens in HIV-infected patients or patients with smear-positive and/or cavitary disease.If does are missed, thern theraphy can be equivalnet to once wkly, which is inferior.									Twice weekly for 36 doses (18 wks)						
Sputum collection (8)	X				X				X	Collect sputa at least monthly until culture conversion occurs						Optional
Chest x-ray	X									(X)	(9)					Optional
Clinical assessment during treatment (10)	X				X				X	X	X	X	X	X		
DOT & compliance evaluation (11)	X				X				X	X	X	X	X	X		
Contact investigation	Screen priority contacts (TST/IGRA or SX & sputa)								Repeat TSTs/IGRA if initially negative							Confirm completion of contact investigation

(1) If patient has a history of injecting drug use, testing for Heptatitis B and C is recommended.

(2) Repeat liver enzyme tests if signs of drug toxicity appear during treatment. Perform monthly liver enzyme tests if high risk for hepatic toxicity (e.g. pre-existing liver disease or with abnormal liver function that does not require discontinuation).

(3) Discontinue ethambutol if *M. tuberculosis* is sensitive to all first line anti-tuberculosis agents.

(4) INH = isoniazid; RIF = rifampin; PZA = pyrazinamide; EMB = ethambutol; RPT= rifapentine

(5) Regimens listed in order of effectiveness, with 1 being the MOST effective and preferred regimen.

(6) Patients with cavitation on initial CXR and (+) culture at completion of 2 months treatment should receive a 7-month continuation phase.

(7) Consult the Alaska TB program to verify count of DOT doses and determine end of treatment date.

(8) Collect 3 sputa monthly until all 3 are culture negative. Consider more frequent collection if clinically indicated. Repeat susceptibility testing if cultures positive after 3 mos of treatment.

(9) If the patient is culture-negative, a repeat CXR is indicated during treatment to demonstrate improvement. A repeat CXR may also be useful if sputum specimens remains culture positive > 3 mo.

(10) Perform monthly clinical assessments throughout treatment. Ask about nausea, vomiting, abdominal pain or swelling, jaundice, joint pain, vision changes, tingling extremities, or flu-like symptoms. When EMB is part of the regimen, test visual acuity and color vision.

(11) Assess adherence to DOT & treatment plan. Use incentives & enablers. Report ≥ 2 missed DOT doses to the Alaska TB Program.

Initial Assessment

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

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

See the Diagnosis and Treatment of Latent Tuberculosis Infection (LTBI) and Tuberculosis Disease in Children section for more information **9.1**.

See the "Alaska TB Program: Timeline for the Case Management of TB Treatment" **(10.5)** in this section for more information.

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.

Case managers should also be sensitive to eliminating stigmatizing language in their work with persons being treated for TB or LTBI. For example, instead of describing patients as being "compliant or non-compliant" with their treatment regimens, use "adherent or non-adherent" as alternatives.

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* (Curry International Tuberculosis Center Web site; 2003) at https://www.currytbcenter.ucsf.edu/products/view/directly-observed-therapy-training-curriculum-tb-control-programs

http://www.currytbcenter.ucsf.edu/products/product_details.cfm?productID=EDP-07

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 https://ncihc.memberclicks.net/assets/documents/ResourceGuideFinal%5b1%5d.pdf#:~:text=Language%20Services%20resource%20Guide%20for%20Health%20care%20Providers,Care%3A%20Wilma%20Alvarado-Little%2C%20Joy%20Connell%2C%20and%20Elaine%20Quinn.

For more information on using interpreters, see the *Addressing Language Barriers* lesson in Module 6: "Managing Patients and Improving Adherence" of the CDC's *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 2013) at https://www.cdc.gov/tb/education/ssmodules/pdfs/Module6.pdf

For more information about non-stigmatizing language, see materials from the Heartland TB Center at: https://heartlandntbc.org/stopthestigma/FactSheet_Final_5_19_16.pdf and the STOP TB Partnership at: http://www.stoptb.org/assets/documents/resources/publications/acsm/LanguageGuide_ForWeb20131110.pdf

Patient's Medical Records

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

Suspected or confirmed TB is a reportable condition in Alaska. As such, the Alaska TB Program can request medical records related to TB and its diagnosis without a signed medical release according to 7 AAC.27.005 and HIPAA.

Case Managers may use the *Consent for Release of Information Form* **(18.1),** if necessary, to obtain the patient's medical records. Send a copy of the medical records to the Alaska TB Program.

Assessment Site

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.

Due to limited travel schedules, itinerant PHNs may have few opportunities for home visits or in-person visits with patients during their TB treatment. If PHN case managers are having difficulty scheduling face-to-face interactions for initial and follow-up visits with patients, they should consult their Regional Nurse Manager (RNM) or the Alaska TB Program to explore options. Alternatives to home visits or other face-to-face encounters may include teleconferences that include the Community Health Aide/Practitioner (CHAP), patient, PHN, and the DOT Aide, individual phone calls to the patient, letters, visits by other providers, etc., during the course of treatment.

Whenever possible, start the initial assessment within one (1) business day of the case report for infectious or smear positive pulmonary cases; and within three (3) business days of the case report for others. Itinerants who provide TB case management for patients in remote villages should initiate assessments as soon as possible. See MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis at http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf

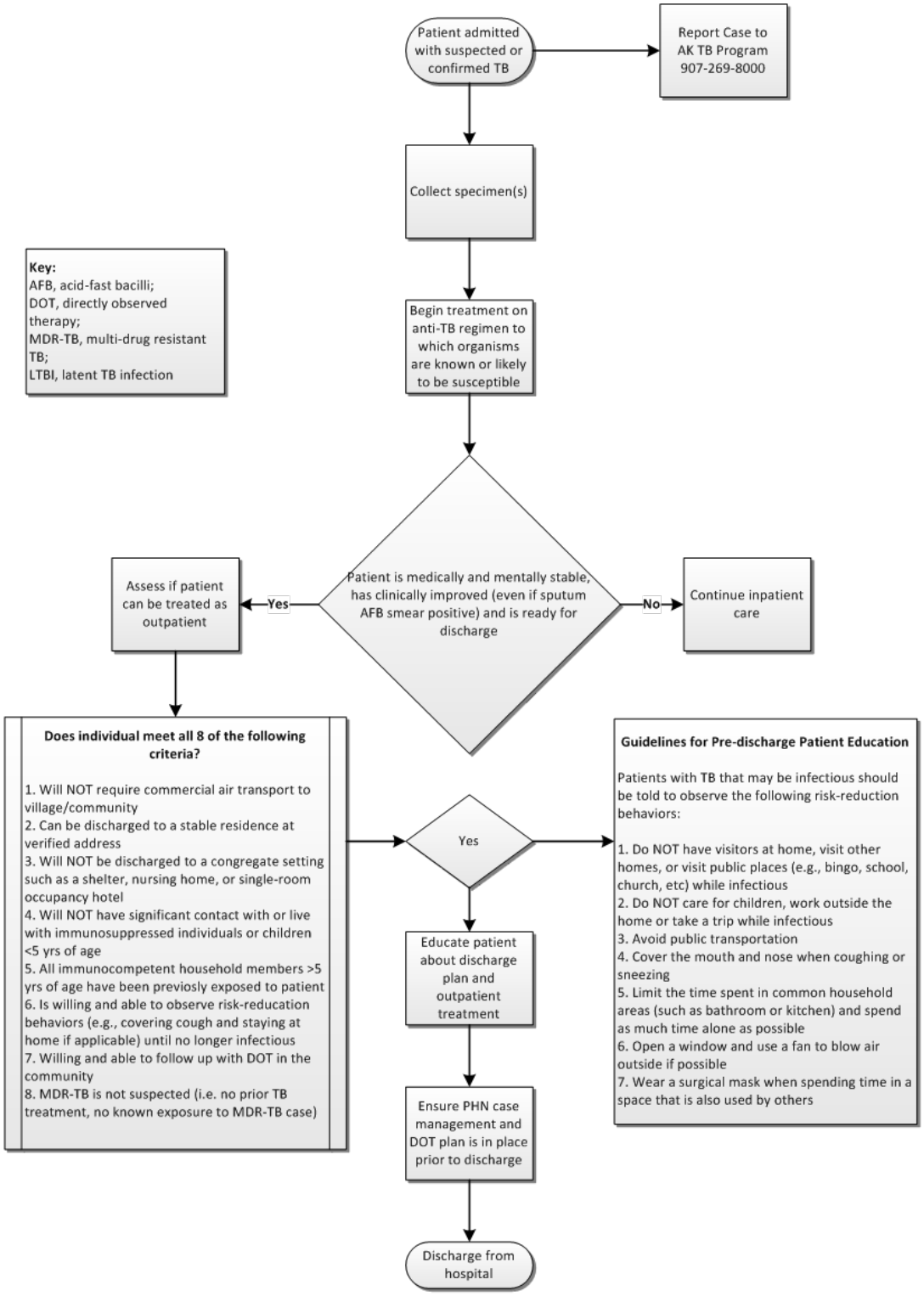
Hospital Discharge Planning

Patients with suspected or diagnosed active TB require collaborative discharge planning before release. 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]

Patients being considered for discharge should meet the following three criteria:

- Complete at least 2 weeks of adequate treatment with anti-TB drugs;
- Demonstrate clinical improvement in TB symptoms; and
- Have three (3) consecutive negative AFB sputum smear results collected in 8 – 24-hour intervals (at least one being an early morning specimen).[16]

Figure 1: **CRITERIA FOR DISCHARGING PATIENTS WITH SUSPECTED OR CONFIRMED TUBERCULOSIS FROM THE HOSPITAL**



Adapted from: New York City Department of Health and Mental Hygiene, Bureau of Tuberculosis Control. Clinical Policies and Protocols, 4th Edition, March 2008. Available at: https://www1.nyc.gov/assets/doh/downloads/pdf/tb/tb-protocol.pdf

Table 1 below provides additional guidance for isolation and release criteria based upon the patient's characteristics at diagnosis.

Table 1: **Guidelines for Home and Hospital Isolation of Infectious Tuberculosis Patients**

TB Patient Characteristics at Diagnosis	Current Isolation and Release Criteria	Guidelines for Adults and Children with Adult Type Disease*
Sputum Acid Fast Bacilli (AFB) smear positive, and/or NAA positive or patient suspected of having active TB	Hospitalized under inpatient airborne isolation or home isolation and being released to: • General hospitalization, *or* • Outpatient congregate setting, *or* • Home or setting with high-risk contacts	Discharge from airborne isolation patient must meet all the following criteria: 1. Have received standard multidrug anti-TB therapy for at least 2 weeks if original AFB smear positive OR on therapy for 5-7 days if original AFB smear was negative 2. Demonstrated adherence to treatment (DOT) 3. Demonstrated clinical improvement 4. Have 3 consecutive negative AFB smears collected at least 8 hours apart with at least 1 early morning specimen 5. Have no risk factors for drug resistance
Sputum AFB smear negative and TB is not suspected, NAA testing if done is negative and/or another diagnosis is likely	Hospitalized under inpatient airborne isolation and being released to: • General hospitalization • Return to school, *or* • Return to work, *or* • Allowed to travel on commercial/ public transportation	Discharge from airborne isolation patient must meet all the following criteria: 1. Have 3 consecutive negative AFB smears collected at least 8 hours apart with at least 1 early morning specimen 2. TB is not likely and another diagnosis is identified
Sputum AFB smear negative and TB is suspected or confirmed through NAA testing	Hospitalized under inpatient airborne isolation or home isolation and being released to return to normal activities including: • General hospitalization • Return to school, *or* • Return to work, *or* • Allowed to travel on commercial/public transportation	Discharge from home isolation patient *must* meet all the following criteria: 1. Have received standard multidrug anti-TB therapy for at least 5-7 days 2. Demonstrated adherence to treatment (DOT) 3. Demonstrated clinical improvement 4. Have 3 consecutive negative AFB smears collected at least 8 hours apart with at least 1 early morning specimen 5. Have no risk factors for drug resistance

Source: Adapted from Heartland National TB Center. Guidelines for Home and Hospital Isolation of Infectious Tuberculosis Patients. Rev. June 2019. Available at: http://www.heartlandntbc.org/assets/products/guidelines_home_hospital_infectious_patients.pdf

Travel

Travel is often a challenging issue for persons being treated for tuberculosis in Alaska because of our reliance on air travel. Patients may be medically ready for discharge but may **not** be able to travel to their community or village by commercial air or other public transport if they do not have three (3) consecutive negative AFB sputum smear results collected in 8 – 24-hour intervals (at least one being an early morning specimen). This can be an issue for individuals from outlying villages who are hospitalized in Anchorage or other hub communities. The CDC can place the patient on the Do Not Board (DNB) list if it determines that the person 1) is known or believed to be infectious with, or at risk for, serious contagious disease that poses public health threat to others during travel AND 2) not be aware of his or her diagnosis, have been told about the diagnosis and not following public health recommendations, or be unable to be located or 3) be likely to travel on a commercial airplane into, through, or from the US or travel internationally by any means or 4) need to be placed on the DNB and Lookout list to respond to a public health outbreak or to help enforce a public health order. Once a person is placed on the list, airlines are instructed not to issue a boarding pass to the person for any commercial domestic flight or for any commercial international flight arriving in or departing from the United States.[17] Local flying services are not covered by DNB lists and would require a request from the Alaska TB Program to restrict travel for suspected infectious patients until they no longer pose a risk to others. Pilots are responsible for the safety of their flights and may refuse to transport individuals who could jeopardize flight safety. This might include persons who are unruly, intoxicated or masked. Although ferries, trains and busses are not covered by the DNB list, the Alaska TB Program and public health officials would advise against travel for a potentially infectious patient on these conveyances.

Hospital staff should discuss discharge options and plans with the Alaska TB Program to ensure a safe and seamless discharge when the patient is ready. For patients unable to return to their residence because they still have positive AFB smears, the Alaska TB Program may be able to provide assistance for local lodging on a case-by-case basis as the payer of last resort.

Hospitals should notify the Alaska TB Program at least 48 hours (2 business days) before discharging a patient with tuberculosis.

Hospital discharge planners should use the *Tuberculosis Discharge Planning Checklist* **(18.1)** to coordinate discharge planning with the Alaska TB Program and local PHNs. Send a copy of the pertinent medical records to the Alaska TB Program or local PHN, as requested.

Initial Assessment Activities

To complete an initial assessment, perform the following activities:

- Visit the patient's home, hospital room or other location;
- If a face-to-face encounter cannot occur, make initial contact with the patient as discussed in the "Assessment Site" topic of this section **10.8;**
- Obtain or review demographic information;
- Ascertain the extent of TB illness;
- Obtain and review the patient's health history;
- Determine infectiousness or potential infectiousness and initiate contact investigation;
- Evaluate the patient's knowledge and beliefs about TB;
- Initiate treatment, if not initiated during hospital stay;
- Determine how the supply of TB medications will be ordered and maintained;
- Monitor the TB medication regimen;
- Identify any barriers or obstacles to adherence;
- Review psychosocial status;
- Identify and document a good history of the patient's social network;
- Gather information for a possible contact investigation; and
- Consider developing a treatment contract between patient and case manager.

Visit the patient's home. During the patient's TB treatment, at least one or more home visits should be conducted, if possible. Home visits are useful for confirming the patient's address, particularly for patients at high risk for non-adherence. 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).[18] Several home visits may be needed, because usually not all of the necessary information is gathered from the patient and his or her family at one time.

Due to limited travel schedules, itinerant PHNs may have few opportunities for home visits or in-person visits with patients during their TB treatment. If PHN case managers are having difficulty scheduling face-to-face interactions for initial and follow-up visits with patients, they should consult their Regional Nurse Manager (RNM) or the Alaska TB Program to explore options. Alternatives to home visits or other face-to-face encounters may include individual phone calls to the patient, teleconferences that include the Community Health Aide/Practitioner (CHAP), patient, PHN, and the DOT Aide, letters, visits by other providers, etc., during the course of treatment.

Obtain or review demographic information, including the name, address, telephone number(s), birth date, and health insurance provider's name, address, and identifying information.[19]

Ascertain the extent of TB illness, including acuity and length of symptoms, bacteriology and radiographic findings, laboratory analyses, tuberculin skin test results, nutritional status, vital signs, and baseline weight (without shoes or excess clothing).

The responsible health care provider and the Alaska TB Program should be consulted immediately upon receipt of a report of suspected tuberculosis. Within one week of a case report, a tuberculin skin test should be placed, measured, and interpreted; and a chest radiograph should be taken and interpreted. Also within one week of a case report, a minimum of three consecutive sputum specimens of good quality should be collected 8–24 hours apart (with at least one being an early morning specimen) and submitted to the Alaska State Public Health Laboratory. The PHN may also collect sputa, arrange for a chest radiograph, and facilitate a provider evaluation and baseline laboratory testing as needed.

Use the *Referral and Authorization for TB Screening and Follow-up Services* **(18.1)** to refer uninsured patients for a single view chest radiograph or hepatic panel/liver function tests if necessary. The Alaska TB Program will provide partial reimbursement for services as indicated on the form. See the "Chest Radiography" topic in the Diagnosis of LTBI section **(7.18)** of this manual in for more information.

In the case of pulmonary TB in children younger than 5 years of age, posterior-anterior and lateral chest radiographs are important in the initial diagnosis.[20] Adults who are suspected of TB or who are active cases usually need only an initial posterior-anterior chest radiograph.

See the Diagnosis and Treatment of Latent Tuberculosis Infection (LTBI) and Tuberculosis Disease in Children section for more information **9.1**.

See the "Alaska TB Program: Timeline for the Case Management of TB Treatment" **(10.5)** in this section for more information.

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

patient's primary care provider and any specialists involved in his or her medical care, previous hospitalizations, allergies, and current medications. It is important to know the history of treatment for TB infection and/or disease, especially for patients who are treatment failures or have a relapse of TB disease, as they are at a higher risk for developing multidrug-resistant (MDR-TB) and extremely drug resistant (XDR-TB). It is also important to determine what the patient perceives as his or her most important medical/health problem. The date of the last menstrual period and contraceptive use should be obtained from female patients.[21]

Some antituberculosis medications may interfere with hormonal contraceptives. For more information, see the "Side Effects and Adverse Reactions" topic in the Treatment of Tuberculosis Disease section **6.13**.

Determine infectiousness or potential infectiousness and initiate contact investigation. To determine where and on whom to initiate contact investigation, the initial assessment should gather information to define the start and end dates of the period of infectiousness. This assessment should include the duration and frequency of symptoms, especially cough, and a review of the radiographic findings. If the patient is infectious or potentially infectious, the case manager should have an understanding of the period of infectiousness. The parameters of a contact investigation, including the need for repeating the tuberculin skin test for contacts that were initially negative, can then be determined.[22]

For more information on the period of infectiousness and when to initiate contact investigations, see the Contact Investigation section **11.1**.

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.[23]

Initiate treatment. Treatment with a four-drug regimen should be initiated promptly when a patient is seriously ill (history of cough, hemoptysis, night sweats, fever, weight loss, chest pain, abnormal radiographs, sputum smear positive) with a disorder that is thought possibly to be tuberculosis. Initiation of treatment should not be delayed because of negative AFB smears for patients in whom tuberculosis is strongly suspected and who have a life-threatening condition. Disseminated (miliary) tuberculosis, for example is often associated with negative sputum AFB smears. Likewise, for a patient with suspected tuberculosis and a high risk of transmitting *M. tuberculosis* if, in fact, she or he had the disease, combination chemotherapy should be initiated in advance of microbiological confirmation of the diagnosis to minimize potential transmission (see

ATS, CDC, IDSA's *Diagnosis of Tuberculosis in Adults and Children* (2017) at https://www.cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf).

Directly observed therapy (DOT) is the standard of care for all persons diagnosed with pulmonary tuberculosis in Alaska. It is also recommended for all persons diagnosed with extrapulmonary tuberculosis.

Determine how the supply of TB medications will be ordered and maintained. The PHN case manager should order drugs immediately upon receipt of medical orders which document drugs, dose, route, frequency, and duration.

Information on ordering TB medications is discussed in the "Ordering Medications for the Treatment of Tuberculosis" topic in this section **10.21**.

It is the responsibility of the prescribing provider to ensure that newly prescribed anti-tuberculosis medications do not interact unfavorably with prescription or over the counter medications that the patient is currently taking. Additional information on common drug interactions can be found in the "Monitoring for Side Effects and Adverse Reactions" topic in the Treatment of Tuberculosis section of this manual **6.13.**

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 observe patients swallow medications. Tuberculosis medications should be given once daily, both inpatient and outpatient. 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 **6.6**.

Identify any barriers or obstacles to adherence in taking TB medications and keeping provider 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.

It is very important for case managers to identify, document, and report nonadherence with TB treatment and DOT to the Alaska TB Program as soon as possible. If DOT Aides are observing patients taking TB medications, they should also be instructed to report two (2) or more consecutive missed DOT doses to the PHN case manager as soon as possible.

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 good history of the patient's social network. This is important to identify and document in the event that the patient does not return for follow-up. The case manager needs to verify the patient/family's address, evaluate residential stability, and assess potential for homelessness. Determine the patient's residence(s) during the past year, particularly any congregate living situations, such as prison, jail, homeless shelter, nursing home, boarding home, or foster care. Establish the patient's occupation and/or student status and document the name and address of business or school. The name and location of a child's babysitter, other caretakers, daycare center, and/or school should be noted. In order to identify those who have shared common air space with the infectious, untreated patient with TB, it is necessary to have an understanding of the patient's social and recreational activities and how he/she spends leisure time. This includes time spent at bars, bingo, circuit parties, faith-based functions, and other venues.

For more information see the Contact Investigation section of this manual **11.1**.

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.

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** because it tailors treatment to the 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 anti-tuberculosis 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 as needed during reviews of clinical progress.[29]

The Alaska TB Program conducts monthly TB case management meetings or teleconferences with PHNs and providers in several regions of the state. Individual patient status and treatment plans are discussed and recommendations are provided during these meetings.

See the "Alaska TB Program: Timeline for the Case Management of TB Treatment" **(10.5)** in this section for more information.

Treatment Plan Components

Recommended components of a treatment plan include the following:

- Patient's verified address and contact information;
- Assignment of responsibilities: case manager, clinical supervisor (nurse, physician, or physician assistant), DOT workers, other caregivers (outreach workers, nurses), and person managing the contact investigation;
- Method for prevention of transmission: no isolation, airborne infection isolation, home isolation, legal order for isolation;
- *Tuberculosis Treatment Contract* signatures of the PHN case manager and the patient (or patient's representative), if a treatment agreement is used;
- Planned course of anti-tuberculosis drug therapy;
- Estimated date of completion of treatment (i.e., treatment plan);
- Test results from initial medical evaluation;
- Medical history;
- Diagnosis;
- Monitoring activities and schedule to assess response to therapy;
- Baseline tests and monitoring activities and schedule to detect potential side effects and adverse reactions;
- Potential drug interactions;
- Potential treatment adherence obstacles;
- Personal service needs;
- Referrals for social services;
- Means of ensuring successful completion of treatment (DOT, incentives, enablers); and
- Location(s) where DOT will be administered.[30]

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; and
- 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.[31] DOT is the standard of care for all persons with suspected or confirmed TB.

Establish time frames in the treatment plan to monitor the plan and patient response. Monitoring should be done at least monthly at the patient's home, ambulatory clinic, health department, or health care provider's office. When itinerant PHNs provide case management for patients in villages, monthly monitoring can be done by teleconference in conjunction with the CHAP or DOT Aide, phone, or may be done by the patients' provider. Each component of the plan should be reviewed to ensure that it is an accurate accounting of the patient's status, 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]

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; and
- Coordinate strategies to improve adherence.

Refer the patient to other healthcare providers, social service agencies, or community organizations, as needed. All patients being treated for active tuberculosis need a medical home. 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 confirmed TB should be tested 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 each

referral to obtain medical information and to determine whether the necessary medical intervention has been completed.

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. Schedule or assist the patient in scheduling appointments and monitor the patient's adherence to the appointment and the results.

An understanding of the patient's financial resources and health insurance coverage is important. Lack of financial resources or health insurance will affect the patient's willingness to keep appointments, which may be critical to his or her health. The case manager may need to discuss essential services with insurance companies or other healthcare providers to obtain the most cost-effective, quality service.[35] Help the patient access financial assistance and receive treatment for psychosocial, alcohol-related, and drug-related conditions.

Negotiate a plan for DOT. 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 may consider having the patient sign a treatment 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 **10.37**.

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. A written contract detailing the agreed upon responsibilities of both the patient and the case manager may be useful to improve adherence to treatment. When incentives and enablers are used, they should be meaningful and specific for a particular patient.[37] Incentives and enablers may be considered for use with all patients.

Use the *Tuberculosis Treatment Contract* to document the responsibilities of the patient and PHN case manager. It is available in the Forms section of the manual **(18.1).**

The Alaska TB Program has limited funding resources for incentives and enablers. Persons being treated for active tuberculosis are the **priority** for incentives and enablers. PHN case managers should request funds through their Regional Nurse Managers.

Ordering Medications for the Treatment of TB

The Alaska TB Program provides medications for the treatment of tuberculosis and LTBI free of charge. The PHN case manager should order drugs immediately upon receipt of medical orders. The *TB/LTBI Prescription and Medication Request* **(18.1)** can be used as a prescription by the provider and may also be used by the PHN case manager to order medications for patients. When providers do not use the new form as a prescription, please include a copy of the prescription with the initial medication request. Anti-tuberculosis medications can be sent directly to the PHN case manager, a clinic or licensed provider.

All providers prescribing and /or requesting medications from the SOE Drug Room agree to use standard and approved regimens as referenced in this AK TB Manual to treat individuals for suspected or confirmed tuberculosis or LTBI. In special situations and after consultation with the Alaska TB Program, other regimens may be approved if clinically indicated.

- Requests for TB medications should be faxed to the Alaska TB Program at 907-563-7868. Please allow at least 2 weeks for processing and shipping. A hardcopy of the drug order DOES NOT need to be mailed.
- The medication order should state the name of the drug(s), dose, route, frequency, and number of doses.
    - Request the total number of DOSES required to complete therapy for each medication.
    - Indicate the number of doses provided from stock or another source – e.g., hospital pharmacy at discharge.
- Most medications are available in unit dose packaging or in bottles. All DOT medications are supplied in labeled unit dose packs. **Dose packs are NOT child proof and must be stored safely and out of the reach of children at all times**. The SOE Drug Room can assist with safe storage options for DOT Aides if requested by PHNs.
- The SOE Drug Room can compound orders and assist with special dosing. Pill splitters, crushers and liquid measuring devices are available.
- Monthly auto refills are generated by the SOE Drug Room. Each week, the Epi

Drug Room will notify PHNs of medication refills for the week. The PHN should review and inform the pharmacy of any changes in therapy – discontinued medications, dosage or regimen changes, treatment interruptions, etc.

- Second line and special-order drugs – Amikacin, Streptomycin, etc. – must be special ordered and are NOT available by auto refill.
- Drug monographs (patient information sheets) are automatically included with each new prescription. Please specify if you need a language other than English. These must be provided to the patient for each new TB medication.

All discontinued, unused, or close-dated medication should be returned to the SOE Drug Room as soon as possible. Mail all returns to: SOE Drug Room, 3601 C St, Ste. 586, Anchorage, AK 99503.

Use the *TB/LTBI Prescription and Medication Request* to order TB medications for a specific patient. Stock supplies can be ordered using the *TB/LTBI Stock Medication Request*. When returning unused or close-dated medications, use the *TB/LTBI Medication Return Form.* Forms are available in the Forms section of the manual **18.1**.

The *TB/LTBI Prescription and Medication Request Guidelines* document contains detailed information on ordering and storing anti-tuberculosis medications. It is available in the Forms section of the manual **18.1**.

Ongoing Assessment and Monitoring

Conduct ongoing assessments and monitor patients at least **monthly** either in an ambulatory clinic setting, local public health agency, or private physician's office. When itinerant PHNs provide case management for patients in villages, monthly monitoring can be done by teleconference in conjunction with the CHAP or DOT Aide, by phone with the patient, or may be done by the patients' provider. Schedule additional assessments throughout the month for patients experiencing problems in their tuberculosis (TB) treatment, or for those patients who are non-adherent 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]

See the "Alaska TB Program: Timeline for the Case Management of TB Treatment" **(10.5)** in this section for more information.

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 for side effects and adverse reactions to medication;
- Assess adherence daily and monthly, and identify positive and negative motivational factors influencing adherence;
- Address 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; and

- Review the status of the contact investigation, if one was started.

Monitor the clinical response to treatment by reviewing TB symptoms, bacteriology reports, radiographic results, weight, vital signs, drug susceptibility results, and 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 three (3) sputa** for acid-fast bacilli (AFB) sputum smear and culture **at least every two (2) weeks until sputum smears are negative.** Thereafter, three (3) sputa should be collected at least **monthly until there are three negative cultures**. If a patient is on DOT, no further specimen collected is indicated unless the patient becomes symptomatic again. A clinician should complete a medical evaluation at the time of diagnosis 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 bacteriological reports in chronological order and correlate them with the patient's current symptoms history and chest radiograph report to ensure accuracy. Also, conduct this review at conversion as evidence for the improving condition of the patient.[40]

Inconsistencies should trigger additional questions, such as the possibility of laboratory contamination. Bring these questions immediately to the attention of the health care provider, case manager and Alaska TB Program (907) 269-8000.

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.[41] 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.[42]

Review the treatment regimen to verify that the physician's orders are clear and that dosages are correct for the patients' age and weight. 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.[43]

For consultation regarding the treatment of TB, contact the Alaska TB Program at 907-269-8000.

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. Dosages may need to be adjusted if a patient's weight changes.

Monitor the side effects of and adverse reactions to medication. Review laboratory findings and contact the treating physician if abnormal results are obtained.[44] The patient should be asked about adverse reactions to the medication prior to each dose of medication administered by directly observed therapy (DOT). If the patient is symptomatic the DOT Aide should hold medications and notify the PHN case manager as soon as possible. Chemistries and complete blood count (CBC), aspartate aminotransferase (AST)/alanine aminotransferase (ALT), or other tests based on specific drugs should be done per orders from the medical provider or medical officer for the Alaska TB Program. See Table 5**: Monitoring and Interventions for Side Effects and Adverse Reactions** in the Treatment of Tuberculosis Disease section **6.13**.

PHN case managers who work with DOT Aides should stress upon DOT Aides the importance of notifying the PHN as soon as possible in these situations:

- The patient misses two (2) or more consecutive DOT doses; OR
- The patient reports symptoms of medication side effects or adverse reactions.

Use the *Referral and Authorization for TB Screening and Follow-up Services* **(18.1)** to refer uninsured patients for a hepatic panel/liver function tests if necessary. The Alaska TB Program will provide partial reimbursement for services as indicated on the form.

Assess adherence daily and monthly and identify positive and negative motivational factors influencing adherence. An assessment of adherence needs to occur at each patient encounter. If the case manager is not directly providing DOT, the DOT Aide should alert him or her if the patient misses a DOT dose. If two (2) or more DOT doses are missed, the DOT Aide should notify the PHN case manager as soon as possible. The PHN case manager should contact the patient the same day or the next business day and should reinforce the need for adherence with the DOT plan. Individualized incentives or enablers should be used to promote treatment adherence.

Direct observation provides immediate information on poor adherence and adverse effects. The key to a successful DOT program is the timely use of this information in order to promptly identify and respond to potential barriers to adherence, missed doses, and potential adverse treatment effects. **It is important not to send a mixed message to a patient by not promptly responding to missed DOT doses**.

A preventable interruption in treatment can be avoided if the PHN case manager is notified immediately, rather than when the monthly DOT calendar is submitted. Also, regularly monitor the effectiveness of enhancement methods (i.e., incentives, enablers, behavioral contracting, or behavior modification).[45] The case manager should review the monthly DOT calendars to ensure that patients have taken all medications. 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 and TB regimen should be documented.[46]

For more information, see the "Directly Observed Therapy" and "Medical Orders" topics in this section **10.37** and **10.44**.

Address 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.[47]

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.[48] The case manager should provide patient and family education as needed and until satisfactory recall is obtained.

For more information, see the Patient Education section **13.1**.

Advocate for the patient with team members and other service providers when necessary. The case manager should demonstrate respect and understanding of the patient's cultural beliefs and values and prevent team members from imposing their own values or belief systems on the patient. The case manager should be able to communicate the patient's fears/anxieties, likes/dislikes, and needs/wants to the team members in a nonjudgmental manner. The case manager must also have an understanding of the team members, and mediate, negotiate, and resolve differences of opinion regarding the patient and interventions.[49]

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.[50] National CDC guidelines recommend that contact investigation should begin within one week of notification of a smear positive suspect or case and be completed as soon as possible. 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 anti-tuberculosis medications and monitor toxicity. The patient should be monitored at least monthly by the PHN for signs and symptoms of adverse reactions until treatment is completed. If a patient is symptomatic, the medications should be held. The Alaska TB Program and 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 per orders

See Table 5**: Monitoring and Interventions for Side Effects and Adverse Reactions** in the Treatment of Tuberculosis Disease section **6.13**.

As is true with all medications, combination chemotherapy for tuberculosis may have adverse reaction, some mild, some serious.[51]

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.[52] 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.[53] The Alaska TB Program medical officer is available for consultations upon request at (907)-269-8000

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 **6.13**.

Use the *Referral and Authorization for TB Screening and Follow-up Services* **(18.1)** to refer uninsured patients for a hepatic panel/liver function tests if necessary. The Alaska TB Program will provide partial reimbursement for services as indicated on the form.

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.[54]

For more information, see the Patient Education section **13.1**.

Assess the patient for adverse reactions and side effects. For patients on self-administered therapy, the case manager ensures that patients are assessed for adverse effects to TB medications at least monthly and at each visit. If the patient is on DOT, the PHN or DOT Aide 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 .[55]

Monitoring Bacteriologic Improvement

Assess and document response to treatment. The case manager should **collect three (3) sputa for AFB sputum smear and culture at least every two (2) weeks until sputum smear conversion. Thereafter, three (3) sputa should be collected at least monthly until there are three negative cultures.** If a patient is on DOT, no further specimen collected is indicated unless the patient becomes symptomatic. [56]

Activities to Monitor for Bacteriologic and Clinical Improvement

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

Acid-Fast Bacilli Sputum Smear Negative

If a patient is AFB sputum smear negative, place laboratory reports promptly in the patient's chart. If previously AFB sputum smear positive and now AFB sputum smear negative on three (3) consecutive specimens collected at 8–24-hour intervals with at least one early morning specimen, consider discontinuing isolation.[57] [58]

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 at least every 2 weeks until three (3) consecutive negative specimens collected at 8–24-hour intervals with at least one early morning specimen.
- **Has new AFB sputum smear positive results and is diagnosed with pulmonary TB:** Notify the Alaska TB Program and provider and initiate isolation. Repeat sputa smears at least every 2 weeks until three (3) consecutive negative specimens collected at 8–24-hour intervals with at least one early morning specimens, have been documented.[59]

Culture-Positive Pulmonary Tuberculosis

For patients with culture-positive pulmonary TB, collect three (3) sputa specimens at least monthly for smears and cultures until persistently negative cultures are documented.[60] Once culture conversion has occurred, discontinue sputa collection.

Continued Positive Sputum Smears or Positive Cultures

If sputum smears or cultures are positive after two (2) months of treatment, call the Alaska TB Program at 907-269-8000 to review the case.

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 (3) months of treatment or become bacteriologically positive after initially converting to negative.

In consultation with the Alaska TB Program, the case manager should initiate the evaluation of the patient and do the following:

1. Review and confirm the patient's medication compliance with the DOT Aide.
2. Reconfirm the appropriateness of the medication regimen, based on drug susceptibility results and other considerations.
3. If additional anti-tuberculosis 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.
4. Consider serum drug levels.
5. Repeat cultures and repeat drug susceptibility testing.[61]

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 and document the patient's symptoms for improvement, if applicable.
4. Review the patient's tuberculin skin testing or IGRA information (retesting may be appropriate if initially negative or if test not initially done) and discuss this with the patient's provider.
5. If the patient is not to be counted as confirmed case of tuberculosis, the Alaska TB Program will classify the patient as a suspect case of tuberculosis. Occasionally, providers may opt to fully treat individuals for culture negative tuberculosis. In these situations, PHN case managers should continue all case management activities as long as the patient is receiving anti-tuberculosis medications for suspected tuberculosis.
6. Discuss the above findings with the Alaska TB Program at 907-269-8000 to determine if the patient is to be reported as a case. Often, determination of status for such clinical cases cannot be done until the end of treatment.

Verification of Isolate Drug Susceptibility Results

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

1. I**f a patient's TB organism is susceptible to all first-line anti-tuberculosis drugs**: Follow the recommended treatment regimen.
2. **If a patient's TB organism is drug resistant**:
   - **a.** Consult with the patient's health care provider and the Alaska TB Program at 907-269-8000.
3. If isoniazid-resistant or multidrug-resistant TB (MDR-TB) or extremely drug resistant TB (XDR-TB):
   - **a.** Place contacts on appropriate latent TB infection (LTBI) treatment regimens. Treatment of LTBI caused by drug-resistant organisms should be provided by, or in close consultation with, an expert in the management of these difficult situations. For patients with MDR-TB, refer to the instructions on multidrug-resistant tuberculosis provided below.

Contact the Alaska TB Program at 907-269-8000 for consultation regarding the treatment of all drug-resistant tuberculosis and management of contacts.

Multidrug-Resistant Tuberculosis

Notify the Alaska TB Controller of all cases of suspected or confirmed MDR-TB or XDR-TB. Consultation regarding the treatment of all drug-resistant tuberculosis and management of contacts is available by calling 907-269-8000.

Clinical Response to Treatment

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

1. Lessening or resolution of TB symptoms;
2. Weight gain; OR
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.[62]

Criteria for starting isolation and discontinuing isolation are provided in the Infection Control section **17.15**.

Closing a Case

If the patient is not to be reported as a verified case of tuberculosis, the Alaska TB Program will notify the PHN case manager that the patient is categorized as a suspect case of tuberculosis vs. a confirmed case.

For more information on closing a case, see the "Completion of Therapy" topic in this section **10.32**.

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 an Alaska TB Program and Centers for Disease Control and Prevention (CDC) goal and important measurement of the effectiveness of tuberculosis (TB) control efforts. Verification of completion of therapy and a completed contact investigation are the responsibility of the PHN case manager.

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 and consulting with the Alaska TB Program to ensure that the patient has received an adequate course of therapy.

- **If culture remains positive beyond two (2) 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 **6.12.**
- **HIV-negative, culture-negative patients:** See “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in the Treatment of Tuberculosis Disease section **6.12**.
- **Relapse of TB following treatment for TB with pan-susceptible organisms.** Treatment may be prolonged to nine (9) months or more. (Current drug susceptibility testing must be performed, and the regimen adjusted if resistance has developed.)[63]

Calculating Completion of Therapy

Base the completion of treatment on the number of doses of directly observed therapy (DOT) and full weeks of treatment received rather than on the chronological passage of time. Each dose should be recorded on the DOT calendar and counted to ensure that the required number of doses has been delivered and consumed over the course of the number of weeks of treatment.

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 **6.6**.

Use the *TB Medication Dose Monitoring* forms to help count each DOT dose. The Form to assist in counting drugs for all approved regimens can be found in the Forms section of this manual **18.1**.

Contact the Alaska TB Program at 907-269-8000 to determine the end of treatment date based upon the number of DOT doses consumed during the number of weeks of treatment.

If unable to locate a patient despite many attempts, call the Alaska TB Program at 907-269-8000 to review the case.

Documenting Completion of Treatment and Follow-up Recommendations

The case manager should ensure that the patient understands when TB treatment is complete and provide written documentation to the patient of an adequate course of treatment. General and individualized specific follow-up recommendations should also be provided in writing to the patient. All individuals completing treatment for active tuberculosis should also be educated about the symptoms of tuberculosis and be advised to be re-evaluated should they occur in the future.

Use the *End of Treatment Letter and Summary* to provide written TB treatment and follow-up information to the patient. It can be found in the Forms section of this manual **18.1**.

Case 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 Alaska TB Program should be notified, and procedures followed as described in the Transfer Notifications section. Cases should be closed as “moved” only if a new address is obtained.

For information on who to alert when a case will move or has moved, refer to the Transfer Notifications section **15.1**.

- **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.”

If unable to locate a patient despite many attempts, call the Alaska TB Program at 907-269-8000 to review the case.

- **Died:** If the patient expired prior to completion of therapy, the case is closed as "Died."[64]

Ensure that the contact investigation on the case is also completed. For more information, see the Contact Investigation section **11.1**.

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?

The Alaska TB Program conducts monthly case management teleconferences with PHNs. Call 907-269-8000 to schedule.

Evaluation Activities

To evaluate case management, perform the following activities:

- Monitor the multidisciplinary care plan at least monthly;
- Identify strengths or weaknesses;
- Conduct a case management teleconference at least every month with the Alaska TB Program;
- Monitor case reporting and the contact investigation; and
- Participate in cohort review.[65]

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.[66]

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

Conduct a case management meeting or teleconference with the Alaska TB Program periodically to identify variances or common elements among a group of patients being

evaluated or treated for TB. Case management teleconferences allow a systematic review of the management of TB patients with TB disease and their contacts. With the information learned from the evaluation, the case manager can make changes to improve patient care outcomes.[67]

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]

Cohort review is a systematic review of patients with tuberculosis (TB) disease and their contacts. A "cohort" of patients from a specific period of time (usually 3 months) is reviewed in terms of individual patient outcomes and program performance. Thus, it is a management process used to increase staff accountability for patient outcomes including completion of treatment for both TB disease and LTBI, improve TB case management and identification of contacts, motivate staff, identify program strengths and weaknesses, and determine staff training and professional education needs. Increased accountability also helps TB control programs meet their program objectives and national objectives.[69]

In lieu of cohort review, the Alaska TB Program uses monthly case management meetings and teleconferences with PHN case managers and select providers to ensure that all patients receive appropriate care and management in order to achieve the best possible outcomes for persons being treated for suspected or confirmed tuberculosis and for high-risk individuals being treated for LTBI. It is anticipated that retrospective cohort review will also be implemented in Alaska in the near future.

Directly Observed Therapy

Provide directly observed therapy (DOT), as required. DOT means that a healthcare worker or other designated individual trained and monitored by the PHN case manager 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. All patients on SAT should be monitored at least monthly for adverse reactions. Ideally, this should occur at the time that medications are dispensed.

DOT is a component of case management that helps to ensure that patients receive effective treatment and adhere to it. The American Thoracic Society (ATS), the Centers for Disease Control and Prevention (CDC), and the Alaska TB Program recommend that every tuberculosis (TB) patient be given medication via DOT.[70] DOT is implemented because

- DOT is the most effective strategy for making sure that patients take their medicines;
- DOT can lead to reductions in relapse and acquired drug resistance;[71] and
- Directly observing each dose provides immediate information on poor adherence and adverse effects, information that cannot readily be obtained from patients treated with SAT.

Candidates for Directly Observed Therapy

DOT is the standard of care for all persons with suspected or confirmed pulmonary and laryngeal TB, both nationally and in Alaska. The goal of the Alaska TB Program is to place all patients on DOT regardless of the patient's circumstances because it has been shown to be such an important treatment tool.[72] DOT is recommended for extrapulmonary TB as well. Additionally, consider DOT for the following:

- Persons with human immunodeficiency virus (HIV) coinfection and on treatment for latent TB infection (LTBI)
- Immunocompromised persons on treatment for LTBI
- Contacts under the age of 5 on treatment for LTBI
- Contacts who are TST converters and on treatment for LTBI
- High risk individuals on the 12-week INH/RPT (3HP) regimen for LTBI should be considered for DOT.

Thrice-weekly doses of TB medications should be scheduled on Monday, Wednesday, and Friday to ensure that the prescribed regimen is delivered by DOT.

Face-to-Face and Video DOT (VDOT)

The standard of care for DOT in Alaska is a face-to-face visit between the patient and PHN or DOT Aide. An increasing number of state TB Programs are using video DOT (VDOT) for treatment of select, lower risk patients. VDOT has been shown to reduce staff costs and travel time, increase patient and staff satisfaction with treatment, allows patients greater freedom and flexibility and increases the likelihood of treatment completion.[73]

In January 2018, the Alaska TB Program implemented a small-scale VDOT pilot project with a limited number of patients using FaceTime. Since then, specific policies and procedures have been developed and are available on the Alaska TB Program website and in this Manual. [74] Most information presented in this Manual regarding DOT is based upon traditional in-person DOT, but many principles also apply to VDOT.

How to Deliver Directly Observed Therapy

In Alaska, PHN case managers are responsible for recruiting, training, and monitoring the work of DOT Aides.

The TB/LTBI Prescription and Medication Request Guidelines contain detailed information on ordering and storing anti-tuberculosis medications. It is available in the Forms section of the manual **18.1**.

The Alaska TB Program has a detailed DOT Manual and training video posted on its website. These materials were developed as a collaborative project between the Alaska TB Program and the Section of Public Health Nursing. http://dhss.alaska.gov/dph/Epi/id/Pages/TB/public%20health.aspx

New materials on VDOT practice guidelines, selection criteria, processes and protocol, and client consent are available on the Alaska TB Program website. http://dhss.alaska.gov/dph/Epi/id/SiteAssets/Pages/TB/SOE_VDOTPracticeGuidelines.pdf and http://dhss.alaska.gov/dph/Epi/id/SiteAssets/Pages/TB/SOE_VDOTConsent.pdf

Video Directly Observed Therapy (VDOT)

Video Directly Observed Therapy (VDOT) can be a more convenient, client-centered approach to medication delivery for some clients compared to traditional face-to-face DOT. VDOT has been implemented in other states with select clients on a voluntary basis. The Alaska Section of Epidemiology (SOE) supports the use of VDOT and is currently only using FaceTime or Skype.

Selection Criteria

The client's Alaska TB Program or Public Health Nurse (PHN) case manager will consider the individual circumstances of each client to determine if the individual is a good candidate for VDOT. The Alaska TB Program, PHN, and the client's treating health care provider will all confer prior to making a decision. Any client who is a candidate for traditional in-person DOT can be considered as a candidate for VDOT and the following are among the factors to be considered when deciding if the client is a good candidate for VDOT:

- Does the client accept the TB/LTBI diagnosis, show motivation, and understand the need for treatment?
- Has the client been on in-person DOT for a minimum of 2 weeks with 100% compliance?
- Is the client experiencing any major side effects or tolerating a stable medication regimen for at least 2 weeks since initiation of therapy?
- Is the client 18 years old or above? Minors can be considered on a case-by-case basis with parental/guardian permission.
- Could the client accurately identify each medication?
- Is the client able to use and maintain the equipment needed for VDOT?
- Is the client able to demonstrate how to properly hold a call via FaceTime or Skype?
- Is the client able to fully participate in VDOT independently (e.g., vision problems, hearing difficulty, language barrier)?
- Does the client have a reliable phone with internet/cellular connection that can support FaceTime or Skype video calls?
- Does the client have any health conditions that are unfavorable to VDOT (e.g., extensively drug-resistant (XDR) TB, severe co-morbidities)?
- Does the client have any risk for poor adherence (e.g., homeless, substance abuse, prior failed TB treatment, psychiatric illness, memory impairment)? Clients initially excluded from VDOT due to concerns of poor adherence may later be a candidate for VDOT based on ongoing assessment.

Reasons to Stop VDOT and Return to In-Person DOT

(Note: The decision to stop VDOT will be made in collaboration with the PHN, SOE, medical provider and the client.)

Reasons to stop VDOT once it is started include:

- Changes to the client's condition or situation that is unfavorable to VDOT.
- Client reports that they would like to return to in-person DOT.
- Client has severe adverse reaction to TB/LTBI medication.
- Client unable to participate in confidential VDOT (e.g., housing or technology issues).
- Client misses VDOT appointments two days in a row and is unresponsive to additional PHN outreach.
- Client misses monthly medical follow-up visits or in-person meetings with PHN or other medical provider.

(Note: VDOT can be restarted if the reasons that caused VDOT to be stopped have been resolved, and it is mutually agreeable between the PHN, Alaska TB Program, medical provider and the client.)

VDOT Process

Initiation of VDOT
All of the following must be completed before initiating VDOT:

- Client completes at least 2 weeks of in-person DOT with PHN or other trained staff.
- The Alaska TB Program, PHN, and provider all agree that the client is a good candidate for VDOT.
- PHN discusses the option of VDOT with the client.
- Client agrees to participate in VDOT and signs a consent form that includes:
- Adherence requirements/expectations for VDOT.
- Possible confidentiality concerns.
- Steps required by client for VDOT.
- Client responsibilities in case of technical failure.
- Client and PHN agree on a regularly scheduled time for live video VDOT.
- PHN reviews with client the procedure for VDOT.
- PHN reviews with client instructions and training on how to use FaceTime or Skype.

- PHN reviews with client information about who to call with questions or in an emergency.

VDOT Provider Responsibilities

PHNs or other trained staff that provide VDOT are responsible to follow all agency policies and procedures related to TB and VDOT, including:

- Provide regular monthly in-person visits to complete full assessments and to provide medications to the client.
- When itinerant PHNs provide case management for clients in villages, monthly monitoring can be done by teleconference in conjunction with assessment by the local health aide, DOT Aide, or the patients' providers.
- Document each VDOT encounter following agency policy.
- In case of technical failure while utilizing VDOT, complete DOT in person.

Protocol for Live Video VDOT

1. PHN/trained staff calls the client via Skype or FaceTime at the scheduled time.
2. PHN/trained staff confirms the identity of the client.
3. PHN/trained staff assesses the patient for any adverse medication reactions prior to observing medication ingestion.
4. Client shows the PHN/trained staff the pill bottle or pouch, and then each pill(s) separately, identifying the medication.
5. Client places the pill(s) in their mouth after identification and drinks at least 4 ounces of fluid following pill ingestion.
6. Client opens mouth after ingesting pills to show the PHN/trained staff that the pills were swallowed.
7. PHN/trained staff confirms the time and date for the next VDOT.

Ensuring Client Confidentiality

While the client has consented to the risks inherent with VDOT technology, PHN/trained staff completing VDOT will adhere to HIPAA to protect patient information, regardless of the type of VDOT technology that is used.

Who Can Deliver Directly Observed Therapy?

- PHNs or other clinical staff, such as a nurse, CHA/CHAP or other healthcare worker;
- Staff at other healthcare settings, such as outpatient treatment centers or clinics;

- Other responsible persons, such as school personnel, employers, others trained by the PHN case manager;
- DOT Aides in Alaska;
- *Not* immediate family members.[75]

DOT Aides, Regimens, and Payment for DOT Services

DOT Aides

PHN case managers are responsible for organizing and managing DOT. These responsibilities include identifying, hiring, training, and monitoring the work of DOT Aides. Per the Alaska Board of Nursing, although state regulations (12 AAC 44.965 Delegation of the Administration of Medication) permit a nurse to delegate the administration of medication to a trained non-nurse; technically, the DOT Aide is not administering the medication. The patient is administering the medication to themselves and the DOT aide is observing and documenting the procedure. [Under 12 AAC 44.990 the "administration of medication" means the direct application of a medication to the body of a patient by injection, inhalation, ingestion, or other means.]

The patient and DOT provider should agree upon the time and place for DOT encounters. Sites might include a clinic, workplace, public meeting place such as a restaurant, or the patient's home. In addition to providing DOT and documenting all doses according to guidelines, the DOT Aide also reports symptoms of adverse reactions, missed doses, and anticipated patient travel to the PHN case manager. DOT can be provided by PHN or public health center staff, CHA/CHAPs, teachers, workplace safety officers and other reliable adults. Immediate family members should only be considered as DOT Aides when all other options have been exhausted and must be approved by the Alaska TB Program.

DOT Regimens

The Alaska TB Program recommends the use of TB treatment regimens contained in the Treatment of Tuberculosis Disease section **(6.6 – 6.12)**. When DOT is used, drugs may be given five (5) days a week and will be considered to be daily dosing[76] The Alaska TB Program does not expect that TB medications will be provided by DOT Aides, PHNs, or others on weekends and will only provide payment to DOT Aides for up to 5 doses of anti-TB medications per patient each week unless pre-approved. Some providers may prescribe anti-tuberculosis medications seven (7) days a week. In such situations, medications will be left with the patient to self-administer during the weekend, but these doses will **not** include in the final dose count since they were not administered by DOT.

Payment for DOT Services

PHN staff is never paid to provide DOT to patients; it is considered part of their job duties. Similarly, in situations where CHAPs administer DOT during their normal work hours, they should not be offered payment for DOT. When CHAPs make home visits or meet the patient for DOT after hours or during their lunch break, they may be eligible for DOT payment if arranged in advance with the Alaska TB program. The Alaska TB Program provides payment to DOT Aides for each day they deliver and observe the patient swallow their TB medications.

Funding for DOT Aides is very limited and must be used wisely. Patients with active TB disease remain the first priority for DOT. However, certain individuals with LTBI should also be considered for DOT based on their risk status.DOT should be considered for high-risk individuals on the 12-week INH/RPT regimen for LTBI.

Use the *DOT Aide Job Description*, *DOT Aide Memorandum of Agreement, DOT Calendar,* and *DOT Monthly Invoice for Payment* **(18.1)** to document activities. Send copies of the completed *DOT Calendar* and *DOT Monthly Invoice for Payment* to the Alaska TB Program to request monthly payment for DOT services.

The Alaska TB Program will only provide payment to DOT Aides for up to 5 doses of anti-TB medications per patient each week unless pre-approved. If the provider wants medications to be taken 7 days a week, it is acceptable for most patients to self-administer weekend doses. Only doses delivered by DOT will be counted to determine the completion of treatment date.

Principles of Directly Observed Therapy

- The healthcare worker or DOT Aide should watch the patient swallow each dose of medication. This is done during a face-to-face encounter.
- Use DOT with other measures such as incentives and enablers to promote adherence.
- DOT can be given anywhere the patient and healthcare worker or DOT Aide agree upon, provided the time and location are convenient and safe.[77,78]

Directly Observed Therapy Tasks

1. Obtain anti-tuberculosis medications from the PHN and ensure that they are stored safely and out of the reach of children at all times. Dose packs are NOT child proof and must be stored securely.
2. Deliver medication.
3. Check for side effects and adverse reactions prior to each observed dose.

For more information, see the “Ongoing Assessment and Monitoring” topic in this section **(10.23)** and the “Side Effects and Adverse Reactions” topic in the Treatment of Tuberculosis Disease section **6.13.**

4. Verify medication.
5. Watch the patient swallow 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.[79]

6. Document the visit.

Use the *DOT Calendar* **(18.1)** to record each dose of medication given via DOT.

7. As necessary and appropriate, do the following:
   - **a.** Provide patient education
   - **b.** Help the patient keep appointments
   - **c.** Offer incentives and/or enablers to encourage adherence[80]

For more information, refer to the Patient Education section **(13.1)** and the “Incentives and Enablers” topic in this section **10.43**.

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.[81]

For more information, see the Patient Education section **(13.1)**. For points to use to explain to the patient why DOT is important, refer to the CDC's *Questions and Answers About TB 2005. Active TB Disease: What is directly observed therapy?* (Division of Tuberculosis Elimination Web site; 2005) at http://www.cdc.gov/tb/publications/faqs/qa_TBDisease.htm .

Agreements

It may be useful to develop a treatment contract 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.[82]

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 **10.46**.

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. The PHN case managers should notify the Alaska TB Program if a patient misses two (2) or more consecutive doses.

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.[83] Incentives and enablers are used to improve patient attitudes and to foster good health behaviors.[84] They help patients stay with and complete treatment.[85]

Incentives are small rewards given to patients to encourage them to adhere to their treatment plan and keep their clinic or field directly observed therapy (DOT) appointments.[86] **Enablers** are those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties. An incentive that works for one patient may not work for another. Whenever possible, it is advisable to identify and use incentives and enablers that will effectively motivate or assist each unique patient to complete treatment.[87]

The Alaska TB has very limited funding for incentives and enablers. **Patients undergoing treatment for active TB are always the highest priority for incentives and enablers to keep them adherent to their TB treatment regimens.** As funding permits, patients being treated for LTBI may also be offered incentives and enablers to encourage completion of treatment.

Table 1: **EXAMPLES OF INCENTIVES AND ENABLERS**

Incentives	Enablers
Food and beverages	Transportation
Clothing	Bus pass
Automotive supplies	Cab fare
Hobby/craft items	Battery for patient's car
Household items	Gas
Laundry services	Childcare
Seasonal/holiday treats	Obtaining and transporting specimens for the patient
Movie passes, movies by mail	Assisting the client to get medication refills
Restaurant/fast food vouchers	Rent or utility assistance
Toys	Assisting the client to complete paperwork to get food/housing assistance
Personal care items	
Gift Cards	Assisting the client to get substance treatment
Inexpensive cell phones/phone cards	Inexpensive cell phones/phone cards

To obtain incentives and enablers, see the "Incentives and Enablers" topic in the Supplies, Materials, and Services section **(16.1)**. PHNs should consult their Regional Nurse Managers (RNMs) to request funds for incentives and enablers.

Medical Orders

Progressive Interventions

Non-adherent adults with infectious pulmonary TB pose the greatest threat to the health of a community. Progressive intervention should begin after learning the possible reasons for nonadherence and addressing the identified problems using methods such as education, directly observed therapy (DOT), incentives, and enablers. The patient should be told orally and in writing of the importance of adhering to treatment and the consequences of failing to do so.[88] It is advisable to have patients sign a contract or treatment agreement acknowledging plans for isolation, DOT arrangements, etc.

The Alaska TB Program may work with the Attorneys' General Office to pursue medical orders for persons suspected or diagnosed with TB who do not adhere to recommendations for examination, TB treatment, or isolation. This is done on a case-by-case-basis and **only** after all attempts at least restrictive alternatives have been attempted. PHN case managers must maintain detailed documentation of all written contracts or verbal agreements with patients, use of incentives and enablers, attempted contacts and patient response, including failure to maintain isolation and/or keep appointments or DOT encounter agreements.

For Alaska State laws on tuberculosis (TB), see the Statutes and Regulations section **19.1**.

Use the *Tuberculosis Treatment Contract* to document written agreements with the patient regarding isolation, DOT, etc. It can be found in the Forms section of this manual **18.1**.

Resources and References

General Case Management Resources

Heartland National Tuberculosis Center, *Case Studies in Tuberculosis: Training in Nurse Case Management. 2016. Available at:* https://www.heartlandntbc.org/assets/products/case_studies_tb_ncm_training_tools.pdf

CDC. Module 4: treatment of Latent Tuberculosis Infection and Tuberculosis Disease. *Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]. 2019. Available at: https://www.cdc.gov/tb/education/ssmodules/pdfs/Module4.pdf

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Directly Observed Therapy Resources

Chapter 7: Tuberculosis Infection Control. *Core Curriculum on Tuberculosis: What the Clinician Should Know (2016)* [Division of Tuberculosis Elimination Web site]. Updated May 2016. Available at: https://www.cdc.gov/tb/education/corecurr/pdf/chapter7.pdf

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Incentives and Enablers Resources

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