

TUBERCULOSIS CONTROL *PROGRAM MANUAL*



UTAH DEPARTMENT OF
HEALTH

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3RD EDITION

Tuberculosis Control

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Note: Effective January 1, 2010 the 'Tuberculosis Control/Refugee Health Program' will be the 'Treatment and Care Program' (encompassing Tuberculosis Control, Refugee Health, and HIV Treatment and Care).

However, the Tuberculosis Control Program name will remain within this manual.

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MISSION STATEMENT

The mission of the Tuberculosis Control Program is to prevent, control and eliminate tuberculosis in Utah, by fostering community health partnerships with those who serve high risk and refugee populations through culturally appropriate health screening, education and referral.

We will accomplish our mission through: policy development, expert consultation, technical assistance, education, and surveillance.

These activities ultimately protect and promote public health in Utah.

INTRODUCTION

In partnership with the local health departments (LHDs) and health care providers, the Utah Department of Health, Bureau of Epidemiology, Tuberculosis Control Program is responsible for implementation of the [Utah Administrative Code Communicable Disease Rule \(R388-804\)](#), which outlines a multidisciplinary approach to communicable and infectious disease control. It emphasizes reporting, surveillance, isolation, treatment, and epidemiological investigation. This manual describes policies, protocols, and recommendations for the State of Utah. The protocols cover common as well as complex clinical issues that arise in the control of tuberculosis (TB). These protocols are based on recommendations of the Centers for Disease Control and Prevention (CDC), the American Thoracic Society (ATS), the Infectious Disease Society of America (IDSA), and the opinions of local and national experts in TB diagnosis, treatment, and control.

Although an attempt has been made to design a comprehensive manual, protocols cannot and should not substitute for clinical judgment. For most clients however, strict adherence to clinical protocols will result in improved care and the control of TB. Clinicians are strongly encouraged to seek consultation for issues related to individual cases that may not be fully discussed here.

TB SPECIAL MEASURES FOR THE CONTROL OF TUBERCULOSIS

Purpose

The Statute gives the TB Control Program the authority to write rules to control tuberculosis. The purpose of this rule is to focus the efforts of tuberculosis control on disease elimination. The standards outlined in this rule constitute the minimum expectations in the care and treatment of individuals diagnosed with, suspected to have, or exposed to tuberculosis.

Policy and Procedure

This rule establishes standards for the control and prevention of tuberculosis as required by section 26-6-4, Section 26-6-6, Section 26-6-7, Section 26-6-8, and Section 26-6-9 of the Utah Communicable Disease Control Act and Title 26, Chapter 6b, Communicable Diseases - Treatment, Isolation, and Quarantine Procedures.

References

[State of Utah, Department of Health Communicable Disease Rule, Special Measures for the Control of Tuberculosis](#)

Utah Department of Health. (2009). [COURT-ORDERED TREATMENT AND INVOLUNTARY – ISOLATION GUIDELINES FOR THE CONTROL OF TUBERCULOSIS.](#)

Follow-Up Responsibility

TB Controller

TB Control Program Manager

PROGRAM

GOALS AND OBJECTIVES

TREATMENT AND CASE MANAGEMENT

Program Objectives:

Objective 1.1: Ensure that at least 90% of individuals with a high-likelihood of having TB receive a medical evaluation within 14 days for active TB disease.

Objective 1.2: Increase the proportion of TB cases with a pleural or respiratory site of disease in patients ages 12 or older that have sputum-culture results reported to 90%.

Objective 1.3: Ensure that 90% of sputum-smear positive clients initiate treatment within 7 days of specimen collection.

Objective 1.4: Ensure that 93% of clients with active TB disease are placed on appropriate therapy following CDC/ATS guidelines.

Objective 1.5: Ensure that at least 90% of clients with active TB disease are provided directly observed therapy.

Objective 1.6: Ensure that at least 55% of patients with positive sputum-culture results, convert to sputum culture-negative within 60 days of initiating treatment.

Objective 1.7: Ensure that at least 90% of patients with newly diagnosed TB, for whom therapy for one year or less is indicated, will complete therapy within 12 months.

Objective 1.8: Collaborate with local health departments, the Utah Department of Health HIV/AIDS Surveillance Program, HIV Counseling and Testing Program, and HIV/AIDS Treatment and Care Program to ensure that at least 80% of all newly diagnosed TB cases are offered counseling and testing for HIV and referred for treatment if found to be HIV positive.

Objective 1.9: Continue to provide TB medications to 100% of contracted pharmacies throughout the state in collaboration with Utah's 12 local health districts and receive monthly inventory tracking of these medications from 90% of the contracted pharmacies with inventory.

Objective 1.10: Continue aggressive assessment of the need and use of incentives and enablers for 100% of newly diagnosed TB cases and high-risk contacts of cases.

Objective 1.11: Continue to provide an effective system of housing support for at least 90% of clients with active TB disease who are homeless or in a high-risk situation for non-completion of therapy.

Objective 1.12: Ensure facilities are available for clients requiring court-ordered treatment, isolation, and quarantine per Utah Health Code, Chapter 26-6-6b.

CONTACT INVESTIGATION

Program Objectives:

Objective 2.1: Contacts will be identified for at least 90% of newly reported sputum AFB-smear positive TB cases.

Objective 2.2: At least 85% of contacts of newly reported sputum AFB-smear positive TB cases will be evaluated for TB infection and disease.

Objective 2.3: At least 80% of contacts to sputum AFB-smear positive TB cases who are newly diagnosed with latent TB infection will start treatment.

Objective 2.4: At least 75% of contacts to sputum AFB-smear positive cases who are children under the age of five receive directly observed preventive therapy (DOPT).

Objective 2.5: At least 74% of infected contacts to sputum AFB-smear positive TB cases who are started on treatment for latent TB infection will complete therapy.

EVALUATION OF IMMIGRANTS AND REFUGEES

Program Objectives:

Objective 3.1: Ensure that at least 90% of patients eligible for participation in the Binational TB Project receive a Binational Card, and that at least 80% of those who move to Mexico during treatment have their care coordinated through Cure TB.

Objective 3.2: Ensure that local health departments locate and initiate medical evaluation for at least 90% of refugees and immigrants with abnormal chest x-rays read overseas as consistent with TB, classified as A or B/TB for active TB disease, within 30 days of being notified of A or B/TB classification.

Objective 3.3: Ensure that local health departments complete the medical evaluation for at least 90% of refugees and immigrants with abnormal chest x-rays read overseas as consistent with TB, classified as A or B/TB for active TB disease, within 90 days of being notified of A or B/TB classification.

Objective 3.4: Ensure that local health departments initiate treatment for at least 70% of refugees and immigrants with abnormal chest x-rays read overseas as

consistent with TB, classified as A or B/TB for active TB disease, upon diagnosis of latent TB infection (LTBI) during the medical evaluation.

Objective 3.5: Ensure that local health departments complete treatment for at least 60% of refugees and immigrants with abnormal chest x-rays read overseas as consistent with TB, classified as A or B/TB for active TB disease, upon diagnosis of latent TB infection (LTBI) during the medical evaluation who begin treatment.

Objective 3.6: Continue to provide funding to facilitate access to culturally and linguistically appropriate resources to the Salt Lake Valley, Weber/Morgan, and Utah County Health Departments to care for TB suspects/cases, contacts, and Tuberculin Skin Test converters in ethnically diverse populations.

Objective 3.7: Ensure that two Bridging the Gap (BTG) Medical Interpreting courses are conducted each year for interpreters who work with refugee health agencies, TB Control, HIV, and STD settings and 80% of participants will successfully pass the course.

TB SURVEILLANCE/REPORTING

Program Objectives:

Objective 4.1: Decrease the TB case rate for foreign-born persons to less than 14.0 cases per 100,000.

Objective 4.2: Decrease the TB case rate for children younger than 5 years of age to less than 0.4 cases per 100,000.

Objective 4.3: Maintain an active surveillance/case finding system. This system will facilitate reporting at least 90% of suspected and confirmed TB cases to the Utah Department of Health and/or local health departments within three days of the first occurrence of suspected/confirmed TB diagnosis, a positive AFB laboratory smear, positive Nucleic Acid Amplification test, or positive *M. tuberculosis* culture.

Objective 4.4: Ensure that all verified cases of TB are reported with at least 99.2% of core data items being complete.

Objective 4.5: Ensure that each core Aggregated Reports of Program Evaluation (ARPE) data items are reported to the CDC with at least 95% of core data items being complete.

Objective 4.6: Drug susceptibility results will be reported for 100% of all newly reported culture-positive tuberculosis cases.

Objective 4.7: Genotyping results will be reported for at least 90% of all culture confirmed TB cases.

Objective 4.8: A positive or negative HIV test result will be reported for at least 88.7% of all newly reported TB cases.

Objective 4.9: Ensure that each core Electronic Disease Notification (EDN) system data item reported to CDC is at least 85% complete.

Objective 4.10: During the reporting period, collaborate with at least one additional partner serving high-risk populations to encourage active case finding, treatment, and completion of therapy.

Objective 4.11: Provide at least 15 hours of technical assistance to local health departments and community providers serving American Indians/Alaskan Natives living both on and off the designated reservations.

HUMAN RESOURCE DEVELOPMENT

Program Objectives:

Objective 5.1: Continue to hold Advisory Committee meetings semi-annually. Broaden the scope and complexity of issues dealt with during these meetings. Identify and invite participation of additional community stakeholders to the committee.

Objective 5.2: Discuss the strategic TB Control and Elimination Plan with the Advisory Committee. Reestablish priorities and objectives on a semi-annual basis.

Objective 5.3: Provide at least 750 hours of state-of-the-art education to community based organizations, health care providers, and case managers practicing in TB.

References

Utah Department of Health, Tuberculosis Elimination Cooperative Agreement

Follow-Up Responsibility

TB Control Program Manager

TUBERCULIN SKIN TESTING

Purpose

To establish a policy for administering the tuberculin skin test (TST), also known as the Mantoux tuberculin skin test. TST screening should be focused on populations most at risk for infection, or if infected, at risk for disease. TST is not necessary for individuals with a documented previous positive TST result.

Policy

Targeted tuberculin skin testing for latent tuberculosis infections (LTBI) is a strategic component of tuberculosis (TB) control. It identifies persons at high risk for developing TB disease who would benefit from treatment, if detected. Persons with increased risk for developing TB disease include those recently infected with *Mycobacterium tuberculosis* and those who have clinical conditions that are associated with an increased risk for progression of LTBI to active TB disease (ATBD). Infected persons who are at high risk for developing ATBD should be considered for treatment of LTBI regardless of age.

Targeted tuberculin skin testing programs should be conducted only among high-risk persons. Persons administering the TST should be properly trained in the administration and reading of the TST. **The decision to administer a tuberculin skin test (TST) should be a decision to assess the client and consider treatment of LTBI if the person has a positive TST result.** Screening persons at low risk for TB is discouraged because this test has poor predictive value in unselected (low risk) populations and diverts resources away from higher priority TB control activities such as the identification and treatment of active cases and contact investigation.

It is recommended that the TST be administered to the following groups:

- Close contacts of persons known or suspected to have TB
- Foreign-born persons, including children, who have recently arrived from areas that have a high incidence of TB (go to the [World Health Organization \[WHO\] Global Atlas for Infectious Diseases](#) for further guidance)
- Health care workers who serve high-risk clients
- Some medically under-served, low-income populations as defined locally
- Employees or residents of high-risk congregate settings such as hospitals, correctional facilities, homeless shelters, nursing homes, or drug treatment centers
- High-risk populations, defined locally as having increased prevalence of TB. In Utah this would include Asians, Africans, Pacific Islanders, Hispanics, Native Americans, migrant farm workers, homeless persons and returned LDS missionaries
- Mycobacterial laboratory personnel
- Persons who inject illicit drugs or other high-risk substance users
- Infants, children, and adolescents exposed to adults in high-risk categories

The following persons are at higher risk for TB disease once infected and testing should be considered if they have risk of exposure:

- Persons with HIV infection
- Persons who have medical conditions known to increase the risk for disease if infection occurs (diabetes, silicosis, prolonged corticosteroid therapy, cancer of the head and neck, hematologic and reticuloendothelial diseases, end-stage renal disease, intestinal bypass or gastrectomy, chronic malabsorption syndromes, low body weight [10% or more below ideal])
- Rheumatoid arthritis clients being treated with more than salicylates or NSAIDs

Procedure

- a. The TST should be administered by the Mantoux technique as described in the [CDC Core Curriculum](#), Fourth Edition, 2000. **Multiple puncture tests (e.g., the Tine Test) should not be used.** Purified protein derivative (PPD), the antigen used in the TST, should be stored between 2 and 8°C (35 and 46°F) and protected from light. Vials in use more than 30 days should be discarded due to possible oxidation and degradation, which may affect potency. Syringes should not be pre-filled and the use of safety syringes is recommended. Care should be taken to avoid inserting air directly back into the serum remaining in the vial. Gloves are optional; consult the infection control requirements of your facility. An informed consent to administer the TST is recommended.
- b. Reading of the TST should only be done by a trained health care worker; clients should **never** be allowed to read their own reaction. Measure only the **hard**, swollen area known as induration and record the size of the induration (between palpable borders laterally) in millimeters (mm), not as “positive” or “negative.” Results are read 48-72 hours after administering the test. If the client fails to return for the scheduled reading but returns up to a week after the test administration, examine the test site and measure any induration present. If there is no reaction or it is too small to be classified as positive, repeat the test.
- c. Classifying the results should be done using: [A Tuberculosis Provider Guide - Testing for TB Infection & Guidelines for Post-Test Referral](#), Utah Department of Health Tuberculosis Control/Refugee Health Program, January 2009.
- d. Tuberculin skin testing is not contraindicated for persons who have been vaccinated with Bacillus Calmette-Guérin (BCG), and the skin test results of such persons are used to support or exclude the diagnosis of LTBI. The booster phenomenon may occur among persons who have had a prior BCG vaccination. A diagnosis of LTBI and the use of treatment for infection should be considered for any BCG-vaccinated person using the same guidelines as described in procedure ‘c’ above, especially if any of the following circumstances are present:
 - The vaccinated person is a contact of a person who has ATBD, particularly if the person is infectious and has transmitted *M. tuberculosis* to others

- The vaccinated person was born or has resided in a country in which the prevalence of TB is high
 - The vaccinated person is exposed continually to populations in which the prevalence of TB is high (e.g., some health care workers, employees and volunteers at homeless shelters, and workers at drug-treatment centers)
- e. The absence of a reaction to the tuberculin skin test does not rule out the diagnosis of TB disease or infection. In immunosuppressed persons, delayed-type hypersensitivity responses such as tuberculin reactions may decrease or disappear. This condition, known as anergy, may be caused by many factors, such as HIV infection, severe or febrile illness, measles or other viral infections, Hodgkin's disease, sarcoidosis, live-virus vaccination, or the administration of corticosteroids or immunosuppressive drugs. On average, 10% to 25% of clients with TB disease have negative reactions when tested with a tuberculin skin test. **Do not rule out diagnosis based on a negative skin test result. Consider anergy in persons with no reaction if:**
- HIV infected
 - Overwhelming TB disease
 - Severe or febrile illness
 - Viral infections
 - Live-virus vaccinations
 - Immunosuppressive therapy/disease

Anergy skin testing is no longer routinely recommended.

- f. In some people who are infected with *M. tuberculosis*, delayed-type hypersensitivity to tuberculin may wane over the years. When these people are tuberculin skin tested many years after infection, they may have a negative reaction. However, this skin test may stimulate (boost) their ability to react to tuberculin, causing a positive reaction to subsequent tests. This booster reaction may be misinterpreted as a new infection. The booster phenomenon may occur at any age: its frequency increases with age and is highest among older persons. Boosted reactions may occur in persons infected with nontuberculous mycobacteria or in persons who have had a prior BCG vaccination.

Two-step testing is used to reduce the likelihood that a boosted reaction will be misinterpreted as a recent infection. If the reaction to the first test is classified as negative, a second test should be done 1-3 weeks later. A positive reaction to the second test probably represents a boosted reaction (past infection or prior BCG vaccination). On the basis of this second test result, the person should be classified as previously infected and cared for accordingly. This would not be considered a skin test conversion. If the second test result is also negative, the person should be classified as uninfected. In these persons, a positive reaction to any subsequent test is likely to represent new infection with *M. tuberculosis* (skin test conversion). Two-step testing should be used for the **initial** skin testing of adults who will be retested periodically, such as health care workers and correctional staff. (If the individual has record of a negative PPD within the past twelve months, then the test done upon hire may be considered the second test.)

g. **False negative** TST reactions may be due to:

- Anergy
- Recent TB infection or overwhelming TB disease
- Very young age (< 6 months age)
- Live virus vaccinations (see below)
- Some viral infections (measles, mumps, chickenpox, and HIV)
- Corticosteroids and other immunosuppressive agents at doses of 2mg/kg/day or greater for 2 or more weeks

Vaccination with live viruses (e.g. Measles, Mumps, Rubella, Varicella, Typhoid oral, Polio oral and Yellow Fever) may also interfere with TST reactivity and cause false negative reactions. TST should be done on either the same day as vaccination with live virus or 4-6 weeks after vaccination.

h. **False positive** TST reaction may be due to:

- Nontuberculous mycobacteria
- BCG vaccination

i. Tuberculin skin testing in pregnant women is safe and reliable. Routine TST screening among pregnant women is not indicated because pregnancy itself does not increase the risk for TB infection. However, pregnant women at high-risk for TB infection or disease should be tested.

j. Adverse reactions to a TST (e.g. severe blistering, ulcerations, necrosis) should be reported to the Food and Drug Administration's Med Watch Program at 1-800-FDA-1088 or via the internet at www.fda.gov/medwatch.

k. *In most cases, the Quantiferon (QFT) blood assay can be substituted for TST.* It appears that its' usefulness would be most evident in identifying infection in those with a history of BCG (BCG will not cause a false positive). This test is available through the Utah State *Unified State Laboratories: Public Health*, as well as private labs. Cost varies, and *will not* be reimbursed by the TB Control Program. Contact the *Unified State Laboratories: Public Health* Immunology Section, 801-965-2400 for more information. For technical assistance, contact the manufacturer at: <http://www.cellestis.com/>

Unified State Laboratories: Public Health QuantiFERON® -TB Gold In-Tube: FAQ's

Test Principle

The QuantiFERON® -TB Gold In-Tube assay is an in vitro diagnostic laboratory test that aids in the detection of infection with *Mycobacterium tuberculosis*. It uses human whole blood, with patented assay technology based on the measurement of Interferon-gamma (IFN- γ) secreted from stimulated T-cells previously exposed to *Mycobacterium tuberculosis*. The QuantiFERON® -TB Gold In-Tube assay is a straightforward laboratory test that involves simple steps. There are several options available for your facility depending on your resources and preferences. Most facilities choose to simply draw blood and send it to the *Unified State Laboratories: Public Health* within 15 hours, but if distance or schedule do not allow for arrival at the public health lab within the 15-hour limit, samples may be incubated and centrifuged at your facility. The following steps outline the procedures for the three different options:

Option 1 (preferred): On-Site Collection (15 hour time constraint)

1. Collect 1 mL blood into each of the three Blood Collection Tubes (Gray, Red, and Purple).
2. After blood collection, mix the tubes thoroughly, by shaking vigorously for at least 5 seconds (please remember that simply inverting the tubes is not sufficient).
3. Transport tubes at room temperature. Tubes need to arrive at the laboratory within 15 hours of collection, and by 4:00 P.M. Mon-Fri.

Option 2 (not recommended): On-Site Collection and Incubation (70 hour time constraint, upright transport)

1. Collect 1 mL blood into the three Blood Collection Tubes (Gray, Red, and Purple).
2. After blood collection, mix the tubes thoroughly, by shaking vigorously for at least 5 seconds (please remember that simply inverting the tubes is not sufficient).
3. As soon as possible, and within 16 hours of collection, incubate tubes upright at 37°C for 16-24 hours. Be certain to document date and time for each step.
4. Tubes need to arrive at the laboratory within 72 hours of incubation completion, and by 4:00 P.M. Mon-Fri.

Option 3 (discouraged): On-Site Collection, Incubation, and Centrifugation (refrigerated transport)

1. Collect 1 mL blood into the three Blood Collection Tubes (Gray, Red, and Purple).
2. After blood collection, mix the tubes thoroughly, by shaking vigorously for at least 5 seconds (please remember that simply inverting the tubes is not sufficient).
3. As soon as possible, and within 16 hours of collection, incubate tubes upright at 37°C for 16-24 hours. Be certain to document date and time for each step.

4. As soon as possible, and within 72 hours of incubation, centrifuge tubes at 2000-3000 g (RCF) for 15 minutes. Be certain to document date and time for each step.
5. After centrifugation, tubes must maintain a temperature of 2-8°C.
6. Tubes need to arrive at the laboratory within a week of centrifugation, and by 4:00 P.M. Mon-Fri. Tubes must be maintained at a temperature of 2-8°C during transport.

Some of the Frequently Asked Questions relating to the assay are listed below. The answers provided act as a guide only.

Blood Collection

The blood hasn't reached the black mark on the side of the Blood Collection Tube. Is this important?

The mark on the side of the tubes indicates the 1 mL fill volume. QuantiFERON® -TB Gold In-Tube Blood Collection Tubes have been validated for volumes ranging from 0.8 to 1.2 mL. If the level of blood in any tube is not close to the indicator mark, it is recommended to obtain another blood sample.

How important is the tube mixing process?

The antigen mixing process ensures even distribution of stimulating antigens to allow white blood cells to ingest and process antigen for presentation to T-cells, thus leading to IFN-secretion. It is a very important step in the QuantiFERON® -TB Gold In-Tube assay and poor mixing will lead to low and incorrect results. Mix the tubes by vigorously shaking the tubes vigorously for at least 5 seconds, ensuring that the entire surface of the tube has been coated with blood. Thorough mixing is required to ensure complete mixing of the blood with the tube's contents. Causing the blood to froth will not adversely affect the performance of the test. Universal blood handling precautions should be used. A demonstration video can be viewed on the Cellestis website at:

www.cellestis.com

Can the blood collection tubes be transported lying down?

Yes and No.

(Option 1)-- Tubes can be transported lying down only after the tube-mixing step has been done and prior to incubation.

(Option 2)-- If tubes are transported after incubation, but prior to centrifugation, care should be taken to ensure that *tubes remain upright during transport*.

(Option 3)-- Tubes transported after centrifugation, may be transported lying down if necessary.

At what temperature can the blood be transported to another site, or held prior to incubation at 37°C?

(Option 1, Option 2)-- Blood should be held and transported at Room Temperature (17°C to 27°C). Do not refrigerate the blood or place on ice.

(Option 3)-- Blood should be held and transported at (2°C to 8°C), refrigerated or placed on ice.

Blood Incubation and Centrifugation

What if 37°C incubation starts more than 16 hours after the time of blood collection?

The Package Insert specifies that the 37°C blood incubation must commence within 16 hours of collection. Blood samples incubated more than 16 hours after collection are likely to exhibit a decreased IFN- γ response due to cellular breakdown (death), leading to loss of sensitivity and inaccurate results.

Can I incubate the blood collection tubes lying down?

QuantiFERON[®]-TB Gold Blood Collection Tubes must be kept upright during incubation at 37°C.

Do I have to centrifuge the tubes immediately after removal from incubator?

QuantiFERON[®]-TB Gold Blood Collection Tubes may be held between 2°C and 27°C for up to 3 days before centrifugation or harvesting.

The gel plug hasn't moved during centrifugation. What should I do?

After incubation of tubes at 37°C, the plasma is separated from the cells by centrifuging for 15 minutes at 2000 - 3000 RCF (g). The gel plug should move to separate the cells from the plasma. If this does not occur, the tubes should be re-centrifuged at a higher speed.

The plasma doesn't appear the color it normally does. Is this OK?

Plasma from the QuantiFERON[®]-TB Gold In-Tube Blood Collection Tubes can appear more red than usual but this is normal. It should be noted that the color of plasma, even those without any red blood cell contamination, can vary from almost colorless to shades of yellow/pale brown; some plasma samples even have an opaque character. These qualities have not been found to affect QuantiFERON-TB[®] Gold In-Tube results.

References

[American Thoracic Society Diagnostic Standards and Classification of Tuberculosis in Adults and Children 1999. \(Page 1387-1391\)](#)

[CDC Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition, 2000. \(Page 25-33\)](#)

[Treatment of Latent Tuberculosis Infection in Children and Adolescents; Pediatrics 2004; 114; 1175-1201.](#)

[Tuberculosis Associated with Blocking Agents Against Tumor Necrosis Factor - Alpha - California, 2002 - 2003 - MMWR 2004; 53 \(No.30\).](#)

Utah Department of Health Tuberculosis Control/Refugee Health Program, [A Tuberculosis Provider Guide - Testing for TB Infection & Guidelines for Post-Test Referral](#), January 2009.

Follow-Up Responsibility

TB Nurse Consultant

TREATMENT OF LATENT TUBERCULOSIS INFECTION (LTBI)

Purpose

To establish a policy for evaluation and treatment of individuals found to have a positive tuberculin skin test (TST) or QFT blood assay.

Policy

Individuals found to have a positive tuberculin skin test, or QFT blood assay, should be carefully evaluated to rule out active TB disease (ATBD). If no evidence of ATBD is found, then evaluate for treatment of latent TB infection (LTBI). Targeted testing programs should be designed to identify persons who are at higher risk for TB and who would benefit from treatment of LTBI. The decision to test is a decision to evaluate for treatment!

Procedure

- a. Medical evaluation should include a history of:
 - Symptoms of disease
 - CXR within past 3 months, or sooner if necessary
 - History of TB exposure, infection, or disease
 - Past TB treatment
 - Demographic risk factors for TB
 - Medical conditions that increase risk for TB disease
 - Bacteriologic or histologic exam
 - Medical contraindications for treatment of LTBI
 - Current medications that may be affected by use of INH or Rifampin
- b. The Mantoux Tuberculin Skin Test (TST) is the preferred method of testing for TB Infection in adults and children. Classification of a positive test is found in [A Tuberculosis Provider Guide - Testing for TB Infection & Guidelines for Post-Test Referral](#).
- c. All individuals being considered for treatment should undergo a chest x-ray to rule out active pulmonary TB disease. Children younger than 10 years old should undergo both a posterior-anterior and a lateral chest x-ray. All other individuals should receive a posterior-anterior chest x-ray only; additional x-rays should be done at the physician's discretion. Consultation with the Utah State Pulmonologist and/or Pediatric Consultant is available. A chest x-ray should be given **even during the first trimester**, to pregnant women who:
 - Have symptoms that are highly suggestive of TB disease (cough, fever, night sweats, chest pain etc.), **or**

- Are HIV seropositive and (1) TST positive or (2) TST negative but have been in close contact with a person who has pulmonary or laryngeal TB disease, **or**
- Are TST positive and have been in close contact with a person who has pulmonary or laryngeal TB disease.

Other pregnant women who have a positive TST reaction should be advised to obtain a chest x-ray after the end of the first trimester. An appropriate lead shield should be used for chest x-rays in pregnant women. (A doctor's order is required for a shielded CXR.)

- d. Persons in the following high-risk groups should be given the highest priority for treatment of LTBI if they have positive skin test results ≥ 5 mm of induration, or the QFT is positive:
- HIV-positive persons
 - Recent contacts of a TB case
 - Persons with fibrotic changes on chest radiograph consistent with old TB
 - Clients with organ transplants
 - Other immunosuppressed clients

In addition, persons in the following high-risk groups should be considered for treatment of LTBI if their reaction to the TST is ≥ 10 mm of induration, or the QFT is positive:

- Recent arrivals from high-prevalence countries (go to the [World Health Organization \(WHO\)](#) for further guidance)
- Intravenous drug users
- Residents and employees of high-risk congregate settings
- Mycobacteriology laboratory personnel
- Persons with clinical conditions that make them high-risk
- Children <5 years of age, or children and adolescents exposed to adults in high-risk categories
- LDS missionaries returning from high-prevalence countries

Persons with no known risk factors for TB may be considered for treatment of LTBI if their reaction to the tuberculin test is ≥ 15 mm of induration, or QFT is positive. This group should be given the lowest priority for treatment efforts. Some contacts that have a negative tuberculin skin test reaction (<5 mm of induration) or QFT should be evaluated for treatment of LTBI, after TB disease has been ruled out. These contacts include children less than 5 years of age, immunosuppressed persons, and others who may develop TB disease quickly after infection. Close contacts that have a negative reaction to an initial TST should be retested 8 weeks after they were last exposed to TB. Treatment for latent infection may be discontinued if the skin test result is again negative **and** if the person is no longer exposed to TB. However, persons known to have or suspected of having HIV infection and other immunocompromised persons should be given treatment for LTBI regardless of their skin test reaction. Because of their age, infants and young children with LTBI are known to have been infected recently, and thus are at a high risk of their infection progressing to disease. Infants and young children are also more likely than older children and adults to develop life-threatening forms of TB. Children less than 5 years of age who are close contacts of person with ATBD should receive treatment for LTBI

even if the TST and x-ray do not suggest infection. A second TST should be placed 8 weeks after the last exposure to infectious TB. Treatment for LTBI can be discontinued if the second test placed at least 8 weeks after exposure was also negative and the infant is at least 6 months of age (a false negative is more likely to occur in a child less than 6 months old due to an underdeveloped immune system).

- e. Before treatment for LTBI is initiated and after ATBD ruled out, the clinician should discuss the risks and benefits of treatment with the client, determine contraindications to treatment and check for adverse reactions to current drugs which have known interactions with drugs used for LTBI. Discuss adherence issues with the client. Written consent to begin therapy must be obtained and maintained in the client record. Commitment to complete the 6 to 9 month course of treatment should be obtained.
- f. Medication used for the treatment of LTBI in adults is described in detail in the [Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000](#), and [ATS/CDC/IDSA Treatment of Tuberculosis](#). Since the publication of the Core Curriculum and General Guidelines on the Management of Tuberculosis Infection and Disease, changes have been made for the use of rifampin and pyrazinamide and are included in the MMWR referenced at the end of this chapter. This regimen is no longer recommended.

Drugs	Duration	Interval	HIV-	HIV+
Isoniazid (INH)	9	Daily	A (II)	A (II)
		Twice Weekly	B (II)	B (II)
Isoniazid (INH)	6	Daily	B (I)	B (I)
		Twice Weekly	B (II)	B (II)
Rifampin (RIF)	4	Daily	B (II)	B (II)

* **A** – Preferred; **B** - Acceptable alternative; **C** - Offer when A and B cannot be given

* **I** - Randomized clinical trial data; **II** - Data from clinical trials that are not randomized or were conducted in other populations; **III** - Expert opinion

- g. The recommended regimen for treatment of LTBI in children and people with HIV is INH for 9 months. If INH cannot be tolerated Rifampin can be used for 4 months in adults and 6 months in children.
- h. Completion of therapy should be based on the total number of doses administered, not duration of therapy. If treatment is interrupted the

recommended number of doses of the regimen should be provided within a certain time frame.

- A 6-month regimen consisting of 180 doses of INH can be given over a 9-month period of time.
- A 9-month regimen consisting of 270 doses of INH can be given over a 12-month period of time.
- A 4-month regimen consisting of 120 doses of RIF can be given over a 6-month period of time.
- A 6-month regimen consisting of 180 doses of RIF can be given over a 9-month period of time.

The entire regimen should be restarted if interruptions were frequent or prolonged enough to preclude completion of doses in the time frames specified. When therapy is restarted after an interruption of more than 3 months, a medical examination and repeat CXR to exclude active disease is indicated.

- i. Clients who are at high risk of developing active TB disease, and who are prescribed treatment for LTBI but have interruptions in treatment, should be encouraged to complete the regimen. However, if the client has failed three attempts to complete treatment, no further efforts should be made. Incentives and enablers may be used to encourage completion in high-risk clients such as contacts, young children and HIV infected individuals.
- j. Monitoring for side effects may include baseline laboratory testing for clients whose initial evaluation suggest a liver disorder, who use alcohol regularly and others who are at risk of chronic liver disease. Baseline testing is also indicated for clients with HIV infection, women who are pregnant or less than 3 months post partum. Testing should be considered on an individual basis, particularly for clients who are taking other medications for chronic medical conditions. See [Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000](#), and [Management of Common Side Effects of INH, RIF, PZA, and EMB](#) for more details.

Monthly monitoring is required for adherence to the prescribed regimen, signs and symptoms of active TB disease, and signs and symptoms of hepatitis or other side effects. Face-to-face visits and assessments are required. Consultation with the client's primary care physician and/or the Utah State Pulmonologist, Infectious Disease Pediatrician, or Nurse Consultant is recommended when adverse reactions occur.

Peripheral neuropathy is associated with the use of isoniazid (INH) but is uncommon at doses of 5mg/kg. Persons with conditions in which neuropathy is common, e.g., diabetes, uremia, alcoholism, malnutrition, HIV-infection, pregnant women and persons with a seizure disorder, may be given pyridoxine (vitamin B6) 10-50mg/day with INH.

- k. Health care providers often do not realize that their clients are not following recommendations. It is very important to determine that clients are taking medications as prescribed, and to have a high index of suspicion of non-adherence. There are several methods for assessing adherence:

- Ask the client
- Communicate effectively
- Help the client to remember
- Listen carefully and ask the client to report any problem with taking the medications
- Monitor appointment keeping, medication refill, and pick-up
- Monitor pills (perform pill counts); if Rifampin, urine may be examined for characteristic rust color
- Directly observe the clients swallowing each dose of medication

Directly observed therapy (DOT) is recommended for clients who are at high risk for progression to disease and whose adherence is questionable (e.g. IV drug users, homeless persons, children, contacts to drug resistant TB and persons with a history of non-adherence with any medical treatment regimen). DOT is required for all intermittent regimens.

- l. A physician or primary care provider must decide the appropriate duration of treatment for LTBI. Both the 6 month and 9 month regimens of INH are acceptable for adults, but only 9 months is acceptable for children or people with HIV. The client should be advised to return to the clinic or report to the public health nurse any time he/she develops symptoms suggestive of ATBD.
- m. Upon completion of therapy, the client should be informed that repeat chest x-rays are not necessary and **repeat TSTs are not advised**. The client should be given completion of LTBI treatment documentation. Selected high-risk individuals such as HIV infected persons who cannot or will not take preventive therapy may have periodic chest x-rays at the discretion of the primary care provider.
- n. The TB Control Program provides medication for LTBI at no cost to those clients without health insurance that would cover the cost of the medication. See the section in this manual on **Ordering Drugs** for more detailed information.
- o. Notify the TB Control Program for adverse reactions to medications taken for LTBI at 1-801-538-6191.

References

[ATS/CDC/IDSA Treatment of Tuberculosis, June 2003](#)

[Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000. \(Page 53-60\)](#)

[MMWR Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection, August, 2003 \(pg. 735\)](#)

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Follow-Up Responsibility

TB Nurse Consultant

ACTIVE TUBERCULOSIS DISEASE (ATBD) INITIAL EVALUATION

Purpose

To establish a policy for the initial evaluation of active TB disease (ATBD).

Policy

A diagnosis of tuberculosis (TB) may be considered for any client who has an abnormal chest x-ray consistent with TB or for any client who has a persistent cough lasting 3 weeks or more or other signs or symptoms compatible with TB including bloody sputum, chest pain, night sweats, fatigue, weight loss, loss of appetite or persistent fever. A qualified medical provider should make the diagnosis. The index of suspicion for TB should be very high in areas of high prevalence or among groups with a high prevalence of TB.

In Utah during 2009, approximately 40% of TB cases were exclusively extrapulmonary with an additional 8% with pulmonary and extrapulmonary TB. The symptoms of TB depend on the site affected. TB of the spine may cause pain in the back; TB of the kidney may cause blood in the urine. Extrapulmonary TB should be considered in the differential diagnosis of ill persons who have systemic symptoms and who are at high-risk for TB. Pulmonary TB should always be evaluated when extrapulmonary TB is diagnosed.

Procedure

- a. For persons whom a diagnosis of TB is being considered a complete medical and social history should be documented. This should include questions pertaining to risk factors for TB exposure, infection or disease, symptoms of TB, underlying health conditions, risk factors for human immunodeficiency virus (HIV) infection or HIV antibody status, and information about contacts (especially high-risk contacts, where immediate action may be necessary). If the client received prior treatment for TB and the drug regimen was inadequate or if the client did not adhere to therapy, TB may recur and may be drug resistant. Clients with an unknown or negative HIV status should be referred for HIV counseling and testing.
- b. A physical examination is an essential part of the evaluation of any client. It cannot be used to confirm or rule out TB, but it can provide valuable information about the client's overall health and other factors that may affect how TB is treated.

- c. If there is no documentation that a tuberculin skin test (TST) or Quantiferon (QFT) has been performed, it should be done, unless cultures for *M. tuberculosis* are positive.
- d. Clients who have a positive TST or QFT result and/or symptoms suggestive of TB should be evaluated with a chest x-ray. Radiographic abnormalities that strongly suggest ATBD include upper-lobe infiltration, particularly if cavitation is seen, and patchy or nodular infiltrates in the apical or subapical posterior upper lobes or the superior segment of the lower lobe (but abnormalities may be present anywhere within the lungs or pleura). If abnormalities are noted, or the client has symptoms suggestive of extrapulmonary TB, additional diagnostic tests should be conducted.

Abnormalities on chest x-ray may be suggestive of, but are never diagnostic of TB. Chest x-rays may be used, however, to rule out the possibility of TB in a person who has a positive reaction to the TST or QFT and no symptoms of disease.

The radiographic presentation of pulmonary TB in HIV-infected clients may be unusual. Typical apical cavitory disease is less common among such clients. They may have infiltrates in any lung zone, mediastinal and/or hilar adenopathy, pleural effusion, or they may have a normal chest radiograph, although this latter finding rarely occurs.

Old, healed TB can produce various radiographic findings such as pulmonary nodules, with or without fibrotic scars or visible calcifications. Nodules and fibrotic scars may contain slowly, multiplying tubercle bacilli with the potential for future progression to active TB.

Pregnant women who are strongly suspicious of having ATBD should undergo a chest x-ray without delay, even during the first trimester. **A lead shield should be used for all chest x-rays in pregnant women.**

Clients suspected of having extrapulmonary TB disease **should** undergo a chest x-ray to rule out pulmonary TB disease.

Children (especially under age 10) commonly present with persistent opacities and/or hilar or subcarinal enlarged nodes. These findings may be difficult to see on a frontal view alone. Therefore a 2-view (anterior/posterior and lateral) film should be done. The patient should, if possible, be referred to Primary Children's Medical Center (PCMC) for their CXR, and the state pediatric consultant may be consulted. Referral forms must accompany the patient, and can be found at the following links:

<http://www.health.utah.gov/cdc/tbrefugee/forms/Primary%20XRay%20Request.pdf>

<http://www.health.utah.gov/cdc/tbrefugee/forms/Primary%20Xray%20Instructions.pdf>

The TB Control Program consults with expert pulmonologists to provide interpretations for suspected/known TB cases in both adults and children. Consult with the TB Control Program for information.

e. Bacteriologic tests are performed on specimens for TB diagnostic purposes:

- Smear examination - the specimen is concentrated, placed on a slide, and stained with a solution that detects acid-fast bacilli (AFB). Many TB clients have negative AFB smears.
- Culture of the specimen for AFB - the specimen is placed in a special media that allows mycobacterial growth. Further biochemical, and DNA tests are used to identify the type of AFB if growth occurs. Positive cultures for *Mycobacterium tuberculosis* complex (MTB) confirm the diagnosis of TB: however TB may also be diagnosed on the basis of signs and symptoms in the absence of a positive culture.
- Direct tests for Mycobacterium tuberculosis complex (MTBC): Respiratory specimens may be tested directly for the presence of MTBC by the detection of genetic material in the sample. Contact the TB Control Program for availability and instructions.
- Susceptibility testing from cultures positive for MTB complex - the organism is tested for resistance to drugs commonly used to treat TB. Isoniazid, rifampin, ethambutol, streptomycin and pyrazinamide are routinely tested. Under certain circumstances, an isolate may be sent to CDC for Molecular Detection of Drug Resistance (MDDR) in order to quickly determine the likelihood of MDR and/or XDR-TB.
- DNA fingerprinting (genotyping) is used to identify specific strains of TB and is a tool to track TB transmission. Related isolates show the same pattern. It can also be used to identify lab contamination.

Sputum samples should be obtained for smear and culture examination when pulmonary or laryngeal TB is suspected. Three samples should be collected 8-24 hours apart, with at least one being an early-morning specimen, **preferably before drugs are started** (see manual section: 'Utah State Laboratory Specimen Collection and Transport' for more details). Because TB can also occur in almost any anatomical site, a variety of other clinical specimens (e.g. urine, cerebrospinal fluid, pleural fluid, pus, or biopsy specimens) should be submitted for examination when extrapulmonary TB disease is suspected. If a diagnosis of pulmonary TB disease cannot be established from sputum, other procedures may be necessary, including bronchoscopy and gastric aspiration.

If AFB Smear is:	and, If Culture is:	Interpretation and Actions
Positive	Pending	Treat as if active TB if clinical history is suggestive of TB until proven otherwise.
Positive	Positive for AFB	Assume MTB until proven otherwise (unless supporting history strongly suggests non-tuberculous mycobacteria (NTM); may be later identified as (NTM).
Negative	Positive for AFB	Await ID; if MTB (or high suspicion of), probably lowly infectious, but manage as active TB.
Positive	Positive for MTB	Diagnosis of active TB disease.
Negative	Positive for MTB	Same interpretation and actions as directly above.
Positive	Positive for non-tuberculous mycobacteria (NTM)	Not infected with MTB, not considered contagious. Refer to primary care provider for treatment.
Negative	Positive for NTM	No bacteriological evidence for MTB; not considered contagious. In many such cases the NTM is a contaminant or colonizer.
Positive or Negative	Negative for MTB and NTM	No bacteriologic evidence for MTB. If client has clinical symptoms not explained by another diagnosis and the suspicion for MTB is high, may still have active infection with MTB. Consult with TB Control Program.
Positive or Negative	Mycobacterium still present	Once identified as MTB do not probe each specimen. If still present after 2 months re-probe and then every month after.

- f. A culture result of MTB or *M. Tuberculosis* complex provides a diagnosis of TB. However, a false-positive culture should be considered when the results do not fit the client's clinical status. Clients having only one positive culture should be re-evaluated for the possibility that the culture may be a false positive.

Other mycobacteria (e.g. *M. Avium* complex [MAC], *M. kansasii*, *M. chelonae*) may cause pulmonary disease but are not contagious. These organisms will be identified on final culture. Additionally, these organisms may also be present intermittently in small numbers and may not be pathogenic. Although uncommon, a person may be infected with more than one type of mycobacteria at any given time. See section 'Utah Public Health Lab Specimen Collection and Transport' in this manual for more details.

Clients who are suspected or diagnosed with ATBD must be reported to the TB Control Program within 24 hours. This would include, but is not limited to: any smear positive or culture AFB positive, and/or positive direct test, clients with a CXR highly suspicious for ATBD, and/or any client started on multiple TB drug therapy.

Helpful checklists for organizing an initial interview with the patient can be found at:

[http://www.health.utah.gov/cdc/tbrefugee/resources/Step%20By%20Step%20Instructions%20for%20Active%20TB%20Case%20\(08-2009\).pdf](http://www.health.utah.gov/cdc/tbrefugee/resources/Step%20By%20Step%20Instructions%20for%20Active%20TB%20Case%20(08-2009).pdf)

[http://www.health.utah.gov/cdc/tbrefugee/resources/Supplies%20List%20For%20Active%20TB%20Kit%20\(7.30.09\).pdf](http://www.health.utah.gov/cdc/tbrefugee/resources/Supplies%20List%20For%20Active%20TB%20Kit%20(7.30.09).pdf)

References

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CDC. [Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005. MMWR 2005;54:RR-17.](#)

[Core Curriculum on Tuberculosis](#), What the Clinician Should Know, Fourth Edition 2000. (Page 39-46)

NTCA/CDC [A Guide to the Application of Genotyping to Tuberculosis Prevention and Control](#), June 2004

Follow-Up Responsibility

TB Nurse Consultant

BASIC GUIDELINES FOR TREATING ACTIVE TUBERCULOSIS DISEASE

Purpose

To establish a policy for treatment of clients who have confirmed active TB disease (ATBD) (e.g. clients with positive cultures for *Mycobacterium tuberculosis* complex (MTB) or a clinical diagnosis by a qualified health care provider) or clients who are considered highly likely to have ATBD.

Policy

Clients who have confirmed ATBD (e.g. clients with positive cultures for MTB or a clinical diagnosis by a qualified health care provider) or clients who are considered highly likely to have ATBD should be started on appropriate treatment immediately. It is not necessary to wait for laboratory confirmation of *Mycobacterium tuberculosis* complex (MTB) before starting treatment.

Procedure

- a. **The responsibility for successful treatment is clearly assigned to the public health provider or private provider and not to the patient. The private physician is carrying out a public health function with responsibility not only for prescribing an appropriate regimen but also for successful completion of therapy.**
- b. Treatment regimens must contain multiple drugs (and correct dosages) to which the organism is susceptible. The administration of a single drug or the addition of a single drug to a failing regimen can lead to the development of a strain of TB resistant to that drug. The preferred regimen for treating ATBD consists of an initial 2-month phase of four drugs: isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB) followed by a 4 to 7 month continuation phase of isoniazid and rifampin. Ethambutol can be discontinued when drug susceptibility results show the infecting organism to be fully drug-susceptible. See [ATS/CDC/IDSA Treatment of Tuberculosis, June 2003](#) for more details on medications.
- c. Extended treatment is recommended for patients with drug-susceptible pulmonary tuberculosis who have cavitation noted on the initial chest film and who have positive sputum cultures at the time 2 months of treatment is completed. Treatment may also be extended when only one of the above is true if disease is extensive or immunosuppression significant. In addition, variations in drugs prescribed due to drug resistance, intolerance or malabsorption may warrant a longer duration of treatment (as will TB of the bone, joints or central

nervous system). Repeat sensitivity testing and/or drug blood levels may be indicated if inadequate response to treatment is suspected.

- d. Pyridoxine (Vitamin B-6) is recommended for some individuals receiving INH as part of their treatment regimen to prevent peripheral neuropathy. It should be used in persons at risk for neuropathy (nutritional deficiency, HIV infection, renal failure diabetes and alcoholism), as well as pregnant and breast feeding women.
- e. Research has shown that non-compliance with self-administered treatment for ATBD leads to high failure rates and development of drug resistance. Therefore it is **required by law** that all clients be on **directly observed therapy (DOT)**. This includes both pulmonary and extrapulmonary TB. See [Utah Administrative Code R388-804, Special Measures for the Control of Tuberculosis](#). It is strongly advised to use a treatment contract which serves both as an education tool for the client and documentation that may prove useful, should the client become noncompliant.
Go to: http://www.health.utah.gov/cdc/tbrefugee/forms/lhd_tbTreatmentplan.pdf for an example.
- f. Clinical experience suggests that clients being managed by DOT administered 5 days a week have a rate of successful therapy equivalent to those being treated 7 days a week. Thus, a daily DOT schedule may be given on a 5 day a week (if not drug-resistant) or 7 day a week schedule. Intermittent therapy (twice or thrice weekly) may be appropriate for some clients. See the [ATS/CDC/IDSA Treatment of Tuberculosis, June 2003](#) guidelines or contact the TB Control Program for details.
- g. TB medications should be administered together as a single dose leading to higher and potentially more effective serum concentrations.
- h. TB transmission prevention precautions **must** be followed for clients who are known or suspected of having ATBD who are sputum smear positive for acid-fast bacilli. Clients with negative sputum smears for acid-fast bacilli, but with positive cultures for *Mycobacterium tuberculosis* complex may still transmit TB, especially if coughing.
- i. Patients are not considered infectious if they meet **all** the following criteria:
 - They are on adequate therapy for 2-3 weeks
 - They have significant **clinical response to therapy** (i.e., reduction in cough, resolution of fever)
 - They have **three** negative AFB sputum smears collected 8-24 hours apart, with at least one being an early morning specimen.

DRUG	ADVERSE REACTIONS	MONITORING	COMMENTS
Isoniazid	<ul style="list-style-type: none"> -Hepatic enzyme elevation -Hepatitis -Hypersensitivity reactions -Peripheral neuropathy -Mild effects on central nervous system -Lupus-like syndrome -Monoamine poisoning 	<ul style="list-style-type: none"> -Baseline (and monthly, as needed) hepatic enzymes for adults -Repeat measurements if baseline is abnormal, if high risk for adverse reactions, if symptoms of adverse reactions 	<ul style="list-style-type: none"> -Hepatitis risk increases with age and alcohol consumption -Pyridoxine can usually prevent peripheral neuropathy *See ATS/CDC/IDSA Treatment of Tuberculosis, 2003, section 7.2.2 for drug interactions.
Rifampin	<ul style="list-style-type: none"> -GI upset -Orange discoloration of body fluids -Hepatitis -Immunologic reactions -Flu-like symptoms -Rash 	<ul style="list-style-type: none"> -Baseline CBC, platelets, and hepatic enzymes for adults -Repeat if baseline abnormal or if symptoms of adverse reactions 	<ul style="list-style-type: none"> -Significant interactions with methadone, birth control pills, and other drugs -Colors body fluids orange -May permanently discolor soft contact lenses *See ATS/CDC/IDSA Treatment of Tuberculosis, 2003, section 7.2.1 for drug interactions
Pyrazinamide	<ul style="list-style-type: none"> -Hepatitis -Rash -GI upset -Joint aches -Hyperuricemia -Gout 	<ul style="list-style-type: none"> -Baseline uric acid and hepatic enzymes for adults -Repeat if baseline abnormal or if symptoms of adverse reactions 	<ul style="list-style-type: none"> -Treat hyperuricemia only if client has symptoms -Little information about the safety during pregnancy
Ethambutol	<ul style="list-style-type: none"> -Optic neuritis -Permanent alterations in visual acuity or color perception -Cutaneous reactions 	<ul style="list-style-type: none"> -Baseline and monthly tests of visual acuity and color vision 	<ul style="list-style-type: none"> -Not recommended for children too young to be monitored for changes in vision unless TB is drug resistant

- j. Clients should be monitored bacteriologically at least every 2-4 weeks until cultures convert to negative, if any new symptoms develop, or if client is not improving. Cultures reported as mycobacterium still present will be re-probed at 2 months and every month it is still positive. If the client is not improving consider the development of resistance, poor absorption of drugs or client not taking drugs. Consult with TB Program.
- k. Consult the TB Control Program for information regarding the treatment of clients if they are:
- Drug resistant
 - Children
 - HIV positive
 - Pregnant
- l. The basic principles that underlie the treatment of pulmonary tuberculosis also apply to extrapulmonary forms of the disease. Thus, a 6-month course of therapy is recommended for treating tuberculosis involving any site with exception of 6-9 month for bone joint and 9-12 for CNS.
- m. First Line TB Drug Monitoring and Adverse Reactions (also see [Management of Common Side Effects of INH, RIF, PZA, and EMB](#), as found in the 'TB resources' page on our website)
- n. Rifampin may decrease the effectiveness of oral contraceptives, as well as interact with multiple other medications. An alternative method of birth control should be used during Rifampin therapy. See [ATS Guidelines](#) for common drug interactions.
- o. All clients with ATBD should be offered HIV counseling and testing. In the presence of HIV infection, it is critically important to assess the clinical and bacteriological response. TB treatment regimens may need to be altered for HIV-positive clients taking protease inhibitors. Because of the complexity of management of TB in the HIV positive client, it is **strongly recommended that consultation with an expert in the management of both TB and HIV disease be considered**. See [TB/HIV drug interactions](#).
- p. Careful attention should be given to measures that foster adherence to therapy (e.g., incentives and enablers). See section on 'Incentives and Enablers' in this manual or consult with the TB Control Program for assistance with incentives and enablers. Intermittent therapy regimens are available for select clients. Consult the TB Control Program for more information.
- q. A case manager should be assigned to ensure that clients receive appropriate monitoring, complete treatment, and contacts are examined. See manual section on 'Contact Investigation' for more details.
- r. When therapy is interrupted see [ATS/CDC/IDSA Treatment of Tuberculosis, 2003](#) section 5.7 for recommendations.

- s. A full course of therapy is determined more accurately by the total number of doses taken, not solely by the duration of therapy. (See [ATS/CDC/IDSA Treatment of Tuberculosis, 2003](#), Table 2)
- t. For pulmonary ATBD, a chest x-ray and sputum should be done at the completion of treatment.
- u. Follow-up of ATBD should be done at scheduled intervals. (See manual section on 'Post-Treatment Evaluation.')

References

[American Thoracic Society Diagnostic Standards and Classification of Tuberculosis in Adults and Children September 1999. \(Page 1360-1370\)](#)

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Follow-Up Responsibility

TB Nurse Consultant

Utah State Pulmonary Consultants

CONTACT INVESTIGATION

Purpose

To establish a policy for determining when a contact investigation needs to be initiated, how to prioritize and evaluate contacts, recommended treatment and follow-up of contacts, and when to expand the investigation.

Policy

Contact investigation is the second most important element of the four prioritized strategies to prevent and control TB in the US and is one of the best ways to find people who have active TB disease (ATBD). The purpose of the investigation is to find contacts who (1) have ATBD so that they can be given treatment and further transmission can be stopped, (2) have latent TB infection (LTBI) so they can be given treatment, and (3) are at high risk of developing ATBD and therefore require prophylactic treatment until LTBI can be excluded. Each local health department is legally responsible for ensuring that a complete and timely contact investigation is done for TB cases and sputum AFB-smear positive suspects with a high index of suspicion for TB reported in its area.

Procedure:

a. Identify: Who is a Contact?

Contacts are persons exposed to someone with infectious TB disease. Exposure to TB is time spent with or near such a person and is determined by the duration, proximity, and intensity of the shared time. Contacts generally include family members, roommates or housemates, close friends, coworkers, classmates, and others. Public health agency staff usually identify contacts by interviewing the person with ATBD and by visiting the places where that person spends time regularly.

b. Identify: When is a Contact Investigation Done?

A contact investigation is a systematic procedure for tracing, testing, and evaluating persons who have been exposed to someone with infectious TB. In general, a contact investigation should always be initiated within three working days of report to the LHD of a sputum AFB-smear positive case or suspect with a high index of suspicion for TB (e.g. symptoms and/or cavitory chest x-rays).

Infectiousness depends on a variety of factors, but is more likely when clients have:

- Hoarseness or other symptoms of laryngeal TB
- Cough
- Positive sputum AFB smear or culture results for *Mycobacterium tuberculosis* complex (MTB). Recent evidence suggests that transmission can occur in sputum AFB smear-negative cases as well
- Cavity on chest x-ray
- Inadequate or no treatment

Young children with pulmonary TB disease are rarely infectious, so a contact investigation is generally not conducted for them. Instead a **source case investigation** (looking for the source of exposure) is done. However, young children with ATBD should be evaluated for infectiousness and a contact investigation may be warranted in some circumstances.

A source case investigation is usually done when:

- A child < 5 years old is found to have TB disease (required by the TB Control Program)
- A severely immunocompromised person who does not have a known history of latent TB infection (LTBI) is found to have ATBD
- A cluster of TST conversions is found in a high-risk institution (e.g. health care or correctional facility)

A source case investigation is conducted to determine who transmitted TB to the child, index patient, or persons in the cluster of skin test conversions; whether this person is still infectious; whether this person was reported to the health department or if others were infected by the same source patient.

Supervisory clinical and management staff should make decisions regarding prioritization of contact investigations. Setting priorities between two or more contact investigations is a decision that should be made based on the likelihood of infectiousness of the index case:

- Positive sputum AFB smear
- Pulmonary TB with positive culture
- Extra-pulmonary TB and/or clinical/provider-diagnosed cases

If program resources are limited, priority should be given to contacts that were exposed to the most infectious TB clients or to those who are at highest risk for progressing to disease, if infected. The TB Control Program **DOES NOT PAY** for testing or follow-up for non-contacts (persons who have not shared time or were not near a person with infectious TB).

c. Steps in a Contact Investigation

A successful contact investigation requires careful gathering and evaluation of detailed information, often involving many people. In general, contact investigations follow a process that includes these basic steps:

1. Medical Record Review

Review of the TB client's medical record and information from the clinician to determine whether the client has been infectious and, if so, for how long. Knowing when the client was infectious helps to determine which contacts are at risk. In general, count back 3 months prior to the time the client reports symptoms, or the first positive finding (i.e. abnormal CXR or positive smear), whichever is longer. If asymptomatic and no positive AFB sputum smears or cavitary CXR, go back 1 month from the date of suspicion of disease.

2. Client Interview (TB Case Interview)

The client interview is one of the most critical parts of the contact investigation, and should be done in person. If the interviewer does not communicate well enough with the client to get accurate information about symptoms, places where the client spent time, and contacts, people who need evaluation and treatment may be missed. The majority of TB patients in Utah are foreign-born individuals; case managers should be prepared to arrange to have the interview conducted in the patient's primary language, if necessary.

The interviewer should keep in mind that if the client first learns of their new TB diagnosis during the initial interview, they may be overwhelmed. Thus, **follow-up interviews should be scheduled to educate clients and to complete a thorough contact investigation.** Good communication (asking open-ended questions), good listening skills, client education, and establishing and maintaining a trusting relationship are essential during all interviews.

The initial interview should occur **no more than 1 working day** after the case is reported for sputum AFB smear positive cases/suspects with a high index of suspicion for TB (3 days for others). During the interview, the TB client should be asked more about:

- Symptoms – type and onset; especially cough and sputum production
- Places where the client spent time while he/she was infectious (e.g. household – including guests and visitors, work, school, leisure, recreation, transportation*, incarceration, travel, medical/dental or beauty appointments)
- Any contacts
- How often and how long the contacts were exposed
- Locating information for the contacts

*If air travel may be involved, WHO guidelines (adopted by CDC) require 8 hours or more contact. Go to:

http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.363_eng.pdf for further guidance. For additional assistance and/or to make a referral to CDC, contact the TB Control Program.

Some clients may be reluctant to identify some or all of the contacts. For example, a client may not want to identify people who use illegal drugs with him/her. The interviewer should be sensitive to the client's fears, explain the importance of testing the contacts, and **assure the client that all information will be kept confidential (including the client's name).**

3. Field Investigation

A field investigation means visiting the TB client's home or shelter, workplace (go to: [Workplace Contact Investigation Protocols](#) for detailed guidance), and other places where the client said he/she spent time while infectious, to identify contacts and evaluate the environmental characteristics of the places where exposure occurred. The public health worker should assess for:

- Room size
- Crowding
- Ventilation
- Contacts (especially children) and their locating information
- Evidence of other contacts who may not be present (e.g. pictures of others who may live in the dwelling, shoes left by others who may live in the house, maintenance/cleaning workers in the home, toys left by children)

Close contacts that are present should 1) receive a tuberculin skin test (TST) or Quantiferon (QFT) and arrange for reading of the results; 2) be educated about the purpose of the investigation, basic TB transmission, risk of transmitting TB to others, and importance of testing, treatment, and follow-up for LTBI and ATBD; and 3) be referred for medical evaluation, including chest x-ray and sputum collection if they have symptoms of TB.

4. Risk Assessment for MTB Transmission

The infectiousness of the TB client is dependent upon the duration of time when the client was infectious and estimated degree of infectiousness. The degree of infectiousness is estimated from information regarding the client's symptoms, sputum smear results, and other conditions identified during the medical record review and client interview. The greater the degree of infectiousness, the more likely transmission will occur.

The risk of transmission in a particular space depends on the concentration of infectious droplet nuclei in the air. Small room size, crowded conditions, poor ventilation and lack of air cleaning systems increase the risk of transmission of MTB.

The length and closeness of exposure between the TB client and a particular contact are key factors in assessing the contact's risk. Persons who frequently spend a lot of time with the TB client or have been physically close to the client are at higher risk of becoming infected.

Finally it must be considered, regardless of the length of exposure, if the contacts are at a high risk of developing TB disease if infected: contacts <5 years of age, HIV-infected or other immunocompromised persons, and persons with certain medical conditions.

5. Prioritization of Contacts

The assignment of high, medium, or low-priority status is dependent on the characteristics of the index patient, the vulnerability of the contact, and circumstances of exposure. To use time and resources wisely, the contact investigation should initially be focused on the high or medium-priority contacts. Low-priority contacts have had limited exposure to the index case and a low probability of recent infection; a TST or QFT at the end of the window period (8-10 weeks after exposure) is preferred for these contacts.

It is recommended that case managers refer to the following figures in the CDC's Contact Investigation Guidelines (<http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf>) for guidance on prioritizing contacts:

INDEX PATIENT CHARACTERISTICS	FIGURE NO	PAGE
AFB sputum smear-positive or cavitory	Figure 2	12
AFB sputum smear-negative	Figure 3	13
Suspected pulmonary TB with abnormal CXR not consistent with TB	Figure 4	14

In addition, the Utah TB Control Program encourages that contact investigations limited to household members be conducted for extrapulmonary, clinical, and provider-diagnosed cases.

6. Evaluation of Contacts

Evaluation of TB contacts includes at least a medical history and TST or QFT. **A reaction of 5mm or greater is considered positive for contacts. A +QFT is positive in all circumstances.** Contacts should also be offered HIV counseling and testing and be asked about: their current symptoms of TB, risk factors for developing TB disease, date of last exposure, history or treatment of previous TB infection or disease, documented previous TST or QFT results, previous exposure to TB. Contacts with a positive reaction should be further evaluated for ATBD. Contacts who have a previously documented positive TST or QFT should not receive another test but should be evaluated for TB disease, including a review of symptoms and obtaining a chest x-ray.

Because it takes 2-8 weeks after TB infection for the body's immune system to react to tuberculin (window period), contacts who had a negative reaction on the initial TST or QFT should be retested 8-10 weeks after their last exposure to the infectious TB patient.

Infants: Infants under 6 months of age may have a false-negative TB skin test reaction because their immune systems are not yet able to react to tuberculin. It is not known whether QFT testing is valid in young children. Thus, infants need careful clinical evaluation. The state pediatric infectious disease consultant should be involved in the decision-making process.

Special Groups: Contacts who have TB symptoms, are HIV-infected, have other immunosuppressive conditions, or are under 5 years of age should have a chest x-ray at the same time as the initial skin test or QFT to evaluate for TB disease. This is because of their high risk of quickly developing TB disease. In addition, these high-risk contacts should be considered for treatment of LTBI (once ATBD is ruled out) even if the initial skin test reaction or QFT is negative during the window period. Treatment may be discontinued if the 8-week follow-up skin test or QFT is still negative and the contact is not at continued risk for exposure to infectious TB. (See Figures 5 and 6 in the CI Guidelines)

Contacts who have an abnormal chest x-ray or symptoms of TB disease should have three sputum specimens collected at least eight hours apart (with one being an early morning sample), for smear and culture examination, regardless of his/her TST or QFT reaction.

It is recommended that case managers refer to the following figures in the CDC's Contact Investigation Guidelines (<http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf>) for guidance on evaluating contacts:

CONTACT CHARACTERISTICS	FIGURE NO	PAGE
Aged <5 years	Figure 5	15
Immunocompromised	Figure 6	16
Immunocompetent adults & children ≥5 years	Figure 7	17
Low-priority Contacts	Figure 8	18
Documented Previously Positive TST	Figure 9	19

Results of all Contact Investigations should be documented on the [UDOH CI Record](#) and sent to TB Control Program at 30 days, 120 days and at completion of treatment for LTBI.

Any out-of-jurisdiction contacts require an Interjurisdictional Referral to be submitted to the TB Control Program. The referral will be forwarded, and follow-up will be assumed by the TB Control Program as needed. (See section on Interjurisdictional Referrals in this manual.)

7. Treatment and Follow-Up for Contacts

The following contacts should be offered treatment for LTBI:

- Contacts with a positive TB skin test reaction and no evidence of TB disease
- High-risk contacts who have a negative TB skin test reaction, or negative QFT, who may develop TB disease quickly after infection (e.g. children under 5 years of age, HIV-infected persons, other immunocompromised contacts)

Contacts recently infected with TB are high-priority for treatment of LTBI because they are at high-risk of developing ATBD (highest risk of developing ATBD is in the first 2 years after infection). HIV-infected contacts or other immunosuppressed contacts may be given a full course of treatment for LTBI, regardless of their TST results, because of the possibility of a false-negative skin test result (inability to react to tuberculin due to a compromised immune system).

Contacts who have a positive sputum smear or chest x-ray result suggestive of current TB disease should begin treatment for ATBD.

Contacts who have started treatment for LTBI or ATBD should be monitored to ensure compliance and completion of treatment. Contacts with LTBI who have a high-risk for progressing to ATBD or who are at risk for non-adherence should be considered for directly observed preventive therapy (DOPT) when possible (e.g., HIV positive or immunosuppressed clients, homeless clients, or substance abuse clients). Children < age 5 **must** receive DOPT.

8. Decision About Whether to Expand Testing

When determining whether to expand the contact investigation, consideration of the following factors is recommended:

- achievement of program objectives with high- and medium-priority contacts; and
- extent of recent transmission, as evidenced by:
 - unexpectedly high rate of infection* or TB disease in high-priority contacts (e.g., 10% or at least twice the rate of a similar population without recent exposure, whichever is greater),
 - evidence of secondary transmission (i.e., from TB patients who were infected after exposure to the source patient),
 - infection of contacts aged <5 years,

- contacts with change in TST or QFT status from negative to positive between their first and second test, and
- TB disease in any contacts who had been assigned a low priority.

In the absence of evidence of recent transmission, a contact investigation should not be expanded to lower priority contacts. When program evaluation objectives are not being achieved, a contact investigation should be expanded only in exceptional circumstances, generally those involving highly infectious persons with high rates of infection among contacts or evidence for secondary cases and secondary transmission. Expanded investigation must be accompanied by efforts to ensure completion of therapy.

The decision about expanding a contact investigation to the next group of contacts should be made by clinical and supervisory staff, based on an assessment of all available information. This should be done as soon as it becomes clear that transmission may have occurred.

9. Evaluation of Contact Investigation Activities

An evaluation of the contact investigation activities should be conducted with or by a supervisor to determine such things as:

- Were an appropriate number of contacts identified?
- Were the highest-priority contacts located and tested?
- Was the contact investigation performed in all settings: household or residence, work or school, and leisure or recreational environments?
- Was the contact investigation expanded appropriately? Were contacts completely evaluated (including second skin test if needed) and given appropriate therapy if they had TB infection or disease?
- How many infected contacts completed a regimen of treatment for LTBI?
- Did all identified cases complete an adequate treatment regimen?
- Did children under age 5 receive DOPT?
- Were HIV+ contacts strongly considered for DOPT?

The answer to these questions will help determine how successful the contact investigation has been.

Results of all TB contact investigation activities should be documented on the [Contact Investigation Record](#) and submitted to the TB Control Program upon completion (including names and locating information for any out-of-state contacts identified). Contacts residing outside of Utah require an Interjurisdictional Referral form be completed by the originating jurisdiction, and forwarded to the TB Control Program (see manual section on Interjurisdictional Referrals). Intrastate referral procedure will depend on the electronic capabilities of both the sending and receiving jurisdiction, but the TB Control Program must still be notified. The information will be compiled and evaluated by TB Control Program management staff as part of ongoing program evaluation activities.

References

[Contact Investigation Record. UDOH. Revised 2008](#)

[Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC](#)

[Tuberculosis and Air Travel, Guidelines for Prevention and Control. Second Edition, WHO 2006.](#)

[Workplace Contact Investigation Protocols. UDOH, Revised 2008](#)

Follow-Up Responsibility

TB Epidemiologist

*To calculate the infection rate among a given group of contacts:

- A. Determine the number of contacts with newly-identified positive TST/QFT.
- B. Determine the total number of contacts without a documented previous positive skin test: subtract the number of contacts with a documented previous positive skin test from the total number of contacts.
- C. Determine the infection rate: divide A by B and multiply by 100; the resulting percentage is the infection rate for the group of contacts.

INTERJURISDICTIONAL REFERRALS

Purpose

To establish a policy for continuity of care of clients who relocate in/out of local/state jurisdiction, or never lived in the originating jurisdiction.

Policy

When a client is moving out of the jurisdiction originating the case, or is discovered to be living in another jurisdiction, the originating department shall ensure that the necessary steps are taken to transfer the case to the receiving jurisdiction, as outlined below. The Utah Department of Health (UDOH) TB Nurse Consultant (when appropriate or requested) will ensure proper routing and follow-up, and report back to the originating department upon request.

Procedure

Patients moving out of Utah: All need to be closed by the local health department (LHD) with an Administrative LHD case status of "Out of State", and the [Interjurisdictional Referral](#) form (found at the end of this section) completed and forwarded to the Nurse Consultant, who will then forward to the appropriate state (or national) health department. Include pertinent paperwork as needed or requested (e.g. labs, radiology reports, prescriptions, monthly medication pick-up/patient assessment or DOT log, summary note). The Nurse Consultant will follow up with the receiving jurisdiction, and report back to the sending jurisdiction, as requested or required.

Patients moving into Utah: All Interjurisdictional Referrals coming into Utah must be routed through the UDOH TB Control Program. The Nurse Consultant will open a file in NEDSS and attach paperwork received from the sending jurisdiction. The Nurse Consultant will also notify the receiving jurisdiction by phone, email or thru the Trisano Task function in NEDSS; and will communicate with the sending jurisdiction as necessary. For those Utah districts not using NEDSS for non-Class B or non-contact Latent TB Infection (LTBI), the Nurse Consultant will route the paperwork via fax or email.

Patients moving within Utah: Since the state needs to track suspects, contacts, active cases, and Class Bs, please reroute in NEDSS and advise the Nurse Consultant and receiving jurisdiction by phone, email, or thru the Trisano Task function. The Nurse Consultant will be happy to assist as needed. For non-Class B and non-contact LTBI, *you may bypass the state, but be aware that not all LHDs are using NEDSS for LTBI.* (Check with the Nurse Consultant for the most up-to-date list.) Use the [Interjurisdictional Referral](#) form for intrastate transfers if the receiving or originating LHD will not use the NEDSS file. In all cases, include pertinent paperwork as needed or requested (e.g. labs, radiology reports, prescriptions, monthly medication pick-up/patient assessment or DOT log, summary note).

A database of all referrals that go through the UDOH TB Control program will be maintained.

Follow-Up Responsibility

TB Nurse Consultant

INTERJURISDICTIONAL TUBERCULOSIS NOTIFICATION

Referring

Jurisdiction city _____ county _____ state _____ Date sent ___/___/___
 Contact Person _____ Phone () _____ FAX () _____

- Verified case State reporting to CDC: _____ RVCT# _____ (attach RVCT) Not reported
 Suspect Case Close Contact Converter (LTBI) Source case investigation A/B Classified Immigrant

Patient name _____ Sex M F
Last First Middle

AKA _____

Date of Birth ___/___/___ Interpreter Needed? No Yes, specify language _____

New Address _____ Hispanic No Yes
Number/street/apt.

Race White Black Asian
 Am. Indian/Nat Alaskan
 Other: _____
 City/State/Zip Code _____

New telephone () _____ Date of expected arrival ___/___/___

New Health provider Unknown Known (name, address, phone) _____

Emergency contact: Name _____ Phone () _____
 Relationship _____

Clinical Information for this referred case/suspect index case for this contact not applicable

Date of Collection	Specimen Type	Smear	Culture	Susceptibility	Chest X-Ray	Other

Site(s) of disease: Pulmonary Other(s) specify all _____
 Date 1st of negative smear ___/___/___ Not yet Date of 1st negative culture ___/___/___ Not yet
 TB skin test #1: Date ___/___/___ Result _____ mm TB skin test #2: Date ___/___/___ Result _____ mm

Contact/LTBI Information

TB Skin Test Not Done

TST #1 Date ___/___/___ Result _____ mm TST#2 Date ___/___/___ Result _____ mm

CXR Not Done Date ___/___/___ Normal Other: _____

Last known exposure to index case ___/___/___ Place/intensity of exposure: _____

Medications this referred case/suspect this referred contact/LTBI Planned completion date ___/___/___

DRUG	DOSE	START DATE	STOP DATE

DOT No Yes; start date ___/___/___

Daily 1x W 2x W 3xW

Last DOT Date ___/___/___

Adherence problems/ significant drug side effects: _____

Patient given ___ days of medication

Comments: _____

For Non-class 3/5 referrals indicate if: Follow-up requested No follow up requested

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ISOLATION CONSIDERATIONS

Purpose

To establish a policy for determining when a client with active TB disease (ATBD) needs to be isolated, quarantined or have restricted activity to reduce disease transmission.

Policy

A client with ATBD will be considered infectious, and therefore capable of transmitting TB to others, when they have disease in the lungs, airways or larynx and have positive acid fast bacilli (AFB) sputum smears. Other factors that correlate with the contagiousness of an active case are the presence of cough, cavitation on chest radiograph, inappropriate or short duration of treatment, or poor clinical response to treatment. Transmission, although less likely, does occur with smear negative, culture positive clients. A facility (hospital, jail, or other congregate setting) housing a potentially infectious patient must consult with public health (the local or state health department) before discharging the person into the public.

Procedure

- a. A client who is considered contagious should be given a surgical mask to wear, instructed to remain at home, or evaluated for the need for hospitalization. The environment should be evaluated for high-risk contacts who may be at risk for developing disease.
- b. Clients are to remain in isolation until they meet the following criteria:

- They are on adequate therapy for 2-3 weeks
 - They have significant **clinical response to therapy** (i.e., reduction in cough, resolution of fever)
 - They have **three** negative AFB sputum smear results collected 8-24 hours apart, with at least one being an early morning specimen
- c. Clients with extrapulmonary TB are not infectious, unless they have pulmonary or laryngeal TB in addition to their extrapulmonary disease, or have an abscess or open lesion requiring treatment that may lead to aerosolization of wound drainage (has been documented, but is a rare occurrence). Wound care requires the use of an N-95 respirator, and the patient should be in airborne and contact isolation if the wound is weeping. Always keep a weeping wound covered.
- d. In general, children who have pulmonary TB are less likely to spread TB than adults because children do not usually develop a cough strong enough to aerosolize TB organisms. However, transmission from children can occur in certain situations, especially if they are diagnosed with upper-lobe, cavitary disease. Therefore, children with TB should be evaluated for infectiousness using the same factors as above for adults.

- e. If a client fails to adhere to isolation and is considered a public health risk, consult the TB Control Program, and refer to manual section 'Isolation of Non-adherent Clients with Tuberculosis.'
- f. If there is a concern of an infectious person travelling on an airplane, the CDC can add them to their 'Do Not Board' list. This will need to be done through the TB Control Program, and the final determination on adding or deleting someone from this list will be the sole responsibility of the CDC. The CDC can also establish a 'border lookout' if there is a concern of an infectious person entering the U.S. by means other than air transportation. See the manual section, Travel Restrictions, for more details.

References

[Core Curriculum on Tuberculosis](#), What the Clinician Should Know. Fourth Edition 2000. (Page 88).

[Federal Air Travel Restrictions for Public Health Purposes --- United States, June 2007--May 2008](#)

[Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, June 2007.](#)

[Tuberculosis and Air Travel. Guidelines for Prevention and Control. WHO 2006.](#)

Utah Department of Health. (2009). [COURT-ORDERED TREATMENT AND INVOLUNTARY – ISOLATION GUIDELINES FOR THE CONTROL OF TUBERCULOSIS.](#)

Follow-Up Responsibility

TB Nurse Consultant

TRANSMISSION PREVENTION & INFECTION CONTROL PLANNING

Purpose

To establish a policy for the community to prevent the transmission of tuberculosis through an effective infection control plan.

Policy

In accordance with federal and state law, an effective TB infection control program must be implemented by all health care facilities, ambulatory-care settings, emergency departments, and other health care settings, and reviewed annually. The extent of the TB infection control program should be based on a risk assessment for transmission of *M. tuberculosis* and appropriate control measures to minimize that risk in a given setting.

Procedure

- a. Personnel should be assigned to perform an assessment of the risk for transmission of TB in a particular setting, area or occupational group based on:
 - The profile of TB in the community
 - The number of infectious TB clients admitted to the area or ward, or the estimated number of infectious TB clients to whom health care workers (HCWs) in an occupational group may be exposed
 - The results of analysis of HCW skin test conversions (where applicable) and possible person-to-person transmission of MTB

- b. **Administrative controls** to reduce the risk of exposure to persons with infectious TB should include:
 - Developing and implementing effective written policies and work practices to ensure the rapid identification, isolation, diagnostic evaluation, and treatment of persons likely to have ATBD
 - Implementing effective work practices among health care workers in the health care facility

c. Written TB infection control protocols must be developed to include:

- Triage to promptly identify clients who may have TB
- Promptly evaluate clients who have TB symptoms
- Place client in a separate area apart from other clients and not in open waiting areas (ideally in a room or enclosure with special ventilation maintained under negative pressure)
- Give client a surgical mask to wear until he/she can be transported to an appropriate isolation room or facility, or until he/she leaves the building
- Give the client a tissue and instruct them to cover their mouth and nose when coughing or sneezing
- Schedule appointments to avoid exposing other clients, especially HIV-infected or immunocompromised persons
- Avoid performing a cough-inducing procedure (e.g., sputum inductions) on clients who may be infectious unless the procedure is absolutely necessary and performed using local exhaust ventilation devices such as booths or special enclosures or in a room that meets ventilation requirements for TB isolation
- Allow enough time to pass for at least 99% of airborne contaminants to be removed before placing another client in a room or area previously occupied by an infectious client (Consult the manufacturers operating instructions or a qualified engineer to define the length of time needed to remove at least 99% of airborne contaminants)
- If the client is placed in TB isolation and is not wearing a mask, all persons entering the room should be fit-tested for and must wear respiratory protection that meets minimum requirements for TB transmission prevention (at least an N-95 mask)
- TB transmission prevention precautions can be discontinued if the diagnosis of TB is ruled out or if contagiousness is ruled out
- Visitors should be limited to close contacts who have already been exposed during the infectious period. They should be offered respiratory protection (i.e., N95) and should be instructed by health care workers on the use of the respirator before entering an airborne infection isolation room. It is recommended that children not be allowed to visit a potentially infectious case.

d. Personnel must be educated and trained, as appropriate for their work responsibilities and duties, regarding tuberculosis. Training should occur before initial assignment, and the need for additional training re-evaluated periodically. Education should include: TB transmission, pathogenesis, diagnosis, difference between therapy for latent TB infection and disease, signs and symptoms of TB, higher risks of disease associated with immunocompromised persons, prevalence of TB in the community and facility, transmission prevention precautions, situations that increase risk for exposure, purpose of tuberculin skin test (TST) or Quantiferon (QFT), significance of a positive TST or QFT result and recommended follow-up, disease reporting procedures (including symptoms in health care workers), confidentiality, information regarding BCG vaccine associated with principles of TST and QFT, and options for work reassignments for immunocompromised HCWs.

- e. Personnel must be counseled and screened for TB and TB infection, which includes developing and implementing a tuberculin skin testing or QFT program for persons in the facility with the potential for exposure to TB. HCWs, including home health nurses, clinic workers and emergency medical technicians, should be included in a TST or QFT and prevention program if the risk assessment indicates that they are at risk for exposure. This means TST upon employment **using the two-step method, (if QFT is used, two-step testing is not necessary or recommended)** and at repeated intervals determined by their risk of exposure thereafter. Any worker who develops symptoms of TB disease or whose TST or QFT result converts to positive should be evaluated promptly and reported to the TB Control Program.
- f. **Engineering controls** to prevent the spread and reduce the concentration of infectious droplet nuclei in the air, include:
- Ventilation systems to maintain negative pressure and exhaust air properly in TB isolation rooms.
 - HEPA filtration and ultraviolet irradiation in high-risk areas.
- g. A respiratory protection program for personnel must include: The selection of **NIOSH-approved particulate respiratory protection** which meets the minimum requirements for TB transmission prevention, medical evaluation and fit testing, training in the use and maintenance of respirators, and program evaluation.
- h. Facilities that admit TB patients must initiate isolation in a private isolation room with special ventilation maintained under negative pressure relative to other parts of the facility. The room must be monitored daily while in use to assure that appropriate ventilation is maintained, the door must remain closed, and the client should only leave the room for medically essential purposes. For the safety of all workers and visitors, the isolation room must be clearly identified as housing a potentially infectious patient. When the client must leave the room, they should wear a surgical mask that covers the nose and mouth at all times. Clients who are placed in isolation rooms should be educated about the transmission of TB, the reasons for isolation, and the importance of staying in their rooms. The client should also be instructed to cover their nose and mouth when coughing or sneezing.

The number of persons entering the room should be limited and those entering the room must wear appropriate personal respiratory protective devices. These devices must adequately fit the worker or visitor and be “user seal” checked before use. **Clients evaluated or admitted to an inpatient facility and determined to have suspected or known active TB disease (ATBD), which is infectious, cannot be released until the state or local health agency has made arrangements for appropriate post discharge management.** They are considered noninfectious when all of the following criteria are met:

- They are on adequate therapy for 2-3 weeks
- They have significant **clinical response to therapy** (i.e., reduction in cough, resolution of fever)
- They have **three** negative AFB sputum smear results collected 8-24 hours apart, with at least one being an early morning specimen

Proper isolation procedures must be maintained while at the facility. Isolation should only be discontinued when it is determined that the patient is no longer contagious. Settings/facilities unable to adequately evaluate patients who have, or are suspected to have, infectious TB should develop a triage system to identify, manage and refer these patients to another facility for diagnostic evaluation and treatment.

- i. Some clients with suspected or known ATBD may be evaluated or treated in an outpatient setting under the supervision of, or directly provided by the local public health agency.
- j. Contact the TB Control Program for consultation regarding the appropriateness of home placement for individual clients. Clients who are placed at home should be instructed to cover their nose and mouth when coughing or sneezing and be instructed on the importance of taking prescribed therapy and directly observed therapy (DOT). Health care workers or visitors must wear appropriate respiratory protection when visiting clients with confirmed or suspect infectious TB. Avoid performing cough-inducing procedures on clients who are infectious or use appropriate respiratory protection and perform in a well-ventilated area.

References

[CDC. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005. MMWR 2005; 54:RR-17.](#)

[Core Curriculum on Tuberculosis](#), What the Clinician Should Know. Fourth Edition 2000. (Page 87-95).

Follow-Up Responsibility

TB Epidemiologist

IMPROVING ADHERENCE WITH THERAPY

Purpose

To establish a policy for improving adherence to therapy for clients with latent TB infection (LTBI) or active TB disease (ATBD).

Policy

Adherence to medication regimens for tuberculosis is a priority and can be accomplished through the use of Directly Observed Therapy (DOT), incentives and enablers. DOT is considered the standard of care for clients with ATBD, is required by the [Utah Administrative Code Communicable Disease Rule \(R388-804\)](#), and is recommended for use with high-risk clients with LTBI. The responsibility for successful treatment is clearly assigned to the public health program or private provider, not to the client.

Procedure

- a. [Directly Observed Therapy \(DOT\)](#) is the standard method of providing treatment to all persons with ATBD. Many health care providers believe they can predict whether a particular client will take medication as prescribed. However, research data indicate that providers, on the average, are correct only 50% of the time. In addition, DOT allows for the immediate detection of non-compliance so that actions can be taken to avoid treatment failure.
- b. Health care providers must recognize that even with DOT, additional strategies and efforts are necessary for treatment success. It is important to use any tool available in order to promote adherence to therapy.
- c. Consider entering into a “[contract](#)” with the client that clearly states the client’s responsibilities in regards to treatment.
- d. Learn as much as possible about your client’s health history, beliefs and attitudes about TB, sources of social support, and potential barriers to treatment prior to starting treatment.
- e. Work with a medical interpreter or a person of the same cultural background as the client, if possible.
- f. Designate a person to do DOT who does not have strong emotional ties with the client. Suitable designees might include school nurse/staff, employee health, public health, or visiting nurse, clergy, or other responsible person. Family members are not the appropriate choice to assist because of power struggles and family dynamics.

- g. Mutually agree on a time and location for DOT; be creative and flexible.
- h. Be aware of clients who may require techniques to assess for complete ingestion of medication (e.g., hiding pills in mouth, vomiting after pills swallowed).
- i. Use incentives and enablers to assist in improving adherence. The TB Control Program can assist with rent, food coupons, payment of limited bills, and rewards for specific milestones in treatment. Housing is available in some communities. Specific incentives are available to assist young children and contacts to cases of Active TB Disease to complete treatment for LTBI. Contact the TB Control Program for more information on the use of incentives and enablers.
- j. Look for early warning signs of future adherence problems (e.g., client feels medicine is no longer needed because they are feeling well, difficulty in accessing health care, transportation issues, worksite concerns, etc.). See 'Procedure for Managing Persons at Risk to Be Lost to Treatment' in the [COURT-ORDERED TREATMENT AND INVOLUNTARY – ISOLATION GUIDELINES FOR THE CONTROL OF TUBERCULOSIS](#)).
- k. Provide effective education to clients and key individuals in their environment.
- l. Provide client with needed health or social services or make referral to other health or social service agencies.
- m. Use a team of personnel whose members work together to assist each client in completing treatment.
- n. Establish an efficient, client-friendly clinic system for scheduling appointments, keeping records, and monitoring adherence.
- o. If, despite your best efforts, the client does not adhere to DOT voluntarily, Utah State statutes allow court-ordered isolation/quarantine. See next manual section on 'Quarantine' or [COURT-ORDERED TREATMENT AND INVOLUNTARY – ISOLATION GUIDELINES FOR THE CONTROL OF TUBERCULOSIS](#)). Contact TB Control Program for more information and assistance.

References

[ATS/CDC/IDSA Treatment of Tuberculosis, June 2003](#)

[CDC Self Study Module on TB, Module 9 Patient Adherence to TB Treatment](#)

[Core Curriculum on Tuberculosis](#), What the Clinician Should Know. Fourth Edition 2000.

[Using Incentives and Enablers in the Tuberculosis Control Program. Columbia: American Lung Association of South Carolina and South Carolina Department of Health and Environmental Control, Division of Tuberculosis Control, 1989.](#) (Table 9.4)

Follow-Up Responsibility

TB Nurse Consultant

ISOLATION OF NON-ADHERENT CLIENTS WITH ATBD

Purpose

To establish a policy for use of isolation with non-adherent clients with highly suspect or confirmed tuberculosis.

Policy

In partnership with the local health departments (LHDs) and health care providers, the Utah Department of Health is responsible for implementation of the [Utah Administrative Code, Title 26, Chapter 6b, Communicable Diseases Treatment, Isolation, and Quarantine Procedures](#). This statute delineates the process for ordering involuntary treatment, isolation, and quarantine of persons with public endangering communicable diseases who are unable or unwilling to fully participate in their prescribed treatment.

Procedure

- a. Within the context of tuberculosis disease, the first priority of public health is to prevent further transmission of tuberculosis in the community by an infectious individual. This is accomplished by identifying all persons with highly suspect or confirmed active TB disease (ATBD), and ensuring appropriately prescribed treatment is completed. **In order to safeguard appropriate use of scarce resources and comply with the civil liberty rights of the individual, it is recommended that the less restrictive levels of care be pursued aggressively before progressing to more restrictive levels.**

The levels of care are:

- **Level of Care 1:** Prescribed outpatient treatment, including directly observed therapy (DOT), provided by a health care provider, clinic, or LHD for those individuals both willing and able to fully participate in the treatment of their active tuberculosis disease.
- **Level of Care 2:** Enhanced provision of outpatient treatment with use of incentives, enablers, directly observed therapy (DOT), electronic surveillance, etc., for individuals who indicate an unwillingness or inability to undergo prescribed medical treatment, or have demonstrated poor adherence to treatment that has been previously initiated. Implementation of these additional measures ensures completion of treatment.
- **Level of Care 3:** Secure/locked housing such as long-term care settings, for those persons who have not responded to Level 2 strategies and are non-infectious. Adequate measures are provided that minimize/eliminate the flight risk of these individuals (this measure is currently not available in Utah).

- **Level of Care 4:** Secure/locked hospital unit or facility offering negative pressure isolation and staff trained in tuberculosis control for accommodating clients with ATBD who have failed adherence to treatment at less restrictive levels of care.
- b. The Advisory Council for the Elimination of Tuberculosis defines non-adherent behavior as the inability or unwillingness to follow a prescribed treatment regimen. This may be demonstrated by refusing medication, taking medication inconsistently, missing healthcare provider appointments, failing to report for DOT, disregarding masking requirements, or disregarding travel restrictions. Individuals appropriate for court-ordered evaluation may also include contacts of active TB cases who are flight risks.
 - c. Although many health care providers believe they can predict a client's adherence to treatment, research indicates their predictions are correct only about 50% of the time. **The strongest predictor of adherence to treatment is the client's history of adherence. The strongest predictor of future adherence problems is a history of non-adherence to treatment, particularly with TB medications.** If there is documentation of non-adherence with previous TB treatment or therapy for LTBI, it is unlikely that the client will be successful in adhering to the current treatment regimen.
 - d. Other indicators for high-risk of non-adherence include: history of other medical treatment non-adherence; substance abuse; mental, emotional, or certain physical impairments that interfere with the ability to self-administer medications; children and adolescents. It is recommended that health care providers formally evaluate each client's potential non-adherence at the time TB medication is prescribed. The issue of treatment adherence is addressed in detail in the publication [Improving Patient Adherence to Tuberculosis Treatment, U.S. Department of Health and Human Services and Centers for Disease Control and Prevention \(1994\)](#). It is also recommended that a treatment plan is used as a contractual agreement. See the following link for an example: http://www.health.utah.gov/cdc/tbrefugee/forms/lhd_tbTreatmentplan.pdf
 - e. If non-adherence with prescribed TB medications is a concern, contact the TB Control Program to discuss prior to initiating any isolation procedures. Documentation of non-adherence is essential to success with this process.

References

[Improving Patient Adherence to Tuberculosis Treatment, U.S. Department of Health and Human Services and Centers for Disease Control and Prevention \(1994\)](#).

[Procedure for Managing Persons with Suspected or Confirmed Active TB Disease Who are at Risk to be Lost to Follow Up or Who Become Lost to Treatment](#)

Utah Department of Health. (2009). [COURT-ORDERED TREATMENT AND INVOLUNTARY – ISOLATION GUIDELINES FOR THE CONTROL OF TUBERCULOSIS.](#)

Follow-Up Responsibility

TB Control Program Manager

TRAVEL RESTRICTIONS

Purpose

To establish a policy providing guidance when a suspect, or confirmed infectious TB case indicates a desire to travel out of jurisdiction.

Policy

The state and/or local health department shall assume the responsibility of identifying the steps necessary to curb transmission of TB, of informing the patient of their responsibilities, and of enforcing the treatment plan as documented (see manual sections on treatment of active disease, and isolation). As it may sometimes become necessary to administratively enforce travel restrictions, procedures are in place to assist in the authority of such restrictions.

Procedure

- a. Ensure that the patient has been thoroughly informed of their responsibility to follow the treatment plan, and of the health department's ability to involuntarily restrict their movement and behavior.
- b. If the patient expresses a desire to leave the jurisdiction of the local health department providing case management, establish a plan of action that will not compromise the public health. This includes maintaining a verifiable continuation of directly observed therapy, and restrictions related to infectiousness.
- c. If the patient is planning to use any form of mass transit, determine the feasibility of such travel and counsel the patient accordingly. This would include bus, train, ship, or plane. Patient infectiousness and need for voluntary isolation is discussed in the manual section, Isolation Considerations; the health department's ability to restrict movement and behavior is discussed in the manual section, Isolation of Non-Adherent Clients with ATBD.
- d. If said travel will involve something other than simply local travel, the Centers for Disease Control and Prevention (CDC) maintains a 'Do Not Board' procedure to prevent travel from occurring. Utilization of CDC's 'Do Not Board' procedure requires that specific steps are followed and case information provided to assist in the decision to include the patient on a 'Do Not Board' list. Only CDC can add a name to/remove a name from this list, under the advice of the jurisdiction managing the case.

Protocol for Air Travel 'Do Not Board List'

In the event that an individual with suspected or confirmed infectious ATBD intends to attempt to board an airplane (or other mode of transportation, e.g. ship, long-distance train or bus), the CDC maintains a 'Do Not Board List' in order to prevent such an individual from doing so. CDC has the final authority as to who to include on this list and when to remove them. Inclusion on this list also places the individual on a 'Border Watch List' in order to restrict such a person's movement across the Mexican or Canadian borders, and isolate them as appropriate.

If an individual is to be considered for this action, the following procedure is required:

The local health department, or other provider, should contact the TB Control Program as soon as an individual's intent is known. The minimum amount of information needed is the patient's name, sex and date of birth. Additional information such as immigration status and citizenship, as well as specific travel plans will be helpful. Contact Cristie Chesler at 801-538-9465 or cell # 801-971-2866. If she cannot be reached, contact Larry Niler at 801-538-9906 or cell # 801-232-7916. Cristie and/or Larry will be able to speak with CDC 24/7, and will be able to take action within 2 hours or less. **CDC and UDOH request that initial communication be facilitated through the UDOH TB Control Program. Local health departments are asked not to call CDC directly.**

A representative from the state and/or local health department needs to be available for a conference call to review the case. Be ready to discuss clinical status (including infectiousness, length of time on adequate regimen, drug resistance), compliance issues, whether (and when) or not the patient has been instructed not to travel, and actions taken to prevent travel.

If the individual does attempt travel, the local health officer should initiate a temporary administrative order for involuntary isolation, and proceed accordingly. See [Quarantine Manual](#) for further details.

CDC will determine whether the individual warrants inclusion on the list. The TB Control Program will contact CDC when it is determined that the individual no longer requires travel restrictions.

For internal use only:

Our CDC contact is Kimberly Crocker, Officer in Charge, CDC, Division of Global Migration and Quarantine, Los Angeles Quarantine Station, Office # 310-215-2365 or Cell # 404-512-2487, email kcrocker@cdc.gov. If after hours, the office number will refer to an after hours # -CDC DEOC which will connect to the duty officer on call. CDC will then determine whether inclusion is warranted. If time is of the essence, Kimberly can be reached on her cell.

LN/Feb/2010

- 1) We are providing a guide for collection of information that may be useful to CDC at the end of this chapter.

References

[Federal Air Travel Restrictions for Public Health Purposes --- United States, June 2007--May 2008](#)

[Tuberculosis and Air Travel. Guidelines for Prevention and Control. WHO 2006.](#)

Follow-Up Responsibility

TB Nurse Consultant

DNB Questionnaire for Local Health Departments

Demographic Information:

- 1) Patient's name (last, middle, first): _____
- 2) Aliases: _____
- 3) Gender: [] Female [] Male [] Unknown
- 4) Date of Birth: _____
- 5) Race: _____
- 6) Ethnicity: _____
- 7) Nationality: _____
- 8) Aliases' Date of Birth: _____
- 9) Identifying features (photo if available):

10) What is the patient's legal status in the United States?

- a. U.S. Citizen
- b. Legal permanent resident
- c. Asylee
- d. Parolee
- e. Refugee
- f. Visa Waiver
- g. B1/B2 Tourist/Business
- h. F1/F2 Student Status/Family of
- i. H1/H2 Working Group/Family of
- j. J1/J2 Exchange Visitor/Family of
- k. Unknown
- l. Other: _____

11) Documents used to establish patient's identity:

- a. Birth certificate
- b. Social Security card and number: _____
- c. Passport
- d. Driver's license (state, number and expiration date): _____
- e. Class B papers
- f. Other: _____

12) Passport Country (can list more than one if patient has more than one passport):

13) Passport Number(s):

14) Is the patient currently in the U.S.? If yes, location:

If no, location:

15) Family/Emergency Contact Information:

- a. Relationship: _____
- b. Name: _____

c. Address (street, city, state, country): _____

d. Phone(s): _____

e. Relationship: _____

f. Name: _____

g. Address (street, city, state, country): _____

h. Phone(s): _____

i. Relationship: _____

j. Name: _____

k. Address (street, city, state, country): _____

l. Phone(s): _____

Travel Plans:

1) Pending travel dates: _____

2) Reservation details (destination, carrier(s), time(s), ticket number(s)):

Clinical Information:

1) Is the patient's disease confirmed? Yes, confirmed No, suspect

2) What was the date (mm/dd/yy) of the confirmed or suspect diagnosis? _____

3) Please note clinical signs, symptoms and any other additional information that supports suspected/confirmed diagnosis, and whether they are current:

4) Has the patient improved since starting drug therapy? Yes No

Explain: _____

5) What treatment is the patient currently receiving? List all drugs, dosages, administration routes and frequency: _____

6) Is patient on DOT by a health care worker? Yes No Unknown

7) How many days a week is DOT? _____

8) Treatment start date: _____

9) Is patient compliant with treatment? Compliant Non-compliant Unknown

10) Does patient have a prior history of TB? Yes No Unknown

a. If yes - date of previous TB diagnosis: _____

b. If yes - prior TB treatment (please list medications if known): _____

c. If yes: was patient compliant with prior TB treatment? Yes No Unknown

11) What is current TB site? Circle all that apply:

a. Pulmonary

b. Extra-pulmonary

c. Laryngeal

d. Unknown

12) Date and results of CXR: _____

Cavity Miliary

13) Date and results of CT scan: _____

Cavity Miliary

14) Was sputum collected? If yes, how?

a. Induced

b. Spontaneous

c. Unknown

d. Bronchial washings (bronchoscopy)

15) Was sputum collected in the U.S.? U.S. Other country: _____

16) **Sputum Results Table:**

Sputum Collection Date	AFB Smear*	Culture**	MTD***

*Options for AFB Smear are 1+, 2+, 3+, 4+, Rare, Few, Numerous

** Options for Culture are MTB Complex, Atyp, Negative, Pending

***Options for MTD are positive, negative, pending

17) Culture sensitivities done? If yes:

a. Pan-sensitive or resistance to no more than one of the first line agents

b. MDR

c. XDR

d. Other: _____

e. Pending

18) If drug sensitivities are pending, is patient a contact to a drug-resistant case? Yes No

Unknown - If yes, what is the index case's resistance pattern? _____

UNIFIED STATE LABORATORIES / MYCOBACTERIOLOGY LABORATORY

Purpose

The [*Unified State Laboratories: Public Health*](#) tests for the presence of acid-fast bacilli (AFB) in clinical specimens submitted by private health care providers and public agencies. The laboratory also determines the identification of AFB species and performs susceptibility testing on *Mycobacterium tuberculosis* complex. Private laboratories also refer isolates to the laboratory for identification and susceptibility testing. With the exception of blood cultures for AFB, these services are provided at no charge.

Policy

Submitting Specimens

Specimens should be delivered to the *Unified State Laboratories: Public Health* at 4431 South 2700 West, Taylorsville, Utah either by courier or U.S. mail as soon as possible after collection. See 'Specimen Collection and Transport' section in this manual for detailed instructions.

Testing Schedule

Specimens are processed once a day, Monday through Thursday and Saturday for AFB culture. Specimens that are received in the laboratory by 10:30 A.M. are included in that day's "run".

AFB smears from specimens processed Monday through Thursday are generally read by 5:00 P.M. on the same day. AFB smears from specimens processed on Saturday are completed on the following Monday morning.

Identification and susceptibility testing is performed as required and completion of testing in some cases can take several weeks.

If a patient is still producing positive cultures after two months treatment, the isolate will be identified to determine if it is *M. tuberculosis*. If the isolate is *M. tuberculosis* the susceptibility testing will be repeated.

Procedure

Testing Methods

AFB smears are stained using the Auramine O method and examined using fluorescent microscopy.

Specimens that are likely contaminated with other bacteria are processed using the NALC-NaOH method and inoculated to 7H11 solid medium and to BACTEC MGIT broth medium.

Specimens from sterile sites are inoculated directly to 7H11 solid medium and to BACTEC MGIT broth medium.

Blood and bone marrow specimens are inoculated to BACTEC Myco/F-Lytic broth.

Identification is determined by Accuprobe DNA probe or DNA Sequencing.

Susceptibility testing is performed using the BACTEC MGIT 960.

Reporting Schedule

AFB reports are made to the requesting provider by the method they have specified. This can be by U.S. mail, fax, or E-mail.

AFB smear results are generally reported at 4:00 P.M. on the day they are processed.

Positive cultures are reported as they are found and identification and susceptibility results are reported as the testing is completed.

Negative cultures are held for a minimum of six weeks. Final "no growth" cultures are reported once a week.

DNA Genotyping of *Mycobacterium tuberculosis*

DNA genotyping of *M. tuberculosis* is a useful epidemiological tool that can be used to detect possible outbreaks, track the transmission of tuberculosis in the population or obtain evidence that cross contamination has occurred in the laboratory. The Centers for Disease Control and Prevention has contracted with several Public Health laboratories to provide this service to the states.

The initial isolate from each new Utah patient found to have *M. tuberculosis* complex in specimens submitted to the *Unified State Laboratories: Public Health* will be sent to a CDC contract laboratory for DNA genotyping. Other laboratories performing AFB testing on Utah residents are requested to send isolates of *M. tuberculosis* to the *Unified State Laboratories: Public Health*, which will then submit them for genotyping.

There are cases where additional isolates may be submitted. Patients whose isolates have become resistant and patients who have become negative on culture and then have reverted to positive will have the second isolate submitted to determine if the patient has become infected with a new strain. The TB Program may also request additional submission of isolates when they feel it is appropriate.

Nucleic Acid Amplification Testing, a direct method of detecting MTB RNA from raw sample was not currently available at the *Unified State Laboratories: Public Health* at the time of this manual revision, but it is performed at several private laboratories. It is anticipated that it will be offered at the *Unified State Laboratories: Public Health* in the near future. Please check with the TB Control Program for the most current information.

Molecular Beacons, and Molecular Detection of Drug Resistance are two new methods of rapid sensitivity testing that can be ordered if specific criteria are met. These are not performed at the *Unified State Laboratories: Public Health*. For further information, contact the TB Control Program.

References

[Guide to the Application of Genotyping to Tuberculosis Prevention and Control. CDC. Retrieved 1/14/09.](#)

[Murray et al. 2003. Manual of Clinical Microbiology, 8th ed. American Society of Microbiology, Washington DC.](#)

Public Health Mycobacteriology, A Guide for the Level III Laboratory, Centers for Disease Control. 1985.

[Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis](#) *MMWR* 2009; 58 (01); 7-10

Unified State Laboratories: Public Health Contacts

The following contacts can all be reached through the main laboratory phone number: **(801) 965-2400**.

Barbara Jepson, MPA, MT(ASCP)

Dan Andrews, MS, MT(ASCP)

Stephanie McGee

Chris Peper, BS, MT(ASCP) Section Chief, Technical Services

[New Laboratory Location](#) – Unified State Laboratories: Public Health

UNIFIED STATE LABORATORIES

SPECIMEN

COLLECTION AND TRANSPORT

Purpose

To establish a policy for collection and transportation of specimens submitted for mycobacterial culture.

Policy

The Utah Department of Health (UDOH) [Unified State Laboratories: Public Health](#) tests a variety of specimens for mycobacterial culture. These tests are provided at no charge to local health departments and health care providers in the state of Utah. The quality of the specimens collected and proper transport of those specimens to the laboratory are critical to the successful isolation of AFB (acid-fast bacilli).

Procedure

- a. Specimens should be collected and submitted in sterile, leak proof, disposable, appropriately labeled, laboratory-approved containers. **Label sputa collection container before giving to the client or collecting specimen.** All specimens can be collected in the sterile collection tubes supplied by the Utah Department of Health *Unified State Laboratories: Public Health*. Do not use waxed containers, as they may provide false-positive smear results.
- b. Initial specimens should ideally be collected prior to the initiation of anti-mycobacterial chemotherapy. Specimens should be collected aseptically, or the collection method should bypass areas of contamination as much as possible in order to minimize contamination with indigenous flora. Avoid contamination with tap water or other fluids that may contain either viable or nonviable environmental mycobacteria, since saprophytic mycobacteria may produce false-positive culture and/or smear results.
- c. Sputum: Sputum, both expectorated and induced, is the principal specimen obtained for the diagnosis of pulmonary tuberculosis. Collect 3 specimens, preferably 5-10 ml, from a deep, productive cough at least 8-24 hours apart, with at least one being an early-morning specimen. It is recommended that dentures, if present, be removed before collection of sputum specimens. If the specimen is not an early morning sample, or if the client has eaten or used tobacco, rinse mouth with water. For expectorated sputum, clients should be instructed to cough deeply to produce specimens distinct from saliva, or nasopharyngeal discharge. The client should be instructed to press the rim of the container under the lower lip at the time of expectoration to minimize the chance of contaminating the outside of the container. For induced sputum, use sterile hypertonic saline,

and avoid sputum contamination with nebulizer reservoir water to avoid possible false-positive culture or smear results due to saprophytic mycobacteria. Indicate on the requisition whether the specimen is induced or expectorated to ensure proper handling, as induced sputa appear watery and much like saliva. Pooled sputum specimens are unacceptable specimens for mycobacterial culture because of increased risk of contamination.* (*See end of this section for a tip on sputum collection with patients having difficulty with spontaneous production.*)

- d. Bronchoalveolar Lavage Fluids and Bronchial Washing: Bronchial washings, bronchoalveolar lavage fluid, transbronchial biopsy specimens, and brush biopsy specimens may all be collected during bronchoscopy. Collect at least 5 ml of bronchial washing or bronchoalveolar lavage fluid in a sterile container. Avoid contaminating the bronchoscope with tap water. Frequently, bronchoscopy causes the client to produce sputum spontaneously for several days after the procedure, and specimens collected a day or two after bronchoscopy enhance detection of mycobacteria.
- e. Gastric Lavage Fluids: Aspiration of swallowed sputum from the stomach by gastric lavage may be necessary for infants, young children and the obtunded. On each of 3 consecutive days, collect 5-10 ml of fluid in a sterile container without a preservative. Fasting, early-morning specimens are recommended in order to obtain sputum swallowed during sleep. Gastric contents are initially collected with a sterile suction syringe connected to a tube inserted in the stomach. Sterile saline (20-30 ml) may then be induced into the stomach and aspirated as lavage fluid. The gastric contents and lavage fluid may be pooled in a sterile container. These specimens should be processed within 4 hours. If the specimens cannot be processed within 4 hours, adjust fluid to neutral pH with 100mg of sodium carbonate immediately following collection. Unneutralized specimens are not acceptable, as acid is detrimental to the mycobacteria.
- f. Blood: Cultures for the isolation of mycobacteria from blood are usually reserved for the immunocompromised clients. The BACTEC Myco/F-Lytic bottle is specifically designed for the recovery of mycobacteria from blood. The Myco/F-Lytic medium can be directly inoculated with 5ml of blood. If blood needs to be transported before inoculation of BACTEC medium, use sodium polyanetholsulfonate (SPS) or heparin as an anticoagulant. Blood collected in EDTA (purple top tube) or blood that is coagulated is not acceptable.
- g. Urine: Collect the first morning specimens, either by catheterization or midstream clean catch, into a sterile container on 3 consecutive days. Appropriate cleaning of genitalia should precede collection. Organisms accumulate in the bladder overnight, and the first morning void provides best results. Specimens collected at other times are dilute and thus not optimal. A minimum of 40 ml is usually required for culture.
- h. Stools: Stool specimens (>1g) should be collected in sterile, wax-free, disposable clean containers or transferred from a bedpan or from plastic wrap stretched over the toilet bowl and sent directly to the laboratory.

- i. **Body Fluids:** Body fluids (cerebrospinal (CSF), pleural, peritoneal, pericardial, etc.) are aseptically collected by aspiration or surgical procedures. Collect as much as possible (10-15ml minimum) in a sterile container or syringe with a luer tip cap. CSF culture requires at least 2 ml.
- j. **Tissues (Lymph Node, Skin, Other Biopsy Material):** Aseptically collect at least 1g of tissue, if possible, into a sterile container without fixative or preservative. Do not immerse in saline or other fluid or wrap in gauze. For cutaneous ulcers, collect biopsy material from the periphery of the lesion. Specimens submitted in formalin are unacceptable.
- k. **Specimen Transport:** All specimens should be refrigerated (except blood) prior to transport to the laboratory unless transport to the laboratory is anticipated within 1 hour of specimen collection. When shipping specimens:
 - Make sure that the specimen is in the appropriate sterile specimen collection container.
 - Seal the container and label appropriately.
 - Place the sealed specimen container into a second shipping container. A test requisition form must accompany each specimen and is also placed in the second container.

The test requisition forms can be obtained from the laboratory Technical Services group at: (801) 965-2400 or on the internet at: <https://health.utah.gov/lab>, click on "Microbiology Client Services Manual" under Bureau of Microbiology.

If a test request form is obtained from the internet it is essential that the proper provider code be entered in the appropriate field. This code determines where test results are sent. If you do not know your provider code, call the Technical Services group or the AFB laboratory at (801) 965-2400.

Specimen Containers suitable for mailing clinical specimens in the U.S. mail can be obtained from the Technical Services group by calling (801) 965-2400. These containers are designed primarily for sputum specimens and have prepaid postage.

Send specimens to:

**Unified State Laboratories: Public Health
4431 South 2700 West
Taylorsville, UT 84119-8600**

[Map & Directions](#)

References

[CDC. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005. MMWR 2005; 54:RR-17.](#)

U.S. Department of Health and Human Services 1985: Public Health Mycobacteria: Guide for Level 3 Laboratory.

Follow-Up Responsibility

Dan Andrews, Unified State Laboratories: Public Health

*Patients who have difficulty producing sputum may find it helpful to deep-breathe steam. One method might be to inhale the vapors from a freshly boiled pot of water, in order to loosen deep secretions.

Unified State Laboratories: Public Health QuantiFERON[®]-TB Gold In-Tube: FAQ's

Test Principle

The QuantiFERON[®]-TB Gold In-Tube assay is an in vitro diagnostic laboratory test that aids in the detection of infection with *Mycobacterium tuberculosis*. It uses human whole blood, with patented assay technology based on the measurement of Interferon-gamma (IFN- γ) secreted from stimulated T-cells previously exposed to *Mycobacterium tuberculosis*. The QuantiFERON[®]-TB Gold In-Tube assay is a straightforward laboratory test that involves simple steps. There are several options available for your facility depending on your resources and preferences. Most facilities choose to simply draw blood and send it to the *Unified State Laboratories: Public Health* within 15 hours, but if distance or schedule do not allow for arrival at the public health lab within the 15-hour limit, samples may be incubated and centrifuged at your facility. The following steps outline the procedures for the three different options:

Option 1 (preferred): On-Site Collection (15 hour time constraint)

1. Collect 1 mL blood into each of the three Blood Collection Tubes (Gray, Red, and Purple).
2. After blood collection, mix the tubes thoroughly, by shaking vigorously for at least 5 seconds (please remember that simply inverting the tubes is not sufficient).
3. Transport tubes at room temperature. Tubes need to arrive at the laboratory within 15 hours of collection, and by 4:00 P.M. Mon-Fri.

Option 2 (not recommended): On-Site Collection and Incubation (70 hour time constraint, upright transport)

1. Collect 1 mL blood into the three Blood Collection Tubes (Gray, Red, and Purple).
2. After blood collection, mix the tubes thoroughly, by shaking vigorously for at least 5 seconds (please remember that simply inverting the tubes is not sufficient).

3. As soon as possible, and within 16 hours of collection, incubate tubes upright at 37°C for 16-24 hours. Be certain to document date and time for each step.
4. Tubes need to arrive at the laboratory within 72 hours of incubation completion, and by 4:00 P.M. Mon-Fri.

Option 3 (discouraged): On-Site Collection, Incubation, and Centrifugation (refrigerated transport)

1. Collect 1 mL blood into the three Blood Collection Tubes (Gray, Red, and Purple).
2. After blood collection, mix the tubes thoroughly, by shaking vigorously for at least 5 seconds (please remember that simply inverting the tubes is not sufficient).
3. As soon as possible, and within 16 hours of collection, incubate tubes upright at 37°C for 16-24 hours. Be certain to document date and time for each step.
4. As soon as possible, and within 72 hours of incubation, centrifuge tubes at 2000-3000 g (RCF) for 15 minutes. Be certain to document date and time for each step.
5. After centrifugation, tubes must maintain a temperature of 2-8°C.
6. Tubes need to arrive at the laboratory within a week of centrifugation, and by 4:00 P.M. Mon-Fri. Tubes must be maintained at a temperature of 2-8°C during transport.

Some of the Frequently Asked Questions relating to the assay are listed below. The answers provided act as a guide only.

Blood Collection

The blood hasn't reached the black mark on the side of the Blood Collection Tube. Is this important?

The mark on the side of the tubes indicates the 1 mL fill volume. QuantiFERON® -TB Gold In-Tube Blood Collection Tubes have been validated for volumes ranging from 0.8 to 1.2 mL. If the level of blood in any tube is not close to the indicator mark, it is recommended to obtain another blood sample.

How important is the tube mixing process?

The antigen mixing process ensures even distribution of stimulating antigens to allow white blood cells to ingest and process antigen for presentation to T-cells, thus leading to IFN-secretion. It is a very important step in the QuantiFERON® -TB Gold In-Tube assay and poor mixing will lead to low and incorrect results. Mix the tubes by vigorously shaking the tubes vigorously for at least 5 seconds, ensuring that the entire surface of the tube has been coated with blood. Thorough mixing is required to ensure complete mixing of the blood with the tube's contents. Causing the blood to froth will not adversely affect the performance of the test. Universal blood handling precautions should be used. A demonstration video can be viewed on the Cellestis website at:

www.cellestis.com

Can the blood collection tubes be transported lying down?

Yes and No.

(Option 1)-- Tubes can be transported lying down only after the tube-mixing step has been done and prior to incubation.

(Option 2)-- If tubes are transported after incubation, but prior to centrifugation, care should be taken to ensure that *tubes remain upright during transport*.

(Option 3)-- Tubes transported after centrifugation, may be transported lying down if necessary.

At what temperature can the blood be transported to another site, or held prior to incubation at 37°C?

(Option 1, Option 2)-- Blood should be held and transported at Room Temperature (17°C to 27°C). Do not refrigerate the blood or place on ice.

(Option 3)-- Blood should be held and transported at (2°C to 8°C), refrigerated or placed on ice.

Blood Incubation and Centrifugation

What if 37°C incubation starts more than 16 hours after the time of blood collection?

The Package Insert specifies that the 37°C blood incubation must commence within 16 hours of collection. Blood samples incubated more than 16 hours after collection are likely to exhibit a decreased IFN- γ response due to cellular breakdown (death), leading to loss of sensitivity and inaccurate results.

Can I incubate the blood collection tubes lying down?

QuantiFERON[®]-TB Gold Blood Collection Tubes must be kept upright during incubation at 37°C.

Do I have to centrifuge the tubes immediately after removal from incubator?

QuantiFERON[®]-TB Gold Blood Collection Tubes may be held between 2°C and 27°C for up to 3 days before centrifugation or harvesting.

The gel plug hasn't moved during centrifugation. What should I do?

After incubation of tubes at 37°C, the plasma is separated from the cells by centrifuging for 15 minutes at 2000 - 3000 RCF (g). The gel plug should move to separate the cells from the plasma. If this does not occur, the tubes should be re-centrifuged at a higher speed.

The plasma doesn't appear the color it normally does. Is this OK?

Plasma from the QuantiFERON® -TB Gold In-Tube Blood Collection Tubes can appear more red than usual but this is normal. It should be noted that the color of plasma, even those without any red blood cell contamination, can vary from almost colorless to shades of yellow/pale brown; some plasma samples even have an opaque character. These qualities have not been found to affect QuantiFERON-TB® Gold In-Tube results.

***The UDOH will typically not pay for Quantiferon testing.** Check with the *Unified State Laboratories: Public Health* for pricing and availability. Quantiferon is approved for use in any situation where a PPD would be used, but its' accuracy in children under age 5 and immunosuppressed individuals is currently unclear. Quantiferon may be used instead of, but not in addition to PPD testing, as the meaning of conflicting results is also unclear.

CONFIDENTIALITY IN TB CONTROL

Purpose

To establish a policy for maintaining confidentiality in Tuberculosis Control.

Policy

The Tuberculosis Control Program recognizes **confidentiality** is an essential issue in many different aspects of TB Control. All information pertaining to individual clients shall be maintained in strict confidentiality according to this written policy.

Health care workers need to be aware of their agency policies on confidentiality, as well as those that are relevant to client health care worker encounters. The collection, management, and sharing of data gathered on TB clients must be held in the strictest confidence.

Procedure

- a. Tuberculosis Control Program employees must read and sign the Utah Department of Health, Bureau of Epidemiology Client Confidentiality Policy upon hire and when updated.
- b. The CDC Self Study Modules on Tuberculosis, Confidentiality in Tuberculosis Control provides in depth information, which is recommended for all health care workers in TB Control.
- c. Reasonable safeguards and policies should be in place to protect an individual's privacy, such as: staff orientation to HIPAA laws and signing of a confidentiality agreement, locked files (preferably behind a locked door), password protection of electronic information, shredding of paper containing sensitive data.

References

[HIPAA Incidental Uses and Disclosures \[45 CFR 164.502\(a\)\(1\)\(iii\)\]](#)

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, [October 1999: Confidentiality in Tuberculosis Control](#).

Follow-Up Responsibility

TB Nurse Consultant

CRITERIA FOR HOSPITALIZATION IN SECURE TB UNIT AT UUMC

Purpose

To provide a secured facility for court ordered, non-compliant TB clients; uninsured clients requiring hospitalization for active TB disease (ATBD); suspect or infectious homeless individuals, and those who pose a public health threat to contacts in their living environment.

Policy and Procedure

Individuals requesting admission to the University of Utah Hospitals and Clinics' (UUH&C) Secured TB Unit (STBU) must follow the STBU Protocol. Prior approval **MUST** be received from the Utah Department of Health, TB Control Program Manager or Nurse Consultant as well as the designated pulmonary physician at UUH&C before attempting to transport the client.

Rule-out TB and TB clients must have funding for their UUH&C admission authorized by the TB Control Program. The TB Control Program will pay for admissions as the payer of last resort.

Non-compliant TB clients must be admitted to the STBU under court order. For details on the isolation process refer to the [Utah Isolation/Quarantine Manual](#).

Clients are not to be sent to the emergency department or admitted through the emergency department, unless prior arrangements have been made.

References

[Request for Admission to the University Hospitals and Clinics' Secured TB Unit \(STBU\) Protocol](#).

[STBU Resource Call List \(2010\)](#)

Utah Department of Health. (2009). [COURT-ORDERED TREATMENT AND INVOLUNTARY – ISOLATION GUIDELINES FOR THE CONTROL OF TUBERCULOSIS](#).

Follow-Up Responsibility

TB Control Program Manager

TB Nurse Consultant

POST TREATMENT EVALUATION

Purpose

To establish a procedure for ensuring that appropriate post-treatment evaluation of ATBD is conducted, so that cure can be well documented.

Policy

The TB Control Program recommends periodic post treatment evaluation of clients with Active TB Disease. A chest x-ray, brief physical examination and signs and symptom review are recommended. Sputum samples should be collected if client is able to produce sputum.

Procedure

- a. The TB Nurse Consultant will send a Post Treatment Evaluation form to the TB Nurse Case Manager at the recommended scheduled evaluation times.
- b. The TB Case Manager will complete the form and return it to the TB Control Program.
- c. The State TB Pulmonary Consultant is available for review of x-rays if local consultant or physician is not available. The TB Nurse Case Manager can arrange to take the client to Chest Clinic at Salt Lake Valley Health Department by calling 801-534-4600.

- d. Recommended frequency of Post Treatment Evaluation:

6, 12, & 24 months	If cultures remain positive at 2 months If cavitory disease If Rifamycin drug not in regimen
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6 & 12 months	All other cases
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- e. A nursing assessment is recommended at 3 & 9 months.

References

[ATS/CDC/IDSA Treatment of Tuberculosis, June 2003](#)

[New York City Bureau of Tuberculosis Control](#)

Follow-Up Responsibility

TB Nurse Consultant

State Pulmonologist

TB EVALUATION FOR CLASS B REFUGEES/IMMIGRANTS

Purpose

To establish a policy for follow up of refugees/immigrants whose overseas medical examination is consistent with findings for tuberculosis.

Policy

The Department of Homeland Security (DHS) and Citizenship and Immigration Services (USCIS) requires an overseas examination of all immigrants and refugees age 15 and older (per [1991 CDC Technical Instructions](#)), or at any age (per [2007 CDC Technical Instructions](#)) for tuberculosis. (A current list of countries that use the 2007 TI is available within the [2007 CDC Technical Instructions](#). Countries not listed still follow the [1991 CDC Technical Instructions](#). Countries are designated based on disease prevalence and the ability of the CDC to implement the newer instruction.) A Tuberculin Skin Test (TST), or Quantiferon (QFT) may be done. A chest x-ray is done to screen for active infectious tuberculosis disease. Refugees/immigrants with abnormal chest x-rays suggestive of clinically active tuberculosis have sputum smear examinations to determine if they have infectious disease. Refugees/immigrants identified with active, infectious TB disease (ATBD) are treated prior to departure for the United States. Once the refugee/immigrant is no longer contagious, and has completed treatment, U.S. resettlement can occur. If disease is extrapulmonary only, travel is not restricted. (See the 2007 TI for exceptions pertaining to children under age 10.) Class B conditions indicate the need for the refugee/immigrant to follow-up in the United States. The TB Control Program considers Class B conditions that include an abnormal CXR as suspect active TB until the evaluation is complete. LHDs have 30 days to locate and evaluate Class B refugee/immigrants.

Procedure

- a. USCIS sends Class B Report on Alien with Tuberculosis to the TB Control, and Refugee Health Program, via their secure electronic system (EDN). If the report is not available on EDN, the refugee resettlement agency will forward the Class B documents to the TB Control Program.
- b. TB Control Program forwards this Class B report to the local health department (LHD) in whose district the refugee/immigrant will reside. The Refugee Health Program will assist in locating refugees and arranging for interpreting services if needed.
- c. LHD completes evaluation for tuberculosis. If refugee/immigrant has ATBD, the TB Control Program will be notified and appropriate treatment begun.
- d. The class B report evaluation is completed, signed by the MD, and sent back to the TB Control Program.

- e. The TB Control Program forwards the completed report electronically to the Division of Quarantine, Centers for Disease Control and Prevention and maintains a copy in the Class B refugee/immigrant files.

References

[2007 Technical Instructions for Tuberculosis Screening and Treatment for Panel Physicians. CDC 2008..](#)

<https://s3.amazonaws.com/cdcgov-prod/s3.amazonaws.com/EDNWebNew/Reports/TBWorksheet.pdf>

[Recommendations for Prevention and Control of Tuberculosis Among Foreign-Born Persons Report of the Working Group on Tuberculosis Among Foreign-Born Persons. MMWR 9/18/98 / 47\(RR-16\); 1-26.](#)

Follow-Up Responsibility

TB Program Health Representative

Refugee Health Program Specialist

TB Nurse Consultant

Alien (Alien #, Name, Address, Phone): **REFUGEE/
IMMIGRANT**
A ___-___-___

Name

Address

City State Zip Phone:

REPORT ON ALIEN WITH TUBERCULOSIS

LOCAL HEALTH OFFICER:
This person recently entered the United States and is referred to you because the X-ray shows findings consistent with tuberculosis, as indicated in the accompanying report of medical examination performed abroad. This person may not have received chemotherapy or chemoprophylaxis and is referred to you because you may wish to initiate preventative treatment. Your initial evaluation would be appreciated. Please check the appropriate boxes below and return this form to the State Health Officer.

If the alien does not report by ___ please check here [] and forward this form to the State Health Officer. Retain for your records the accompanying report of examination performed abroad.

Military will send direct to the CDC.

Sex M F Date of Birth (Mo./Day/Yr):

Class B-1 - Tuberculosis clinically active, not infectious
 Class B-2 - Tuberculosis, not clinically active, noninfectious

Your Initial Evaluation:

A. Direct Smear (in U.S.)	B. X-ray (in U.S.)	C. X-ray (abroad)	D. Presumptive Diagnoses
<input type="checkbox"/> Positive	<input type="checkbox"/> Normal	<input type="checkbox"/> Normal	<input type="checkbox"/> Pulmonary TB - Active
<input type="checkbox"/> Negative	<input type="checkbox"/> Abnormal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> Pulmonary TB - Not Active
<input type="checkbox"/> Not Done	<input type="checkbox"/> Not Done	<input type="checkbox"/> Not Done	<input type="checkbox"/> Pulmonary TB - Activity
<input type="checkbox"/> Unavailable	<input type="checkbox"/> Undetermined		<input type="checkbox"/> Extrapulmonary TB
			<input type="checkbox"/> Non-TB Abnormality
			<input type="checkbox"/> No Abnormality

E. Has patient received chemotherapy/prophylaxis in the past?
 Yes No Unknown

F. Are you prescribing chemotherapy/prophylaxis?
 Yes No

Signature of Physician:

Date of Evaluation:

Name of Health Department:

Protocol for Class B TB^β

(Class B status per 2007 CDC Technical Instructions, amended 10/1/09;
all previous 2007 Technical Instructions versions have been superseded)

1) No TB class^ψ

No Class B follow up

If arrival subsequently has a +PPD or QFT^{ψψ} at their refugee health screening, proceed accordingly, *but do not submit any Class B paperwork.*

2) Class B1 Pulmonary TB

Obtain history, do PPD or QFT* if no record (from either Class B paperwork or refugee health screening). Bring to clinic** (or the provider your LHD uses for Class B follow up), repeat CXR. If there is suspicion of active disease, the arrival is HIV+, or if the repeat film in the U.S. is abnormal, collect sputums. Sputums may also be ordered at provider discretion.

3) Class B1 Extrapulmonary TB

Obtain history, do PPD or QFT* if no record, and bring to clinic**. Obtain CXR (if pre-departure CXR exists, repeat if respiratory s/s, if CXR >3 months old, or at provider discretion). Collect sputums if indicated.

4) Class B2 (LTBI)

Obtain history, repeat CXR prn or if film from country of origin is >6 months old. If treatment will be offered, CXR must be no more than 3 months old. ***May have MD sign after a chart check, if appropriate.******

5) Class B3

Evaluate for Contact prophylaxis.

Proceed as with any contact. If pre-departure TST is < 5mm, or QFT negative, repeat if it cannot be verified as being done > 8 weeks after exposure. If CXR was done before departure, repeat prn or if film is > 6 months old. If treatment will be offered, CXR must be no more than 3 months old. ***May have MD sign after a chart check, if appropriate.******

Submit Worksheet signed/dated by provider. If the patient is pending starting LTBI treatment, please submit the Worksheet as soon as the provider has signed off; we can update the record after treatment has begun.

**If Class B papers indicate hx of infection or disease, do PPD or QFT at provider discretion.*

***with pre-departure documentation and film(s), if available.*

****It is always preferable to repeat the CXR and have the applicant examined by a physician, but this is subject to physician discretion with B2 and B3. (If the CXR is >6 months old, repetition is mandatory.)*

LN/In 2/10

Ψ Some arrivals may appear to be misclassified. The Class assigned on the paperwork cannot be changed, but appropriate clinical follow up should be done regardless.

β Occasionally, an arrival (especially an immigrant from a lower incidence country) may still be classified under the 1991 Technical Instructions. If their designation is 'B2', but their pre-departure CXR was diagnosed as a TB-related abnormality, work them up as a B1.

ΨΨ UDOH will not routinely pay for QFT, except at refugee health screening.

For further information, go to: http://www.cdc.gov/ncidod/dq/panel_2007.htm

A1. Name (Last, First, Middle)		A2. Alien Number:	A3. Visa Type:	A4. Initial U.S. Entry Date:
A5. Age:	A6. Gender:	A7. DOB:	A8. TB Class:	A9. Class Condition:
A10. Country of Examination:			A11. Country of Birth:	
A12. Data Entry Q-Station:		A13. Officer in Charge:		A14. Q-Station Phone:
A15a. Address: A15b. Phone: A15c. Other:			A16a. Sponsor Agency Name: A16b. Sponsor Agency Phone: A16c. Sponsor Agency Address:	

B. Jurisdictional Information

B1. Destination State:	B2. Jurisdiction:	B3. Jurisdiction Phone #:
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C. U.S. Evaluation

C1. Date of Initial U.S. Medical Evaluation:

C2a. TST Placed: Yes No Unknown

C2b. TST Placement Date:

C2c. TST mm:

C2d. TST Interpretation: Positive Negative Unknown

C2e. History of Previous Positive TST

C3a. Quantiferon (QFT) Test: Yes No Unknown

C3b. QFT Collection Date:

C3c. QFT Result: Positive Negative Indeterminate Unknown

U.S. Review of Overseas CXR	Domestic CXR	Comparison
C4. Overseas CXR Available? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Verifiable	C7. U.S. CXR Done? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Verifiable C8. Date of U.S. CXR:	C11. U.S. CXR Comparison to Overseas CXR: <input type="checkbox"/> Stable <input type="checkbox"/> Worsening <input type="checkbox"/> Improving <input type="checkbox"/> Unknown
C5. U.S. Interpretation of Overseas CXR: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Poor Quality <input type="checkbox"/> Unknown	C9. Interpretation of U.S. CXR: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown	
C6. Overseas CXR Abnormal Findings: <input type="checkbox"/> Abnormal, not TB <input type="checkbox"/> Cavity <input type="checkbox"/> Fibrosis <input type="checkbox"/> Infiltrate <input type="checkbox"/> Granuloma(ta) <input type="checkbox"/> Adenopathy <input type="checkbox"/> Other (Specify)	C10. U.S. CXR Abnormal Findings: <input type="checkbox"/> Abnormal, not TB <input type="checkbox"/> Cavity <input type="checkbox"/> Fibrosis <input type="checkbox"/> Infiltrate <input type="checkbox"/> Granuloma(ta) <input type="checkbox"/> Adenopathy <input type="checkbox"/> Other (Specify)	

C12. U.S. Microscopy/Bacteriology Specimen not collected in U.S.

#	Spec Source	Date	AFB Smear Result	Culture Result	Drug Resistance (DR)
1			<input type="checkbox"/> Not Done <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown	<input type="checkbox"/> Not Done <input type="checkbox"/> NTM <input type="checkbox"/> Negative <input type="checkbox"/> Contaminated <input type="checkbox"/> MTB Complex <input type="checkbox"/> Unknown	<input type="checkbox"/> Not Done <input type="checkbox"/> Mono-RIF <input type="checkbox"/> No DR <input type="checkbox"/> MDR-TB <input type="checkbox"/> Mono-INH <input type="checkbox"/> Other DR
2			<input type="checkbox"/> Not Done <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown	<input type="checkbox"/> Not Done <input type="checkbox"/> NTM <input type="checkbox"/> Negative <input type="checkbox"/> Contaminated <input type="checkbox"/> MTB Complex <input type="checkbox"/> Unknown	<input type="checkbox"/> Not Done <input type="checkbox"/> Mono-RIF <input type="checkbox"/> No DR <input type="checkbox"/> MDR-TB <input type="checkbox"/> Mono-INH <input type="checkbox"/> Other DR
3			<input type="checkbox"/> Not Done <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown	<input type="checkbox"/> Not Done <input type="checkbox"/> NTM <input type="checkbox"/> Negative <input type="checkbox"/> Contaminated <input type="checkbox"/> MTB Complex <input type="checkbox"/> Unknown	<input type="checkbox"/> Not Done <input type="checkbox"/> Mono-RIF <input type="checkbox"/> No DR <input type="checkbox"/> MDR-TB <input type="checkbox"/> Mono-INH <input type="checkbox"/> Other DR

C13. Overseas Treatment Recommended by Panel Physician:

- Yes
- No
- Unknown

C14. US Review of TB Disease Overseas Treatment:

- Yes No Unknown
- If Yes
- Patient-Reported
- Panel Physician-Documented
- Both

C15. Arrived on Treatment:

- Yes
- No
- Unknown

C16. Completed Treatment Overseas:

- Yes
- No
- Unknown

C17. Overseas Treatment Concerns: Yes No

D. Disposition

D1. Disposition Date:

D2. Evaluation Disposition:

Completed Evaluation

Initiated Evaluation / Not Completed

Did Not Initiate Evaluation

Treatment Recommended

Moved within U.S.

Not Located

No Treatment Recommended

Lost to Follow-Up

Moved within U.S.

Returned to Country of Origin

Lost to Follow-Up

Refused Evaluation

Returned to Country of Origin

Died

Refused Evaluation

Other, specify

Died

Unknown

Other, specify

D3. Diagnosis

Class 0 - No TB exposure, not infected

Class 1 - TB exposure, no evidence of infection

Class 2 - TB infection, no disease

Class 3 - TB, active disease

Class 4 - TB, inactive disease

Pulmonary

Extrapulmonary

Both Sites

D4. RVCT Reported

D5. RVCT #:

E. U.S. Treatment

E1. U.S. Treatment Initiated:

E2. U.S. Treatment Start Date

E3. U.S. Treatment Completed:

E4. U.S. Treatment End Date:

- No Treatment
- Active Disease
- LTBI
- Unknown

- Yes
- No
- Unknown

F. Comments

G. Screen Site Information

Provider's Name:

Clinic Name:

Telephone Number:

Physician Signature:

Date (mm/dd/yyyy)

TUBERCULIN SKIN TESTING IN SCHOOLS

Purpose

To establish a policy for tuberculin skin testing (TST) in elementary, and secondary schools.

Policy

Universal tuberculin skin testing (TST) of all students in school settings **is not recommended**. Only children at increased risk of TB exposure should be considered for TST. In Utah, high-risk children include contacts of persons with active TB disease (ATBD), newly arrived foreign-born children from high prevalence areas, children of migrant farm workers, children with socio-economic risk factors such as homelessness, living in a shelter, or caretaker with risks such as IV drug use.

Procedure

- a. Decisions regarding implementation of a school-based TST program should be made jointly by local public health professionals in collaboration with school nurses and school administrators. The TB Control Program is available for consultation.
- b. A decision to conduct a TST program is a decision to treat latent TB infection (LTBI), if identified and resources are available. Targeted testing of children at high-risk for LTBI must be accompanied by a plan for providing necessary follow up. This plan must include resources for providing a chest x-ray, medical evaluation and treatment for LTBI, which includes medication and nursing case management time.
- c. It is recommended that new students be assessed for risk factors upon entrance to school. Go to the [World Health Organization \[WHO\] Global Atlas for Infectious Diseases](#) for the WHO's most up-to-date listing of international TB prevalence.
- d. If a TST program is implemented, students with identified risk factors should then be screened with the tuberculin skin test at age 4-6 and 14-16.
- e. Evaluation of the data on the number of tests administered, results of the test, number identified with LTBI or ATBD, and number who complete treatment should be reviewed with local health departments (LHDs). If a low prevalence of ATBD or LTBI is identified, decisions to continue the screening program should be re-evaluated.

References

[American Academy of Pediatrics Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents Pediatrics 2004; 114; 1175-1201](#)

[Minnesota Department of Health Guidelines for Decisions Regarding Tuberculosis Screening of Elementary and Secondary School Students.](#)

[Tuberculosis School Nurse Handbook, New Jersey Medical School, National Tuberculosis Center, 1998](#)

[Utah Department of Health, Bureau of Epidemiology, TB Rule, R388-804-4 Screening priorities and Procedures.](#)

Follow-Up Responsibility

TB Nurse Consultant

TUBERCULIN SKIN TESTING IN POST SECONDARY SCHOOLS

Purpose

To establish a policy for tuberculin skin testing (TST) in post secondary schools.

Policy

Universal tuberculin skin testing (TST) of all students in school settings is **not recommended**. Targeted tuberculin skin testing is recommended for all international students originating from high prevalence countries. (Go to the [World Health Organization \[WHO\] Global Atlas for Infectious Diseases](#) for the WHO's most up-to-date listing of international TB prevalence.) Students whose studies or obligations involve **extensive** international travel to high prevalence countries are also candidates for testing prior to travel and 8-10 weeks following their return to the United States. Risk in addition to being foreign born should be considered in determining who to screen (see ACHA guidelines and Heartland links below for more information). Screening of students in health care professions is addressed in the manual section 'Screening for TB in Health Care and other Congregate Settings.'

Procedure

- a. Decisions regarding implementation of a school-based TST screening program should be made jointly by local public health professionals in collaboration with school nurses and school administrators. The TB Control Program is available for consultation.
- b. A decision to conduct a TST program is a decision to treat latent TB infection (LTBI) if identified and resources are available. Targeted testing of students at high risk for LTBI or active TB disease (ATBD) must be accompanied by a plan for providing necessary follow up. This plan must include resources for providing a chest x-ray, medical evaluation, and treatment for LTBI, which includes medication and nursing case management.
- c. Evaluation of the data on the number of tests administered, results of the test, number identified with LTBI or ATBD, and number who complete treatment should be reviewed with local health departments (LHDs). If a low prevalence of ATBD or LTBI is identified, decision to continue the screening program should be re-evaluated.

References

[American Academy of Pediatrics Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents Pediatrics 2004; 114; 1175-1201](#)

[Minnesota Department of Health Guidelines for Decisions Regarding Tuberculosis Screening of Elementary and Secondary School Students.](#)

[Model Tuberculosis Prevention Program for College Campuses. Heartland National TB Center. June 2007.](#)

[Tuberculosis School Nurse Handbook, New Jersey Medical School, National Tuberculosis Center, 1998](#)

[Tuberculosis Screening and Targeted Testing of College and University Students. ACHA Guidelines. July 2008.](#)

[Utah Department of Health, Bureau of Epidemiology, TB Rule, R388-804-4 Screening priorities and Procedures.](#)

Follow-Up Responsibility

TB Nurse Consultant

TUBERCULIN SKIN TESTING IN DIALYSIS CENTERS

Purpose

To establish a process for tuberculin skin testing (TST) or Quantiferon (QFT) testing (and subsequent evaluation for active disease) of clients in Dialysis Centers for latent tuberculosis infection or active tuberculosis disease.

Policy

Routine tuberculin skin testing (TST) or Quantiferon (QFT) of hemodialysis clients is recommended.

Rationale: The incidence of tuberculosis in end stage renal disease (ESRD) clients is estimated to be 10-15 times higher than in the general population. ESRD is associated with immunosuppression, and clients are more likely to be elderly or belong to certain minority groups in which TB rates are higher. ESRD clients are more likely than the general population to have diabetes. Those with latent tuberculosis infection (LTBI) may be more likely to progress to active TB disease (ATBD).

ATBD may be difficult to diagnose with symptoms often attributed to underlying chronic renal disease. Clients receiving hemodialysis spend prolonged periods of time together in health care facilities, thereby increasing the potential for tuberculosis transmission if a person has active disease.

Procedure

- a. Each new client entering a dialysis program should be assessed for symptoms of tuberculosis and risk factors for tuberculosis.
- b. A Mantoux tuberculin skin test should be placed by a trained professional unless there is a documented history of a previous positive skin test. QFT may be used in place of a TST.
- c. Tuberculin skin testing is not contraindicated for BCG vaccinated persons.
- d. If the tuberculin skin test is negative, a second test should be placed in 1-3 weeks. A negative QFT does not require a second confirmatory test.
- e. Each new client with an identified risk factor for tuberculosis should also have a chest x-ray regardless of skin test results.
- f. Active TB disease should be considered with abnormal x-ray results if:
 - the client is from an area of high incidence of tuberculosis

- the skin test result is ≥ 5 mm
 - there is known exposure to someone with active TB disease
 - the client is experiencing symptoms of active TB
- g. Any client with a positive tuberculin skin test or a documented history of a previous positive tuberculin skin test (or positive QFT) should be evaluated for treatment and started on isoniazid (INH) if appropriate.
- h. Annual testing should be performed on patients with negative results.
- i. Any client placed on INH for LTBI should be considered for directly observed therapy (DOT).
- j. Questions regarding dosing and timing of INH with dialysis should be directed to the TB Control Program at (801) 538-6191 or the local health department.

References

[Core Curriculum on Tuberculosis](#), What the Clinician Should Know. Fourth Edition 2000. (Page 25-33)

[Tuberculosis Transmission in a Renal Dialysis Center --- Nevada, 2003. MMWR 9/24/04 / 53\(37\); 873-875.](#)

Utah Department of Health Tuberculosis Control/Refugee Health Program, [A Tuberculosis Provider Guide - Testing for TB Infection & Guidelines for Post-Test Referral](#), January 2009.

Follow-Up Responsibility

TB Nurse Consultant

SCREENING FOR TB IN HEALTH CARE & OTHER HIGH-RISK CONGREGATE SETTINGS

Purpose

To establish a process of screening for both latent and active TB of employees and volunteers (and residents, when applicable) of high-risk congregate settings.

- a. A high-risk congregate setting would include: health-care facilities (both in and outpatient), long-term care facilities (i.e. nursing homes), correctional facilities, homeless shelters, and substance abuse treatment programs.

Policy

Employees and volunteers will be screened for TB in all high-risk congregate settings, according to [Centers for Disease Control and Prevention](#) (CDC) guidelines and rules established by the [Occupational Safety and Health Administration](#) (OSHA). Clients of these facilities will be screened using the same guidelines as for employees, except that acute care, in and outpatient health care facilities (i.e. hospitals, medical clinics) should not routinely screen patients except for cause (i.e. symptoms suspicious for TB, client is high risk for TB).

Procedure

- a. All facilities: *Baseline* screening, of all new employees and volunteers with a potential for exposure to *M. tuberculosis* through air space shared with persons with infectious TB disease, should be initiated before they are permitted to work. This would include PPD skin testing (2-step for those without a documented negative skin test within the past year), or Quantiferon Gold (QFT-G) blood testing (do not 2-step), and/or a chest x-ray for those with (or a documented history of) a positive test. **Do not skin test an individual with a documented history of a previous positive PPD. Do not use QFT-G as a confirmatory test to a positive PPD without first seeking expert consultation. A history of BCG is not a valid reason to not be tested. Pregnancy is not a contraindication to being tested.** A new employee with an abnormal chest x-ray and/or symptoms suspicious for TB may not work until cleared by the local health department, or a private provider. Screening should also be done after any significant exposure to active TB. Consult with the local and/or state health department for assistance.

- b. Health-care and long-term care facilities: CDC guidelines permit a facility to establish a schedule for periodic testing of employees based on their assessed risk. An annual risk assessment is necessary to determine the procedure to follow. A facility classified as *low risk* is not required to do periodic testing; *medium risk* would require annual testing, and facilities classified as having *potential ongoing transmission* might need to test employees every 8 – 10 weeks, until lapses in infection control have been corrected. See the [guidelines](#) for definitions and procedures for each risk class, as well as a risk assessment tool.
- c. Correctional facilities: [CDC guidelines](#) classify facilities as *minimal*¹ or *non-minimal risk* (see the guidelines for definitions). Most facilities should screen employees at least annually. Employees of minimal risk facilities may not need to be screened periodically, and employees of nonminimal risk facilities may need to be screened more frequently. Testing intervals should be based on an annual risk assessment, and with consultation from the local and/or state health department.
- d. Homeless shelters: Employees should be screened at least annually, and more frequently if warranted. Residents should be screened at admission. Consult with the local and/or state health department for further guidance.
- e. Substance abuse treatment programs: While probably not essential, it would be prudent to consider annual screening of employees; and screening of residents (and their children if being housed with them) at admission. This recommendation is based on the fact that substance users, especially IDUs, are at higher than average risk for exposure to TB (although statistics in Utah don't currently reflect this statement).

References

[CDC. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005. MMWR; 54:RR-17.](#)

[CDC. Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC. MMWR; 55:RR-09.](#)

Follow-Up Responsibility

TB Nurse Consultant

¹ **Minimal risk** is defined as: a) no cases of infectious TB occurring in the facility in the past year + b) substantial numbers of inmates with TB risk factors (e.g. HIV, IDU) are not housed + c) substantial numbers of immigrants (arriving in the U.S. within the past 5 years) from parts of the world with high rates of TB are not housed + d) employees are not otherwise at risk for TB. Facilities not meeting these criteria should be considered **nonminimal risk**.

DISEASE REPORTING

Purpose

The purpose of these reporting requirements is to focus efforts on tuberculosis control and disease elimination. The standards outlined constitute the minimum expectations.

Policy

The following is a summary of reportable conditions related to tuberculosis in the state of Utah:

Condition / Test Result	Reportable by Whom
Confirmed or suspected cases of <u>active tuberculosis disease</u> , regardless of whether confirmed by laboratory test	Physicians, health care providers, hospitals, other similar private or public institutions, or any other person providing treatment to the confirmed or suspected case must report within 24 hours to the TB Control Program or Local Health Department. A report of test results by a laboratory does not relieve the attending physician/health care worker of his/her reporting obligation.
Sputum smears positive for acid-fast bacilli (AFB) and cultures positive for <i>Mycobacterium tuberculosis</i> (MTB)	All laboratories that perform TB testing and in-state laboratories that send specimens for out-of-state testing must report within 24 hours to the TB Control Program or Local Health Department. A report by the physician/health care worker does not relieve the laboratory of its reporting obligation.
Any active TB disease client on directly observed therapy that has missed one dose.	Medical providers and health care organizations must report within 7 days to the TB Control Program or Local Health Department.

Procedure

The TB Control Program will need the following information regarding a reported confirmed/suspect TB case:

- Name
- Date of birth
- Address
- Sex
- Race/ethnic origin
- Marital status
- Site of disease

- ❑ Symptoms/onset dates
- ❑ Hospital admission information
- ❑ Bacteriology results, date(s), and name of laboratory performing test(s)
- ❑ X-ray results (if applicable)
- ❑ HIV testing information
- ❑ TB skin test results (in mm), or Quantiferon test results and date of test
- ❑ Drug therapy (medications used, dates given)
- ❑ Type of isolation/quarantine arrangements
- ❑ Other pertinent medical & epidemiological information
- ❑ Provider's names/addresses/telephone numbers

Whom to Notify Regarding Active/Suspect TB:

All cases, suspect cases and positive laboratory results must be reported within 24 hours to the local health department or the TB Control Program.

Telephone report to the Utah Department of Health, TB Control Program at (801) 538-6191. Fax reports to (801) 538-9913.

References

[Special Measures for the Control of Tuberculosis, Rule R388-804.](#)

Follow-Up Responsibility

TB Nurse Consultant

TB Control Program Manager

TUBERCULOSIS

OUTBREAK RESPONSE PLAN

Purpose

The purpose of this plan is to ensure adequate and timely response to TB outbreaks by outlining the roles of the Utah Department of Health, Bureau of Epidemiology, and the local health departments. These actions will include TB outbreak evaluation and management, especially in low morbidity areas in Utah. The goal of this plan is to prevent the potential of TB transmission in schools, workplaces, or community settings. Indications for executing the outbreak plan include: when the observed rate of TB disease in a geographical area exceeds the normal (endemic) rate, or a single case of unusual (e.g. multi-drug resistant) TB occurs.

Policy

When endemic levels have been exceeded, the manager of the TB Control Program will declare an outbreak after consultation with the State Epidemiologist, and local health officer. At that time, the Outbreak Response Team will implement the Utah State Outbreak Response Plan.

Procedure

The procedure for responding to an outbreak is outlined in detail as part of the Utah State TB Outbreak Response Plan. This document has been included as a reference.

References

[Utah State TB Outbreak Response Plan, Utah Department of Health, 2001.](#)

Follow-Up Responsibility

TB Control Program Manager

PROGRAM RESOURCES

Purpose

One of the purposes of the TB Control Program is to provide enhanced TB treatment and public health follow-up for those diagnosed with latent TB infection (LTBI) or active TB disease (ATBD). All newly diagnosed cases of ATBD will receive the appropriate evaluation, treatment, follow-up and incentives/enablers necessary to complete treatment within 12 months of diagnosis (> 12 months if resistant to at least Rifampin). Screening activities (to include evaluation of symptoms, tuberculin skin test, and chest x-ray) will be provided for contacts of cases and migrant school children and their families.

Policy

The TB Control Program provides funding for TB medications, pharmacy dispensing fees and administrative costs, at no charge to clients with no insurance coverage, for the treatment of TB disease and infection through local health departments.

The TB Control Program will provide incentives to encourage clients to complete a prescribed course of TB treatment. Appropriate incentives include food coupons, limited housing expenses, time limited utility expenses, clothing, household items, or others that are deemed appropriate by the nurse consultant and case manager and receive prior approval by the program manager.

Medical and pharmaceutical consultants who specialize in the diagnosis and treatment of tuberculosis infection and disease are available to provide technical advice.

Procedure

For those services covered under local health department contracts, request for payment should be submitted on a Monthly Expenditure Report.

Direct reimbursement for pre-authorized services can be completed by submitting a detailed summary of expenses and original statements to the TB Control Program (i.e., rent expenses, utility expenses, limited hospital expenses). Request for food coupons and/or other incentives can be requested by telephoning staff of the TB Control Program (documentation of clients receiving food coupons is required).

Medical consultants may either be contacted by local health department staff or through the Utah Department of Health nurse consultant. Billing for consulting services is done directly between the consultant and the Utah Department of Health. Pharmaceutical questions should be referred through the Utah Department of Health nurse consultant.

References

[CDC Enablers and Incentives](#), August 1989.

Local Health Department Contracts

Follow-Up Responsibility

TB Nurse Consultant

TB Control Program Manager

ORDERING ANTI-TUBERCULOSIS MEDICATION

Purpose

To establish a policy for ordering and obtaining medication for tuberculosis.

Policy

The Tuberculosis Control Program provides anti-tuberculosis medications for suspected and active TB disease cases and for the treatment of latent tuberculosis infection at no expense to the client who lacks medical coverage to pay for these medications.

Procedure

- a. Local health departments shall establish a relationship with a local pharmacy to provide dispensing services.
- b. Medications will only be provided to approved pharmacies. Minimum inventories will be maintained at each pharmacy to allow sufficient access for clients.
- c. The purchase of anti-tuberculosis medication is based upon funding availability. Should funding become impacted these services may be reduced or eliminated. The TB Control Program reserves the right to make decisions on client eligibility based on current medical practice, fund availability and recommendations from the most current treatment guidelines endorsed by the American Thoracic Society and the Centers for Disease Control and Prevention.

References

[ATS/CDC/IDSA Treatment of Tuberculosis, June 2003](#)

Follow-Up Responsibility

TB Health Program Representative

REQUIRED REPORTS AND FORMS

Purpose

To establish a policy for required reports and forms for the TB Control Program.

Policy

The TB Control Program requires the following reports from local health departments: 1) Monthly TB Skin Test Report, 2) Monthly TB Activity Report, 3) Aggregate Reports for Tuberculosis Program Evaluation (ARPE), 4) Report of Verified Case of Tuberculosis (RVCT). While forms generated at the local health department level may be of assistance in documentation of TB evaluation, treatment for latent TB infection (LTBI) or active TB disease (ATBD), they are not required to be sent to the TB Control Program.

Procedure

- a. The [Monthly TB Skin Test Report](#) is required for agencies receiving PPD from the TB Control Program; the [Monthly TB Activity Report](#) and [Pharmacy Inventory](#) is required for agencies receiving medication from the program. The completed reports are due by the 10th of each month for the previous month and can be faxed, mailed or e-mailed.
- b. A [CI Record](#) (Contact Investigation) form, documenting follow up testing and treatment of contacts to ATBD should be completed by the case manager and returned to the TB Program Nurse Consultant at 30 days, 120 days, and when all contacts have completed treatment for LTBI.
- c. The [Report of Verified Case of Tuberculosis \(RVCT\)](#) is completed on new cases of ATBD. The TB Nurse Consultant completes this with the case manager by telephone when the case is confirmed.
- d. Sample forms recommended to assist the case manager in accurate record keeping are available on the [TB Program website](#).

References

[Guide for Completing Monthly TB Activity Report](#)

[Instructions for Completing the Contact Investigation \(CI\) Record](#)

Follow-Up Responsibility

TB Control Program Epidemiologist

SITE VISITS

Purpose

To establish a policy for site visits to local health departments by the TB Control Program.

Policy

Tuberculosis services are provided in a variety of settings. The official agency, the Utah Department of Health, is charged by law with the responsibility of overseeing the control of TB. Public health's oversight role has been expanded even further beyond mandatory reporting of cases and ensuring completion of treatment. Health department TB control programs are reviewing the quality of the diagnostic, treatment, and prevention services given to clients. The quality of care and effectiveness of the TB Control Program is reviewed and evaluated in the following ways: telephone consultation, reports, site visits, and cohort review.

Procedure

- a. The TB Control Program will contact the local health department (LHD) nursing director and TB nurse to schedule a site visit.
- b. The [TB Clinic Structure and Management Form](#) will be used to evaluate the LHD TB Program and services provided. See Site Visit Tool on the following pages.
- c. A report of findings of the site visit will be sent to the health officer, nursing director and TB nurse.
- d. The site visit will be utilized for the TB Control Program staff to meet with TB nurses in their environment, to provide consultation and education as indicated, and to strengthen the partnership of the agencies.

References

Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Standards of Care. The National Tuberculosis Controllers Association, First edition 1997.

Follow-Up Responsibility

TB Nurse Consultant

TB CLINIC STRUCTURE AND MANAGEMENT

Name of reviewer: _____ Date of review: _____

Name/site of clinic: _____

Key: NA = Not applicable; M = Met; NM = Not Met

A. ACCESSIBILITY	NA	M	NM
1. Clinic hours sufficient to meet clients' needs			
2. Open at least two days a week for TB testing			
3. Services free, minimal, or on a sliding scale (Cost of TST) \$_____			
Comments:			
B. RANGE OF SERVICES			
1. Capability to evaluate patients for possible latent tuberculosis infection (LTBI)			
a. Personnel trained to place and read tuberculin skin tests (TSTs)			
b. Chest radiographs available on site and/or by referral			
c. Personnel trained to properly collect sputum samples			
2. Capability to evaluate and/or refer patients for active tuberculosis disease			
3. Treatment capability for LTBI and/or TB disease			
4. Medical consultation available (to include prescription writing)			
Comments:			
C. CLINIC ENVIRONMENT			
1. Signs at entrance indicate location of TB testing services			
2. Waiting areas clean and ventilated			
3. Culturally appropriate education materials for patients			
4. Patient information regarding clinic hours, costs, services			
5. PPD stored at 2-8C or 36-46F			
6. Examination rooms clean and private			
7. Staff are courteous and respectful			
8. Staff discuss patient information confidentially			
9. Culturally and linguistically appropriate services are available			
Comments:			
D. MEDICAL RECORDS OF PATIENTS DIAGNOSED WITH LTBI (NO MEDICATIONS)			
1. Date and results of TST documented			

2. TB reactor form (or other assessment tool) completed			
3. Chest radiograph results documented			
4. Documented justification for not offering medications or signed refusal			
Comments:			
E. MEDICAL RECORDS OF PATIENTS DIAGNOSED WITH LTBI (ON MEDICATION)			
1. Patient assigned to nurse for case management			
2. MD order for medication			
3. Consent for INH (or other meds) signed by patient			
4. INH questionnaire completed (if applicable)			
5. LFTs drawn as per hepatotoxicity risk			
6. Documentation of face to face visits for medication compliance and response to medication			
7. Documentation of therapy completed and card sent with signs and symptoms of active TB disease			
8. Blood tests available on site and/or referral			
9. Confidentiality of medical records maintained			
F. MEDICAL RECORDS OF PATIENTS DIAGNOSED WITH ATBD			
1. Assigned to nurse/case manager and evaluated within 14 days			
2. Contact investigation initiated within 3 days of smear positive AFB or confirmed case			
3. Appropriate consent forms, documentation of assessment			
4. Patient on DOT and documentation of compliance with medication regimen. Cost analysis of daily vs. intermittent therapy, weekend doses.			
5. Documentation of assessment of medication side effects, and interactions at least monthly			
6. Appropriate laboratory reports including blood, HIV test, sputum, x-rays and vision screening if on EMB			
7. Monthly nursing notes documenting response to treatment, problems interventions			
8. Contact investigation completed and appropriate forms sent to TB Program			
9. Case completed and appropriate follow up arranged			
Comments:			
G. CLINIC MANAGEMENT STRUCTURE			
1. Staff orientation and training conducted and documented			

2. Clinic policies and procedures documented and updated as needed			
3. Universal precautions observed			
4. Isolation procedure for suspected TB cases documented			
Comments:			
H CASE REPORTING			
1. Reports of confirmed or suspected TB disease called in to the state health department on the same working day of notification			
2. Contact investigations started on all confirmed or suspected TB disease cases within 3 working days			
3. Source Case investigation conducted for all children under the age of 4 and reported to UDOH.			
Comments:			

CLINIC REVIEW

1. Describe the clients who utilize the services of your health department?

2. Are you seeing changes in the population you serve (such as increase in foreign born, homeless, drug use)?

3. Do you conduct any type of targeted testing?

4. Do you collaborate with the correctional facilities in your area? If so, in what way and who is your contact. Would you like assistance in working with corrections in your area?

5. What is the rate of TB for your community (how many active cases per year, number of LTBI cases seen each year)? _____

How is this changing? _____

6. What languages are spoken in your community and what medical interpreter resources do you have?

7. What incentives and enablers are you using with LTBI/ATBD? Are you doing any DOPT for high-risk clients? _____

Who is high-risk in your community? _____

Is education to high-risk groups provided? If so, how? _____

8. How do you maintain confidentiality? _____

9. What are your training needs (list three and rank)? Are there training needs for other professionals in your community? Can we assist with this? _____

10. What can we do to assist you with providing TB care and treatment? _____

Strengths of program: _____

Weaknesses or needs of program: _____

EDUCATION

Purpose

To promote the Centers for Disease Control and Prevention and the American Thoracic Society's guidelines for Tuberculosis control/elimination in the United States.

Policy

- a. The TB Control Program provides training, education, and expert consultation to local health departments and others involved with TB control/prevention in Utah. This would include:
 - Mantoux Tuberculin Skin Testing Certification
 - Educational presentations on Tuberculosis
 - Educational material design and development
 - In-services, technical assistance, and expert consultation on state-of-the-art TB information, standards, and policies

Procedure

To access these services please contact:

Tuberculosis Control
Utah Department of Health
Box 142104
Salt Lake City, Utah 84114-2104
Phone: (801) 538-6191
Fax: (801) 538-9913
[TB Control Staff](#)

References

Centers for Disease Control and Prevention
Division of Tuberculosis Elimination (DTBE)
1600 Clifton Rd., NE
MS E10
Atlanta, GA 30333
800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348
24 Hours/Every Day
E-mail: cdcinfo@cdc.gov
Website: <http://cdc.gov/tb/>

Follow-Up Responsibility

TB Health Educator

Internet Resources for Tuberculosis

The internet is one of the quickest and easiest ways to locate accurate information on TB. The following is a list of Websites that may be useful:

American Thoracic Society

www.thoracic.org/

Brown University TB-HIV Research Laboratory

<http://research.brown.edu/research/labs.php>

Centers for Disease Control and Prevention, Division of Tuberculosis Elimination

cdc.gov/tb/

EthnoMed

www.ethnomed.org/

Francis J. Curry National Tuberculosis Center

www.nationaltbcenter.edu/

International Union Against Tuberculosis and Lung Disease

www.theunion.org/

National Institute for Occupational Safety and Health

www.cdc.gov/niosh/npptl/topics/respirators/

National Jewish Medical and Research Center

www.nationaljewish.org/

National Library of Medicine

www.ncbi.nlm.nih.gov/PubMed/

New Jersey Medical School, National Tuberculosis Center

www.umdnj.edu/globaltb/home.htm

Occupational Safety and Health Administration

www.osha.gov/SLTC/tuberculosis/index.html

Stanford Center for Tuberculosis Research

www.stanford.edu/group/molepi/

The Stop TB Partnership

www.stoptb.org/

Surveillance of Tuberculosis in Europe

www.eurotb.org/

TB Education & Training Resources

www.findtbresources.org/

Utah Department of Health, TB Control/Refugee Health Program
health.utah.gov/cdc/tb_home.htm

WHO Global TB Programme
www.who.int/tb/en/

MEDICAL INTERPRETERS/TRANSLATORS

Purpose

To promote the Office for Civil Rights policy guidance on the Title VI prohibition against national origin discrimination as it affects persons with limited English proficiency.

Policy

Title VI of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, or national origin by any entity that receives federal financial assistance. Under Title VI of the law, hospitals, Health Care Maintenance Organizations, social services and other entities that receive Federal financial assistance from the Department of Health and Human Services (HHS) are required to take the steps necessary to ensure that individuals with limited English proficiency (LEP) can meaningfully access the programs and services. The requirements apply to state-administered, as well as private and non-profit facilities and programs, that benefit from HHS assistance. The Office for Civil Rights is responsible for compliance with the law as it applies to HHS assisted programs.

Procedure

Interpreting/translating services can be found in the yellow pages under “Translators & Interpreters.” There are also Medicaid funded interpreters available.

References

The Department of Health and Human Services
Office for Civil Rights
Carole Brown or Ronald Copeland
Room 506F
200 Independence Avenue, S.W.
Washington D.C. 20201
(202) 619-0805
TDD 1-800-537-7697
www.hhs.gov/oct/
LEP Guidance and Policy

Utah Department of Health Medicaid
Box 143101
Salt Lake City, Utah 84114-3101
1-800-662-9651
<http://health.utah.gov/medicaid/provhtml/interpreter.html>

Follow-Up Responsibility

Refugee Health Program Specialist

STAFF RESPONSIBILITY

TB Controller (Cristie Chesler, BA): This individual is responsible for policy direction regarding the TB Control Program within the State of Utah.

Program Manager (Cristie Chesler, BA): This individual is responsible for program administration of Tuberculosis Control Program activities, contract oversight, and supervising Program employees.

Nurse Consultant (Larry Niler, RN, BS, MS): This individual is responsible for TB case management, coordination with local health departments, consultation with health care providers and other interested parties, assistance with policy-making, targeted testing outreach, and case reporting to the Centers for Disease Control and Prevention.

Epidemiologist II (Jerry Carlile, MSPH): This individual is responsible for the TB surveillance system, provides technical assistance to local health departments in establishing surveillance networks, and is responsible for TB statistical report generation and dissemination.

Health Educator (Marcee W. Mortensen, BS, CHES): This individual assists with tuberculin skin test certification, publishes educational products, and coordinates annual conferences. This person also provides TB education to providers throughout the state.

Health Program Representative: This individual is responsible for the data management and the medication program for the TB Control Program.

Refugee Health Program Specialist (Jelena Pasalic, BS): This individual is responsible for following-up on refugees that require a mental health evaluation and for those with positive TB skin tests and/or abnormal chest x-rays detected in the overseas and/or U.S. health screenings. This person also conducts the "Bridging the Gap" medical interpreters' training and represents the UDOH on various committees pertaining to refugees.

Surveillance and Follow-Up Health Program Specialist (Gerrie Dowdle, MSPH): This individual is responsible for maintaining the Refugee Health database, generating and disseminating statistical reports, and managing the medical interpreters' listserve. This individual is also responsible for following-up on persons with Class B TB status and health conditions other than TB detected in the refugee health screening.

STATE CONSULTANTS

The following state consultants may be contacted by public health and health care practitioners only:

Richard E. Kanner, MD

Pulmonology
801-581-7806

Wayne Samuelson, MD

Pulmonology
801-581-7806

Gary Alexander, MD

Pulmonology
801-773-4840

Krow Ampofo, MD

Pediatric Infectious Disease
801-581-6791

Paul Swoboda, MD

Salt Lake Family Health
801-350-4479

Mara Rabin, MD

Salt Lake Family Health
801-350-4479

GLOSSARY OF TERMS

Acid-fast bacilli (AFB) - Organism that retains certain stains, even after being washed with acid alcohol. Most acid-fast organisms are mycobacterium. When AFB is seen on a stained smear of sputum or other clinical specimen, a diagnosis of TB should be considered a possibility.

Active TB Disease (ATBD) - Clinical and/or radiographic evidence of current TB, as determined by a physician. Established most definitively by isolation of *M. tuberculosis* on culture.

Adherence - Following the recommended course of treatment by taking all the prescribed medications for the entire length of time necessary to adequately treat the disease or infection.

Anergy - Inability to mount a delayed-type hypersensitivity response to one or several skin-test antigens as a result of immunosuppression from disease (e.g., HIV infection) or immunosuppressive drugs (chemotherapy, organ transplant medication).

Antigen - Any substance that is capable under the appropriate conditions of inducing a specific immune response and of reacting with the products of that response; that is, with specific antibodies or specifically sensitized T-lymphocytes or both. Purified protein derivative (PPD) is one such antigen that induces an immune response when antibodies react to the protein of the tubercle bacillus in the body. Thus, a positive tuberculin skin test is produced, as evidenced by an induration at the antigen injection site.

ATS - American Thoracic Society.

Atypical - Also known as “atypicals”, mycobacterium other than TB (MOTT), and non-tuberculous mycobacterium (NTM). Members of the mycobacteria family, but not TB, these are not of public health concern.

BACTEC (radiometric method) - A rapid culture method using radioactive carbon dioxide. Identification of the mycobacterial organism can take place in as little as 10 days.

Bacteriological examination - Test done in a mycobacteriology laboratory to diagnose TB disease; includes examining a specimen under a microscope, culturing the specimen, and doing drug susceptibility testing.

BCG - (Bacillus of Calmette and Guérin) - An organism of the strain *Mycobacterium bovis* rendered avirulent in a vaccine given to humans to prevent TB disease. Used primarily in countries other than the United States. Not routinely used in the United States because it has not been determined to be effective in adults. Considered for use only with select persons who meet specific criteria. May be effective in preventing TB meningitis in children. An alternate clinical use is in the treatment of bladder cancer.

Booster phenomenon - One to three weeks after an initial negative tuberculin skin test, a second test is administered, resulting in a positive tuberculin skin test reaction. This phenomenon is the result of the immune system being “boosted” to remember the tubercle protein in situations where there is slight immune suppression due to age or illness.

Case reporting - Informing the state or local health department when a new case (an occurrence) of TB disease has been diagnosed or is suspected.

Cavity - A hollow space in the lung and destruction of lung tissue, most likely (but not exclusively) caused by *Mycobacterium tuberculosis*; contains millions of tubercle bacilli.

CDC - Centers for Disease Control and Prevention.

Cell-mediated immunity - Immunity in which the participation of lymphocytes and macrophages is predominant. A localized reaction.

Class B - Designation, according to CDC's Division of Global Migration and Quarantine, of a mental or physical defect in a refugee or immigrant, requiring some degree of follow-up in the U.S.

Colonization - The development of colonies (collections or groups of bacteria) in a culture derived from the reproduction of an isolated single organism or group of organisms; or the development of cells in a part of the body to which they have been carried.

Compliance - Ongoing cooperation by clients in all aspects of the treatment regimen as prescribed by the medical provider.

Congregate setting – Non-household place of potential exposure that may involve close contact due to proximity and length of contact, e.g. worksite or school.

Contact - Person who has shared the same air space with a person with infectious TB for a sufficient period of time to make transmission of infection likely.

Contact (casual) - Person who has shared the same air space with a person with infectious TB, but is at low risk of developing infection with *M. tuberculosis* because of the length of time and/or the intensity of exposure.

Contact (close) - Person who has shared the same air space with a person with infectious TB, but is at high risk of developing infection with *M. tuberculosis* because of the length of time and/or the intensity of exposure.

Contact (high-risk) - Contact who is < age 5, and/or is immunosuppressed.

Contact (household) - Person who has shared air with the index case in a living situation.

Contact Investigation - A methodical, epidemiological study conducted with, or for each newly reported index case of active TB disease.

Containment - Stopping the spread of tuberculosis. Aggressively treating persons with ATBD, treating persons with LTBI, and applying effective infection control measures.

Conversion (tuberculin skin test) - A term suggested to designate the change from a tuberculin negative to tuberculin positive state. An increase of 10mm in skin test reaction size within a 2-year interval.

Conversion (sputum) - In response to effective treatment, serial sputum tests convert from positive to negative. Conversion is considered to have occurred when there have been three consecutive negatives, after positive specimens have been identified. True conversion means that there is no reversion to positive.

Culture - Organisms grown on/in media (substances containing nutrients) so that they can be identified; a positive culture for *M. tuberculosis* contains tubercle bacilli, whereas a negative culture contains no detectable tubercle bacilli.

Delayed-Type Hypersensitivity (DTH) - a slowly developing cell-mediated immune response to a specific antigen.

Directly Observed Therapy (DOT) - A compliance-enhancing strategy in which a professional, lay worker, or other responsible person observes the client take each dose of medication.

Disseminated TB - Occurring at more than one site in the body as a result of hematogenous spread. Indicates some failure of the immune system to control the spread to one site.

Droplet nuclei - Microscopic particles (1-5 microns), produced by respiratory actions, such as coughing and sneezing that carry the tubercle bacilli and remain airborne by normal air currents in a room.

Drug resistance - Inability of anti-TB medications to kill *M. tuberculosis* organisms.

Drug susceptibility - Ability of anti-TB medications to kill *M. tuberculosis* organisms.

Enablers - Anything that assists the client to more readily complete therapy.

Engineering controls - Engineering systems used to prevent the transmission of TB in health care facilities, including ventilation, high-efficiency particulate air (HEPA) filtration, and ultraviolet germicidal irradiation.

Erythema - Acute inflammatory reaction, caused by vasodilation and congestion of the capillaries (redness) at tuberculin skin test site. Not indicative of a positive tuberculin reaction.

Exposure - The amount and intensity of time spent with someone who has infectious TB disease.

Extrapulmonary - Refers to sites of clinically active TB located outside the lung parenchyma. Pleural TB and TB located in the hilar lymph nodes of the lungs are included in this definition.

Extensively Drug-resistant TB (XDR TB) - resistant to isoniazid and rifampin, plus resistant to any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin).

False-negative reaction - A negative reaction to the tuberculin skin test in a person who has TB infection. May be caused by anergy, recent infection (within the past 10 weeks), overwhelming disease, very young age (< 6 months old), or recent administration of a live virus vaccination.

False-positive reaction - A positive reaction to the tuberculin skin test in a person who does not have TB infection. May be caused by infection with nontuberculous mycobacteria or by vaccination with BCG.

Genetic probe - Rapid method of identifying species of mycobacteria, utilizing genetic probes that are bound to specific pieces of mycobacterial DNA/RNA. Used in place of standard biochemical tests to identify mycobacteria. A DNA probe requires growth in liquid or solid media, while an RNA Nucleic Acid Amplification Test can detect MTB directly from raw sample.

HEPA (High-efficiency particulate air) filter - Specialized filter that is capable of removing 99.97% of particles 3 micron in diameter. Filters may be used in ventilation systems or in personal respirators to filter air. HEPA ventilation systems require expertise in installation and maintenance.

High-Risk Congregate Settings – High-risk environments are settings where: a) persons who have infectious TB are more likely to live, b) environmental characteristics are conducive to transmission and, c) many susceptible persons are at risk for prolonged exposure to potentially infectious clients. This includes prisons and jails, nursing homes and other long-term health care facilities, homeless shelters and residential settings.

Incentives - Rewards in return for adherence with medical regimen.

Incidence - The number of cases of disease having their onset during a prescribed period of time. It is often expressed as a rate (for example, the incidence of measles per 1000 children 5-15 years of age during a specified year). Incidence is a measure of morbidity or other events that occur within a specified period of time.

Index case - The initial individual whose condition leads to the investigation of TB.

Induration - Immune response to a particular antigen involving lymphocyte sensitization and cellular infiltration. It is a firm, raised, usually round bump with definable borders, at the site of injection.

Infectious - Capable of being communicated; capable of spreading infection.

Infiltrate - The formation of a group of tuberculosis cells and bacilli in a tissue; commonly observed on x-ray.

Intermittent therapy - Refers to once-weekly, twice-weekly or thrice-weekly directly observed treatment such as DOT. Not recommended as an unobserved method of treatment, because the client will miss large doses of medicine should he/she become non-compliant.

Intradermal - Referring to placement of the tuberculin skin test with the Mantoux method, just beneath the top surface of the skin.

Isolation - The physical separation of the infected person from others to prevent transmission of TB.

Latent TB Infection (LTBI)- Condition in which living tubercle bacilli are present in an individual, without producing clinically active disease. An infected individual usually has a positive tuberculin skin test, a normal chest x-ray, does not have symptoms related to the infection, and is not infectious.

Liver Function Tests (LFT) - Serological testing used to detect damage to the liver.

Mantoux tuberculin skin test (TST) - Diagnostic tuberculin skin test using an intradermal injection of 5 tuberculin units (T.U.) purified protein derivative (PPD). Method of choice for screening purposes.

Miliary TB - TB disease that occurs when tubercle bacilli enter the bloodstream and are carried to all parts of the body, where they grow and cause disease in multiple sites.

Multidrug-Resistant TB (MDR TB) - TB that is resistant to isoniazid and rifampin: more difficult to treat than drug-susceptible TB.

Multiple puncture skin test - Skin test using a device that contains small prongs that are dipped in either O.T. (old tuberculin) or 5 TU PPD. These are pressed onto the skin with the prongs breaking the surface and depositing a nonspecific amount of the skin testing material into the skin. Not acceptable for screening purposes.

Mycobacterium tuberculosis complex - The complex of mycobacterial species that cause TB. Includes *M. tuberculosis*, *M. bovis*, and *M. africanum*.

Non-compliant - Not adhering to the treatment regimen.

Nontuberculous mycobacteria (NTM) - Also known as atypical mycobacteria or MOTT (mycobacterium other than tuberculosis). Members of the mycobacteria family other than *M. tuberculosis*. Some of the more prominent members are *M. avium*, *M. intracellulare*, *M. chelonae/abscessus*, *M. goodii*, *M. kansasii*, *M. fortuitum*, etc.

Purified Protein Derivative (PPD) - Material used in tuberculin skin testing using the Mantoux method. Consists of tubercle protein that has been killed by heat and placed in a special diluent for skin testing. Produces an immune response (delayed-type hypersensitivity) if TB infection is present in the body.

Prevalence - The total number of cases of a disease that are present at a certain point in time.

Quantiferon - A whole blood test for use in identifying *M. tuberculosis* infection, approved by the U.S. Food & Drug Administration in 2005. As of this revision, the current kit is called *In-Tube*.

Quarantine - Using public health laws to confine an uncooperative, potentially contagious client in his home or in a facility.

Relapse - The return of disease after a partial or complete apparent recovery from the disease.

Smear - A specimen that has been smeared onto a glass slide, stained, washed in an acid solution, and then placed under the microscope for examination. Used to detect acid-fast bacilli in a specimen.

Sputum smear-positive - Having acid-fast bacilli (AFB) that is visible after staining when viewed under a microscope. Individuals who are sputum smear-positive for AFB are considered more infectious than those with sputum smear-negative.

Source case - The infectious person who is believed to have transmitted infection to the index case.

Surveillance - Activities related to finding cases of disease or injury, guiding them into the health care system, and maintaining records on their cases for such purposes as identifying high-risk groups and trends in morbidity and related mortality. Includes activities related to identifying and maintaining records on persons with tuberculosis infection as well, in order to identify candidates for medication and, in institutional settings, to identify the quality of infection control practices.

Susceptibility testing - Refers to the laboratory testing done on mycobacterial cultures to determine susceptibility of the organisms to specific anti-TB drugs. Should be done on initial positive culture, and on certain subsequent cultures should the emergence of drug resistance be suspected.

Transmission - The spread of an organism, such as *M. tuberculosis*, from one person to another. Factors to consider include contagiousness of the patient, the type of environment, and the length of exposure.

Tubercle bacilli - Term often used to refer to organism of the *Mycobacterium tuberculosis* complex.

Tuberculosis - An infectious disease of man and animals caused by the species *Mycobacterium tuberculosis* and characterized by the formation of tubercles and caseous necrosis in the tissues.

Two-step skin testing - Refers to the “booster test” in which a second skin test is given 1-3 weeks after an initial negative test. The purpose is to “boost” the immune system to recognize tubercle protein, if infection is actually present in the body but suppressed due to age or illness. Recommended when repeat testing is required such as with health care workers.

Wheal - A discrete, pale elevation of the skin as a result of the intradermal injection of 5 TU PPD for the purpose of tuberculin skin testing.

CLASSIFICATION SYSTEM FOR TB

Class	Type	Description
0	No TB exposure Not infected	No history of exposure Negative reaction to tuberculin skin test or QuantiFERON-TB test
1	TB exposure No evidence of infection	History of exposure Negative reaction to tuberculin skin test or QuantiFERON-TB test
2	TB infection No disease	Positive reaction to tuberculin skin test or QuantiFERON-TB test Negative bacteriological studies (if done) No clinical, bacteriological, or radiographic evidence of active TB
3	TB, clinically active	<i>M. tuberculosis</i> cultured (if done) Clinical, bacteriological, or radiographic evidence of current disease
4	TB Not clinically active	History of episode(s) of TB or Abnormal but stable radiographic findings Positive reaction to the tuberculin skin test or QuantiFERON-TB test Negative bacteriologic studies (if done) and No clinical or radiographic evidence of current disease
5	TB suspected	Diagnosis pending

Reference

CDC. (2008). [Self-Study Modules on Tuberculosis, Module 1](#) (pg. 26; Table 1.3).



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