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Case Management

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Forms Used in this Section

- [Acknowledgement of TB Counseling](#) (PHSKC)
- [Authorization for Care Coordination](#) (PHSKC)
- [Authorization for Disclosure of Protected Health Information](#) (PHSKC)
- [Chart Audit Tool](#)
- [Civil Detention Flowchart](#)
- [Clinic Record](#) (SHD)
- [Contact Investigation](#)
- [Contact Investigation Instructions](#)
- [DOT Agreement](#) (PHSKC)
- [DOT Agreement](#) (Virginia)
- [DOT Audit Tool](#)
- [Drug Interview Sheet](#) (SHD)
- [Guidelines for Use of Videophone for DOT/DOPT](#) (SHD)
- [Home Evaluation](#) (SHD)
- [Home Isolation Agreement](#) (SHD)
- [Interjurisdictional TB Notification](#)
- [Intake/Evaluation](#) (Clark/Skamania Counties)
- [Inventory and Tracking of Videophones](#)
- [Isolation Instructions](#) (TPCHD)
- [Isolation Instructions/Spanish](#) (TPCHD)
- [Job Description](#) (SHD)
- [Laboratory Data Sheet](#)
- [Medication Orders](#) (SHD)
- [Release of Liability](#)
- [Report of Loss, Theft, or Damage](#)
- [Requests for Loan of Videophone](#)
- [RVCT Form](#)
- [Personal Safety for Field Workers](#) (Chelan/Douglas County)
- [Protocol and Standing Orders](#) (SHD)
- [Public Health Directive \(Adherence\)](#) (PHSKC)
- [Public Health Directive \(Non-Compliance\)](#) (PHSKC)
- [Screening Record](#) (SHD)
- [Sputum Collection](#) (Chelan/Douglas County)
- [TB Control Referral](#)
- [TB Flow Chart](#)
- [TB Staffing Standards Model](#)

Forms Used in this Section, Cont.

- [Treatment Agreement](#) (TPCHD)
- [Treatment Agreement \(Spanish\)](#) (TPCHD)
- [Tuberculosis Drug Record](#)
- [Tuberculosis Screening Guidelines](#)
- [Videophone Direct Observed Therapy](#) (TPCHD)
- [Videophone Directly Observed Therapy Consent](#)
- [Videophone Directly Observed Therapy Memorandum](#)
- [Vision and Hearing Log](#) (Virginia)

Quick Start Check List: Case Management

This check list is designed to assist public health nurses/TB case managers when managing a case. The tasks below should be performed by licensed nursing, medical, laboratory, and Disease Investigator staff. This check list requires understanding the instructions in the manual and familiarity with local protocols and standing orders.

Forms can be submitted by fax to the attention of the Washington State TB Services at 360-236-3405 or mail to:

Washington State TB Services

Mailing address: P.O. Box 47837 Olympia, WA 98504

Physical address: 111 Israel Rd SE Tumwater, WA 98501

Tasks for Case Management	Instructions and Forms
<p>When a suspected or confirmed case of tuberculosis (TB) disease is reported to the local public health agency:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Receive the case report <input type="checkbox"/> Assign the case manager <input type="checkbox"/> Report electronically via PHIMS TB 	<p>Instructions:</p> <ul style="list-style-type: none"> • Reporting Tuberculosis (2.8) • In the WAC, see Chapter 246-101 (Notifiable conditions) in the Title 246 (Department of Health) at http://apps.leg.wa.gov/wac/default.aspx?cite=246-101 • Also, see Notifiable Conditions Guidelines, at http://www.doh.wa.gov/PublicHealthandHealthcareProviders/NotifiableConditions/Tuberculosis.aspx • Protocol and Standing Orders (SHD) • Job Description (SHD) • Chart Audit
<p>Take infection control precautions:</p> <p>Isolate the patient, if necessary (if the patient has positive acid-fast bacilli [AFB] sputum smear results and/or cavitary disease) or high suspicion for active TB even if smear negative</p> <p>Advise staff to take personal respiratory precautions, if necessary</p>	<p>Instructions:</p> <ul style="list-style-type: none"> • Infection Control (11.1) <p>Forms:</p> <ul style="list-style-type: none"> • Personal Safety for Field Workers (Chelan/Douglas County) • Home Isolation Agreement (SHD) • Isolation Instructions (TPCHD) • Isolation Instructions (Spanish) (TPCHD) • Acknowledgement of TB Counseling (PHSKC) • Public Health Directive (Adherence) (PHSKC) • Public Health Directive (Non-Compliance) (PHSKC) • Authorization for Care Coordination (PHSKC) • Authorization for Disclosure of Protected Health Information (PHSKC) • Civil Detention Flowchart

Tasks for Case Management	Instructions and Forms
<p>Perform the initial assessment of the patient:</p> <p>Start the initial assessment within ≤ 1 business day of the case report for infectious patients; and ≤ 3 business days of the case report for others.</p> <p>Consult with medical provider, local health officer, or DOH TB Medical Consultant within ≤ 1 business day of the case report</p> <p>Conduct an initial interview of the patient and visit the patient's home:</p> <ul style="list-style-type: none"> • 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 • Collect and submit 3 sputum samples for AFB smear and culture (if not done earlier). Obtain specimens 8 to 24 hours apart with one being an early morning specimen • Visit the patient's home (if initial visit occurred in the hospital) within ≤ 3 business days of hospital discharge • Reinterview the patient within 1 to 2 weeks after the initial interview <p>If the patient is hospitalized outside of his or her county of residence: The role of the LHJ TB Program in which patient is hospitalized is to coordinate with the LHJ TB Program of the patient's residence.</p> <p>Assure medical evaluation of the patient within 1 week of referral</p> <p>Submit the "Tuberculosis Contact Investigation Form" to WA State TB Services within 2 weeks</p> <p>Use the data collected from the physician consultation(s), record review, and patient interviews to complete the following tasks:</p> <ul style="list-style-type: none"> • Review demographic information • Ascertain the extent of TB illness (See below for diagnosis of TB disease.) • Review the patient's health history • Determine the index patient's infectious period (count 3 months back from start of symptoms-cough, weight loss, fever, chest pain, night sweats) • Evaluate the patient's knowledge and beliefs about TB • Administer, measure, and interpret a Mantoux TST or IGRA • Screen for HIV • Obtain baseline biochemistry tests (CBC, Liver function) for toxicity monitoring (choose tests based on regimen and for special situations such as HIV infections, history of liver disease, alcoholism, and pregnancy): 	<p>Instructions:</p> <p>Effective TB interviewing for Contact Investigation</p> <p>Forms:</p> <ul style="list-style-type: none"> • Home Evaluation (SHD) • RVCT Form • Intake/Evaluation (Clark/Skamania Counties) • Contact Investigation <ul style="list-style-type: none"> • Instructions

Tasks for Case Management	Instructions and Forms
<ul style="list-style-type: none"> • Complete blood count • Platelets • Liver function tests <ul style="list-style-type: none"> • Uric acid measurements Assure MD physical exam • Perform baseline visual acuity and color discrimination tests for toxicity monitoring if the patient is prescribed ethambutol • Initiating medical treatment (if not initiated during hospital stay) is recommended with a positive AFB sputum smear results • Monitor the TB medication regimen • Identify any barriers or obstacles to adherence • Review psychosocial status • Identify and document a complete history of patient's social network, to include home, social, work, and church site(s) • Initiate a contact investigation, if indicated • Assure that face-to-face initial encounters and skin testing or IGRAs are conducted among high and medium priority contacts within 7 business days after their being listed in the investigation <p>Submit the "TB Contact Investigation Form" to WA State TB Services within 2 weeks</p> <ul style="list-style-type: none"> • Assess patient for need to restrict travel (Do Not Board) 	<p>Instructions for Visual Acuity</p> <ul style="list-style-type: none"> • http://www.toledobend.com/colorblind/Ishihara.asp <p>Forms:</p> <ul style="list-style-type: none"> • Contact Investigation <ul style="list-style-type: none"> • Instructions • Do Not Board Protocol
<p>Assist in diagnosing TB disease:</p> <p>Assure that medical evaluations are conducted and treatment started for LTBI in high priority contacts who are children and/or have high-risk factors within 5 business days after initial encounters</p> <p>Assure that diagnostic tests and/or assessments are completed to diagnose TB disease or to rule out TB disease</p> <p>Receive initial AFB sputum smear tests (laboratory has to report within 2 days of AFB smear result)</p> <p>Assure NAA test is ordered, if needed to quickly confirm diagnosis of TB for a patient with positive AFB sputum smear. Results in 2-3 working days report of NAA</p> <p>Assure a medical evaluation of patient within 1 week of referral</p>	<p>Instructions:</p> <ul style="list-style-type: none"> • Diagnosis of Tuberculosis Disease (4.1) • Bacteriology Tests (4.19) • Tuberculosis Screening Guidelines
<p>Communicate to state TB Services staff:</p> <p>Submit to WA State TB Services via TB PHIMS within 7 days of the LHJ receiving notification of the suspect OR case</p> <p>Submit electronically TB PHIMS case reports from Level 1 sites; DOH receives these reports weekly on Friday</p>	<p>Forms:</p> <ul style="list-style-type: none"> • RVCT Form

Tasks for Case Management	Instructions and Forms
<p>Send to DOH via TB PHIMS when suspect becomes a case</p> <p>Submit the "TB Contact Investigation Form" to WA State TB Services within 2 weeks</p>	<ul style="list-style-type: none"> • Contact Investigation • Instructions
<p>Assure that a treatment plan is developed and promptly initiated:</p> <p>Begin implementing the treatment plan:</p> <ul style="list-style-type: none"> • Refer the patient to other healthcare providers, social service agencies, or community organizations as needed (case manager works as a liaison between the patient and other providers) • Broker and locate needed services relating to TB treatment • Negotiate a plan for directly observed therapy (DOT), Videophone DOT, or self-administration • Coordinate strategies to improve adherence <p>If the patient is hospitalized, clarify the hospital discharge arrangements and assure that they are communicated to the hospital's outpatient coordinator and the treating physician(s)</p> <p>Identify and document drug treatment plan</p>	<p>Instructions:</p> <ul style="list-style-type: none"> • Treatment (5.10) • Directly Observed Therapy (DOT)/Videophone (8.51) <p>Forms:</p> <ul style="list-style-type: none"> • Treatment Agreement (TPCHD) • Treatment Agreement (Spanish) (TPCHD) • DOT Agreement (Virginia) • DOT Agreement (PHSKC) • Tuberculosis Drug Record • Medication Orders (SHD)
<p>Gather baseline data for toxicity monitoring:</p> <p><input type="checkbox"/> Obtain baseline biochemistry tests for toxicity monitoring (choose tests based on regimen and for special situations such as human immunodeficiency virus [HIV] infection, history of liver disease, alcoholism, and pregnancy):</p> <ul style="list-style-type: none"> • Complete blood count • Platelets • Liver function tests <ul style="list-style-type: none"> • Perform baseline visual acuity and color discrimination tests for toxicity monitoring if the patient is prescribed ethambutol 	<p>Instructions:</p> <ul style="list-style-type: none"> • Side effects and Adverse Reactions (5.19) <p>The CDC has released "Severe Isoniazid-Associated Liver Injuries Among Person Being Treated for Latent Tuberculosis Infection," available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5908a3.htm</p> <p>Forms:</p> <ul style="list-style-type: none"> • Treatment Agreement (TPCHD) • Treatment Agreement (Spanish) (TPCHD) • Laboratory Data Sheet <p>Instructions For Visual Acuity http://www.toledo-bend.com/colorblind/Ishihara.asp</p>
<p>Provide DOT:</p> <p>Initiate DOT or Videophone DOT</p> <p>Assess adherence and drug toxicity at each visit</p> <p>Follow up missed appointments on the same day</p>	<p>Instruction:</p> <ul style="list-style-type: none"> • Directly Observed Therapy (DOT)/Videophone (8.51) • Dot Audit Tool

Tasks for Case Management	Instructions and Forms
<p>Monitor the patient regularly:</p> <p>Conduct ongoing assessment and monitoring at least monthly for clinical response, drug toxicity, and adherence</p> <p>Obtain and document HIV status. Refer patient for HIV treatment, if indicated</p> <p>Receive and review drug susceptibility results; results on first-line drugs should be available within 30 days from specimen receipt in the PHL.</p> <p>Review treatment. If there is concern regarding response or drug toxicity, consult with the medical provider, LHJ Health Officer, or DOH TB Services Medical Consultant 206- 718-2664. If a change directed, then document and implement the new medication orders</p> <p>Ensure that medications are ordered and are the correct dosage.</p> <p>If the patient is on isolation, determine when isolation can be discontinued</p> <p>If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported (this usually occurs within 2 months of treatment. If beyond 2 months then other tests are ordered.)</p> <p>Review the status of the contact investigation</p> <p>Submit the "TB Contact Investigation Form" to WA State TB Services within 2 weeks</p>	<p>Instructions:</p> <ul style="list-style-type: none"> • Roadmap (8.11) • Available Laboratory Tests (10.8) • Drug Treatment (5.10) <p>Forms:</p> <ul style="list-style-type: none"> • Treatment Agreement (TPCHD) • Treatment Agreement (Spanish) (TPCHD) • RVCT Form <ul style="list-style-type: none"> • Contact Investigation <ul style="list-style-type: none"> • Instructions
<p>Monitor the clinical response to treatment:</p> <p>Reassess information about the index patient weekly until drug susceptibility results are available or for 2 months after the case report, whichever is longer contact local health officer, medical provider, or WA State TB services medical consultant.</p> <p>Susceptibility reports are usually available within 28 days (first line of drugs)</p> <p>When the patient has negative AFB sputum smear results, then each month collect sputum specimens and submit them for testing until 2 consecutive negative culture results are reported</p> <ul style="list-style-type: none"> • For multidrug-resistant TB (MDR-TB) patients, monthly specimens are required • For non-MDR-TB patients who can produce sputum, monthly specimens are recommended 	<p>Forms:</p> <ul style="list-style-type: none"> • RVCT Form <p>Forms:</p> <ul style="list-style-type: none"> • Tuberculosis Screening Guidelines

Tasks for Case Management	Instructions and Forms
<p>Monitor the clinical response to treatment (continued):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Complete field investigation (visiting all potential transmission sites) within 5 days after starting the investigation <input type="checkbox"/> Assess patient for need to restrict travel (do not board) 	<p>Forms:</p> <ul style="list-style-type: none"> • Do Not Board Protocol
<p>Monitor the patient for drug toxicity: Assess drug toxicity at each DOT visit</p> <p>Repeat liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and serum bilirubin) when the patient is taking isoniazid, a rifamycin, or pyrazinamide if</p> <ul style="list-style-type: none"> • Baseline results are abnormal • The patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions • The patient has symptoms of adverse reactions <p>If the patient is taking ethambutol, evaluate the patient monthly regarding possible visual disturbances, including blurred vision or scotomata</p> <p>Test visual acuity and color discrimination monthly when the patient is taking ethambutol</p>	<p>Instructions:</p> <ul style="list-style-type: none"> • Side effects and Adverse Reactions (5.19) <p>Instructions For Visual Acuity</p> <ul style="list-style-type: none"> • http://www.toledobend.com/colorblind/lshihara.asp
<p>Assess adherence and address obstacles to adherence:</p> <p>Assess adherence weekly and monthly and identify positive and negative motivational factors influencing adherence</p> <p>Determine the unmet educational needs of the patient</p> <p>Educate the patient about the TB disease process</p> <p>Advocate for the patient with team members and other service providers</p> <p>Each week, review documentation to ensure that the contact list is complete</p> <p>Assure that contacts are assessed monthly for:</p> <ul style="list-style-type: none"> • Clinical follow-up • Adherence to LTBI treatment • Adverse reactions to LTBI treatment <p>On contacts whose results were initially negative, repeat TST or IGRA 8-10 weeks after contacts last exposure to the index patient during the infectious period</p> <p>Address nonadherence, if necessary:</p> <ul style="list-style-type: none"> • Review with the patient the treatment agreements and directly observed therapy arrangements 	<p>Forms:</p> <ul style="list-style-type: none"> • Treatment Agreement (TPCHD) • Treatment Agreement (Spanish) (TPCHD) • DOT Agreement (Virginia) • DOT Agreement (PHSKC)

Tasks for Case Management	Instructions and Forms
<p>Assess adherence and address obstacles to adherence (continued):</p> <ul style="list-style-type: none"> Educate the patient about TB and its treatment Refer the patient to social services, if necessary Provide incentives and enablers <p>Initiate legal orders, if other measures do not improve adherence</p>	<p>Instructions:</p> <p>Due Process</p> <ul style="list-style-type: none"> WAC 246-170-051 WAC 246-170-055
<p>Confirm the completion of treatment:</p> <p>Verify completion of treatment after treatment was started based on:</p> <ul style="list-style-type: none"> Regimen Interruptions Response to treatment Number of weeks on DOT Number of doses taken (weekly and twice, thrice, and once weekly) <p>Submit to DOH via PHIMS TB</p>	<p>Forms:</p> <ul style="list-style-type: none"> RVCT Form DOT Agreement (Virginia) DOT Agreement (PHSKC)
<p>Evaluate case management activities:</p> <p>Monitor the activities against the treatment plan monthly (or more frequently if needed)</p> <p>Document as activity occurs and at least monthly on the LHJ patient record</p>	<p>Forms:</p> <ul style="list-style-type: none"> Clinic Record (SHD) Sputum Collection (Chelan/Douglas County)



To understand the evaluation process in diagnosing TB disease and LTBI, view the “Tuberculosis Screening Guidelines” provided on page [4.6](#).

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

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

MONTH 1 - Week 1*				
Start of initial assessment	Receive the TB suspect/case report and notify the WA State DOH [___]	Assign the case manager [___] <ul style="list-style-type: none"> Advise staff to take personal respiratory precautions, if necessary 	Isolate the patient, if necessary (if the patient has positive AFB sputum smear results and/or cavitary disease) [___]	Start the initial assessment within ≤1 business day of notification of the case [___]
Initial interviews and consultations	Consult with the responsible physician and/or program medical consultant for medical examination/case review within ≤1 day of notification of the case [___]	Interview the patient within ≤1 business day of the case report (begin patient education, collect patient data to determine infectious period, and gather contact investigation data if needed) [___] <ul style="list-style-type: none"> Home evaluation RVCT Form/TB contact report 		Visit the patient's residence within ≤3 business days after first interview (collect contact investigation data if needed) [___] <ul style="list-style-type: none"> Reinterview 1-2 weeks
Medical evaluation	Assure a medical evaluation of the patient within 1 week of referral [___] Refer to Protocol and Standing Orders	Screen for HIV [___]	Administer, measure, and interpret a Mantoux TST (or IGRA) [___]	Collect and submit 3 sputum specimens for AFB smear and culture (if not done earlier). Obtain specimens 8 to 24 hours apart with one being an early morning specimen [___]
	Gather medical history [___]	Conduct a physical examination [___]	Order chest radiography [___]	
After AFB sputum smear testing completed	Receive results of AFB sputum smear tests (laboratory has to report within 2 days of AFB smear result) [___] In the WAC, see chapter 246-101 (Notifiable Conditions)	Assure that an NAA (MTD) test is ordered, if needed to quickly confirm diagnosis of TB for a patient with positive AFB sputum smear. Results in 2-3 working days report of MTD [___]	Send the written "Confirmed/Suspected Report of Tuberculosis Disease" to the Washington TB Program within 7 days LHJ receiving notification of suspect or confirmed case [___]	Determine the index patient's infectious period (count three months back from start of symptoms-cough, weight loss, fever, chest pain, night sweats) [___]
After sufficient medical and laboratory assessment data gathered	For a hospitalized patient, clarify the hospital discharge arrangements and assure that they are communicated to the hospital's outpatient coordinator and the treating physician(s) [___]	Obtain baseline biochemistry tests† for toxicity monitoring (choose tests based on regimen and for special situations such as HIV infection, history of liver disease, alcoholism, and pregnancy): <ul style="list-style-type: none"> Complete blood count Platelets 	Perform baseline visual acuity and color discrimination tests† for toxicity monitoring if the patient is prescribed ethambutol [___]	Begin implementing the treatment plan [___] Refer to Protocol and Standing Orders
			Assure that a written treatment plan is developed [___]	Initiating medical treatment is recommended with a

		<ul style="list-style-type: none"> ▪ Liver function tests ▪ Uric acid measurements [___] 	Assure that education is provided to the patient and provider as needed when their signatures are obtained on the treatment plan [___]	positive AFB sputum smear results [___]
Decision to conduct an investigation	Gather the index patient's medical records (from hospital, clinic, and/or healthcare provider) (See patient interview and home visit above in the Initial Interviews row.) [___]		Decide if a contact investigation is indicated (based on positive AFB sputum smear results and/or cavitary disease or pleural TB) [___]	If an investigation is indicated, start the contact investigation within ≤1 business day of notification of the suspect or confirmed case [___]
Contact list	During the index patient interview, start listing names and locating information of named contacts and continue listing them throughout the investigation [___]		Assign an initial priority classification to each contact (and revise as needed when new information is received) [___]	Review all documentation to ensure that the contact list is complete [___] <ul style="list-style-type: none"> ▪ Report contacts to DOH TB Services within 2 weeks

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

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

MONTH 1 - Week 2*				
Case management of index patient	Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [___]	If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported (this usually occurs within 2 months of treatment. If beyond 2 months then other tests are ordered.) [___]	Reassess information about the index patient weekly until drug susceptibility results are available or for 2 months after the case report, whichever is longer Susceptibility reports are usually available within 28 days (first line drugs) if drug resistance then it may take 30 or more additional days to determine total drug resistance. [___]	If the patient is isolated, determine whether isolation can be discontinued based on conversion of negative sputum smear and culture and if patient is sensitive to all first line drugs. [___]
	Follow up missed appointments on the same day [___]	If the patient initially had positive AFB sputum smear results quantified as 3+ to 4+ and/or cavitation, continue collecting one specimen each week until 3 consecutive negative smears and negative culture [___]	Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs [___] Refer to Protocol and Standing Orders	

Field investigation and interviews	Complete the field investigation (visiting all potential transmission sites) within 5 days after starting the investigation [___]	Reinterview the index patient in their home within 2 weeks after the first interview [___]		
Contact evaluation	Assure that face-to-face initial encounters and skin testing or IGRAs are conducted among high- and medium-priority contacts within 7 business days after their being listed in the investigation [___]	Assure that medical evaluations† are conducted and treatment started for LTBI in high-priority contacts who are children and/or have high-risk factors within 5 business days after initial encounters [___]	Assure that medical evaluations† are conducted of other high-priority contacts to index patients with positive AFB sputum smear results within 5 business days after initial encounters [___]	Review and assess the completeness of contacts' medical follow-up and treatment plans within 5 business days after their medical evaluations [___]
Data review and reporting	Each week, review documentation to ensure that the contact list is complete [___]	Each week, collect and analyze data on contacts and TSTs or IGRAs; reassesses contact priorities [___]	Decide whether to continue/expand the investigation based on analysis of TST or IGRA data [___]	Report to the Washington TB Program after initial tuberculin skin testing or IGRA is completed [___]

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

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

MONTH 1 - Weeks 3 and 4*				
Case management of index patient	Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [___]	If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported [___]	Reassess information about the index patient weekly until drug susceptibility results are available and then reassess at least monthly [___]	If the patient is isolated, determine whether isolation can be discontinued based resolution of symptoms and current treatment and 3 negative smears and negative cultures and patient is on current treatment with antituberculosis regimen to which strain is known to be susceptible. [___]
	Follow up missed appointments on the same day [___]		Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs [___] Refer to Protocol and Standing Orders	
Contact evaluation and treatment	Assure that face-to-face initial encounters and skin (or IGRA) testing are conducted among high- and medium-priority contacts within 3	Assure that medical evaluations† are conducted and treatment started for LTBI in high-priority contacts who are children and/or have high-risk factors	Assure that medical evaluations† are conducted of other high-priority contacts to index patients with positive AFB sputum smear results within 5	Assure that medical evaluations† are conducted of high-priority contacts to AFB-sputum-smear-negative index patients and medium-priority contacts

	business days after their being listed in the investigation [___]	within 5 business days after initial encounters [___]	business days after initial encounters [___]	within 10 business days after initial encounters [___]
	Assure that treatment is started for LTBI in adult high- and medium-priority contacts without high-risk factors within 10 business days of their medical evaluations [___]	Review and assess the completeness of contacts' medical follow-up and treatment plans within 5 business days after their medical evaluations [___]	Review and assess the timeliness of initiating the treatment plans for contacts within 10 business days after their medical evaluations [___]	
Data review and reporting	Each week, review documentation to ensure that the contact list is complete [___]	Each week, collect and analyze data on contacts and TSTs or IGRAs; reassesses contact priorities [___]	Decide whether to continue/expand the investigation based on analysis of TST or (IGRA) data [___]	Report to the Washington State DOH TB Program after initial tuberculin skin testing is completed [___]

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

MONTH 2*				
Case management of index patient	Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [___]	Conduct ongoing assessment and monitoring at least monthly (clinical response, adverse reactions, adherence) [___]	If the patient has negative AFB sputum smear results, each month collect sputum specimens and submit them for testing until 2 consecutive negative culture results are reported [___]	If sputum smear results are positive after 2 months of treatment , call the local health officer, medical provider, or Washington State Medical Consultant 206-718-2664 [___]
	Follow up missed appointments on the same day [___]	If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported [___]	Call the local health officer, medical provider, or Washington State Medical Consultant to determine how to monitor when the patient <ul style="list-style-type: none"> ▪ Is culture negative ▪ Had AFB 3+ or 4+ results and/or cavitation on x-ray or ▪ Had no sputum specimens collected [___]	Refer to Protocol and Standing Orders

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

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

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

MONTHS 3 through 5*

Case management of index patient	<p>Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit</p> <p>[___]</p>	<p>Conduct ongoing assessment and monitoring at least monthly (clinical response, adverse reactions, adherence)</p> <p>[___]</p>	<p>When the patient has negative AFB sputum smear results, each month collect sputum specimens and submit them for testing until 2 consecutive negative culture results are reported</p> <p>[___]</p>	<p>If sputum smear results or culture results are positive after 2 months of treatment, call the medical provider, local health officer, or Washington</p>
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	Follow up missed appointments on the same day [___]	If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, each week collect sputum specimens and submit them for testing until 3 consecutive negative AFB sputum smear results are reported [___]	Call the local health officer or Washington State Department of Health Medical Consultant to determine how to monitor when the patient <ul style="list-style-type: none"> Is culture negative Had AFB 3+ or 4+ results and/or cavitation on x-ray or Had no sputum specimens collected [___] 	State Medical consultant (206) 718-2664 [___]
	Repeat liver function tests (AST, ALT, and serum bilirubin)† when the patient is taking isoniazid, a rifamycin, or pyrazinamide if <ul style="list-style-type: none"> Baseline results are abnormal Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions Patient has symptoms of adverse reactions [___] 	Question the patient taking ethambutol monthly regarding possible visual disturbances, including blurred vision or scotomata [___] Test visual acuity and color discrimination monthly when the patient is taking ethambutol† <ul style="list-style-type: none"> In doses >15–25 mg/kg For >2 months With renal insufficiency [___] 	Reassess treatment, side effects, and adherence and, if concerned, consult with the medical provider, local health officer, or Washington State Medical consultant 206-718-2664. If a change is decided upon, obtain new physician's orders and order drugs [___] Refer to Protocol and Standing Orders	Send updates with changes to the treatment plan to Washington State DOH TB Services [___]
Contact treatment and investigation	Assure that contacts are assessed monthly for <ul style="list-style-type: none"> Clinical follow-up Adherence to LTBI treatment Adverse reactions to LTBI treatment [___]	Each week, review documentation to ensure that the contact list is complete [___]		

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

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

MONTHS 6 through 9*				
Case management of index patient	Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [___]	Follow up missed appointments on the same day [___]	Conduct ongoing assessment and monitoring at least monthly (clinical response, adverse reactions, adherence) [___]	When the patient has negative AFB sputum smear results, each month collect sputum specimens and submit them for testing until 3 consecutive negative culture results are reported [___]

	<p>Repeat liver function tests (AST, ALT, and serum bilirubin)† when the patient is taking isoniazid, a rifamycin, or pyrazinamide if</p> <ul style="list-style-type: none"> ▪ Baseline results are abnormal ▪ Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions ▪ Patient has symptoms of adverse reactions <p>[___]</p>	<p>Question the patient taking ethambutol monthly regarding possible visual disturbances, including blurred vision or scotomata [___]</p>	<p>Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs [___]</p> <p>Refer to Protocol and Standing Orders</p>	<p>Send updates for completion of therapy to Washington State DOH TB Services [___]</p>
		<p>Test visual acuity and color discrimination monthly when the patient is taking ethambutol†</p> <ul style="list-style-type: none"> ▪ In doses >15–25 mg/kg ▪ For >2 months ▪ With renal insufficiency <p>[___]</p>	<p>Verify completion of treatment 6 to 9 months after treatment was started (depending upon regimen, adherence, response to treatment, number of weeks on DOT, and number of doses taken) [___]</p>	
Contact treatment and investigation	<p>Assure that contacts are assessed monthly for</p> <ul style="list-style-type: none"> ▪ Clinical follow-up ▪ Adherence to LTBI treatment ▪ Adverse reactions to LTBI treatment <p>[___]</p>	<p>Verify completion of treatment 6 to 9 months after treatment was started (depending upon regimen, adherence, number of weeks on treatment and/or number of doses taken) [___]</p>	<p>Each week, review documentation to ensure that the contact list is complete [___]</p>	

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

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

MONTHS 10 through 12*				
Case management of index patient	<p>Provide directly observed therapy and assess adherence and side effects/adverse reactions at each visit [___]</p>	<p>Follow up missed appointments on the same day [___]</p>	<p>Conduct ongoing assessment and monitoring at least monthly (clinical response, adverse reactions, adherence) [___]</p>	<p>When the patient has negative AFB sputum smear results, each month collect sputum specimens and submit them for testing until 3 consecutive negative culture results are reported [___]</p>

	<p>Repeat liver function tests (AST, ALT, and serum bilirubin)† when the patient is taking isoniazid, a rifamycin, or pyrazinamide if</p> <ul style="list-style-type: none"> ▪ Baseline results are abnormal ▪ Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions ▪ Patient has symptoms of adverse reactions <p>[___]</p>	<p>Question the patient taking ethambutol monthly regarding possible visual disturbances, including blurred vision or scotomata [___]</p>	<p>Reassess treatment, side effects, and adherence and, if concerned, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs [___]</p> <p>Refer to Protocol and Standing Orders</p>	<p>Send updates for completion of therapy to Washington State DOH TB Services [___]</p>
		<p>Test visual acuity and color discrimination monthly when the patient is taking ethambutol†</p> <ul style="list-style-type: none"> ▪ In doses >15–25 mg/kg ▪ For >2 months ▪ With renal insufficiency <p>[___]</p>	<p>Verify completion of treatment if treatment time was prolonged (depending upon regimen, adherence, response to treatment, number of weeks on DOT, and number of doses taken) [___]</p>	
Contact treatment and investigation	<p>Assure that contacts are assessed monthly for</p> <ul style="list-style-type: none"> ▪ Clinical follow-up ▪ Adherence to LTBI treatment ▪ Adverse reactions to LTBI treatment <p>[___]</p>	<p>Verify completion of treatment 9 to 12 months after treatment was started (depending upon regimen, adherence, number of weeks on treatment and/or number of doses taken) [___]</p>	<p>Each week, review documentation to ensure that the contact list is complete [___]</p>	<p>Report to the Washington State DOH TB Program after contacts complete treatment for LTBI [___]</p>
			<p>Collect and analyze data [___]</p>	<p>Collect data to complete the <i>ARPE</i> form [___]</p>

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

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

Introduction

Purpose

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

Use this section to understand and follow national and Washington State guidance to do the following:

- Conduct initial assessments
- Develop treatment plans for case management activities
- Conduct monthly ongoing assessments
- Monitor adverse reactions to antituberculosis medications and monitor toxicity
- Monitor bacteriologic and clinical improvement
- Verify completion of therapy
- Evaluate case management activities
- Understand Cohort Review
- Provide directly observed therapy (DOT) and videophone DOT
- Use incentives and enablers to improve adherence to therapy
- Understand when and how to use legal orders, if necessary, for adherence to therapy

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

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

These adverse outcomes are preventable by case-management strategies provided by TB control programs, including use of DOT and videophone DOT.⁵ It is strongly recommended that the initial treatment strategy utilize patient-centered case management with an adherence plan that emphasizes DOT.⁶ It is essential to provide patient-centered case management in which treatment is tailored and supervision is based on each patient's clinical and social circumstances.⁷ Programs utilizing DOT as the central element in a comprehensive, patient-centered approach to case management (enhanced DOT) have higher rates of treatment completion than less intensive strategies.⁸

Policy

Although some patients may undergo most of their evaluation and treatment in settings other than a local public jurisdictions, LHJs 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.

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



For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the Introduction ([1.16](#)).



For more information regarding Protocol and Standing Orders for local health jurisdictions, please see “[Protocol and Standing Orders](#)” located in the **FORMS** section of the manual.

Forms



To identify required and recommended forms, refer to the “Quick Start Check List: Case Management” in this section ([8.4](#)).

Acknowledgments

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

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

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

Initial Assessment

Conduct initial assessments of 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, medical providers, schools, and other healthcare facilities.⁹



When the patient with TB is a child, the case manager should involve both the child and family in the assessment process.¹⁰



To report TB cases (both suspected and confirmed), use PHIMS TB.

Cultural Sensitivity and Language Issues

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



For more information on cultural sensitivity, refer to the *Participant's Workbook* for Session 4: "Working with Culturally Diverse Populations" in *DOT Essentials: The DOT Trainer's Curriculum* (Curry International Tuberculosis Center Web site; 2003) at <http://www.currytbcenter.ucsf.edu/catalogue/epub/index.cfm?tableName=DOTE>



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 <http://www.healthlaw.org/images/stories/issues/ResourceGuideFinal.pdf> .



Minnesota Department of Health's (MDH) Refugee Health and Tuberculosis Programs are pleased to offer a show about tuberculosis (TB) for the public, which can be found at <http://www.health.state.mn.us/divs/idepc/diseases/tb/echo.html>



Another resource for information about cultural beliefs, medical issues and other related issues pertinent to health care can be found at <http://www.ethnomed.org/>



For more information on using interpreters, see the *Interpretation Services* lesson in Module 9: “Patient Adherence to Tuberculosis Treatment” of the CDC’s *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 1999) at <http://www.cdc.gov/tb/education/ssmodules/module9/ss9contents.htm> .



The Georgia Department of Health website has treatment consent forms for LTBI, active disease, DOT etc in a variety of languages at <http://health.state.ga.us/programs/tb/phclinicforms.asp>.

Patient’s Medical Records

The case manager needs all medical records in order to provide case management and recommend a case management plan. Prior to the visit with the patient, the case manager should ensure that a copy of all of the patient’s medical records (from hospitals, clinics, and other healthcare providers) and chest radiographs are available to the treating physician. Without the medical records, the physician may not be able to make the correct judgments in medical management.¹¹

Assessment Site

If the patient is hospitalized, conduct the initial assessment during the patient’s hospitalization. If the patient is hospitalized outside of his or her county of residence, coordinate with the other county or hospital’s infection control staff to conduct the assessment. If the patient is not hospitalized, conduct the initial assessment at the first clinic visit or during a home visit. Start the initial assessment within 1 business day of the case report for infectious or smear positive pulmonary cases; and ≤ 3 business days of the case report for others. See MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis.

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

Discharge Planning



Patients who are diagnosed with TB during a hospitalization will require discharge planning. The case managers should ensure that appropriate discharge planning occurs for all patients with TB, to prevent transmission in the community and interruption in treatment.¹²

Initial Assessment Activities

To complete an initial assessment, perform the following activities:

Visit the patient's home within ≤ 3 days of the initial interview. See "Field Investigation", p. 8, MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis.

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

- 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 window of infectiousness, if patient is sputum smear positive or has cavitation on CXR; see MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, specifically Factors for Assigning Contact Priorities, p. 10 and Figures 2-4 on pgs 12-14.

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

Evaluate the patient's knowledge and beliefs about TB

- Initiate treatment, if not initiated during the hospital stay
- Monitor the TB medication regimen
- Identify any barriers or obstacles to adherence
- Review psychosocial status
- Identify and document a complete history of the patient's social network, to include home, social, work, and church site(s)
- Initiate a contact investigation, if indicated

Visit the patient's home. During the patient's TB treatment, at least one or more home visits are required. Home visits are useful for confirming the patient's address, particularly for patients at high risk for default from treatment. Information gathered at the patient's home is often more revealing than assessments performed in the hospital, 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).¹³ 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.

After patient interview and identification of patient's social network, then initiate visit to employment sites. Site visits are complementary to interviewing. Contacts from these sites are often the most reliable source of information regarding transmission. See MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, specifically "Congregate Settings" p. 26) <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm>

Obtain or review demographic information, including the name, address, telephone number(s), birth date, and health insurance provider's name, address, and identifying information.¹⁴

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

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



In the case of pulmonary TB in children younger than 5 years of age, posterior-anterior and lateral chest radiographs are important in the initial diagnosis.¹⁵ Adults who are suspected of TB or who are active cases usually need only an initial posterior-anterior and lateral chest radiograph.

Obtain and review the patient's health history to determine concurrent medical problems, including human immunodeficiency virus (HIV) disease or risk factors, country of birth, sexual history and partners, allergies, or medications that may interfere with TB drugs. The case manager should obtain the names, addresses, and telephone numbers of the patient's medical provider and any specialists involved in his or her medical care, previous hospitalizations, allergies, and current medications. It is important to know the history of treatment for TB infection and/or disease, especially for patients who are treatment failures or have a relapse of TB disease, as they are at a higher risk for developing multidrug-resistant TB (MDR-TB). It is also important to determine what the patient perceives as his or her most important medical/health problem(s). The date of the last menstrual period and contraceptive use should be obtained from female patients.¹⁶



Some antituberculosis medications are contraindicated when a patient is taking birth control pills. For more information, see the “Side Effects and Adverse Reactions” topic in the Treatment of Tuberculosis Disease section of the manual ([5.19](#)).

PRIORITY: Determine infectiousness or potential infectiousness. “Infectious” refers either to TB disease of the lungs or throat, which has the potential to cause transmission to other persons, or to the patient who has TB disease.

This focuses the contact investigation on those contacts most likely to be at risk for infection and sets the timeframe for testing contacts. 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 (window of infectiousness). The parameters of a contact investigation, including the need for repeating the tuberculin skin test or IGRA tests, test for contacts that were initially negative, can then be determined.¹⁷



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



For more information on the period of infectiousness and contact investigations, see “Infectious Period” in the Contact Investigation section of the manual ([9.22](#)).

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.¹⁸



It is important to interview both the child and parent or guardian in their own language when assessing TB knowledge; however, adolescents should be given the opportunity to speak to a healthcare provider alone. Keep in mind that parents who have misinformation or cultural bias about TB may affect their children’s understanding of the disease.¹⁹ Use age-appropriate educational materials and methods, especially when working with children. When working with a school-aged child, it is important to explain that TB is treatable; and with the adolescent, it may be necessary to constantly reaffirm confidentiality.²⁰

Initiate treatment. Initiation of 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 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 MMWR Treatment of Tuberculosis, 2003, specifically “Deciding to Initiate Treatment”, p. 40 at <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>).

The case manager should order drugs immediately upon receipt of medical orders which document drugs, dose, route, frequency, and duration.

Monitor the TB medication regimen. The case manager should ensure that medications and dosages are prescribed according to the current guidelines of American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC)/Infectious Diseases Society of America (IDSA). If the initial assessment occurs during the patient’s hospitalization, the case manager should ensure that the ingestion of the TB medication is observed by a nurse. It is important to ensure that hospitals order and give dosages according to current ATS/ CDC/IDSA guidelines and are observing patients taking medications. Since the outpatient phase of treatment will involve giving all TB medications at one time, hospitals should be discouraged from splitting dosages for two reasons: (1) taking medications more than once a day creates an expectation for the patient that will have to change after discharge from the hospital, and (2) tolerance to the full dosage cannot be assessed while in the hospital. The patient’s tolerance to TB medications should be noted. Additionally, possible interactions with other medications should be determined prior to the patient starting TB medications.²¹



For more information on “Treatment regimens and dosages” see the Treatment of Tuberculosis Disease section of the manual ([5.10](#)).



For more information regarding Protocol and Standing Orders for local health jurisdictions, please see “[Protocol and Standing Orders](#)” located in the **FORMS** section of the manual.

Identify any barriers or obstacles to adherence in taking TB medications and keeping physician or clinic appointments. This includes such issues as language, availability of transportation, the patient’s preference for place and time of directly observed therapy (DOT), and the ability to swallow pills. Many adolescents and adults who have difficulty swallowing pills are embarrassed to report this to the healthcare provider. It may be necessary to teach people how to take pills, or it may be necessary to crush the pills and put them in food, such as pudding or applesauce. In addition, the case manager should determine the need for enablers and identify incentives that will be most valuable to the patient.²² See “Incentives and Enablers” in this section of the manual ([8.59](#)).

Review psychosocial status to identify unmet needs, the use of alcohol and/or illegal drugs, and any pre-existing psychiatric diagnoses.²³

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

Gather information for a possible contact investigation.



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

Treatment Plan

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

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

Each patient's management plan should be individualized to incorporate measures that facilitate adherence to the drug regimen, such as social service support, treatment incentives and enablers, housing assistance, referral for treatment of substance abuse, and coordination of TB services with those of other providers.²⁴

In the initial management strategy, regardless of the source of supervision, always include an adherence plan that emphasizes directly observed therapy (DOT), in which patients are observed as they ingest each dose of antituberculosis medications, to maximize the likelihood of completion of therapy.²⁵

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.²⁶ The treatment plan should be reviewed and updated at least monthly during reviews of clinical progress.²⁷



See other forms listed:

- [Acknowledgement of Counseling](#) (PHSKC)
- [Public Health Directive \(Adherence\)](#) (PHSKC)
- [Public Health Directive \(Non-Compliance\)](#) (PHSKC)
- [Authorization for Care Coordination](#) (PHSKC)
- [Authorization for Disclosure of Protected Health Information](#) (PHSKC)
- [Protocols and Standing Orders](#) (SHD)
- [Civil Detention Flowchart](#)

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 outreach workers, other staff providing direct patient care, and person managing the contact investigation
- Patient educator's name and dates of education sessions
- Method for prevention of transmission: no isolation, airborne infection isolation, home isolation, legal order for isolation
- Contract Treatment Agreement -signatures of the local health jurisdiction representative and the patient (or patient's representative)
 - [Acknowledgement of Counseling](#) (PHSKC)
 - [Public Health Directive \(Adherence\)](#) (PHSKC)
 - [Public Health Directive \(Non-Compliance\)](#) (PHSKC)
 - [Authorization for Care Coordination](#) (PHSKC)
 - [Authorization for Disclosure of Protected Health Information](#) (PHSKC)
 - [Civil Detention Flowchart](#)
- Planned course of antituberculosis 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
- Process of ensuring successful completion of treatment (DOT, incentives, enablers)
- Location(s) where DOT and Video DOT will be administered and time of day
- Intermediate and expected outcomes²⁸



For a list of intermediate and expected outcomes, see *Module 2: “Fundamentals of TB Case Management,”* pages 23–25 in the New Jersey Medical School National Tuberculosis Center’s *Tuberculosis Case Management for Nurses: Self-Study Modules* (New Jersey Medical School Global Tuberculosis Institute Web site) at <http://www.umdnj.edu/globaltb/products/tbcasemgmtmodules.htm> .

Planning Activities

To complete planning, perform the following activities:

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

Establish the treatment plan, ensuring that all the components are included. The case manager should ensure that the treatment plan is useful and meaningful. It becomes the internal standard of care for the patient as well as the performance standard for the case manager. Good planning will allow the patient to experience TB care and treatment along the healthcare continuum and prevent duplication and fragmentation of services. The plan should be discussed and validated with all team members and the patient.²⁹

Directly observed therapy (DOT) is the preferred initial strategy of care for all TB cases and suspects. DOT and Video DOT, coupled with individualized case management, leads to the best treatment. DOT should be used for all patients residing in institutional settings (i.e. hospitals, nursing homes, correctional facilities) or other settings, such as methadone treatment sites. Priority situations for the use of DOT and Videophone DOT include children and adolescents and patients with the following conditions/circumstances:

- Pulmonary tuberculosis with positive sputum smears
- Treatment failure
- Drug resistance
- Relapse
- HIV infection
- Previous treatment of either active tuberculosis or latent tuberculosis
- Current or prior substance abuse
- Psychiatric illness
- Memory impairment
- Previous nonadherence to therapy

Establish time frames in the treatment plan to monitor the plan and patient response.

Monitoring should be done at least monthly at the patient's home, ambulatory clinic, health department, or private physician's office. Each component of the plan should be reviewed to ensure that it is an accurate accounting of the patient's problems, required tests, and interventions. To track progress toward outcomes, document all treatment activities and their dates: medications taken, tests and results, patient visits, monitoring activities, side effects, adverse reactions, education sessions, social service referrals, incentives, enablers, isolation status changes, and patient problems.³⁰

Negotiate and adjust the treatment plan as needed, to meet new realities. Since patient circumstances are usually fluid and personnel resources often change over time, it is essential that the plan be negotiated with the patient and changed to adjust to new situations. The adjusted plan should be discussed with the team members, as well as the patient.³¹

Implementation Activities

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

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

Refer the patient to other healthcare providers, social service agencies, or community organizations, as needed. The referral process requires the case manager to locate and coordinate accessible, available, and affordable resources for the patient. After the referral is made, the case manager should monitor the patient's adherence to the referral and obtain the consultation or follow-up report in writing. Immediate intervention may be necessary if the patient or the referring agency experiences difficulty.³² All patients with suspected or proven TB should be tested for HIV infection, with referral for HIV treatment services when necessary. Referrals to medical specialists for conditions that would endanger the patient and/or affect the outcome of treatment should be made as soon as possible. The patient should be sent to an emergency department if the condition is serious when assessed by the case manager. The case manager should follow up a referral to obtain medical information and determine whether the necessary medical intervention has been completed.

Refer patient for services relating to the TB treatment if not available at the LHJ. This may include laboratory, auditory, or visual acuity testing; additional radiographs; or other tests required specifically for the patient. It is important to schedule or assist the patient in scheduling appointments and to monitor the patient's adherence to the appointment and the results.

An understanding of the patient's financial resources and health insurance coverage is important.³³ In Washington State, each LHJ is responsible for providing treatment of tuberculosis (both pulmonary and extra-pulmonary) if patients lack of financial resources or health insurance (see [WAC-246-170-031](#)).

Negotiate a plan for evaluation of DOT, Videophone DOT or self-administration medications. DOT is the preferred initial strategy of care for all TB cases and suspects. DOT and Videophone DOT, coupled with individualized case management, leads to the best treatment. The case manager should ensure the plan is suitable for the patient's needs and achievable by the healthcare provider(s) and then have the patient sign a DOT agreement. Due to the length of TB treatment, the patient's circumstances may change. The case manager needs to verify that the time and place for DOT administration originally agreed upon is still agreeable to the patient and provider. It also may be necessary to coordinate the arrangements for DOT with facilities outside the LHJ, such as school nurses, drug treatment center nurses, pharmacies, fire departments and employers.³⁴



Refer to the "Directly Observed Therapy and Videophone DOT" topic in this section of the manual (**8.57**).

Coordinate strategies to improve adherence. The case manager must have knowledge of and proficiency in strategies to improve patient adherence, understand the importance of developing and maintaining a therapeutic relationship, and be familiar with the principles and practices of behavioral contracting and behavioral modification. Collaboration with team members is essential to obtain as much information as possible about strategies to improve adherence of individual patients and elicit opinions, attitudes, and feelings expressed by the patient. Depending on the identified obstacles to completion of therapy, the treatment plan may also include enablers and incentives (see MMWR Treatment of Tuberculosis, 2003, specifically p.17 table 8, at <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>). To be effective, incentives and enablers should be meaningful and specific for a particular patient.³⁵ Incentives and enablers should be considered for use with all patients.

Ongoing Assessment and Monitoring

Conduct ongoing assessments and monitor patients at least monthly, either in an ambulatory clinic setting, LHJ or private physician's office. Schedule additional assessments throughout the month for patients experiencing problems in their tuberculosis (TB) treatment, or for those patients who are nonadherent to directly observed therapy (DOT), Videophone DOT or follow-up appointments.³⁶

There are countless stories from nurses and outreach workers reinforcing the fact that not all information is obtained from the patient or family during the initial visit. Therefore, the case manager must ensure that the list of contacts is updated as follow-up visits are made to the patient and other contacts. The updated information is necessary to determine the need for further testing. It is important to review the status of the contact investigation to ensure that timelines and standards are followed. Additionally, checking for the accuracy of previously gathered information should occur throughout the patient's TB treatment.³⁷

Ongoing Assessment Activities

To complete an ongoing assessment, perform the following activities:

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

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

Also, conduct this review at conversion of both smear and culture as evidence for the improving condition of the patient.³⁸



Inconsistencies should trigger additional questions, such as the possibility of laboratory contamination. Bring these questions immediately to the attention of the patient's medical provider, local health officer and WA State TB Services 360-236-3443.



A child's clinical response to treatment may not be as significant as that of an adult. Therefore, it is important to reinforce what the expected response to treatment should be for the individual child during the course of treatment and to weigh the child monthly.³⁹

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 completed 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.⁴⁰ 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.⁴¹

Review the treatment regimen to verify that the physician's orders are clear and concise. One of the case manager's primary responsibilities is to ensure that the patient completes treatment according to the physician's orders. It is also important to ensure that the plan is specific for the individual patient and follows the principles of TB treatment.⁴² For questions regarding treatment, contact Washington State TB Services Medical Consultant at 206-718-2664.



For more information regarding Protocol and Standing Orders for local health jurisdictions, please see "[Protocol and Standing Orders](#)" located in the **FORMS** section of the manual.

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

Monitor the side effects of and adverse reactions to medication. Review laboratory findings and contact the treating physician if abnormal results are obtained.⁴³ The patient should be monitored by a registered nurse and/or clinician or case manager at least monthly for signs and symptoms of adverse reactions until treatment is completed. If a patient is symptomatic, the provider should be immediately consulted and the patient monitored more frequently. Chemistries and complete blood count (CBC), aspartate aminotransferase (AST)/alanine aminotransferase (ALT), or other tests based on specific drugs should be done periodically per

physician's order. See **monitoring and Interventions for “Side Effects and Adverse Reactions”** in the Treatment of Tuberculosis Disease section of the manual ([5.19](#)).



If a child is taking TB medications at school, communicate at a minimum on a monthly basis with designated staff to determine whether the child is experiencing medication side effects or adverse reactions.⁴⁴

Assess adherence daily and monthly, and identify positive and negative motivational factors influencing adherence. An assessment of adherence needs to occur at each patient encounter. If the case manager is not involved in providing DOT or Videophone DOT, a notification system should alert him or her if the patient misses a DOT dose or if there is suspicion of nonadherence if the case is on self-administered therapy (i.e. via pill count or pharmacy checks). If a DOT or Videophone DOT dose is missed, the patient should be contacted the same day or the next business day and the issue escalated to the case manager's supervisor. Direct observation provides immediate information on poor adherence and adverse effects. The key to a successful DOT program is the timely use of this information in order to promptly identify and respond to potential barriers to adherence, missed doses, and potential adverse treatment effects. **It is important not to send a mixed message to a patient by not promptly responding to missed DOT doses.** If the patient is self-administering TB medications, make a weekly visit to the patient's residence to assess adherence and monitor for side effects and adverse reactions. Also, regularly monitor the effectiveness of enhancement methods (i.e., incentives, enablers, behavioral contracting, or behavior modification).⁴⁵ DOT and Videophone DOT is highly recommended if adherence is compromised (see MMWR Treatment of Tuberculosis, 2003, specifically p. 16, table 7, at <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>).

The case manager should ensure that the patient is informed about the consequences of nonadherence, including legal interventions and has signed contracts of understanding between the patient and the LHJ, both regarding the treatment of TB and Videophone DOT. Changes in the patient's attitude toward the healthcare worker should be documented and verified with the patient.⁴⁶



For more information, see the following topics in this section: “Directly Observed Therapy” (**8.51**) and “Legal Orders” (**8.59**). Also, see following forms:

- [Acknowledgement of Counseling](#) (PHSKC)
- [Public Health Directive \(Adherence\)](#) (PHSKC)
- [Public Health Directive \(Non-Compliance\)](#) (PHSKC)
- [Authorization for Care Coordination](#) (PHSKC)
- [Authorization for Disclosure of Protected Health Information](#) (PHSKC)
- [Civil Detention Flowchart](#)

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



For more information, see the Patient Education section of the manual ([15.1](#)).

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

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 or IGRA negative persons to become infected.

Monitoring Side Effects and Adverse Reactions

Assess and document side effects and adverse reactions to antituberculosis medications and monitor toxicity. The patient should be monitored by a registered nurse and/or clinician or case manager at least monthly for signs and symptoms of adverse reactions until treatment is completed. If a patient is symptomatic, the provider should be consulted immediately and the patient monitored more frequently. Chemistries and CBC, AST/ALT, or other tests based on specific drugs should be done periodically. See "Side Effects and Adverse Reactions" in the Treatment of Tuberculosis Disease section of the manual ([5.19](#)). As is true with all medications, combination chemotherapy for tuberculosis is associated with a predictable incidence of adverse effects, 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.⁵³ In addition, proper management of more serious adverse reactions often requires expert consultation.⁵⁴ Washington State TB Services Medical Consultant at 206-718-2664 is available upon request.



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 of the manual ([5.19](#)).

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 at least monthly 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.⁵⁵



For more information, see the [Patient Education](#) section of the manual ([15.1](#)).

Assess the patient for adverse reactions and side effects. For patients receiving DOT and Videophone DOT, staff should assess them 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 providing the DOT for patients on self-administered therapy, the case manager ensures that patients are assessed for side effects and adverse reactions to TB medications at least monthly and at each visit.⁵⁶

Monitoring Bacteriologic Improvement

Sputum Smears and Cultures

During treatment of patients with pulmonary TB, a sputum specimen for microscopic examination and culture should be obtained at a minimum of monthly intervals until two consecutive specimens are negative on culture and then monthly for remainder of treatment. More frequent acid-fast bacilli (AFB) smears may be useful to assess the early response to treatment and to provide an indication of infectiousness. For multidrug-resistant TB (MDR-TB) and extremely-drug-resistant TB (XDR) patients, monthly specimens are required. For patients with “Extrapulmonary TB” ([10.22](#)) the frequency and types of evaluation will depend on the site involved.

Activities to Monitor for Bacteriologic and Clinical Improvement

If the patient initially had positive AFB sputum smear results quantified as 1+ to 2+, collect one sputum specimen per week and submit it for testing until one specimen tests negative. After the specimen tests negative, then obtain two more consecutive sputum specimens collected 8 to 24 hours apart, with at least one being an early morning specimen (see MMWR Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005, specifically “Sputum Specimen Collection”, p. 51).

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e

If earlier AFB sputum smears were positive and now AFB sputum smears are negative on three separate, consecutive days, consider discontinuing isolation.⁵⁷

For patients with culture-positive pulmonary TB, collect at least one sputum specimen for smear and culture until persistently negative cultures are documented.⁵⁸ See “[TB Lab Flow](#) Chart” to view the PHL Algorithm.

Continued Positive Sputum Smears or Positive Cultures

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

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



For more information regarding Protocol and Standing Orders for local health jurisdictions, please see “[Protocol and Standing Orders](#)” located in the **FORMS** section of the manual.

1. Review and confirm the patient's medication adherence.
2. Place the patient on DOT, if not already on DOT.
3. Reconfirm the appropriateness of the medication regimen, based on drug susceptibility results and other considerations.
4. Consultation with a provider experienced with TB relapse and/or failing regimens is highly recommended. Washington State TB Services Medical Consultant is available at 206-718-2664.
5. If additional antituberculosis drugs are added to the treatment regimen, ensure that at least two new drugs that the patient has not been treated with previously are used. **Never Add a Single Drug to a Failing Regimen.**
6. Consider serum drug levels.
7. Repeat cultures and repeat drug susceptibility testing.

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 status, i.e. improving, worsening, or stable.
3. Review the patient's symptoms and weight for improvement, if applicable.
4. Review the patient's tuberculin skin testing or IGRA testing information (retesting may be appropriate if initially negative or test not initially done), and discuss this with the patient's medical provider.
5. Review information with the provider regarding his or her reasons for continuing TB medications.
6. Discuss the above findings with the LHJ health officer to determine if the patient is to be reported as a case.



Verification of Isolate Drug Susceptibility Results

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

1. **If a patient's TB organism is pan-susceptible:** Follow the recommended treatment regimen.
2. **If a patient's TB organism is drug resistant,** consult with patient's medical provider, local health officer, or Washington State TB Services Medical Consultant at 206-718-2664.

- 3. If isoniazid-resistant, multidrug-resistant TB (MDR-TB) or extremely drug resistant TB (XDR-TB):** Treatment of LTBI caused by drug-resistant organisms should be provided in close consultation with an expert in the management of these difficult situations. For patients with MDR-TB or XDR-TB contact Washington State TB Services Medical Consultant at 206-718-2664 in consultation with the local health officer.

Multidrug-Resistant Tuberculosis

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

1. Notify his or her supervisor and the patient's provider the same day that MDR-TB findings are reported/known.
2. For consultation regarding the treatment of drug-resistant TB, contact the Washington State TB Services Medical Consultant at 206-718-2664.
3. Initiate transfer of patient care to a more appropriate provider, if necessary. The case manager, with TB clinician/ Washington State TB Services Medical Consultant, should confer with the provider and arrange transfer of the case to a provider with experience/expertise in the management of MDR-TB. The case manager must document transfer of care and ongoing follow-up.
4. Obtain appropriate medications from suppliers.
5. Initiate DOT and maintain accurate DOT records. If the patient is nonadherent with DOT, the case manager must document attempts to correct the situation and notify his or her supervisor.
6. Provide the following for patients with MDR-TB:
 - Patient education, including information regarding second-line TB drugs
 - DOT at the patient's convenience
 - Incentives and enablers
 - Legal orders



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

Clinical Response to Treatment

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

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

Isolation

If a patient is isolated, ensure and document the patient's adherence to respiratory isolation. ⁵⁹



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

Closing a Case

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



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

Completion of Therapy

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



Record verification and closure information in TB PHIMS. For more information, see the TB PHIMS User Manual at <http://www.doh.wa.gov/Portals/1/Documents/Pubs/343-099-PHIMSTBUserManual.pdf>

Verifying Adequate Course of Treatment

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



For more information regarding Protocol and Standing Orders for local health jurisdictions, please see “[Protocol and Standing Orders](#)” located in the **FORMS** section of the manual.

- **If culture remains positive beyond two months of treatment**, reasons for persistent positive cultures should be examined and treatment adjusted and/or prolonged.
- **For TB involving the bones or joints or tuberculous meningitis:** These are exceptions to the standard six-month course. See “Bone and joint tuberculosis” and “Tuberculosis meningitis” in the “Treatment in Special Situations” ([5.32](#)) section of Treatment of Tuberculosis Disease of the manual or MMWR Treatment of Tuberculosis at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>
- **HIV-negative, culture-negative patients:** MMWR Treatment of Tuberculosis at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>
- **Relapse of TB following treatment for TB with pan-susceptible organisms.** (Current drug susceptibility testing must be performed and the regimen adjusted if resistance has developed.)⁶⁰ See “Management of Relapse, Treatment Failure, and Drug Resistance” <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>

Calculating Completion of Therapy

So that doses missed due to nonadherence or other treatment interruptions are still given after treatment is resumed, the 2003 revised TB treatment guidelines “Treatment of Tuberculosis” (MMWR 2003;52[No. RR-11]) at <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf> recommend basing the completion of treatment on the number of doses of directly observed therapy (DOT) received rather than on the chronological passage of time (e.g., six months).⁶¹



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

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

Closures Other than Completion of Therapy

- **Moved:** The case manager should obtain the new or forwarding address. Complete and submit copy of the [Interjurisdictional Tuberculosis Notification](#) form, to both the receiving site and Washington State TB Services. If possible, this form should be submitted to both the receiving site and DOH prior to the patient’s move. Cases should be closed as “moved” **only** if a new address is obtained.
- **Not TB:** If the completed diagnostic evaluation determined that the diagnosis of TB is not substantiated and another diagnosis is established, the case is closed as “Not TB”.
- **Died:** If the patient expired prior to completion of therapy, the case is closed as “Died.”⁶² The LHJ should provide the date of death on the completion of therapy report and also indicate if death was “TB related death” or “Non-TB related death”. Submit the completed form WA State TB Services. Note in the PHIMS TB “comment section” if death was TB related or not.



Ensure that the contact investigation on the case is also completed. For more information see Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis at

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

Evaluation

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

Evaluation activities answer the following questions:

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

To evaluate case management, perform the following activities:

- Review the patient's record (i.e., medications, bacteriology, radiographs, patient status, and etc.) and Update Reports sent to Washington State TB Services
- Review Cohort Review Report
- Review the contact investigation

Review the treatment plan at least monthly, or more frequently, depending on the complexity of treatment and patient variables. Review the appropriateness of interventions, as well as dates when intermediate and/or expected outcomes were achieved. Pay attention to how rapidly the treatment plan was changed when the need was identified (i.e. timeline). If the treatment plan has remained unchanged, determine the reason why.⁶³

Review reports and the contact investigation to ensure that the TB case reports are accurate and updated and that the contact investigation is complete.⁶⁴

TB Staffing Standards

Tuberculosis programs throughout the Country are struggling with developing staffing standards. There is no standardized way of determining how many nurses, outreach workers, disease investigators, or medical support staff are required to do TB control. On face value this may appear to be a very simple computation, but in reality is not. Determination of staffing levels for TB programs is compounded by many issues, including, but not limited to:

- Multiple risk factors associated with a large percentage of TB clients
- Travel distance in rural areas and/or traffic congestion in urban areas
- Cultural issues
- Communication issues
- Acceptance of diagnosis
- Length of treatment
- Prevalence of drug-resistant TB
- Partnership and private sector

Even with this type of information many administrators and policy makers continue to question the amount of staffing required in TB control programs. What many of them fail to understand is that for every active TB patient there is an average of seven to ten contacts. There may be substantially more if there is a work, institutional, or school exposure. Each of these contacts must be assessed for signs and symptoms of TB skin tested and/or referred for testing and or chest radiograph and medical examination.

Additionally, there are many individuals who are referred to a TB control program who are suspects. They must be assessed and case managed as if they have active TB disease until lab tests and or/clinical diagnosis rules this out, but are not counted in the number of confirmed cases which is what usually drives staffing levels and TB control programs. Further it deemed necessary, contact investigations will be done for “TB suspects”.

This may seem complicated enough, but thus far we have not even taken into consideration the prevention aspect of TB control. More than 16,000 new cases of TB disease still occur each year in the United States, and an estimated 10-15 million persons have latent TB infection with the attendant risk of future disease. To effectively eliminate TB these infected individuals must be identified and treated. Such prevention and control interventions are beyond the scope of many TB control programs in the United States. Most programs are struggling to cope with the workload created by individuals with active disease and have no, or minimal resources for effective prevention interventions.

If all the facets of TB control are considered what may seem like a small number of clients mushrooms into a substantial workload. We must be able to capture the nature of this work and translate it into a staffing standard that definitively defines the number of staff required to do all aspects of the work.

The National TB Controllers Association and the National TB Nurse Consultant Coalition recognized this as a major concern and in September 1999 created a joint NTCA/NTNC Staffing Standards Committee to develop a methodology to determine staffing standards for TB Control. The Committee consisted of eight TB nursing experts from four different states and was representative of both urban and rural programs. The Committee has worked diligently to develop and test instruments that can be used to determine required staffing levels in TB Control programs and completed a nine month multi-state trial of these instruments in 2004.

For training and assistance with the tools provided please call the Washington State TB Services 360-236-3443 or email at tbservices@doh.wa.gov.



[TB Staffing Standards Model](#) (Forms Section)

Cohort Review in Washington State

History

The 2000 Institute of Medicine report *Ending Neglect: The Elimination of Tuberculosis in the United States* concluded that tuberculosis (TB) elimination is feasible, but will require “aggressive and decisive action beyond what is now in effect.” The report recommended adopting an aggressive strategy in order to maintain control and ensure the most efficient application of resources. To this end, TB control programs must develop new standards by which to monitor and evaluate program performance⁶⁵.

One such evaluation method is cohort review, a systematic review of patients with TB disease and their contacts. A “cohort “ (which can be defined as “a group of individuals having a statistical factor , such as age or disease in common’ in a demographic study) of tuberculosis patients is reviewed in terms of each individual patient and contacts outcomes, as well as for program performance. Cohort review is a management process used to motivate staff, identify program strengths and weaknesses, determine staff training and professional education needs, and hold staff accountable for completion of treatment for both TB disease and latent TB infection (LTBI)⁶⁵.

The cohort review process can take many forms. In its most simplified form, TB control staff at the local level meet to review the treatment outcomes of every patient listed in a chronological patient register. Today, with computerized TB registries, multimedia projection, and long-distance communications options, it can be adapted for a variety of uses and settings⁶⁵.

Washington State Medical Case Review / Cohort Review Process

Washington adopted the cohort review process in 2003 based on the New York City model, which was then modified a year later to meet specific WA State needs. Since then Cohort Review has become an integral part of the TB Program. However in late 2010, due to budget cuts, staffing time and dissatisfaction with the process, a workgroup was formed to revise and develop an improved case management and cohort review process that will better suited to meet our state’s needs. Ideas that were proposed by the workgroup and subsequently implemented by the TB Program include:

- Reviewing cases in real-time – Medical case management oversight
- Eliminating the cohort review presentation forms – capturing all necessary data in PHIMS TB
- Changing quarterly format from retrospective cohort review presentations to a clinical review of open, counted cases
- Incorporating biannual program evaluation (based on core objectives and measures) with a review of selected cases with a pre-selected cohort criteria
- Making the process more effective, efficient, and interactive

In January 2012, the Medical Case Review / Cohort Review Process (formerly known as just the Cohort Review Process) was implemented. The following table shows what the new, two part, process looks like.

Medical Case Review / Cohort Review 2012

The following definitions may be helpful in this new process:

- **Case Review** – Discussion of patient case management; report on clinical status of the patient and identify variances/barriers in progress.
- **Quality Assurance** – A program for the systematic monitoring and evaluation of the various aspects of a project or program to ensure that standards of quality are being met.
- **Cohort Review** – A systematic, retrospective review of the management and outcomes of patients with TB disease and their contacts.

Quarterly Medical Case Review

Bi-annual Cohort Review

<p><i>Attendees:</i></p> <ul style="list-style-type: none"> • DOH Medical Consultant • LHJ Representative(s) • DOH Nurse Consultants 	<p><i>Attendees:</i></p> <ul style="list-style-type: none"> • DOH Medical Consultant • DOH TB Program • DOH Epidemiologist • All LHJs • Other interested parties
<p><i>DOH will organize conference call by:</i></p> <ul style="list-style-type: none"> • Pulling a list of current cases from PHIMS TB two weeks prior to case review date • Providing LHJs and DOH Medical Consultant with a list of the RVCT numbers of current open cases that will be reviewed • Emailing an agenda to LHJs with current cases stating their case will be reviewed and provide a time frame of when DOH will contact them 	<p><i>DOH will organize meeting by:</i></p> <ul style="list-style-type: none"> • Two months prior to Cohort Review researching cases and selecting a limited number to be presented • One month prior to cohort review date contacting the LHJs with selected cases to offer the option of presenting their case or having DOH present • Emailing all attendees the agenda/meeting information to attend via webinar or in-person • Providing each LHJ a copy of county-specific data for use in assessing how their LHJ is meeting core indicators
<p><i>During the call:</i></p> <ul style="list-style-type: none"> • Each case and their contacts will be reviewed in PHIMS TB with LHJ staff and DOH during a brief discussion • DOH Medical Consultant/DOH Nurse Consultants will provide recommendations/follow-up for cases and contacts as needed 	<p><i>During the meeting:</i></p> <ul style="list-style-type: none"> • DOH will present data on core indicators for Washington State • Facilitated discussion of issues identified related to case management • Presentation by LHJ or DOH of the selected cases and interactive discussion of cases

During the biannual Cohort Review, the epidemiologist will report on a variety of timeliness measures as well as focusing on the following six core indicators:

- Cases who complete treatment in 12 months
- Sputum culture conversion
- Time from sputum smear positive result to starting TB treatment
- Treatment failures and relapse rates
- Contacts evaluated
- Contacts who start/complete treatment for LTBI

Directly Observed Therapy

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

DOT is a component of case management that helps to ensure that patients receive effective treatment and adhere to it. The American Thoracic Society (ATS), the Centers for Disease Control and Prevention (CDC), and the Washington State Department of Health recommend that every tuberculosis (TB) patient be considered for DOT.⁶⁶ 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,⁶⁷ and
- Directly observing each dose provides immediate information on poor adherence and adverse effects, information that cannot readily be obtained from patients treated with SAT.

Candidates for Directly Observed Therapy

DOT *should be* the standard of care for all TB cases and suspects. In Washington State, DOT *is* the standard of care, that is, it is our goal to place all patients on DOT regardless of the patient’s circumstances, because it has been shown to be such an important treatment tool.⁶⁸ Priority situations for the use of DOT include TB cases and suspects with the following conditions/circumstances:

- Pulmonary tuberculosis with positive sputum smears
- Children and adolescents
- Treatment failure
- Drug resistance
- Relapse
- HIV infection
- Previous treatment of either active tuberculosis or latent tuberculosis
- Current or prior substance abuse
- Psychiatric illness
- Memory impairment
- Previous nonadherence to therapy

All patients being treated with regimens that use intermittent drug administration have all doses administered under DOT because of the potentially serious consequences of missed doses (see Treatment of Tuberculosis, “Promoting Adherence”, p. 16).

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

DOT for Contacts Receiving Treatment for Latent TB Infection (LTBI): One of the national health objectives for 2010 is to complete treatment in 85% of contacts who have latent TB infection (LTBI). Washington State and the nation have fallen short of national objectives. To increase these rates, CDC recommends focusing resources on the contacts most in need of treatment, monitoring treatment (including contacts receiving care outside the LHJ) and providing DOT (see Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, “Treatment for Contacts with LTBI”, pg. 16).

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

How to Deliver Directly Observed Therapy



For an example job description outlining duties of DOT worker, go to:

<http://www.doh.wa.gov/Portals/1/Documents/Pubs/343-Non-PositionDescription.pdf>

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

- TB clinic personnel or other healthcare workers trained by the LHJ to provide DOT.
- Staff at other healthcare settings, such as outpatient treatment centers
- Facilities outside the LHJ, such as school nurses, drug treatment center nurses, pharmacies, fire departments and employers. .
- *Not* family members⁶⁹

Principles of Directly Observed Therapy (DOT) and Videophone-DOT

- The healthcare worker, or whoever is providing the DOT, should watch the patient swallow each dose of medication.
- Use DOT with other measures to promote adherence such as enablers and incentives, see Treatment of Tuberculosis, “Promoting Adherence”, Table 8, pg. 17.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>
- DOT can be given anywhere the patient and LHJ agree upon, provided the time and location are convenient and safe.^{70,71}

Directly Observed Therapy Tasks (in Person)

1. Deliver medication.
2. Check for side effects and adverse reactions.
3. Verify medication (by person providing DOT).
4. Have the patient verify the medication
5. Watch the patient take pills.



DOT Resources (8.61)



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.⁷²

6. Document the Visit



- [Videophone Directly Observed Therapy Form](#) (TPCHD) (Forms)
- [Guidelines for Use of Videophone for DOT and DOPT](#) (SHD) (Forms)

7. As necessary and appropriate, do the following:

1. Provide patient education
2. Help the patient keep appointments
3. Connect the patient with social services and transportation
4. Draw upon familiarity with the patient's home environment to identify household contacts
5. Offer incentives and/or enablers to encourage adherence⁷³



- For more information, refer to the “Incentives and Enablers” (8.58) topic in this section of the manual or “Treatment of Tuberculosis” <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>

Videophone Directly Observed Therapy (VDOT) Tasks

1. [Videophone Directly Observed Therapy Form](#) (TPCHD)
[Guidelines for Use of Videophone for DOT and DOPT](#) (SHD)
2. Follow same process as DOT tasks, i.e. have patient verify medication, observe patient swallowing the medication, and document the event.



The article titled “Videophone utilization as an alternative to directly observed therapy for tuberculosis” was written by our colleges from DOH, Snohomish Health District, and Tacoma Pierce County Health Department TB Programs. Abstract available at <http://www.ingentaconnect.com/content/iuatld/ijtld/2010/00000014/00000006/art00019>

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.⁷⁴



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

Children with Tuberculosis

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



For more information on adherence strategies for different developmental stages, see Appendix C in the New Jersey Medical School National Tuberculosis Center's *Management of Latent Tuberculosis Infection in Children and Adolescents: A Guide for the Primary Care Provider* (New Jersey Medical School Global Tuberculosis Institute Web site; 2004) at <http://www.umdnj.edu/ntbcweb/products/mgmtltbi.htm>

Agreements

It is recommended to develop a letter of agreement or acknowledgment between the patient and the local health jurisdiction (LHJ). Many LHJs in Washington State have successfully used Videophone DOT (VDOT) 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.⁷⁵



- [Videophone Directly Observed Therapy \(DOT\) Consent Form](#)
- [Direct Observed Therapy Agreement](#)

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 of the manual (**8.59**).

Missed Directly Observed Therapy Dose



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

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

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

Directly Observed Therapy/Videophone

Background

Directly observed therapy (DOT) for tuberculosis increases patient adherence. This increased adherence both reduces the risk of disease recurrence and also prevents the development of drug-resistant *Mycobacterium tuberculosis* strains.

DOT can be resource intensive and a burden to under-funded public health departments. Costs include personnel time and travel expenses.

The use of Videophone technology in selected patients provides DOT at a decreased cost while maintaining the benefits.

Application

Ideal candidates are those living at a considerable distance from the health department, those who will require therapy at atypical times and those who may require prolonged daily therapy. All potential patients will receive their initial four weeks of DOT through standard in-home visits.

All patients who agree to participate in Videophone DOT will sign a consent form and a statement of responsibility for the videophone equipment. Training on the videophone will be over two treatment days. During both of these days a health worker will be present in the patient's home to assist with the equipment and to provide practical instruction in its use.

During remote DOT, a monthly supply of pre-packaged medication doses will be given to the patient at each clinic visit.

The Local Health jurisdiction personnel will arrange a set time for the remote video call with the patient. During the video call the patient will be expected to display the medications onscreen. The health worker will then witness the patient swallowing the medication.

Exclusion Criteria

- Lack of land line telephone at patient location
- Less than 90% compliance with therapy during the initial four weeks of standard DOT
- Inability to maintain effective communication via the videophone either due to patient disability or language barriers
- Inability of the patient to demonstrate effective use of the equipment during the two-day training period.



Available Forms:

- [DOT Audit Tool](#)
- [Policies and Procedures Inventory](#)
- [Policies and Procedures Request](#)
- [Report of Lost/Stolen](#)
- [VDOT Consent](#)
- [VDOT Tacoma-Pierce](#)
- [VDOT Snohomish](#)
- [VDOT Release of Liability](#)
- [VDOT Memorandum](#)

Incentives and Enablers

Use incentives and enablers to enhance adherence to therapy.⁷⁶ Incentives and enablers are used to improve patient attitudes and to foster good health behaviors.⁷⁷ They help patients stay with and complete treatment.⁷⁸

Incentives are small rewards given to patients to encourage them to either take their own medicines or keep their clinic or field directly observed therapy (DOT) appointments.⁷⁹ **Enablers** are those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties.⁸⁰

Use of incentives and/or enablers should be considered for all cases of tuberculosis (TB) as an adherence-improving measure. The local TB case manager should determine the most appropriate incentive and/or enabler on a case-by-case basis. Some **examples** of incentives and enablers used previously are listed below.

TABLE 1: AVAILABLE INCENTIVES AND ENABLERS

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

Legal Orders



For Washington State laws and rules on tuberculosis (TB) and Due Process, see the following: [RCW 70.28.032](#) Due Process.

Understand when and how to use legal orders, if necessary, for adherence to therapy. Nonadherent adults with pulmonary TB pose the greatest threat to the health of a community. It is the local health jurisdiction's responsibility to ensure that compliance is maintained, treatment is completed, and the risk of transmission to others is eliminated. These responsibilities require that TB staff members be innovative and always "go the extra mile" to see that patients take their medicine as prescribed. The public health mandate and good judgment dictate that program staff should go to every extent possible to fulfill the job responsibilities outlined above before resorting to legal action.⁸¹

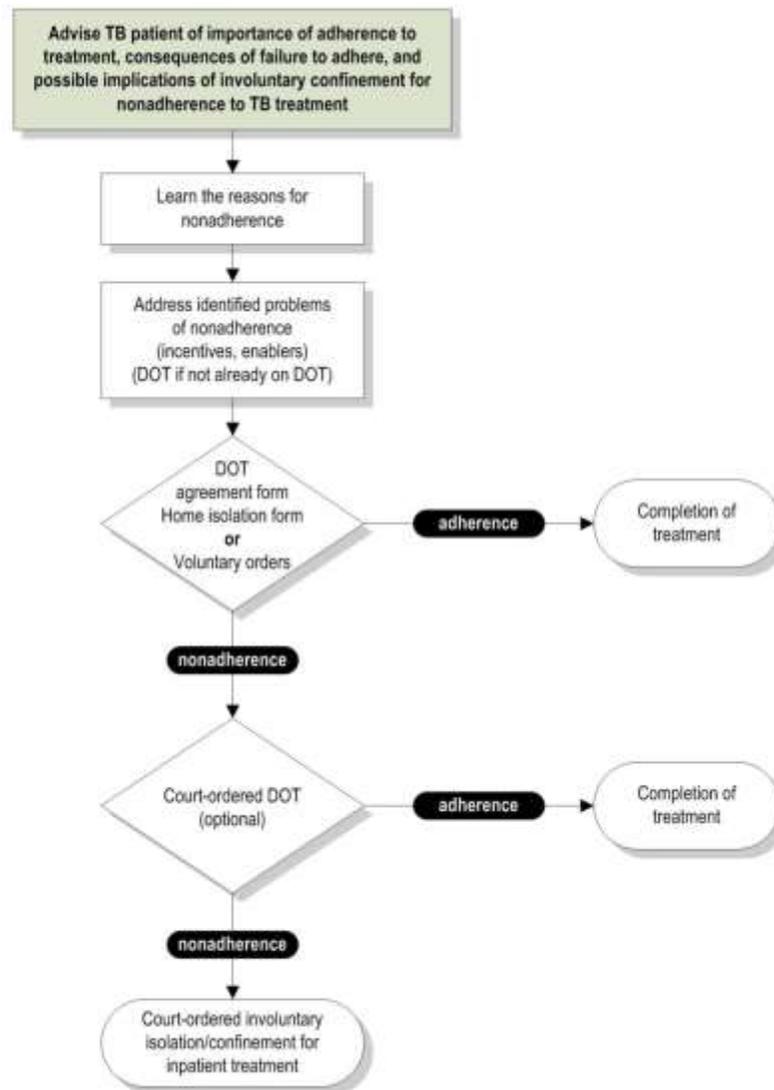
Have an intervention plan that goes step-by-step from voluntary participation to involuntary confinement as a last resort. Refer to Figure 1: Progressive Interventions for Nonadherent Patients. Progressive intervention should begin with learning the possible reasons for nonadherence and addressing the identified problems using methods such as directly observed therapy (DOT) and Videophone DOT (VDOT), incentives, and enablers. Prior to initiating treatment, the patient should be told verbally and in writing of the importance of adhering to treatment, the consequences of failing to do so, and the legal actions that will have to be taken if the patient refuses to take medication.⁸² Thus, it is important to ensure an interpreter is provided during this process, if indicated.

Before legal measures are taken with a patient who has been taking TB drugs on a self-administered basis, DOT and/or Videophone DOT should be offered to the patient.⁸³

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

If the patient does not adhere to DOT and/or Videophone DOT voluntarily, the next step may be court-ordered DOT. An optional step toward other legal orders, court-ordered DOT can be successful in convincing a patient that his or her TB treatment is an important public health priority. Involuntary confinement or isolation for inpatient treatment should be viewed as the step of last resort, to be used only when all other options fail. However, when a patient with infectious TB refuses treatment and voluntary isolation, emergency detention to isolate the person is appropriate.⁸⁴

FIGURE 1: PROGRESSIVE INTERVENTIONS FOR NONADHERENT PATIENTS⁸⁵



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

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

Resources and References

General Case Management Resources

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