

Tuberculosis

1. DISEASE REPORTING

A. Purpose of Reporting and Surveillance

1. To identify and ensure the adequate treatment of persons with active tuberculosis (TB).
2. To identify the contacts of active TB cases and ensure their evaluation.
3. To ensure that all eligible infected contacts are offered and complete a course of treatment for latent TB infection (LTBI).
4. To identify other infected persons who may be at high risk for progression to TB disease (i.e., Targeted Testing) and ensure treatment of persons identified with LTBI. Targeted Testing activities should only occur when program goals are consistently met for items 1-3 above and the local health department (LHD) has resources to assure treatment completion for all persons found to be infected in the targeted group. (See §6.E.)

B. Laboratory and Physician Reporting Requirements

1. Health Care Providers and Health Care Facilities

- a. Report all cases and suspected cases to the LHD within one working day of making or presuming a TB diagnosis. (OAR 333-018-0000)
- b. Cooperate with local Public Health Authorities in the investigation and implementation of appropriate TB control measures. (OAR 333-019-0002)

2. Laboratories

- a. Report all test results that are indicative of and specific to TB (e.g., positive acid fast smear, or positive culture identified as *Mycobacterium tuberculosis* or *M. tuberculosis* complex) to the LHD within one working day. (OAR 333-018-0015)
- b. Forward primary *M. tuberculosis* complex isolates to the Oregon State Public Health Laboratory (OSPHL). (OAR 333-018-0018)

C. Local County Health Department Reporting and Follow-up Responsibilities

1. Reporting

Report all confirmed and suspected cases to the Department of Human Services (DHS) TB Program within one week of initial health care provider or laboratory report. (OAR 333-018-0020) Use the standard DHS TB Program reporting forms and timelines. (See Table 1.) The forms are available from the DHS TB Program and Internet website <http://www.dhs.state.or.us/publichealth/tb>.

2. Follow-up

The local Public Health Authority is assigned the responsibility to investigate reportable diseases (including TB) in a timely manner, carry out appropriate control measures, and follow procedures outlined in these DHS *Investigative Guidelines* or other procedures approved by DHS. (ORS 433.006, OAR 333-019-0000)

Basic requirements include:

- a. A TB Nurse Case Manager (TB-NCM) will be assigned to each suspected or confirmed active TB case.
- b. The TB-NCM will assure that the case begins appropriate therapy within one day of receipt of the case/suspect report or, when appropriate, after disease work up is completed. Directly Observed Therapy (DOT) is the standard of care for treatment of all TB cases in Oregon.
- c. The TB-NCM will monitor the TB case's treatment and clinical response to treatment through the completion of therapy.

- d. The TB-NCM will begin the contact investigation within 72 hours of verifying the case/suspect.
- e. The TB-NCM will assure appropriate and timely contact investigation is performed, and will follow infected contacts through the completion of their therapy.

The LHD triennial TB performance reviews and the TB Program Element of the Financial Assistance Contracts contain the minimum components of effective TB prevention and control programs and are based on the objectives in Oregon’s TB Cooperative Agreement with the Centers for Disease Control and Prevention (CDC). LHDs should take steps to meet or exceed these stated levels of TB program function and outcomes.

Table 1. TB Reporting Forms and Timeframes

Report Name	Function	Submission Time
Initial Report of Suspect Case of TB	Collects case information	Within 1 week of initial notification to the LHD
TB Preventability Data Form	Collects medical and exposure history of case	Send with Initial Report
TB Contact Investigation Data Form	Collects information on contacts of cases	Initial: within 1 month Interim: after 3 month follow-up testing is done Final: when infected contacts complete treatment
TB Epidemiological Worksheet	Assists investigation of individual case to identify their contacts	Not submitted - keep with LHD record
Verification Report of Suspect Case of TB	Verifies case of TB and reports susceptibilities or reclassifies as not active TB	Within 1 week of susceptibility results or no later than at 3 month clinical evaluation
Completion Report for Verified Case of TB	Provides information on completion or end of treatment	Within 1 month of closing
TB /Suspect Inter-jurisdictional Transfer Notification Form	Vehicle for transferring information when case leaves a jurisdiction	Send a copy when case is transferred to another jurisdiction
Contact Follow-up Inter-jurisdictional Transfer Notification Form	Vehicle for requesting follow-up of contacts in other jurisdictions	Send a copy when referrals for contacts are made to another jurisdiction
CURE-TB Bi-national Referral Form	Vehicle to transfer care to Mexico or request treatment information from Mexico	Send a copy to State TB program when original is sent to Cure-TB

D. State TB Program Responsibilities

1. Consultation and Assistance

- a. Discuss and consult on all aspects of TB and TB care including:
 - Appropriate diagnostic evaluation, medical treatment and clinical monitoring
 - Current TB guidelines and practice standards
 - TB case management and contact investigation
 - Reporting and surveillance
 - Screening, testing and treatment of LTBI
 - TB program development and evaluation
 - Policies, TB Statutes and Administrative Rules
 - Assistance with or supervision of TB investigations (OAR 333-019-0000)
- b. Consultation with and referral to local and national TB expert consultants as needed.
- c. Inter-jurisdictional transfer assistance and coordination as needed.

2. TB Medications and Enhancing Adherence

- a. The DHS TB Program supplies the LHDs with medications specific for the treatment of active TB and LTBI. The medications are provided based on the availability of funds provided in the state General Funds budget.
 - i. Exceptions include TB patients who are incarcerated, hospitalized, and those covered by Indian Health Services or Veterans Administration programs. However, if co-payments or utilization of such programs interferes with compliance for treatment of active TB, the TB medications will be provided to the LHD for those cases to assure adequate treatment.
 - ii. TB medications are not provided for the treatment of disease causing mycobacteria other than TB (e.g., *M. avium*, *M. chelonae*, *M. xenopi*, etc.)
- b. DOT Incentives and Enablers: The DHS TB Program provides funds, if awarded in the federal TB grant, to purchase or secure incentives or enablers for cases on DOT. Forms to request Incentives funds are available from the DHS TB Program. (See Appendix B)

3. Chest X-rays for Selected TB Patients

The DHS TB Program provides a modest reimbursement to private health care providers for performing and reading TB-related chest x-rays on selected patients. Instructions and forms to authorize use of chest x-ray funds are available from the DHS TB Program. (See Appendix B)

4. Funds for TB Case Management

The DHS TB Program provides supplemental TB case management funds to LHD TB programs. These funds are not intended to be the sole funding for the LHD's TB control program. The funds are awarded by contract and are distributed proportionately based on the 5-year mean number of verified TB cases (per national case definition) in each county, and the available TB funds in the state General Funds budget.

2. THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiological Agent

Tuberculosis is caused by the bacteria *Mycobacterium tuberculosis*, which is usually reported by the laboratory as *M. tuberculosis* complex. The complex is a grouping of five closely related mycobacteria comprised of *M. tuberculosis*, *M. bovis*, *M. microti*, *M. africanum*, and *M. canetti*. *M. bovis* is sometimes identified as the causative agent of human disease and is treated essentially the same as *M. tuberculosis*. (See §5.C.3.a.) *M. microti*, *M. canetti*, and *M. africanum* are only very rarely identified in the United States.

Many other species of mycobacteria live in a wide variety of environments including animals, soil and water. Most mycobacteria do not cause disease in humans; however, some can colonize, cause disease, or cause "TB-like" illness. These species may be referred to as "Mycobacteria other than TB" (MOTT), atypical mycobacteria or nontuberculous mycobacteria. Other than *M. leprae*, the causative agent of leprosy/Hansen's disease, nontuberculous mycobacteria are not reportable and do not require public health investigation. Cases initially diagnosed as suspected TB, but after evaluation are found to have disease caused by a mycobacteria other than *M. tuberculosis* complex, may be closed to public health services and referred back to the private health care provider for follow-up. However, patients can have mixed infection/disease of both *M. tuberculosis* and another mycobacteria concurrently.

B. Natural History of Infection

TB infection and disease is a two-phase process. Generally, prolonged repeated exposure to an infectious case is required for infection to occur. Most TB-infected persons control the infection (LTBI) and never progress to active disease. In the general population, only about 10% of infected persons will progress to active TB disease. Of those that do progress, 50% do so within the first two years after becoming infected. Infants, young children and

immunocompromised persons are at much higher risk to progress to active disease and to develop more life-threatening forms of TB. Persons with specific co-existing medical conditions are also at increased risk of progressing to TB if infected. These risk factors and clinical conditions include: recent TB infection (within two years), chest x-ray findings of old TB, HIV infection, silicosis, underweight by >5%, diabetes mellitus, chronic renal failure/hemodialysis, gastrectomy, jejunioileal bypass, solid organ transplantation, and carcinoma of the head or neck.

C. Description of Illness

1. Latent TB Infection (LTBI)

Persons with LTBI are not ill and have no symptoms of pulmonary or extrapulmonary TB. The chest x-ray is usually normal; however, some persons may have findings indicating evidence of old, healed TB.

2. Active TB Disease

TB infection that progresses to active disease can manifest as pulmonary, extrapulmonary, or multiple site (i.e., disseminated) TB disease. Development of disease is generally not rapid with symptoms usually starting subtly and progressing, over weeks to months, until the patient finally recognizes that something is wrong and presents for care. The typical symptoms are not unique to TB, but can be divided into the following categories:

- a. Generalized (can occur with any site): fever, night sweats, weight loss/decrease in appetite, malaise/tiredness
- b. Pulmonary: cough, sputum production, hemoptysis, chest pain
- c. Extrapulmonary: symptoms correlate to the organ involved (e.g., TB meningitis will have symptoms of meningitis; TB of bone can have swelling or pain at the affected site, etc.)

If left untreated, about 25% of TB cases die within two years, 50% die within five years, and 25% will remain infectious. Extrapulmonary TB, if untreated, may result in death or deformity and may progress to disseminated TB, including pulmonary disease. Often, patients with extrapulmonary TB will also have pulmonary TB at the time of initial TB diagnosis.

D. Reservoirs

Infected humans are the primary reservoir for *M. tuberculosis*. Rarely, human cases have been linked to transmission to/from non-human primates and other mammals.

Infected cattle are the important reservoir for *M. bovis*, particularly in countries where dairy cattle are not screened for TB.

E. Modes of Transmission

1. Airborne

TB infection is usually acquired by inhalation of droplet nuclei, which contain TB bacilli, into the alveolar sacs of the lungs. These droplet nuclei are produced when a person with pulmonary or laryngeal TB coughs, shouts, or sings. Droplet nuclei can also be produced during aerosolizing procedures such as bronchoscopies, autopsies, or processing of tissue and cultures in laboratories.

Larger particles expelled by TB patients do not result in transmission because the particles do not remain airborne and are too large to reach the alveolar sacs in the lungs. Large particles and many droplet nuclei containing TB bacilli impact on the upper airway walls and are expelled to the oropharynx and expectorated or swallowed, thereby avoiding infection. For TB infection to occur, a person must breathe in enough TB bacilli, on small enough particles, over a long enough period of time, which results in some TB bacilli lodging in the alveolar sacs of the lungs. Organisms landing on intact mucosa or skin do not invade tissue.

Factors that affect the likelihood of TB transmission:

- a. Number of organisms being expelled into the air
- b. Concentration of the organisms in the air (volume of space and ventilation)
- c. Length of time an exposed person breathes contaminated air

2. GI absorption (*M. bovis*)

Ingestion of unpasteurized dairy products from diseased cows can lead to infection with *M. bovis*. *M. bovis* bacilli can penetrate the gastrointestinal mucosa or invade the lymph tissue of the oropharynx when drinking milk or eating soft cheeses containing large numbers of organisms. Transmission of *M. bovis* via the airborne route may be possible when pulmonary disease is present.

3. Vaccination

The *M. bovis* Bacille Calmette-Guerin (BCG) vaccine is a live attenuated vaccine. Two kinds of medically administered BCG are produced, one for immunization against TB and one for use as a bladder infusion agent to stimulate immunity against transitional-cell carcinoma of the urinary bladder. Rare adverse reactions to both types can result in dissemination and active *M. bovis* disease. As such cases are not naturally occurring, they are not verified as incident TB cases for reporting purposes. However, active BCG disease cases do require usual TB follow-up activities to assure that no transmission to the community occurs and that the case receives adequate treatment.

4. Other Rare Situations

a. Needle sticks

Transmission of *M. tuberculosis* to health care workers via needle sticks has been documented. The usual route of transmission is a biopsy needle or needles used by laboratory technicians while manipulating positive culture material. Phlebotomy needles should not be suspect unless the blood cultures are positive for *M. tuberculosis* complex (a rare occurrence).

b. Bronchoscopes and endoscopes

Transmission of *M. tuberculosis* has been well documented due to improper cleaning of instruments between patients.

F. Incubation Period

The incubation period for TB is highly variable and is usually a lifetime. Most infected persons do not progress to disease. Between two to ten weeks post-infection, the immune system develops a cell-mediated immune response. During this time, TB bacilli continue to multiply and are spread via the lymphatic system, to regional lymph nodes, to the blood stream, and to the rest of the body. The TB bacilli multiply until there are sufficient numbers to stimulate the immune response. Eventually, the cell-mediated immune response controls the TB infection. This same immune response creates the delayed-type hypersensitivity reaction to the tuberculin skin test (TST). The risk of progression to disease is discussed in §2.B.

G. Period of Communicability

1. TB Infection

Persons with LTBI do not have disease and are not infectious.

2. Active TB Disease

Results of sputum smear examination are the primary means for determining infectiousness and the need for patient isolation. If three sputum specimens were not already collected and processed for acid-fast bacilli (AFB) smear and culture as part of the initial diagnostic process, such specimens should now be collected and the patient should be considered infectious until sputum smear results are known. A case who is unable to produce sputum with induction but has cavitory disease, should be treated as if smear positive.

Generally speaking, most cases with drug susceptible TB will respond quickly to treatment and become non-infectious within a few weeks. However, some may be slow to respond due to malnutrition, malabsorption of drugs, advanced disease, or drug resistant TB; therefore, each case is assessed by their individual clinical presentation and response to treatment.

a. Pulmonary TB cases with initial AFB smear positive sputum:

Consider infectious from the time coughing began until all of the following criteria are met:

- i. Three sputum specimens, collected consecutively at least eight hours apart, are AFB smear negative, and
 - ii. At least two weeks of an appropriate four drug TB regimen, and
 - iii. Clinical evidence of response to treatment (e.g., cough is decreasing or gone, fever has subsided, etc.)
- b. Pulmonary TB cases with initial AFB smear negative sputum or unable to produce sputum (with induction), and non-cavitary disease
- Such cases are less infectious than patients with smear positive disease, but may still spread TB to close contacts and those to whom they have prolonged exposure. Consider somewhat infectious from the time coughing began until all of the following criteria are met:
- i. All three initial sputum specimens, collected consecutively at least eight hours apart, are AFB smear negative, and
 - ii. At least two weeks of an appropriate four drug TB regimen, and
 - iii. Clinical evidence of response to treatment (e.g., cough is decreasing or gone, fever has subsided, etc.)
- c. Extrapulmonary TB
- Generally, extrapulmonary TB is not considered communicable. The exception is highly contagious laryngeal TB. Laryngeal TB cases should be handled as pulmonary sputum smear positives. In addition, it is not uncommon for persons with extrapulmonary TB to also have some pulmonary involvement as well. Therefore, every case of extrapulmonary TB must have a chest x-ray at diagnosis and be assessed for pulmonary symptoms. If the chest x-ray is abnormal or the case has pulmonary symptoms, three sputum specimens must be collected before concluding that the patient is non-infectious.

H. Immunization with BCG

Vaccination with BCG (a live attenuated *M. bovis* strain) is rarely used in the United States, but is widely used in many parts of the world. Studies have shown that BCG vaccine can decrease mortality of infants and reduce the severity of disease in infants and children in high morbidity areas, but has little protective benefit for older children or adults. Also, the BCG vaccine's protective effect is short lived. If the vaccine results in an immune response, the person will have a reaction to the TST. Such reactions are usually small and thus usually below the individual patient's appropriate cut-point for TST. Studies have demonstrated that about 50% of persons revert to a negative TST within two years after BCG vaccination and 90% revert to a negative TST within five years after vaccination. Because this is a live vaccine, active TB disease may result either shortly after vaccination or many years later. (See §2.E.3.) Because the BCG vaccine does not usually prevent infection or progression to disease, and the TST reactions due to BCG are usually less than 10mm, a history of BCG vaccination:

- Is not a contraindication for a TST
- Does not change how the TST is interpreted
- Does not alter the indications for offering treatment for LTBI

Additional BCG information for patients and health care workers is available from the DHS TB Program. (See Appendix B)

I. Overview of Treatment

1. Latent TB Infection (LTBI)

Follow the current CDC Targeted Testing and Treatment guidelines for complete details of the diagnostic work-up and treatment for LTBI. TB nurses providing treatment for LTBI should be familiar with these standards. The guidelines are available from CDC. (See Appendix A §1.c.)

- a. Generally, Isoniazid (INH) for six or nine months is used.
 - i. Research supporting the six-month regimen is found in the CDC Targeted Testing and Treatment guideline, Table 4. "Efficacy of various durations of INH in persons with abnormal chest x-ray". (See Appendix A §1.c.)

- ii. Nine months of INH is preferred for infected persons with significant abnormal chest x-ray (not active disease), those who are immune compromised and children.
 - iii. The two-month regimen of Rifampin (RIF) and Pyrazinamide (PZA) is no longer recommended due to serious and fatal hepatitis associated with this regimen. (See Appendix A §1.c.)
 - iv. All intermittent regimens (e.g., bi-weekly) must be DOT.
- b. All patients should be monitored monthly, in person as recommended, for side effects and adherence while on treatment.

2. Active Disease

Follow the current CDC Treatment guidelines for complete details of treatment of active TB. TB nurses providing treatment for active TB should be familiar with these standards. The guidelines are available from CDC. (See Appendix A §1.b.)

- a. DOT is the standard of care for all TB cases in Oregon. All cases on intermittent therapy (e.g., bi-weekly) must be DOT.
- b. Option 1 is the preferred treatment regimen.
- c. All cases should be started on 4 drugs: INH, RIF, PZA, and Ethambutol (EMB) pending susceptibility results. When the patient isolate is found to be susceptible to INH and RIF:
 - i. For cases on daily therapy (Option 1), EMB may be discontinued
 - ii. For cases on bi-weekly therapy (Option 2), continuation of the EMB until the Initial Phase of treatment is completed may be preferable. There is no evidence that it is safe to discontinue EMB, which has been given less than daily, before completing the Initial Phase.
 - iii. PZA is discontinued at the end of the Initial Phase, not simply upon receipt of susceptibility results.

3. CASE DEFINITIONS, DIAGNOSIS, AND LABORATORY SERVICES

A. Case Definitions

1. Laboratory Confirmed Case (reportable as verified to CDC)

Case has culture positive specimen(s) identified as *M. tuberculosis* or *M. tuberculosis* complex.

2. Clinical Case (reportable as verified to CDC)

Culture negative cases that meet all the criteria below:

- a. Have a positive TST, and
- b. Have signs and symptoms compatible with TB, and
- c. Received a complete work-up for active TB, including collection of appropriate specimen(s) that were sent for AFB smear and culture, and
- d. Have been on four drug therapy for TB, and
- e. Have a clear clinical response to the treatment for active TB disease

3. Physician Diagnosis (empiric treatment for TB)

This category was defined for AIDS patients with active TB who are anergic and do not meet the confirmed or clinical case definitions above but meet all of the criteria below:

- a. Have a result of a negative TST, performed during the diagnostic work-up, and
- b. Have signs and symptoms compatible with TB, and
- c. Received a complete work-up for active TB, including collection of appropriate specimen(s) that were sent for AFB smear and culture, and
- d. Have been on four drug therapy for TB (via DOT), and
- e. Have a clear clinical response to the treatment for active TB disease.

Most cases in this category will not be reported to the CDC. Only AIDS patients in this category will be verified as incident cases. Rarely, private physicians may want to continue TB treatment, empirically, for cases that do not meet the CDC definition. The reason these cases are not verified is due to the wide variety of clinical judgment used to make the diagnosis (i.e., some physicians would consider them a case, while others would not). The

application of case definitions for TB surveillance purposes does not mean the suspect case does not have TB or should not be treated; LHDs generally should continue to follow these cases. However, LHDs may close these cases to Public Health follow-up if providing that care adversely affects delivery of care to confirmed, clinical, or other suspect cases, and reasonable evidence has not been shown that the suspect case really has active TB.

B. Diagnosis

1. Follow the current CDC Diagnostic guidelines for complete details of diagnosis recommendations. TB nurses should be familiar with these standards. The guidelines are available from CDC (see Appendix A §1.a.)
2. The Oregon Coalition to Eliminate TB (ORCET), using the above standards, developed a set of guidelines and algorithms for work-up of TB suspects. The Oregon guidelines include separate documents for the diagnosis of pulmonary, pleural, and extrapulmonary TB in adults, as well as pediatric TB diagnosis for children who are suspect cases or are contacts to cases. Health care providers and LHD nurses can use these guidelines to assure a complete TB diagnostic work-up. The documents are available from the DHS TB Program (see Appendix A §1.a.)
3. TST information is included in the CDC Diagnostic guidelines (see Appendix A §1.a.). Nurses who perform TSTs should have specific training in this procedure and be familiar with the CDC TST recommendations. Additional Mantoux TST administration and interpretation training materials are available from CDC (see Appendix A §2.a.)
 - a. Criteria for interpreting a TST result are dependent on the individual person's risk for TB. The person's personal risk and which category to use for a TST cut-point should be determined before the test is read, and that category should be used for interpreting the result. The three categories are 5mm, 10mm, and 15mm. A result smaller than the cut-point for the category is considered a negative test. Careful attention should be given to correctly identifying the patient's risk to select the appropriate category for determining a positive reaction. Approximately half of the "positive" TSTs in low morbidity areas are estimated to be false positives due to cross-reactions with other mycobacteria and improper selection of TST cut-point.
 - b. 15mm is the appropriate cut point to determine a positive TST in most health care workers (unless current TB risk assessment at the facility of employment indicates otherwise) and others who have no personal/social risk factors to use a lower cut point.
 - c. A history of BCG is not a contraindication for tuberculin skin testing and does not affect selection of cut-point or interpretation of the TST result. (See §2.H.)
 - d. Two-step testing is discussed in the CDC Diagnostic Standard. Two-step testing is not indicated when doing contact investigations, as any positive should be considered a result of recent exposure. (See Appendix A §1.a.)
 - e. Repeating TSTs
 - i. TST should be repeated when results are ambiguous or inconclusive.
 - ii. Persons without documentation of a past positive test, who need to be screened for TB for some reason, should have the test repeated if they cannot provide the documentation of the past positive test. Documentation means a written record with the type of test (Mantoux), the date of the test, and the result in millimeters of transverse induration. A result of just "positive" or "negative" is not acceptable.
 - iii. Time limitations for repeating a TST
 - Two-Step testing requires at least one week, but not more than three weeks, between the tests.
 - Live viral vaccination requires a one-month wait after vaccination to place a TST. Live viral vaccines interfere with the immune system's ability to react to the TST. Therefore, the TST can be placed before or the same day as a live viral vaccine. Wait 1 month after administration of a live viral vaccine before placing the TST to avoid a false negative TST reaction.

- Contact follow-up requires that the final TST be placed 10-12 weeks after the last exposure to the infectious case.
 - Otherwise, there are no time limits on how frequently a TST may be placed.
- f. Age limits - none
However, TSTs placed in infants < 6 months old may be falsely negative as their immune systems may not be sufficiently developed. A positive TST is valid at any age.
- g. Pregnancy is not a contraindication for TST.

C. Laboratory Services

The OSPHL performs the tests and provides results of mycobacteriology smear, culture, identification and susceptibilities. For more information, refer to the OSPHL's *Guide to Services*.

1. AFB smear is special staining and microscopic examination of the specimen. All species of mycobacteria appear essentially the same on smear.
2. AFB culture involves inoculation of the specimen into both rapid test media and standard culture media for growth, isolation, and identification. OSPHL specifically identifies only *M. tuberculosis* complex, and *M. avium* complex from specimens with AFB growth. Therefore, a culture may be reported as AFB positive, but negative for *M. tuberculosis* complex.
3. Drug susceptibility tests determine the TB isolate's susceptibility or resistance to standard TB drugs.
4. Genotyping is analysis of genetic components of a TB isolate to determine strain type. OSPHL, per DSH TB Program policy, sends a sample of the TB isolate from every culture positive TB patient to a CDC contracted laboratory for genotype testing. The results of the genotyping program, in conjunction with epidemiologic and clinical data, will:
 - a. Help evaluate suspected lab cross-contamination, clusters, and outbreaks
 - b. Provide information about TB strains common to Oregon
 - c. Identify unrecognized clusters or outbreaks
 - d. Allow comparisons with other states in outbreak situations or inter-jurisdictional exposures

Discovery of matching genotypes does not identify who gave TB to whom, but rather only identifies genotypes that match. The epidemiological investigation will help determine the meaning of matches, and help to find either an unknown source case or transmission environment (e.g., bar, shelter, jail, etc.). The DHS TB Program will guide LHDs through any further epidemiological investigations that may need to occur when matches are found including re-interviewing TB cases, even those who have been closed to service.

4. ROUTINE INVESTIGATION

A. Contact Investigation

Contact Investigation (CI) is the process for identification of potentially exposed persons. The CI process identifies those who had contact with the case during the infectious period and determines which contacts need to be evaluated. The concentric circle approach separates contacts by risk of transmission and classification, which helps the TB-NCM work in a systematic manner to assess the risk of infection of all the contacts.

The TB-NCM should have completed and passed the CDC Self Study Modules to learn about the various TB transmission risks and aspects of performing a contact investigation. The modules may be obtained from CDC (See Appendix A §2.a.)

Timelines for CI are:

- Begin CI within 72 hours of initial contact with the case for all pulmonary and laryngeal TB cases.
- Identify all close contacts and complete the TSTs within 14 days of their identification.

- Assure appropriate medical evaluation and treatment of contacts within 14 days of positive TST result.
- Assure contacts that were initially TST negative are re-tested 10-12 weeks after their last exposure to the infectious case.

1. Period of Infectiousness of the Case

Determination of precisely when a TB case became infectious to others is not possible. (See also §2.G.2.) However, the TB-NCM can utilize the chart below (Table 2.) to identify the likely period of infectiousness.

Table 2. Determining the Period of Infectiousness

Case characteristics				Estimate for beginning of likely infectious period
TB symptoms		AFB smear positive sputum		
No	Yes	No	Yes	
X		X		4 weeks prior to date of suspected TB diagnosis
	X	X		Date of symptom onset; or if symptom onset is unclear, use 4 weeks prior to date of suspected TB diagnosis
X			X	4 to 8 weeks prior to date of suspected TB diagnosis depending on how smear positive they are and if they have cavitory disease.
	X		X	Date of symptom onset; or 8 to 12 weeks prior to suspected TB diagnosis depending on how smear positive they are and if they have cavitory disease.

2. Risk of Transmission

a. Transmission environment

The TB-NCM must identify contacts in each transmission setting of the TB case.

- Home, residence, or place the patient usually sleeps
- Leisure, social activities, sports teams, places of worship
- Work, school, or usual daytime setting

b. Proximity or duration of time with the TB case while infectious

The TB-NCM determines who were the close contacts and who were the lower-risk, not-close contacts. These decisions require professional judgment, as no scientific evidence exists to determine the boundary between close, casual, or remote contacts.

c. Individual contact's characteristics

Persons who have significant exposure who also have personal risk factors to rapidly progress to disease (e.g., children 4 years old and younger or HIV infected) should be included as close contacts.

3. Concentric Circles Approach

a. First circle/Close contacts

- Defined as persons who have significant exposure through many hours or in a high-risk setting (smaller enclosed spaces with low ventilation). These contacts are those who that spent the most time sharing air with the infectious TB case.
 - Household (8-24 hours per day)
 - Significant others (girlfriends and boyfriends)
 - Closest friends and coworkers
 - Teammates of indoor activities that involve daily "forceful exhalation" activities (wrestling, basketball, etc.)
- Evaluate – Always (regardless of case smear result)
 - If no evidence of transmission is found in this group, the CI is not expanded further.

- If evidence of transmission is found in this group, the second circle/casual contacts require evaluation.

iii. High-risk contacts

Some individuals (e.g. infants, children age 4 and younger, and HIV infected persons) have a very high risk to progress to disease if they become infected. For this reason, a lower threshold is used to identify them as a contact that should be evaluated. When they are identified as needing testing, they automatically fall into the category of needing primary prophylaxis if their first evaluation is negative for TB, pending the result of the 3-month follow-up TST. (See CDC Targeted Testing and Treatment guidelines, Appendix A §1.c.)

b. Second circle/Casual contacts

- Defined as persons who have regular but less frequent exposure in lower risk settings (larger open spaces with high ventilation). Includes lower risk contacts in each possible transmission setting.
 - Co-workers: 8 hours per day for 5 days a week in the same space (e.g., share the same office, work in the same area of a warehouse, etc.)
 - Friends: spend time together for a couple of hours a day, every day
 - Choir members (e.g., sing one or more performances each week, plus practices during the week)
- Evaluate
 - Always evaluate if the case is sputum smear positive or has cavitory disease, or if there was transmission among close contacts to smear negative cases.
 - If no evidence of transmission is found in this second circle group, the CI is not expanded further.
 - If evidence of transmission is found in this second circle group, the third circle/remote contacts require evaluation.
- Regular "bar mates"

Due to crowded conditions and poor ventilation, some tavern/bar environments are conducive for TB transmission. Infectious cases who frequent a bar several times a week need to have this setting evaluated and persons who frequent the establishment, during the same times as the case, should be evaluated.

c. Third circle/Remote contacts

- Defined as persons who have less frequent or irregular contact in low risk settings including general conversational, no forceful exhalation, or outdoor settings.
 - Co-workers who work with the case less than 8 hours per day or less than 5 days per week. This includes co-workers of cases who move about the business all day (e.g., mail clerks, janitors, etc.) Such cases may potentially expose a lot of people but only in small amounts and transmission is much less likely.
 - Friends who see the case a couple times a week for a few hours or less.
 - Various membership-type groups or meetings (e.g., weekly bridge group, monthly Elk's Club, etc.)
 - Persons at no to very low risk of exposure to the TB case (i.e., "worried well")
- Evaluate - generally are not evaluated unless there is evidence of transmission in the second circle.

4. Evaluation of Contacts

- A Mantoux TST and a symptom review

A TST does not need to be repeated if documentation (date, type of test, and millimeter result) of a past positive TST is obtained.

- b. Chest x-ray
A chest x-ray is obtained if the TST is positive, if the person has symptoms compatible with TB disease, or if the contact is going to be placed on primary prophylaxis. All of these contacts also need a medical evaluation.
 - c. Medical evaluation
A medical evaluation for TB includes a medical history, a physical examination, review of the TST and chest x-ray results, and obtaining any appropriate bacteriologic or histological examinations. At this point, a diagnosis is made (active TB or LTBI) and appropriate treatment is begun.
 - d. Follow-up TST
If the initial TST was negative, a repeat TST is given 10-12 weeks after the last exposure to the infectious case.
 - i. If the follow-up TST is negative, the evaluation is complete.
 - ii. If the follow-up TST is positive, the person is referred for a chest x-ray and a medical evaluation as in sections b. and c. above.
- 5. CI Follow-up**
- a. Cases should be re-interviewed.
After rapport has been established and trust built, the case may name additional important contacts. Also, if evidence of transmission is found, the TB-NCM can use that information to reinforce the urgency of identifying all significant contacts so that anyone infected can be treated before they become ill.
 - b. Identify **all** contacts who were exposed during the infectious period, not just those who are still around.
Infectious periods are usually one month or longer. Some household contacts may have had significant exposure, but moved out before the case was diagnosed (i.e., people who lived at the house temporarily, etc.).
 - c. Re-evaluate results of the investigation.
 - i. After the initial round of TSTs, if evidence of transmission is found, the investigation should be expanded to the next circle of contacts.
 - ii. After the 3-month follow-up TSTs, if evidence of transmission is found, the investigation should be expanded to the next circle of contacts.
- 6. Contact Investigations for Extrapulmonary TB Cases**
If the extrapulmonary (other than laryngeal) TB case has no pulmonary symptoms and the chest x-ray is normal, then no contact investigation is indicated. However, source case finding should be performed on all infants (less than one year of age) with active TB disease of any site. See section B. below.

B. Source Case Finding (SCF)

Source case finding is the identification of an unknown case who is the possible source of infection to the known case. This process is the reverse of contact investigations.

1. Source Case Finding for TB infection (LTBI) is not recommended.
2. Source Case Finding for active TB disease
 - a. Infants under one year old with active TB disease
An investigation (TST and symptom review) of household contacts to the case infant (including persons who live in the home and the equivalents such as babysitter, maid, etc.) can be done. The yield for a source case is usually very low, particularly in foreign-born children from high prevalence countries. The results of this investigation can be reported on the regular CI forms and marked as "SCF."
Limited data exists for SCF. One study reported that only 2 (4%) of the pediatric cases resulted in identification of a possibly unknown source case. Most studies indicate delayed diagnosis of the source case and poor contact investigation are significant factors in progression to TB disease in young children. Research indicates that pediatric case birthplace in the US and less than one year of age increase the chances of finding a source

case, although the yield is still low. Higher priority should be given to contact investigations around infectious cases rather than SCF activities.

- b. Children and adults with active TB disease
SCF is not recommended in these groups due to poor yield and is thus not an effective use of public health nursing time. The brief inquiry on the Preventability Data Form regarding history of past known TB exposure is adequate. However, regular contact investigations should still be performed.

C. Environmental Evaluation

The environment where the exposures took place should be taken into account when classifying the contacts as close, casual, or remote. Generally, closed poorly ventilated spaces increase the chances of transmission; whereas, large well ventilated spaces decrease the chances of transmission. Outdoor settings would pose little risk for transmission due to the rapid dilution of airborne droplets. See CDC Self Study Module #6. (See Appendix A §2.a.)

5. CONTROLLING FURTHER SPREAD

A. Education

1. Instruct the case to cover both mouth and nose when coughing or sneezing.
2. Instruct the case and household about modes of transmission, risk of progression from infection to disease, importance of isolation of the case until non-infectious, and the benefits of treatment for active disease, LTBI and primary prophylaxis. Household members should be included in TB education to gain their support for contact evaluation, treatment of LTBI, influencing cooperation of the case, and providing support to the case.
3. Infectious cases should be provided with a surgical mask and instructed on how and when to wear the mask. N-95 or higher respirators should not be given to the patient to wear. Cases do not need to be masked when isolated at home. Infectious cases should only leave isolation at home to attend medically necessary appointments and should be masked when they leave the home until they return.
4. Educate cases about their prescribed TB medication.
A patient education tool is available from the DHS TB Program. (See Appendix B.)
 - a. TB is curable if they take their medication.
 - b. DOT is the way TB medications are delivered. Drug resistance and incurable TB can result if medication is not taken correctly.
 - c. Medication is taken for many months, even after symptoms improve. A certain number of doses are needed before the medication can be stopped.
5. A wide variety of patient education materials are available in many languages from CDC. (See Appendix A §2.a.)

B. Isolation and Environmental Measures

Infectious cases should be isolated at home or in a health care facility until they are no longer considered infectious. (See §2.G.2.)

1. **Infectious cases at home**
 - a. Cases should be treated at home whenever possible if their condition does not otherwise require hospitalization. However, if candidates for primary prophylaxis also reside in the home, they should have completed their evaluation and be on medication before the infectious case is discharged to the home.
 - b. Infectious cases should be educated regarding the purpose of isolation and their responsibility to adhere to the isolation requirements.
 - c. Infectious cases in isolation should sign a Home Isolation Agreement, a sample of which is available from the DHS TB Program. (See Appendix B.)
2. **Infectious Cases in Health Care Facilities or Residential Settings**
 - a. Infectious cases should be in appropriate respiratory isolation (i.e., negative pressure rooms) when housed in health care facilities or residential settings.

- b. If a facility does not have the capability to provide appropriate respiratory isolation, the case should be transferred to a facility that can accommodate respiratory isolation until the case is non-infectious. Once non-infectious, the case may return to the original facility.

3. Homeless cases

Infectious homeless cases may be housed in a motel that has outside access to rooms (i.e., not via interior hallways). The motel manager must be advised:

- a. That the patient is in respiratory isolation.
- b. To report to you if the patient does not stay in their room or has guests.
- c. To advise the motel staff that they are not to enter the room. Arrangements should be made for the days that the patient sets out the linens they want replaced. The motel staff can knock on the door and leave fresh linens with the patient.
- d. That upon release from isolation, the room will only need to be aired out for one day; otherwise, there are no special cleaning requirements.
- e. That LHD staff will be delivering medication and the frequency of the deliveries.
- f. That arrangements have been made for food delivery to the patient.

4. Work, School, and Other Social Restrictions

Infectious cases should not be allowed to go to work, go to school, or leave their place of respiratory isolation for social gatherings until they are non-infectious. Additionally, infectious cases in respiratory isolation should not allow visitors to the home until they are no longer infectious. The LHD can provide a letter of non-infectiousness to the case to show their employer or school when isolation has been lifted and the patient is allowed to return. A sample letter is available from the DHS TB Program. (See Appendix B.)

C. TB Case Management

The LHD must assign at least one nurse to be the designated TB-NCM. The responsibility of the TB-NCM will be to assure TB cases/suspects and their contacts are managed according to current guidelines. Staff newly assigned as TB-NCM must complete, at a minimum, the CDC Self Study Modules on TB 1-9 and obtain passing certificates within 6 months of such assignment. (See Appendix A §2.a.) The CDC issued certificates should be kept on file at the LHD. The TB-NCM should also complete the New Jersey National TB Center's TB Management for Nurses module. (See Appendix A §2.b.) The TB-NCM may delegate some case management tasks, as allowed by the State Board of Nursing; however, the TB-NCM retains the responsibility to assure the tasks are completed appropriately.

TB case management is the process where the LHD TB-NCM investigates suspected TB cases, opens the case to service, and coordinates care for the case and their contacts with the private medical providers and the LHD. This case management continues until the case and their contacts complete treatment or are otherwise closed to service, and all necessary forms are submitted to the DHS TB Program. The steps listed below are the basic steps required but are not intended to be a comprehensive guide. Each case is unique and will require different interventions to achieve adherence and completion of therapy.

1. Investigation of a suspect case report

The TB-NCM may receive information about potential TB suspects/cases from many sources.

- a. A call from a health care provider's office or a lab report.
The suspect case should be discussed with the health care provider to obtain relevant clinical information, to assure that a complete work-up is performed, and to lay the foundation for future follow-up. The TB-NCM may use a LHD designed form for investigating communicable diseases (as long as it includes all information needed for a TB investigation) or may use the sample TB Case Monitoring Sheet (See Appendix B.) to collect the initial information. If the case has not had all the elements of a complete work-up, review the appropriate Oregon Diagnostic Guidelines with the health care provider. (See Appendix A §1.a.) Identify the elements that need to be performed, and coordinate

who will assure each is done (e.g., the TB-NCM could collect needed sputum specimens, perform TST, arrange for chest x-ray, etc.)

- b. A call from a community resident desiring a TST because a neighbor just told them they have TB.

The TB-NCM should obtain as much information as possible to determine if further investigation is warranted and then contact the suspect and the suspect's health care provider for additional information. Often TB education and reassurance is all the resident needs (i.e., LTBI vs. active disease).

- c. Receipt of Immigrant or Refugee TB Class A/B waiver forms
Follow the steps outlined in the "Evaluation Procedure for A and B Waiver TB Patients" This document is available from the DHS TB Program. (See Appendix B.)

2. Opening a Suspect Case or Confirmed TB Case

Sometimes TB is initially very low on the differential diagnosis and a case is not reported until the culture is positive for *M. tuberculosis* complex. Other times a case will be reported when the health care provider first suspects TB or contacts the LHD for guidance with the TB diagnostic or treatment process.

- a. If the suspicion for TB is high enough to start the case on treatment (see ORCET Diagnostic Guidelines, Appendix A.), the case should be opened as a suspect, management arranged, and reported to the DHS TB Program.
 - i. Arrangement for coordination of care with the private health care provider is necessary. A sample "Coordination with PMD for TB Case Management" letter is available from DHS TB Program. (See Appendix B.) The TB-NCM should follow LHD protocols regarding issuing prescription medication from health care providers who are not LHD employees.
 - ii. If the health care provider is transferring medical care to the LHD, notify the LHD physician who will assume care of the patient (usually the Health Officer). Follow the case specific orders from the Health Officer or follow the Standing Orders and procedures that the Health Officer has approved, depending on LHD policy.
- b. If the likelihood of TB is low, and the health care provider is not going to start treatment
 - i. *And* the TB-NCM is comfortable with that decision, the TB-NCM should keep this suspect open for service, monitor for culture results, and request the physician notify them when the diagnosis is final. Possible outcomes include:
 - a) Health care provider calls back and the culture was negative & active TB has been ruled out. TB-NCM should inquire if the physician plans to treat for LTBI infection (if the TST was positive) and close the chart.
 - b) Negative TB culture lab report is received. Call the health care provider to inquire about the status of the TB diagnosis as some early cases or extrapulmonary cases can be culture negative. If TB was ruled out, close the chart. If active TB is still suspected, you may wish to consult with the DHS TB Program.
 - c) Lab report is received of a positive culture identified as *M. tuberculosis* complex. Call the health care provider to discuss case and arrange coordination of care (e.g., DOT, who will assume responsibility for side effects monitoring, etc.)
 - ii. *But* if the TB-NCM is not comfortable with that decision; the TB-NCM should contact the DHS TB Program for consultation.

3. Management of the Case

- a. Treatment

The responsibility of the LHD in the control of tuberculosis includes ensuring that an appropriate course of treatment is prescribed and completed successfully. The TB-NCM should encourage conformity with the ATS/CDC/IDSA TB treatment guidelines to avoid possible discontinuation of TB treatment too early or continuation of TB treatment beyond accepted standards, as well as use of ineffective or excessive medication

regimens. (See Appendix A §1.b.) Departures from the TB guidelines should be documented in the client's chart and discussed with the prescribing private provider, LHD supervisors and the local Health Officer. Consultation with the local Health Officer, DHS TB Program and/or one of the national TB centers (See Appendix A §2.c.) should be offered when a prescribing private provider differs from the TB guidelines. When a private provider continues to prescribe a course of treatment unsupported by the ATS/CDC/IDSA guidelines and national TB center consultation, the situation should be documented with a formal letter to the provider suggesting the appropriate course of treatment. In addition, LHDs may close a case to public health service once TB control needs have been met, i.e., adequate treatment per TB guidelines has been accomplished. Private providers may make additional TB treatment decisions for their patients, but Public Health monitoring, provision of state funded medications and DOT may cease with the completion of an appropriate treatment regimen. These issues should be taken into consideration in development of LHD policy for when the TB-NCM is taking orders from a private provider.

b. Monitoring

TB Case Management requires ongoing monitoring of several clinical issues. A sample "Timeline for the Management of TB Suspects/Cases" sheet is available from the DHS TB Program. (See Appendix B.) The TB-NCM may use the sheet to track what activities have been done and which are due.

i. Infectiousness

For pulmonary & laryngeal TB, calculate both the beginning and end of infectiousness. (See §2.G.2. and 4.A.1. for details)

ii. Clinical response to treatment

Case's TB symptoms are improving (e.g., decrease in cough, fevers are gone, gaining weight, feeling better). If pulmonary, the repeat 2-3 month chest x-ray comparison demonstrates radiological improvement.

iii. Adherence

a) DOT

At least monthly, the TB-NCM reviews case's adherence to DOT. Cases may occasionally miss a dose; however, sometimes a pattern emerges slowly that the DOT provider may not immediately recognize. A separate review will often identify the problem. The issue should be addressed and resolved with the case's help. Sample DOT record forms are available from the DHS TB Program. (See Appendix B.)

b) Self Administered Therapy (SAT)

Cases on SAT who sporadically or inconsistently take their TB medication are at risk to relapse, and also at risk to develop drug resistance due to the possibility of taking a single drug at a time. In the rare instance that a case is on SAT, the TB-NCM must assure:

1) Combination therapy

- Rifater (INH+RIF+PZA combination tablet) + EMB for the initial phase
- Rifamate (INH+RIF combination tablet) for the continuation phase

The use of the combination medicine, instead of individual drugs, reduces the risk of acquiring drug resistance if the case does not take all their medication as directed.

2) Unscheduled Pill Counts

Perform unannounced pill counts every 3-4 weeks. A first discrepancy can be investigated and problem solved with the case. However, a second failure should result in a call to the health care provider to advise them of the case's inability to take their medication as directed. Explain the need to change to DOT and that this is a TB control measure with which the health care

provider must cooperate (OAR 333-019-0002). A sample pill count form is available from the DHS TB Program. (See Appendix B.)

iv. Side effects

The TB-NCM assures that the case is tolerating the medications and provides a periodic educational reminder to the case so they will be more likely to report symptoms early before permanent damage occurs. If caught early, most toxicity is reversible when the medications are discontinued. If complications arise that are not addressed in the current CDC guidelines, consult with the DHS TB Program. Further consultation with one of the National TB Centers may also be needed. (See Appendix A §2.c.)

a) Daily

If during daily or biweekly DOT, the case complains of side effects, the TB-NCM is responsible to evaluate if the symptoms are mild and just need nursing intervention, or if they are evidence of possible toxicity. If the symptoms may be due to toxicity, the TB medication should be stopped until the case is medically evaluated. (Refer to LHD protocols) If an Outreach Worker (or other contracted provider) is providing the DOT, the TB-NCM is responsible for teaching those individuals the importance of reporting complaints and when to hold TB medications pending clearance from the TB-NCM or health care provider.

b) Monthly

All cases on treatment should have a symptom review performed monthly by the TB-NCM. This is done in person to observe for signs of jaundice, which may otherwise go unreported by the patient. Required monthly monitoring details vary by which TB drugs the case is taking. (See Appendix A §1.b.)

v. Sputum Conversion to Culture Negative:

One sputum specimen should be collected monthly to monitor the culture converting to negative. Over 85% of cases will become culture negative by the end of the second month of treatment.

c. Length of Treatment

A case's necessary treatment length depends on many factors including regimen selection, drug susceptibility, drug tolerance, adherence, and clinical response. (See Appendix A §1.b.)

i. Initial Regimen Selection

The treatment regimen should be an approved regimen from the current CDC guidelines (See Appendix A §1.b.). At the beginning of treatment, a six-month regimen of Option 1 or Option 2 is usually selected. Option 4 is used if the case is resistant to or cannot take PZA and thus requires treatment for nine months. However, this initial treatment plan may require adjustments that necessitate extension. The case must take all the doses for the Initial Phase before moving into the Continuation Phase of treatment. Forty (40) DOT doses are the minimum acceptable for the initial phase. The minimum dose requirement includes the situation of LHDs who give DOT five days a week (Monday thru Friday). Additional packets of medicine for weekends or official holidays should be given to the patient to take as self-administered doses. However, none of the self-administered doses, nor doses given during a drug challenge, count toward the 40 DOT doses required of the Initial Phase. The self-administered doses do increase the chance of a successful outcome.

ii. One- and Two-Month Evaluations

a) Sputum smear conversion: Infectiousness evaluation

- 1) If sputum is still AFB smear positive, keep in isolation, collect additional sputum & re-evaluate adherence and clinical findings.

- 2) If three consecutive smear negative sputum specimens reported, release from isolation.
 - b) Culture conversion: Determines length of treatment
 - 1) If last resulted cultures are still positive, collect additional sputum & re-evaluate adherence and clinical findings.
 - 2) If culture negative on two consecutive sputum specimens, no further sputum collection is necessary.
 - c) When the case has completed all doses for the Initial Phase (about 2 months), the decision is made regarding which drugs will be included in the Continuation Phase of treatment and for what duration. The treatment plan is still contingent upon culture conversion and adherence for determination of the final length of treatment. Cases with mild disease may already have 2 negative sputum cultures, thus the length of treatment is dependent only on adherence and susceptibilities.
- iii. Third- and Fourth- Month Evaluations
- a) Sputum smear conversion: Infectiousness evaluation
 - 1) If sputum is still AFB smear positive, keep in isolation, collect additional sputum & re-evaluate adherence and clinical findings. Cases with advanced cavitory disease may take longer to convert to smear negative. A case with mild disease should have converted by now; if not, consult with the DHS TB Program.
 - 2) If three consecutive smear negative sputum specimens reported, release from isolation.
 - b) Culture conversion: Determines length of treatment
 - 1) If last resulted cultures are still positive, collect additional sputum & re-evaluate compliance and clinical findings.
 - The case must have at least 2 consecutive negative cultures by the end of 2 months of treatment to be eligible for a 6-month regimen.
Note: 6-8 weeks are required for a negative culture to be reported; therefore, a specimen collected at the end of 2 months of treatment may not be reported back until the end of the fourth month of treatment.
 - If sputum cultures are still positive after 2 months of therapy, treatment must be continued to complete at least 9 months of treatment. A careful evaluation of the patient's adherence, drug susceptibilities, and extent of disease should be performed. Some cases with advanced disease take longer to convert and have corresponding higher relapse rates, thus the need longer treatment.
 - Cases with sputum cultures that remain positive after 4 months of therapy are considered treatment failures and require consultation with one of the National TB Centers or other TB expert. Consult with the DHS TB Program regarding such cases.
 - 2) If culture negative on two consecutive sputum specimens, no further sputum collection is necessary.
- iv. Six-Month or End of Treatment Evaluation
- Before treatment is discontinued, reevaluate adherence, number of doses taken, and response to treatment. If cultures converted and the case responded clinically, the treatment may be discontinued after all the Continuation Phase doses have been taken, per LHD protocol.

4. Management of the contacts: Contact Investigations

See §4.A.

6. MANAGING SPECIAL SITUATIONS

A. Medical Situations

The following medical situations are specifically addressed in the CDC treatment guidelines (See Appendix A §1.b.)

1. Common adverse side effects
2. Culture negative TB
3. Drug resistance and MDR-TB
4. Hepatic disease
5. Pregnancy and breastfeeding
6. Renal insufficiency and end stage renal disease
7. Treatment failure and relapse
8. Treatment interruptions

B. Legal Issues in TB Control

All efforts to gain voluntary cooperation of TB cases and suspect cases should be documented before pursuing legal action (i.e., Public Health Measure). All patient education performed and treatment plan agreements should be documented in the case's chart. All episodes of non-compliance and attempts to resolve compliance problems should also be noted in the case's chart. Written agreements and orders are useful and necessary to establish clear expectations and provide evidence of what the case agreed to (or refused) when legal action is pursued. (See sample Orders, Appendix B)

Complete Oregon Statutes and Administrative Rules regarding controlling communicable diseases may be found in the front of the full set of the DHS *Investigative Guidelines* or at <http://www.dhs.state.or.us/publichealth/acd/disrpt.cfm#rules>. The following is an excerpted list of these citations, organized by those that can be performed by the local public health administrator, and those that require court orders.

1. County Authority to Order

Voluntary enforcement of control measures. If the patient does not voluntarily comply, then the Public Health Measure can be invoked.

a. Oregon Revised Statutes (ORS)

433.006 Investigation and Control Measures

In response to each report of a reportable disease, the local public health administrator shall assure that investigations and control measures, as prescribed by Department of Human Services rule, shall be conducted.

433.008 Confidentiality of disclosure; exception; privilege; authorization of disclosure

(1) Notwithstanding ORS 192.410 to 192.505, the Department of Human Services, the local public health administrator, all officers and employees thereof and all persons to whom disclosures are made under this subsection or subsection (2) of this section shall not disclose the name or address of, or otherwise disclose the identity of, any person reported under ORS 433.004 except to officers or employees of federal, state or local government public health agencies as may be necessary for the administration or enforcement of public health laws or rules.

(2) If the department or local public health administrator has determined that a reported person's disease or condition is in a contagious state and that the person is violating the rules of the department pertaining to control of that disease, it may disclose that person's name and address to persons other than those stated in subsection (1) of this section if clear and convincing evidence in the particular instance requires disclosure to avoid a clear and immediate danger to other individuals or to the public generally. A decision not to disclose information under this subsection, if made in good faith, shall not subject the entity or person withholding the information to any liability. [Section continues]

433.010 Spreading disease prohibited; health certificates to be issued by physician; rules

(1) No person shall willfully cause the spread of any communicable disease within this state. [Section continues]

433.022 Taking subject into custody; information to subject; notice to court; court orders; duration of custody

(1) Without the necessity of first filing a petition and affidavits under ORS 433.019; if the Director of Human Services or local public health administrator has probable cause to believe that the person or property which is the subject of a petition under ORS 433.019 requires immediate custody in order to avoid a clear and immediate danger to other individuals or to the public generally, the assistant director or local public health administrator may direct a sheriff or other peace officer to take the subject into custody and the peace officer shall do so immediately. [Section continues]

433.035 Examination of certain persons prior to imposition of public health measure

(1) Whenever the Director of Human Services or any local public health administrator reasonably believes any person within the jurisdiction of the assistant director or local public health administrator has any communicable disease identified by rule of the Department of Human Services to be a reportable disease or condition that is the basis of a state of impending public health crisis declared by the Governor as authorized by ORS 433.441, the director or local public health administrator may cause a medical examination to be made of such person to determine whether the person has a communicable disease. [Section continues]

433.156 Enforcement of isolation or quarantine by police

All state and local police officers shall cooperate with any officer authorized to impose isolation or quarantine in the enforcement thereof.

b. Oregon Administrative Rules (OAR)

333-019-0000 Responsibility of Public Health Authorities to Investigate Reportable Diseases

(1) The Local Public Health Authority shall use all reasonable means to investigate in a timely manner all reports of reportable diseases, infections, or conditions. To identify possible sources of infection and to carry out appropriate control measures, the Local Public Health Authority shall investigate each report following procedures outlined in the DHS's *Investigative Guidelines* or other procedures approved by DHS. DHS may provide assistance in these investigations. [Section continues]

333-019-0002 Cooperation with Public Health Authorities

Every Health Care Provider attending a person with a reportable disease, infection, or condition shall instruct the person in measures appropriate to controlling the spread of the disease and shall cooperate with Local Public Health Authorities and DHS in their investigation and in implementation of appropriate control procedures.

c. Voluntary Compliance and Adherence Documentation

i. Cases and suspect cases that fail medical appointments can be issued "Orders for Examination" which requires a medical evaluation and compliance with control measures.

ii. Cases who, by assessment or history, are unlikely to be compliant can be issued "Orders to Comply with Tuberculosis Control Measures" (See sample, Appendix B.)

- These define the measures needed to control TB.
- These clearly define what is expected of the case and the LHD.
- These established the legal documentation that may be needed when pursuing a Public Health Measure.

iii. Cases who, by assessment or history, are likely to be compliant, can utilize the agreements for DOT and isolation, instead of the full set of orders. Samples of these forms are available from the DHS TB Program. (See Appendix B.)

iv. Educate the case about TB and the plan for treatment. You may use the "Usual TB Treatment Plan" education tool during this process to explain why medication is

needed for a long time. This tool is available from the DHS TB Program. (See Appendix B.)

- v. Discuss and agree to a DOT treatment schedule. The TB-NCM and the case should sign a DOT Agreement to make sure both parties are clear as to when and where DOT will occur. A sample agreement is available from the DHS TB Program. (See Appendix B.)
- vi. Document DOT delivery. Use progress notes to document any non-adherent behavior (e.g., late for appointment, no shows, missed doses, etc.) Samples of DOT recording forms are available from the DHS TB Program. (See Appendix B.)
- vii. For cases that have verified or suspected infectious TB, discuss the need for isolation until non-infectiousness is established to prevent the spread of TB to others. The TB-NCM and the case should sign a Home Isolation Agreement. A sample agreement is available from the DHS TB Program. (See Appendix B.)
- viii. Document in the progress notes all adherence problems, problem solving that occurred with the case, and agreed action to improve adherence (e.g., every call, visit with the patient, etc.). Examples include: failure to bring in follow-up sputum samples, missed doctor appointments, missed DOT doses, attempts made to locate the case, etc. Such documentation is essential to validate least restrictive measures attempted when later imposing a Public Health Measure.

2. County Needs Court Action

Involuntary enforcement of control measures.

a. ORS

433.019 Procedure to impose public health measure; enforcement

(1) As used in this section: ... (b)"Subject of the petition" means the person or the property upon which the public health measure is sought to be imposed.

(2) Except as provided in ORS 433.022, proceedings for imposing a public health measure shall be initiated by filing a petition in the circuit court for the county in which the subject of the petition is located. [Section continues]

433.106 Power to impose public health measures

(1) When compliance with a necessary control measure is not voluntarily obtained or where noncompliance is imminently threatened, the Director of Human Services or any local public health administrator, in the manner described in ORS 433.019 and 433.022 may impose a public health measure on a person or property in order to prevent the spread of or exposure to a disease or a contaminant that is a threat to the public.

(2) Nothing in this section or in ORS 433.019 or 433.022 prohibits excluding any person from any occupation or from attendance in any school or facility as is otherwise authorized by law.

433.130 Magistrate's authority to enforce public health measures

Any magistrate authorized to issue warrants in criminal cases shall issue a warrant upon affidavit of the Director of Human Services or any local public health officer, directing the warrant to the sheriff of the county or the deputy of the sheriff, or to any constable or police officer, requiring them under the direction of the Department of Human Services to enforce all public health measures required by orders under ORS 433.019, 433.022, and 433.106.

433.135 Providing for quarantined persons

When a person is quarantined on account of a communicable disease, the local board of health having jurisdiction may provide for such persons confined, the necessities of life, including medical care when necessary.

433.140 Payment of quarantine expenses; assistance

(1) The expenses incurred under ORS 433.135, when properly certified by the executive officer of such board, shall be paid by the person quarantined, when able to pay them.

(2) The Department of Human Services may provide general assistance, including medical care for such person, on the basis of need, provided that no payment shall be made for the care of any such person in or under the care of any public institution or public agency or municipality.

433.156 Enforcement of isolation or quarantine by police

All state and local police officers shall cooperate with any officer authorized to impose isolation or quarantine in the enforcement thereof.

b. OAR

333-019-0000 Responsibility of Public Health Authorities to Investigate Reportable Diseases and 333-019-0002 Cooperation with Public Health Authorities

See §6.B.1.b.

c. Steps to implement a Public Health Measure for a non-adherent TB suspect/case

- i. Clearly determine that the case will not comply with TB treatment and monitoring plan (e.g., home visits, clinic visits, DOT, incentives, etc.)
- ii. Notify your supervisor and Public Health Administrator or Health Officer of the problem.
- iii. Notify county counsel, or contract legal advisor for your LHD, and express your desire to initiate the process of invoking a public health measure. Discuss the time frame for such a process.
- iv. Follow steps in ORS 433.019 Procedure to impose public health measure: Enforcement. Update, then utilize the information in the "Individualized assessment of your circumstances..." section of the "Order to Comply with Tuberculosis Control Measures" when preparing the affidavit.

C. Inter-jurisdictional Coordination and Transfers

1. Coordination of Contact Investigations

When a TB case lives in one jurisdiction and works or has other social contacts in another jurisdiction, the TB-NCM needs to coordinate the contact follow-up with the other jurisdiction. To facilitate this process, use the "Contact Follow-up Inter-jurisdictional Transfer Notification" form, which is available from the DHS TB Program and <http://dhs.state.or.us/publichealth/tb>.

For contact investigations of social contacts, the TB-NCM should fill out the form and fax it to the appropriate jurisdiction. The TB-NCM should subsequently contact the jurisdiction for the follow-up information if it is not sent back as requested. For contact investigations of worksites or schools, in addition to the form, the TB-NCM should call the jurisdiction to alert them to the referral and to discuss significant factors relating to the case.

2. Transfer of TB Case Care

Occasionally, TB cases move before treatment is completed. When this happens, the TB-NCM should determine the new locating information, fill out a "TB Case/Suspect Inter-jurisdictional Transfer Notification" form and fax it to the new jurisdiction and submit a copy to the DHS TB Program. (See §1.C. Table 1.)

- a. If the TB-NCM is aware the patient is moving before they have gone, the TB-NCM should contact the LHD in the new jurisdiction to alert them to the pending transfer and facilitate a smooth transition.
- b. If the case leaves without letting the TB-NCM know, the TB-NCM should obtain new locating information from the case's friends, family, work, U.S. Post Office, etc. (See Appendix B for Post Office form.)
- c. Contacting the receiving jurisdiction
 - i. United States
The CDC maintains a list of State TB Control Offices and the appropriate inter-jurisdictional contact for each State. (See Appendix A §2.a.)

- ii. California
The California TB Controllers Association (CTCA) maintains a list of the appropriate inter-jurisdictional contact for each county in California. (<http://www.ctca.org>)
- iii. International
 - Mexico
CURE-TB is a program to facilitate transfer and follow-up of TB cases that move between the U.S. and Mexico. Contact the DHS TB Program for the current referral forms to fax. Note: telephone numbers and addresses in Mexico are written in a format different from U.S. postal regulations.
 - All other countries
The CDC maintains a List of International Notification of TB Cases of the appropriate inter-jurisdictional contact for each country. (See Appendix A §2.a.)

D. Long Term Care Facilities for the Elderly

See Appendix A §1.e. for complete guidelines.

E. Targeted Testing

See Appendix A §1.c. for complete guidelines.

1. Implementation of Targeted Testing Program

Most TB infected persons do not experience clinical illness and the only evidence of the infection may be a reaction to a TST. However, infection can persist for years, and infected persons can remain at risk for developing clinical TB, especially if the immune system becomes impaired. Thus, the third priority of TB control programs is screening populations at high risk for TB to locate persons infected with TB and giving complete therapy to prevent the infection from progressing to active, contagious disease. Screening persons in low-risk groups is not likely to be cost-effective and should not be undertaken.

Feasibility for screening activities should be determined by assessment of available resources and the probability of infection and disease among groups in the community. Screening programs that identify infected persons without current disease should be undertaken only if:

- a. TB Program goals are consistently met for evaluation and treatment of active cases and contacts.
- b. The diagnostic evaluation and a course of prescribed therapy can be initiated and completed for members of the identified high-risk group. This includes identification, availability, and funding of necessary facilities for patient evaluation and treatment, and assurance that such patients found to be infected are likely to complete treatment for LTBI.

2. Identification of High-risk Groups

High-risk groups for the purpose of TB screening are defined as groups at risk for recent infection with TB and those who, regardless of duration of infection, are at increased risk for progression to active TB. The changing epidemiology of TB indicates that the risk for TB among groups currently considered high priority may decrease over time, and groups currently not identified as at risk subsequently may be considered as high priority. LHDs should analyze their TB surveillance data to identify high-risk groups based on local trends in the epidemiology of TB. Examples of previously identified high-risk groups include: persons infected with HIV, persons who inject illicit drugs, persons who have medical risk factors known to increase the risk for disease if infection occurs (e.g., silicosis, diabetes mellitus, etc.), residents and employees of high-risk congregate settings (e.g., correctional institutions, shelters for the homeless, etc.), foreign-born persons recently arrived from countries that have a high TB incidence or prevalence, and some medically underserved low-income populations, etc.

3. Steps to implement a targeted testing program

- a. Assess the community's TB problem, identify high-risk groups based on the local epidemiology of TB, and ascertain the sites of most convenient access to those groups (e.g., schools, correctional facilities, community health clinics, etc.).
- b. Develop a plan and identify resources to complete a course of treatment in persons found to have LTBI. Such planning should include arrangements for medical evaluation of persons with positive TSTs and for the medical supervision of the course of LTBI treatment. A decision to test is a decision to treat those found infected.
- c. Determine responsibility for program coordination, evaluation of performance standards, and overseeing quality of service.
- d. Identify resources to provide staffing, tuberculin, chest x-rays and TB drugs.
- e. Produce written protocols for activities including patient tracking and skin testing.
- f. Anticipate and reduce potential barriers to a high rate of acceptance of testing and completion of treatment in the identified high-risk group. Such barriers may include:
 - Unfamiliar concept of taking medicine to treat a latent infection that is not causing current health problems
 - Differing culturally derived health beliefs
 - Inability to communicate with medical providers in one's primary language and availability of translated patient educational materials
 - Inability to afford the costs of medical evaluation and treatment, and lack of access to medical care. Patients should not be expected to pay directly for public health interventions (e.g., testing, evaluation, and treatment of LTBI).
- g. Collect data to determine yield and relative effectiveness of the program. Ongoing LHD evaluation should include development and monitoring of program indicators (e.g., rates of skin tests administered that are read, initiation and completion rates of treatment, etc.). Report all treatment for LTBI to the DHS TB Program as usual. (See §6.F.)

F. Treatment of Latent TB Infection

See Appendix A §1.c. for complete guidelines. Report using the standard DHS TB Program form for Treatment of LTBI and submit when the patient completes treatment or stops for any other reason. The LTBI form is available from the DHS TB Program and <http://www.dhs.state.or.us/publichealth/tb>.

Appendix A References and Resources

1. TB References

All documents available from the DHS TB Program and

<http://www.dhs.state.or.us/publichealth/tb>

CDC documents are also available at <http://www.cdc.gov/nchstp/tb>

a. Diagnosis

- CDC/ATS. Diagnostic Standards and Classification of Tuberculosis in Adults and Children. *Amer J Respir Crit Care Med* 2000; 161. pp 1376-1395.
- ORCET. Guidelines for Diagnosis And Initial Management for Persons With Suspected Tuberculosis. December 2003.

b. Treatment

- CDC. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Disease Society of America. *MMWR* 2003; 52 (No. RR-11).

c. Targeted Testing and Treatment of LTBI

- CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. *MMWR* 2000; 49 (No. RR-6).
- ORCET. Treatment of Latent TB Infection Guidelines for Oregon. January 2004.
- CDC. Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States 2003. *MMWR* 2003; 52 (No. 31) pgs. 735-739.
- CDC. Essential Components of a Tuberculosis Prevention and Control Program; and Screening for Tuberculosis and Tuberculosis Infection in High-risk Populations: Recommendations of the Advisory Council for the Elimination of Tuberculosis. *MMWR* 1995; 44 (No. RR-11).

d. Health Care Facilities

- CDC. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994. *MMWR* 1994; 43 (No. RR-13).
- OAR 333-019-041 (1)

e. Long Term Care Facilities

- CDC. Prevention and Control of Tuberculosis in Facilities Providing Long-Term Care to the Elderly. *MMWR* 1990; 39 (No. RR-10).
- ORCET. Oregon Guidelines TB Exposure Control Plan for Long Term Care Facilities for the Elderly. November 2002.
- OAR 333-019-041 (2) b.

2. TB Resources

a. CDC: <http://www.cdc.gov/nchstp/tb>

- Self-Study Modules on TB
- Major TB Guidelines (see TB References above)
- State TB Control Offices
- International Notification of TB Cases
- TST training materials
- TB Education and Training materials: <http://www.findtbresources.org/>

b. New Jersey Medical School National TB Center: <http://www.umdnj.edu/ntbcweb/>

- TB Case Management for Nurses Self Study Modules
- TB program guidelines and products

c. Francis J. Curry National TB Center: <http://www.nationaltbcenter.edu/>

- Warmline clinical consultation, telephone: (415) 502-4700
- TB tools, staff training products, and courses

Appendix B Oregon TB Tools and Samples

Contents:

1. DOT Incentive/Enabler Reimbursement Protocol and forms
2. Chest X-ray Policy and Procedure for Reimbursement and forms
3. BCG Information for Patients
4. BCG Information for Health Care Workers
5. Usual Length of TB Treatment Plan
6. Home Isolation Agreement - sample
7. Non-Infectious Letter - sample
8. TB Case Management Monitoring Record
9. Evaluation Procedure for A and B Waiver TB Patients
10. TB Case Co-Management Coordination with PMD letter - sample
11. Timeline for TB Case Management Activities
12. DOT Record - Initial Phase
13. DOT Record - Continuation Phase
14. Pill count form
15. DOT Agreement - sample
16. Orders to Voluntarily Comply with TB Control Measures - sample
17. Post Office Address Request

Also available at: <http://www.dhs.state.or.us/publichealth/tb>