Tuberculosis Policies and Procedures Manual For Public Health Authorities and Health Professionals

Introduction/Background

This manual was created for the use of Public Health Authorities and Health Professionals for controlling, monitoring, treating, notifying, and testing of Tuberculosis Disease and infection in the State of Nebraska. It is the result of the joint efforts of Public Health Department Professionals and the State of Nebraska Tuberculosis Program.

Purpose

These Policies and Procedures were created as guidelines to assist both the state and local health departments in controlling, monitoring, treating, notifying, and testing of Tuberculosis Disease and infection for the State of Nebraska. These Policies and Procedures must be adapted according to each health department's needs. It is not possible for any guideline to address all situations for individuals; therefore, clinical judgment must always be exercised.

The Standards of practice and guidelines are extrapolated from the standards of care set forth by the Centers for Disease Control & Prevention (CDC) and the American Thoracic Society (ATS) in reference to Tuberculosis Disease and Infection.

Tuberculosis Program Contact Information

Please contact the State of Nebraska Tuberculosis Program if there are any questions. The State of Nebraska Tuberculosis Program may act as a health professionals' main source of information on Tuberculosis control guidelines and policies. The State of Nebraska Tuberculosis Program can be reached at the following:

Communicable Disease
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Definitions

The following terms are defined for clarification and universal understanding in reference to this document and its relation to the controlling, monitoring, treating, notifying, and testing of Tuberculosis Disease and Infection for the State of Nebraska.

Isolation: means the voluntary separation from other persons of a person with infectious tuberculosis in a place and under conditions that will prevent the transmission of the infection

Quarantine: means the involuntary medically or statutorily imposed isolation of a person to prevent the spread of Tuberculosis disease.

Infectiousness/infectious: Capable of being transmitted by infection, with or without actual contact.

Department: shall mean the Department of Health and Human Services, Regulation and Licensure of the State of Nebraska.

Drugs or medications: shall mean only those types of drugs and other medications specifically authorized by the Department of Health and Human Services as appropriate for the care and treatment of persons afflicted with tuberculosis, or as otherwise approved as necessary and proper by the Department.

Health Care Facility: shall mean any health care facility, which is licensed by the Department of Health and Human Services pursuant to Chapter 71, article 20, Reissue Revised Statutes of Nebraska, 1943 and approved by the Department of Health and Human Services for the care and treatment of communicable tuberculosis persons.

Third Party Payer: shall mean any individual, firm, partnership, corporation, company, association or any other entity responsible for, or otherwise under an obligation to provide, the payment of all or part of the cost of the care, treatment or maintenance or of the transportation of a tuberculosis person; but shall not mean the tuberculosis person himself, any health care practitioner or any hospital or other health care facility providing services to such person, or the Department of Health and Human Services.

Tuberculosis consultant: shall mean a physician who is both licensed and under contract with the State of Nebraska and acting under the supervision of the Department of Health and Human Services; and is versed in the current tuberculosis management and treatment practices. Tuberculosis Consultants may advise the Department on each case of Communicable Tuberculosis and the appropriate method of treatment of the same.

Tuberculosis Infection is a condition in which TB bacteria are alive but inactive in the body. People with TB infection have no symptoms, don't feel sick, can't spread TB to others, and usually have a positive skin test reaction. But they may develop TB disease later in life if they do not receive preventive therapy.

Tuberculosis Disease is an illness in which TB bacteria are multiplying and attacking different parts of the body. The symptoms of TB disease include weakness, weight loss, fever, no appetite, chills, and sweating at night. Other symptoms of TB disease depend on where in the body the bacteria are growing. If TB disease is in the lungs (pulmonary TB), the symptoms may include a bad cough, pain in the chest, and coughing up blood.

Tuberculosis person shall mean a person afflicted with communicable tuberculosis and or Latent Tuberculosis Infection (LTBI).

Tuberculosis Program Manager shall mean individual(s) which oversee the daily operations of Tuberculosis Program.

BCG - a vaccine for Tuberculosis named after the French scientists Calmette and Guérin. BCG is not widely used in the United States, but is often given to infants and small children in other countries where TB is common.

Cavity - a hole in the lung where TB bacteria have eaten away the surrounding tissue. If a cavity shows up on your chest x-ray, you are more likely to cough up bacteria and be infectious.

Chest X-Ray a picture of the inside of your chest. A chest x-ray is made by exposing a film to x-rays that pass through your chest. A doctor can look at this film to see whether TB bacteria have damaged your lungs.

Contact - a person who has spent time with a person with infectious Tuberculosis.

Culture - a test to see whether there are Tuberculosis bacteria in your phlegm or other body fluids. This test can take 2 to 4 weeks in most laboratories.

Directly Observed Therapy (DOT) - a way of helping patients take their medicine for Tuberculosis. If you get DOT, you will meet with a health care worker every day or several times a week. You will meet at a place you both agree on. This can be the TB clinic, your home or work, or any other convenient location. You will take your medicine at this place.

Extrapulmonary Tuberculosis - Tuberculosis disease in any part of the body other than the lungs (for example, the kidney or lymph nodes).

HIV infection - infection with the human immunodeficiency virus, the virus that causes AIDS(acquired immunodeficiency syndrome). A person with both Tuberculosis infection and HIV infection is at very high risk for Tuberculosis disease.

INH or isoniazid - a drug used to prevent Tuberculosis disease in people who have TB infection. INH is also one of the five drugs often used to treat Tuberculosis disease.

Miliary Tuberculosis - Tuberculosis disease that has spread to the whole body through the bloodstream.

Multi-drug - resistant Tuberculosis (MDR Tuberculosis) - Tuberculosis disease caused by bacteria resistant to more than one drug often used to treat Tuberculosis.

M. tuberculosis - bacteria that cause Tuberculosis infection and Tuberculosis disease.

Negative - usually refers to a test result. If you have a negative Tuberculosis skin test reaction, you probably do not have Tuberculosis infection.

Positive - usually refers to a test result. If you have a positive Tuberculosis skin test reaction, you probably have Tuberculosis infection.

Preventive therapy - treatment for people with Tuberculosis infection that prevents them from developing Tuberculosis disease.

Pulmonary Tuberculosis - Tuberculosis disease that occurs in the lungs, usually producing a cough that lasts longer than 2 weeks. Most Tuberculosis disease is pulmonary.

Resistant bacteria - bacteria that can no longer be killed by a certain drug.

TB skin test - a test that is often used to detect TB infection. A liquid called tuberculin is injected under the skin on the lower part of your arm. If you have a positive relation to this test, you probably have TB infection.

Smear - a test to see whether there are TB bacteria in your phlegm. To do this test, lab workers smear the phlegm on a glass slide, stain the slide with a special stain, and look for any TB bacteria on the slide. This test usually takes 1 day.

Sputum - phlegm coughed up from deep inside the lungs. Sputum is examined for TB bacteria using a smear; part of the sputum can also be used to do a culture.

Tuberculin - a liquid that is injected under the skin on the lower part of your arm during a TB skin test. If you have TB infection, you will probably have a positive reaction to the tuberculin.

Transmission and Pathogenesis of Tuberculosis

Explanation

Tuberculosis is a communicable disease caused by Mycobacterium tuberculosis. It is spread primarily by tiny airborne particles (droplet nuclei) expelled by a person who has infectious Tuberculosis. If another person inhales air containing these droplet nuclei, transmission may occur. Some bacilli reach the alveoli, where they are ingested by macrophages. Infection begins with the multiplication of tubercle bacilli within these alveolar macrophages. Some of the bacilli spread through the bloodstream when the macrophages die; however, the immune system response usually contains the bacilli and prevents the development of disease. Persons who are infected but who do not have Tuberculosis disease are asymptomatic and not infectious; such persons usually have a positive reaction to the tuberculin skin test. About 10% of infected persons will develop Tuberculosis disease at some time in life, but the risk is considerably higher for persons who are immunosuppressed, especially those with HIV infection. Although the majority of Tuberculosis cases are pulmonary, Tuberculosis can occur in almost any anatomical site or as a disseminated disease.

In the United States, the vast majority of Tuberculosis cases are caused by Mycobacterium tuberculosis, sometimes referred to as the tubercle bacillus. M. tuberculosis and three very closely related mycobacterial species (M. bovis, M. Africanum, and M. microti) can cause tuberculosis disease, and they compose what is known as the M. tuberculosis complex. M. bovis and M. Africanum are very rare causes of disease in the United States; M. microti is not known to cause disease in humans. Non-tuberculous mycobacteria may cause pulmonary disease resembling Tuberculosis.

Transmission

Tuberculosis is spread from person to person through the air. When a person with pulmonary or laryngeal Tuberculosis coughs, sneezes, speaks, or sings, droplet nuclei containing M. tuberculosis are

expelled into the air. Depending on the environment, these tiny particles (1-5 microns in diameter) can remain suspended in the air for several hours.

If another person inhales air containing droplet nuclei, transmission may occur. The probability that Tuberculosis will be transmitted depends on four factors: (1) the infectiousness of the person with Tuberculosis (the number of organisms expelled into the air), (2) the environment in which exposure occurred, (3) the duration of exposure, and (4) the virulence of the organism.

The best way to stop transmission is to isolate patients with infectious Tuberculosis immediately and start effective Tuberculosis therapy. Infectiousness declines rapidly after adequate therapy is started, as long as the patient adheres to the prescribed regimen. Persons at the highest risk of becoming infected with M. tuberculosis are close contacts. Close contacts are person(s) who have had prolonged, frequent, or intense contact with a person with infectious Tuberculosis. Close contacts may be family members, roommates, friends, coworkers, or others. Among contacts of persons with drug-resistant Tuberculosis, infection rates seem to be similar. However, because they may have a poor response to treatment, persons with drug-resistant disease are often infectious for longer periods and therefore have the potential to infect more contacts. HIV-positive persons with Tuberculosis disease are not considered more infectious than HIV-negative persons with Tuberculosis disease.

Extrapulmonary Tuberculosis is rarely contagious (except for laryngeal Tuberculosis); however, transmission from extrapulmonary sites has been reported during aerosol-producing procedures, such as autopsies and tissue irrigation.

Pathogenesis

When droplet nuclei are inhaled, most of the larger particles become lodged in the upper respiratory tract, where infection is unlikely to develop. However, smaller droplet nuclei containing the tubercle bacilli may reach the alveoli, where infection begins.

The tubercle bacilli that reach the alveoli are ingested by alveolar macrophages; the majority of these bacilli are destroyed or inhibited. A small number multiply intracellularly and are release when the macrophages die. These bacilli can spread through the lymphatic channels to regional lymph nodes and then through the bloodstream to more distant tissues and organs. The areas in which Tuberculosis disease is most likely to develop are the apices of the lung, the kidneys, the brain, and bone. Extracellular bacilli attract macrophages from the bloodstream; this immune response kills most of the bacilli, leading to the formation of a granuloma. At this point the person has Tuberculosis infection, which can be detected by using the tuberculin skin test. It may take 2-10 weeks for the infected person to develop a positive reaction to the tuberculin skin test. Immune responses soon develop to kill the bacilli. Within 2 to 10 weeks after infection, the immune system is usually able to halt the multiplication of the tubercle bacilli, preventing further spread.

Persons who are infected with M. Tuberculosis but who do not have Tuberculosis disease cannot spread the infection to other people. Tuberculosis infection in a person who does not have Tuberculosis disease is not considered a case of Tuberculosis and is often referred to as latent Tuberculosis infection (LTBI).

In some people, Tuberculosis bacilli overcome the defenses of the immune system and begin to multiply, resulting in the progression from Tuberculosis infection to Tuberculosis disease. This process may occur soon after or many years after infection. In the United States, unless they are treated, approximately 5% of persons who have been infected will develop the disease within the first two years of being infected, and another 5% will develop disease sometime later in life. Recent infection (within the past 2 years) with M. tuberculosis is therefore an important risk factor for progression to Tuberculosis disease. In all, in approximately 10% of persons with normal immune systems who are infected with M. Tuberculosis, Tuberculosis disease will develop at some point during their lifetime.

Some medical conditions increase the risk that Tuberculosis infection will progress to Tuberculosis disease. Some studies suggest that the risk may be approximately 3 times greater (as with diabetes) to more then 100 times greater (as with HIV infection) for persons who have these conditions than for those who do not. HIV infection is the strongest known risk factor for development of Tuberculosis disease in persons with LTBI. Compared with immuno-competent persons who are infected with M. Tuberculosis, infected persons who are immunosuppressed are at considerably greater risk of developing Tuberculosis disease.

Conditions that increase the risk of progressions to Tuberculosis disease include the following:

- HIV infection
- Substance abuse (especially drug injection)
- Recent infection with M. tuberculosis (within the past 2 years)
- Chest radiograph finding suggestive of previous Tuberculosis (for persons who received inadequate or no treatment)
- Diabetes mellitus
- Silicosis
- Prolonged corticosteroid therapy
- Other immunosuppressive therapy
- Cancer of the head and neck
- Hematological and reticuloendothelial disease (e.g., leukemia and Hodgkin's disease)
- End-stage renal disease
- Intestinal bypass or gastrectomy
- Chronic malabsorption syndromes
- Low body weight (10% or more below the ideal)

Tuberculosis disease most commonly affects the lungs; 73% of Tuberculosis cases are exclusively pulmonary. Patients with pulmonary Tuberculosis usually have a cough and an abnormal chest radiograph, and are likely to be infectious. However, Tuberculosis is a systemic disease and may also commonly occur in the following ways: as a pleural effusion; in the central nervous, lymphatic, or genitourinary systems; in the bones and joints; or as disseminated disease (Miliary Tuberculosis). More rarely, Tuberculosis can occur in other body sites; for example, the breast, skin, or peritoneum. Extrapulmonary Tuberculosis is more common in immunosuppressed persons. Extrapulmonary Tuberculosis is often accompanied by pulmonary Tuberculosis.

Testing for Tuberculosis infection

Guidelines for Administering the Tuberculin Skin Test

The Mantoux tuberculin skin test (TST), intradermal injection of purified protein derivative (PPD) is the standard method of identifying persons infected with Mycobacterium Tuberculosis (M. tuberculosis). Multiple puncture tests (MPTs), such as the Tine test, should not be used. The amount of tuberculin injected intradermally, using MPTs, cannot be precisely controlled and therefore will not give a reliable result. Tuberculosis skin testing has proven to be safe and reliable during pregnancy and while breastfeeding.

Supplies

- Vial of tuberculin – 5 tuberculin units (TU) purified protein derivative (PPD) solution
- Single-dose disposable tuberculin syringe
- 2x2 gauze pads or cotton balls
- Alcohol swabs
- Puncture-resistant sharps disposal container
- Mantoux Tuberculin Skin Test Record Form (See Forms sections)
- Appointment cards
- Gloves
- Measurement Device (approved for measurement of Tuberculosis skin tests)

Preparation

- Purified protein derivative (PPD) solution must be kept refrigerated at 36-46˚ F.
- To avoid fluctuations in temperature, do not store on the refrigerator door.
- Read the vial label to ensure that the correct solution and tuberculin unit (TU) strength have been selected.
- Check the expiration date and the date that the vial was opened. The vial should be discarded if it has been open for more than 30 days or the expiration date has passed. Date and initial the label when a new vial is opened.
- Select a well-lighted area for administering the test. Have all the equipment and supplies on hand.
- Introduce yourself to the patient.
- Verify the patient's name to ensure that the correct patient receives the Tuberculosis skin test.
- Ask the patient if he/she has any food or drug allergies.
- Review the patient's tuberculin skin test history. Inquire about (a)documentation of previous tuberculin skin test results, and (b) if previously treated for Tuberculosis Disease.
- Provide patient education to answer questions, address fears and ease anxieties. Discuss the purpose of the test, testing procedure, and the time frame for returning to have the test read. If the patient cannot return 48-72 hours after the test to have the induration measured and evaluated, do not administer the test. Instead, schedule another time that is more convenient for the patient.
- A Tuberculosis skin test will not be given if the patient has a documented positive skin test.

Administration of Skin Test

Administer the tuberculin skin test; syringes must be filled immediately prior to administration, using an intradermal injection of purified protein derivative (PPD). NOTE: Some PPD vial stoppers contain 41.6% latex, which could pose a concern for those with latex allergy. For those persons who have a latex allergy, use vials without latex stoppers or remove the stopper prior to drawing up PPD.

- Wash your hands.
- On a firm, well-lighted surface, expose the patient's arm and slightly flex at the elbow. The injection should be placed on the palm-side-up surface of the forearm, about 2 to 4 inches below the elbow. Avoid areas of skin with veins, sores, rashes, scars, or excess hair.
- Put on gloves (recommended).
- Clean the injection site with an alcohol swab, using circular motion beginning in the center and working your way outward. Allow the site to dry completely before injection .
- Wipe the top of the vial with a new alcohol swab and allow it to dry thoroughly.
- Fasten the needle tightly on the syringe by holding the cap and twisting it onto the tip of the syringe. Remove the needle cap and make sure that the needle bevel is facing up.
- Hold vial between your thumb and fingers and insert the needle through the stopper. Inject air into the empty space in the vial, not the solution.
- Invert the vial. With the tip of the needle below the fluid level in the vial, draw out slightly more than 0.1 ml of solution.
- Remove the needle from the vial. Hold the syringe in an upright position and gently tap the syringe to break up any air bubbles.
- Expel all air from the syringe and excess solution from the needle, leaving exactly 0.1 ml of tuberculin solution in the syringe.
- Stretch the skin taut over the injection site to provide a surface that is easy for the needle to penetrate. This can be accomplished by stretching the skin between the thumb and index finger or grasping the patient's forearm and gently pulling the skin from under the arm.
- Hold the syringe between your thumb and index finger with the needle bevel facing up and the syringe parallel to the forearm.
- With the needle against the patient's skin, insert the needle slowly at a 5- to 15-degree angle, just below the surface of the skin (you should be able to see the bevel of the needle just below the skin surface).
- Release the stretched skin and hold the syringe in place. Slowly inject the tuberculin solution, forming a 6 to 10 mm wheal (pale, raised area with distinct edges; has orange peel appearance and does not disappear immediately).
- If no wheal forms, repeat the test on the opposite arm.
- Remove the needle without massaging or pressing the area and immediately discard the used syringe in the sharps container.
- If minor bleeding occurs, use a 2x2 gauze pad or cotton ball to dab the injection site.
- Do not cover the site with an adhesive bandage as it could cause irritation.
- Wash your hands.
- Record the following information on the record-keeping form: the date, time, location of injection site, name of manufacturer, lot number, and expiration date of PPD solution, name of person administering the skin test.
- Inform the patient that mild itching, swelling, or irritation is normal and usually goes away within 1 week.

- Explain how to care for the injection site: avoid scratching the site; keep the site clean and dry; and avoid creams, lotions, or adhesive bandages.
- Inform the patient that it is important to return within 48 to 72 hours to have the test result read
- Give the patient a written appointment to return for the skin test reading.

Guidelines for Reading the Mantoux Tuberculin Skin Test

The results of the skin test must be read by a trained health care professional 48 to 72 hours from the time the test was administered. (Results reported as "positive" or "negative" are not acceptable.) Contact the State of Nebraska Tuberculosis Program Manager if there is any clarification needed on identifying who is considered a Health Care Professional.

Supplies
- Small, plastic, flexible ruler marked in millimeters
- Ball point pen to mark edges of the induration
- Alcohol pad to clean off pen marks
- Mantoux Tuberculin Skin Test Record Form
- Patient education materials

Preparation
- Verify that the correct patient has returned for TST reading.
- Explain the procedure to the patient to put him/her at ease.
- Wash your hands.
- Make the patient feel at ease with his/her arm in a relaxed position.

Inspect for site
- Inspect the arm in good light and on a firm surface .
- Locate the site of injection on the palm-side-up surface of the forearm with the patient's arm supported and slightly flexed at the elbow.

Palpate
- Keep your fingernails short enough so they do not extend beyond the fingertip.
- Since the induration is not always visible, you must rely on palpation with your fingertips to determine induration at the site.
- Touch the area lightly with the pads of your fingertips.
- Lightly sweep your fingertips in 2-inch diameters from the injection site in all four directions to locate the edges of the induration.
- Use a zig-zag, feather-like touch to palpate the area for margins of induration. Be careful not to confuse a margin of induration with a margin of muscle on the forearm. To check this, repeat the palpation with the patient's arm raised to a 45-degree angle.

Mark
- Rest one fingertip firmly against the induration margin on one side before marking the margin. The fingertip should remain in contact with the skin at all times.
- Use a ball point pen to mark lightly with a fine dot at the widest edge of the induration.
- Repeat the procedure from the other side of the patient's forearm and place the second mark on the margin of induration.
- Palpate again, repeating finger movements toward the injection site, to ensure that the induration was marked correctly and adjust the dots, if necessary.

- If the margins are not equally clear all the way around the induration, it is still necessary to mark the margins on each side of the induration. For irregular margins of induration, mark and measure the longest diameter across the forearm.

Measure

- Measure the TST result in a good light with the forearm supported on a firm surface and slightly flexed at the elbow.
- When measuring the TST, disregard erythema or redness.
- Using a flexible millimeter ruler or caliper, measure the diameter of induration at its widest diameter transversely (side-to-side) to the long axis of the forearm.

Reactions to the tuberculin skin test at the injection site will vary. If there is blistering, palpate the induration gently as it may be painful. Measure only the induration. Only the margins of the induration are significant; redness and swelling should not be measured.

Record

- Record the exact measurement in millimeters of induration on the Mantoux Tuberculin Skin Test Record Form. Do not record the interpretation of the results as "positive" or "negative."
- Record the date and time the test was read, the name and signature of the person who read the skin test, and the presence or absence of adverse effects (i.e., blistering, redness, and swelling).
- If there is no induration, this measurement should be recorded as 0 mm of induration.
- Become familiar with the interpretation guidelines for your facility.

Education

- Explain the significance of a positive skin test. For example, a positive skin test result means latent infection with Tuberculosis. A negative skin test result means there is no Tuberculosis infection.
- If skin test result is positive direct the patient for follow-up chest x-ray.
- Answer the patient's questions.
- Provide culturally and linguistically appropriate educational materials and documentation to the patient.

The Tuberculin Skin Test must ALWAYS be read 48 to 72 hours after the injection.

- If the individual fails to show up for the scheduled reading, positive reactions may still be measurable up to one week after testing.
- If the results appear negative and more than 72 hours have passed, the test should be repeated. It can be repeated immediately, or after 1 week if two-step testing is required.
- TST results should be read by designated, trained personnel. Do not accept self-reading of TST results.

Always record the test result in mm, *not* as "positive" or "negative." An exact reading in mm may be necessary to interpret whether conversions occur on a subsequent test. Record a tuberculin skin test with no induration as "0 mm."

Adverse reactions to a TST (e.g. blistering, ulcerations, necrosis) can be indicative of a strong positive, and should be reported to the State of Nebraska Tuberculosis Program Manager.

If a patient has had an adverse reaction to a prior TST, the patient should not be tested again. In this situation, the State of Nebraska Tuberculosis Program Manager should be contacted for advice.

Classifying TST Reactions

Explanation

Whether a reaction to the Mantoux tuberculin skin test is classified as a reaction, or positive for the purpose of explanation, depends on the size of induration and the person's risk factors for Tuberculosis. Classifications are as follows:

≥ 5 mm of induration is considered a positive reaction in:

- HIV-infected persons
- Close contacts of a person with infectious Tuberculosis
- Persons who have chest x-ray findings consistent with prior Tuberculosis
- Organ transplant recipients
- Persons who are immunosuppressed for other reasons (e.g., taking the equivalent of ≥ 15 mg/day of prednisone for 1 month or more

≥ 10 mm of induration is considered a positive reaction in:

- Recent immigrants (within last 5 years) from a high-prevalence country
- Injection drug users (with unknown or HIV negative status)
- Residents or employees of high-risk congregate settings (for example, nursing homes or correctional facilities)
- Mycobacteriology laboratory personnel
- Children < 4 years of age, or children or adolescents exposed to adults at high risk
- People with other high-risk conditions such as diabetes

≥ 15 mm of induration is considered a positive reaction:

- Persons with no known risk factors for Tuberculosis

In most cases, people who have a very small reaction or no reaction to the tuberculin skin test probably do not have LTBI. For people who may be exposed to Tuberculosis on the job (such as health care workers and staff of nursing homes or correctional facilities), the classification of the skin test reaction as positive or negative depends on the following:

1. Size of the induration
2. Employee's individual risk factors for Tuberculosis
3. Risk of exposure to Tuberculosis in the person's job

Most people who have a positive skin test reaction will have a positive reaction if they are tested later in their lives, regardless of whether they receive treatment. This is because the tuberculin skin test detects the immune response to tuberculin, not the presence of tubercle bacilli in the body. Additionally, it is important to note that a false-positive or a false-negative reaction may occur. Contact the Tuberculosis Control Program Manager for more information.

Table: TST Reaction Interpretations- Close Contacts and LTBI

MEASUREMENT OF INDURATION	INTERPRET AS POSITIVE AND REFER TO CLINICIAN

> 5mm	Close contact to an infectious case, abnormal CXR, immunospupression, HIV infection
> 10mm	All others

*Contact the State of Nebraska Tuberculosis Program Manger with any questions regarding interpretation.

False-Positive Reactions

Explanation

The skin test is a valuable tool, but it is not perfect. Several factors can affect the skin test reaction. Two of these factors are infection with non-tuberculous mycobacterium and bacilli Calmette-Guérin (BCG) vaccination. BCG is a vaccine for Tuberculosis disease that is used in many countries. However, it is rarely used in the United States because studies have shown that it is not completely effective and does not confer life-long immunity.

People who are infected with non-tuberculous mycobacterium or who have been vaccinated with BCG may have a positive reaction to the tuberculin skin test even if they do not have LTBI. This is called a false positive reaction.

False positive reactions etiology

- Non-tuberculous mycobacterium
- BCG vaccination
- Local latex allergic reactions

False-Negative Reactions

Explanation

Some people may have a negative reaction to the tuberculin skin test even though they have LTBI. These are called false-negative reactions. The most common cause of false-negative reaction is Anergy, the inability to react to the skin test because of a weakened immune system. While HIV infection is a main cause of Anergy, many conditions (such as cancer or severe Tuberculosis disease) can weaken the immune system and cause Anergy. Another cause of false-negative reaction is recent Tuberculosis infection (infection within the past 10 weeks). It takes 2 to 10 weeks after Tuberculosis infection for the body's immune system to be able to react to tuberculin. Therefore, after Tuberculosis has been transmitted, it takes 2 to 10 weeks before Tuberculosis infection can be detected by the tuberculin skin test. For this reason, close contacts of someone with infectious Tuberculosis disease with a negative reaction to the tuberculin skin test should be retested 10 weeks after the last time they were in contact with the person who has Tuberculosis disease. A third cause of false-negative reaction is a very young age. Children younger than 6 months old may have a false-negative reaction to the tuberculin skin test because their immune systems are not yet fully developed.

False negative reactions etiology

- Anergy
- Recent Tuberculosis infection (within the past 10 weeks)
- Very young age (< 6 months of age-because their immune systems are not fully developed)

- Overwhelming Tuberculosis disease
- Live virus vaccination
- Some viral infections (measles, mumps, chickenpox, and HIV)
- Corticosteroids and other immunosuppressive agents at doses of 2 mg/kg/day or greater for 2 or more weeks

BCG (Bacillus Calmette-Guerin) Vaccines

Explanation

BCG vaccines are live vaccines derived from a strain of Mycobacterium bovis (M. bovis). Because their effectiveness in preventing infectious forms of Tuberculosis is uncertain, they are not recommended as a Tuberculosis control strategy in the United States except under rare circumstances. They are, however, used commonly in other countries.

Tuberculin Skin Testing an Individual with a History of BCG Vaccination

1. A history of BCG vaccination is not a contraindication to tuberculin skin testing if the person is at risk of exposure to Tuberculosis.

2. A false positive reaction may occur in persons vaccinated with BCG. However, tuberculin reactivity caused by BCG vaccination wanes with time and is unlikely to persist >10 years.

3. Consider treatment for LTBI in BCG-vaccinated persons who are infected with HIV and who are at risk for LTBI if they have a skin test reaction of >5 mm induration or with a non-reactive skin test if they have a history of contact to infectious Tuberculosis.

4. A diagnosis of LTBI and the use of therapy should be considered for any BCG vaccinated person who has a TST reaction of >10 mm induration, especially if:

    - The vaccinated person is exposed continually to populations in which the prevalence of Tuberculosis is high (e.g., some health care workers, employees and volunteers at homeless shelters and workers at drug-treatment centers)
    - The vaccinated person was born or has resided in a country in which the prevalence of Tuberculosis is high; or
    - The vaccinated person is a contact of another person who has infectious Tuberculosis, particularly if the infectious person has transmitted Tuberculosis to others.

There is no reliable way to distinguish a positive tuberculin reaction caused by vaccine with BCG from a reaction caused by a true Tuberculosis infection. However, the reaction is more likely to be due to LTBI if any of the following are true:

- The reaction is large (> 10mm)
- The person was vaccinated a long time ago
- The person comes from an area of the world where Tuberculosis is common
- The person has been exposed to someone with infectious Tuberculosis disease
- In contact investigation, reaction > 5mm

People who have positive reaction should be further evaluated for Tuberculosis disease, regardless of whether they were vaccinated with BCG.

For More information on BCG please visit:
http://www.cdc.gov/mmwr/preview/mmwrhtml/00041047.htm

Two Step Tuberculin Skin Testing ("Booster Phenomenon")

Explanation

Delayed type hypersensitivity (a skin test reaction) may wane over the years in some people who are infected with Tuberculosis. When these people are skin tested many years after infection, they may have a negative reaction. However, this negative skin test may stimulate (boost) their ability to react to tuberculin, causing a positive reaction to subsequent tests. This boosted reaction may be interpreted as new infection. Two-step testing is used to establish a true baseline skin test. Thus, it is recommended that a baseline two-step tuberculin skin test be performed on workers in health care facilities, correctional institutions and jails, long term care facilities for the elderly, homeless shelters, drug treatment centers, residents of long-term care facilities, and other adults who will be re-tested periodically. Two-step tuberculin skin testing should be performed on these individuals who cannot document a history of a negative tuberculin skin test within the past year.

Procedure

1. Apply the tuberculin skin test.
2. If the initial skin test is positive, consider person infected.
3. If the initial tuberculin skin test is negative:
    - It should be repeated within 1-3 weeks using the same dose and strength of tuberculin.
    - If the second test is negative, the individual is classified as uninfected and retested at routine intervals (two-step testing is not required for subsequent tests unless one or more years have elapsed since the last test).
4. If the second test is positive, consider person infected.

Tuberculin Skin Testing: What to do after Interpreting the Skin Test

Algorithm

See Forms & Tables section for Algorithm on "What to do after interpreting Tuberculosis skin test."

Culture Negative Pulmonary Tuberculosis in Adults

Explanation

Failure to isolate M. tuberculosis from appropriately collected specimens in persons who, because of clinical or radiographic findings, are suspected of having pulmonary Tuberculosis does not exclude a diagnosis of active Tuberculosis. Low bacillary populations, temporal variations in the number of bacilli being expelled, and errors in specimen processing all may

result in failure to isolate organisms from patients who have active Tuberculosis. It should be emphasized that alternative diagnoses must be considered carefully and appropriate diagnostic studies undertaken in patients who have what appears to be culture-negative Tuberculosis. At a minimum, patients suspected of having pulmonary Tuberculosis should have three sputum specimens for AFB smears and cultures as part of the diagnostic evaluation. Depending on the clinical features and differential diagnosis, other diagnostic testing, such as bronchoscopy with Bronchoalveolar Lavage and biopsy, should be considered before making a presumptive diagnosis of culture-negative Tuberculosis.

Patients who, on the basis of careful clinical and radiographic evaluation, are thought to have pulmonary Tuberculosis should have treatment initiated with INH, RIF, PZA, and EMB even when the initial sputum smears are negative. If M. tuberculosis is isolated in culture, treatment for active disease should be continued. Patients who have negative cultures but who still are presumed to have pulmonary Tuberculosis should have a thorough follow-up clinical and radiographic evaluation at the time 2 months of therapy has been completed to determine whether there has been a response that can be attributed to anti-tuberculosis treatment. If there is either clinical or radiographic improvement and no other etiology is identified, treatment should be continued for active Tuberculosis. A 4-month, INH and RIF regimen for culture-negative Tuberculosis has been demonstrated to be successful. However, because the results of cultures may not be known for 3-8 weeks and because of the possibility of drug resistance, initiation of two-drug therapy with INH and RIF alone is not recommended, but the continuation phase can be shortened to 2 months using INH and RIF.

On occasion, patients who are being evaluated for pulmonary Tuberculosis will be found to have positive AFB smears but negative cultures. There are several potential explanations for this occurrence, including the possibilities that the acid-fast organisms are non-tuberculous and difficult to culture, that they are nonviable tubercle bacilli, and that they are the result of laboratory error. The approach taken in such cases should be individualized on the basis of clinical and radiographic findings. If suspicion of Tuberculosis is high and the patient has positive AFB smears, even with negative cultures, he/she should be treated as if the culture is positive, using one of the recommended regimens.

Diagnosis of Tuberculosis Infection & Disease

A diagnosis of pulmonary Tuberculosis may be considered for any patient who has an abnormal chest x-ray consistent with Tuberculosis, for any patient who has a persistent cough (i.e., a cough lasting 3 weeks or more) or other signs and symptoms compatible with Tuberculosis (e.g., bloody sputum, chest pain, night sweats, easy fatigability, weight loss, anorexia or fever). A qualified medical provider should make the diagnosis. The index of suspicion for Tuberculosis should be very high in areas or among groups of patients in which the prevalence of Tuberculosis is high.

The following is needed for whom a diagnosis of Tuberculosis is being considered. Please also make these copies available to the Tuberculosis Program Manager (or) Tuberculosis Case Manager for which the patient is assigned.

1. Medical History

A complete medical history should be obtained and should include questions pertaining to risk factors for Tuberculosis exposure. These are demographic history, infection or disease, symptoms of Tuberculosis, 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 patient received prior treatment for Tuberculosis and the drug regimen was inadequate or if the patient did not adhere to therapy, Tuberculosis may recur and may be drug resistant. Patients with an unknown or negative HIV status should be referred for HIV counseling and testing.

2. Physical Examination

A physical examination is an essential part of the evaluation of any patient. It cannot be used to confirm or rule out Tuberculosis, but it can provide valuable information about the patient's overall condition and other factors that may affect how Tuberculosis is treated.

3. Tuberculin Skin Test (see Forms & Tables section for "Tuberculin Skin Testing")

Although a tuberculin skin test (TST) should be obtained on individuals for whom the diagnosis of Tuberculosis is being considered, it is important to note that a negative TST does not exclude the diagnosis of active Tuberculosis. On average, 10% to 25% of patients with active Tuberculosis disease have negative TSTs at diagnosis.

4. Chest X-ray

Patients who have a positive TST result or symptoms suggestive of Tuberculosis (regardless of TST result) should be evaluated with chest x-rays (PA and lateral views). Radiographic abnormalities that strongly suggest active Tuberculosis 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. If abnormalities are noted, or if the patient has symptoms suggestive of extrapulmonary Tuberculosis, additional diagnostic tests should be conducted. Abnormalities on a chest x-ray may be suggestive of, but are never diagnostic of, Tuberculosis. However, chest x-rays may be used to rule out the possibility of pulmonary Tuberculosis in a person who has a positive reaction to the TST and no symptoms of disease.

5. Confirmed Specimen

Persons suspected of having pulmonary or laryngeal Tuberculosis should have at least three sputum specimens examined by smear and culture. It is best to obtain a series of early morning specimens collected on 3 consecutive days. Specimens should be obtained in an isolated, well-ventilated area or a sputum collection booth. A health care worker should coach and directly supervise the person at least the first time sputum is collected. Persons should be properly instructed in how to produce a good specimen. Patients should be informed that sputum is the material brought up from the lungs and that mucus from the nose or throat and saliva are not good specimens. Coaching patients individually on how to expectorate can facilitate sputum

collection. Unsupervised patients are seldom successful in providing an adequate specimen, especially the first time. The amount of coaching required on later visits will depend on individual patient needs.

Extrapulmonary Specimens (biopsies, needle aspirates, urine specimens) should be collected if possible to confirm diagnosis.

Physician Resources

Physicians may use the following web resources as reference to clinical protocols:

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

Treating Tuberculosis

Treatment of Active Tuberculosis Disease

Explanation

The responsibility for successful treatment is clearly assigned to the public health program or private provider, not to the patient. The prescribing physician (private or public) is carrying out a public health function with responsibility not only for prescribing an appropriate regimen, but also for successful completion of therapy.

- It is essential that treatment is tailored and supervision be based on each patient's clinical and social circumstances (patient-centered care), with an adherence plan that emphasizes directly observed therapy.
- Patients who have confirmed active Tuberculosis (e.g. patients with positive cultures for M. tuberculosis or clinical diagnosis by a qualified health care provider) or patients who are considered highly likely to have active Tuberculosis should be started promptly on appropriate treatment. It is not necessary to wait for laboratory confirmation of Tuberculosis before starting treatment for patients highly likely to have Tuberculosis.
- Patients with confirmed or suspect active Tuberculosis must be under the medical supervision of a qualified health care provider.
- Treatment regimens must contain multiple drugs 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 Tuberculosis resistant to that drug. All patients should be started on a four-drug regimen containing isoniazid (INH), rifampin (RIF), pyrazinamide (PZA) and ethambutol (EMB) at proper dosing. (See "ATS Tuberculosis Medication Dosing Table" in the Forms & Tables Section).
- Consult the Tuberculosis program for information regarding the treatment of patients with drug resistant Tuberculosis.
- Tuberculosis medications should be administered together as a single dose rather than in divided doses. A single dose leads to higher and potentially more effective, peak serum concentrations and facilitates DOT.

- Although ingestion with food delays or moderately decreases the absorption of Tuberculosis medications, the effects are of little clinical significance.
- 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, diabetes, HIV infection, renal failure, alcoholism, and pregnant or breastfeeding women).
- Research has shown that non-compliance with patient-administered treatment for active Tuberculosis leads to high failure rates (e.g. failure to cure the Tuberculosis and the development of multiple-drug-resistant Tuberculosis).
- DOT means observation of the patient by a health care provider or other responsible person (i.e., home health care worker, minister, school nurse, or migrant health worker) as the patient ingests antiTuberculosis medications (the observer should generally not be a family member). DOT may be administered to patients in the office or clinical setting, the patient's home, place of employment, school, or other mutually agreed-upon place.
- Clinical experience suggests that patients being managed by DOT administered 5 days/week have a rate of successful therapy equivalent to those who have been taking drugs 7 days/week. Thus, daily therapy may be given on a 7 days/weeks (182 doses) or 5 days/week (130 doses) DOT schedule.
- Patients should be monitored bacteriologically for sputum starting two weeks after treatment until there are Three (3) negative smears. Patients under quarantine may be retested more often (e.g. every 2 weeks) to expedite release from public health restrictions, if no longer contagious.
- Patients with persistently positive cultures after three months of therapy, with or without ongoing symptoms, should be evaluated promptly to identify the cause. Treatment failure is defined as continued or recurrent positive cultures after four months of treatment. There are multiple, potential reasons for treatment failure including non-adherence to therapy such as spitting out or deliberately regurgitating pills after DOT, failure of the health care system to reliably deliver the drugs, unrecognized drug resistance, or malabsorption of medications.
- Careful attention should be given to measures that foster adherence to therapy (See "How to Motivate People to Comply With Therapy" in the Forms & Tables section). National health statistics indicate that culturally inappropriate care and lack of understanding of cultural differences may negatively affect health outcomes. Thus, it is imperative to become culturally competent and guide other health providers towards culturally competent health care. A culturally competent system acknowledges cultural differences with regard to health care and incorporates appropriate care policy, provider and consumer levels. It is important to have an understanding of different conceptions of illness and healing when providing health care to culturally and ethnically diverse populations. It may be necessary to utilize the assistance of language/cultural interpreters and to alter the plan of care so that patients are treated with dignity and respect for their culture.
- Because rifamycins (e.g. rifampin, rifabutin, rifapentine) may decrease the effectiveness of oral contraceptives (the "pill"), an alternate birth control method should be used.
- Other drug interactions can occur. It is important to notify the pharmacy when patients are taking other medications to learn about potential interactions.

- The determination of whether treatment has been completed is based upon the total number of doses taken and not solely on the duration of therapy. The initial phase of treatment should be completed within three months and the continuation phase completed within 6 months. Thus, the doses for a six-month regimen should be completed within 9 months.

Smear Results

Three consecutive negative sputum smears are needed to release a patient from quarantine. New AFB smears and cultures (including susceptibility testing) should be obtained if new symptoms develop during therapy. One sputum specimen for AFB smear and culture should also be obtained at the end of treatment.

Nebraska Tuberculosis Policy: One (1) Negative Culture and Three (3) negative smears.

Treatment of LTBI

Identifying LTBI Patients -Criterion for and Treatment Eligibility Based on TST Results

< 5 mm reaction

Persons who have close contact to active Tuberculosis are candidates for treatment of LTBI if their skin test result is < 5 mm regardless of age, no clinical evidence of disease is present, and they have the following risk factors:

- Investigation suggests a high probability of infection
- Evaluation of other contacts with a similar degree of exposure demonstrates a high prevalence of infection
- The contact is a child or adolescent in a very high-risk exposure situation
- The contact is immunosuppressed (e.g., HIV infected, suspect HIV infected, other immunocompromised persons)

LTBI Retesting
The above persons should be skin tested again in 3 months following cessation of exposure. Those with skin test reactions >5 mm should continue treatment of LTBI. Those with reactions <5 mm may be discharged, except for immunosuppressed persons, who may be anergic.

>5mm reaction
Persons are candidates for treatment of LTBI if their skin test result is >5mm, regardless of age, if they have the following risk factors:

- Persons with HIV infection not known to be a close contact
- Recent contacts of persons with newly diagnosed infectious Tuberculosis
- Persons with abnormal chest radiographs that show fibrotic lesions likely to represent old healed Tuberculosis
- Persons with organ transplants, and other immunosuppressed patients (receiving the equivalent of >15 mg/day of prednisone for >1 month)

>10 mm reaction

Persons are candidates for treatment of LTBI if their skin test result is >10 mm, regardless of age, and they have the following risk factors:

- Foreign-born persons who have recently arrived (within five years) from countries that have a high Tuberculosis incidence or prevalence (most countries in Africa, Asia, Latin America, Eastern Europe, and Russia)
- Persons who inject drugs or use other high risk substances, such as crack cocaine, and alcoholics
- Residents and employees of high risk congregate settings such as correctional institutions, long-term residential care facilities (nursing homes, mental institutions, etc.), hospitals and other health care facilities, and homeless shelters
- Mycobacteriology laboratory personnel
- Persons with medical conditions that increase the risk of Tuberculosis disease (diabetes mellitus, silicosis, recent infection with M. Tuberculosis--within the past 2 years, bone marrow and organ transplant recipients, prolonged high-dose corticosteroid therapy and other immunosuppressive therapy, chronic renal failure who are on hemodialysis, some hematological disorders--e.g., leukemia's and Hodgkin's disease, other specific malignancies--e.g., carcinoma of the head or neck, chronic malabsorption syndromes, weight of 10% or more below ideal body weight, and intestinal bypass or gastrectomy)
- Children less than 4 years of age, or children and adolescents exposed to adults in high risk categories

Administering Treatment for Latent Tuberculosis Infection (LTBI)

Treatment of latent Tuberculosis infection (LTBI) is essential to controlling and eliminating Tuberculosis. Although not required, treatment of LTBI substantially reduces the risk that Tuberculosis infection will progress to active Tuberculosis disease. There are different treatment regimens available for the treatment of LTBI. Certain groups are at high risk for developing Tuberculosis disease once infected and every effort should be made to begin appropriate treatment and ensure that the entire course of LTBI treatment is completed.

Checklist: Before beginning treatment of LTBI

1. Rule out the possibility of active Tuberculosis.
    - CXR and medical history
    - Physical examination (it is especially important to do a physical exam of infected children due to 50% of children with Tuberculosis present as asymptomatic contacts to an active Tuberculosis case).
    - Bacteriology examination (for persons with signs or symptoms consistent with active Tuberculosis)

2. Ask about previous treatment for LTBI or Tuberculosis disease (someone with adequate previous therapy may not require re-treatment; please contact the Tuberculosis Program for further information).

3. Check for adverse reactions to current drugs which have known interactions with Tuberculosis drugs.

4. Recommend HIV testing, if risk factors are present.

5. Establish rapport with patient and emphasize possible side effects (see "How to Monitor for Side Effects" located in Forms & Tables section), benefits of treatment, importance of adherence to the treatment, and establish an optimal follow-up plan.

6. If sputum cultures have been obtained, await final results prior to initiating treatment for LTBI.

Treating Children and Adolescents

Explanation

Children most commonly develop Tuberculosis as a complication of the initial infection with M. tuberculosis (primary Tuberculosis). Radiographically, primary Tuberculosis is characterized by intrathoracic adenopathy, mid- and lower-lung infiltrates, and the absence of cavitation. However, children, occasionally, and adolescents, more frequently, develop adult-type Tuberculosis (upper lobe infiltration and cavitation associated with sputum production). The lesions of primary Tuberculosis have a smaller number of M. tuberculosis organisms than those of adult-type pulmonary Tuberculosis; thus, treatment failure, relapse, and development of secondary resistance are rare phenomena among children.

It is more difficult to isolate M. tuberculosis from a child with pulmonary Tuberculosis than from an adult; therefore, it is frequently necessary to rely on the results of culture and susceptibility tests of specimens from the person presumed to be the source of the infection in the child to guide the choice of drugs for the child. In children in whom drug resistance is suspected or for whom no index case isolate is available, attempts to isolate organisms via three early morning gastric aspirations (optimally during hospitalization), Bronchoalveolar Lavage, or tissue biopsy should be considered.

Because Tuberculosis in infants and children younger than 4 years of age is more likely to disseminate, treatment should be started as soon as the diagnosis is suspected. Asymptomatic children with a positive PPD-tuberculin skin test and an abnormal chest radiograph (atelectasis, parenchymal infiltrate, or hilar adenopathy) should receive combination chemotherapy, usually with INH, RIF, and PZA as initial therapy.

Several controlled and observational trials of 6-month therapy in children with pulmonary Tuberculosis caused by organisms known or presumed to be susceptible to the first-line drugs have been published. Six months of therapy with INH and RIF has been shown to be effective for hilar adenopathy and pulmonary disease caused by drug-susceptible organisms. However, most studies used 6 months of daily treatment with INH and RIF, supplemented during the first 2 weeks to 2 months with PZA. This three-drug combination has a success rate of greater than 95% and a rate of adverse effects of less than 2%.

Many experts prefer to treat children with three (rather than four) drugs in the initial phase because the bacillary population is low, because many infants and children cannot tolerate the pill burden required with four oral drugs, and because of the difficulty in performing visual acuity tests in young children who are being treated with EMB. In children suspected or known to have been infected with an M. tuberculosis strain that is fully susceptible, the initial phase should consist of INH, RIF, and PZA. If the susceptibility of the presumed infecting strain is not known and the likelihood of failure is low (primary Tuberculosis), some experts prefer to use three drugs. However, children and adolescents with adult-type pulmonary Tuberculosis, as defined above, should be treated with the four-drug initial phase regimen, unless the infecting strain is known to be susceptible. When epidemiologic circumstances suggest an increased risk of drug-resistant organisms being present, EMB can be used safely in a dose of about 15-20 mg/kg per day, even in children too young for routine eye testing. Older children should have monthly evaluations of visual acuity and color discrimination while taking EMB. SM, kanamycin, or amikacin can be used as the fourth drug, when necessary.

The usual doses for daily and twice weekly treatment in children are listed on "ATS Medication Guidelines" located in the Tables Section. Three times weekly therapy is not recommended for children. Pyridoxine is recommended for infants, children, and adolescents who are being treated with INH and who have nutritional deficiencies, symptomatic HIV infection, or who are breastfeeding.

DOT should be used for all children with Tuberculosis. The lack of pediatric dosage forms of most anti-tuberculosis medications necessitates using crushed pills and suspensions. Even when drugs are given under DOT, tolerance of the medications must be monitored closely. Parents should not be relied on to supervise DOT.

Because of the difficulties in isolating M. tuberculosis from children, bacteriological examinations are less useful in evaluating the response to treatment and clinical and radiographic examinations are of relatively greater importance. However, hilar adenopathy and resultant atelectasis may require 2--3 years to resolve. Thus, a persisting abnormality on chest radiographs is not necessarily a criterion for extending continuing therapy. Recognition of treatment failure or relapse in a child is subject to the same difficulties as making a diagnosis. Thus, clinical and radiographic worsening may not be accompanied by positive AFB smears or mycobacterial cultures. A decision to modify the drug regimen should not be made lightly, but often must be made on clinical grounds only.

In general, extrapulmonary Tuberculosis in children can be treated with the same regimens as pulmonary disease. Exceptions may be disseminated disease and meningitis, for which there are inadequate data to support 6-month therapy. A fourth drug is recommended in the initial phase when there is disseminated Tuberculosis. The recommended duration is 9-12 months.
The optimal treatment of pulmonary Tuberculosis in children and adolescents with HIV infection is unknown. The American Academy of Pediatrics recommends that initial therapy should always include at least three drugs (INH and RIF, plus PZA for the first 2 months), and the total duration of therapy should be at least 9 months.

Children and Adolescents Treatment Guidelines

General Guidelines

The treatment of Tuberculosis in children should be undertaken in consultation with physician experienced in its management, especially for patients with CNS, miliary, or multi-drug-resistant (MDR) Tuberculosis and with HIV-infection.

- Tuberculosis in infants and children is commonly primary disease, which presents with intrathoracic adenopathy, middle and lower lung infiltrates, or pleural effusion. However, older children and adolescents may manifest an adult-type or reactivation pattern Tuberculosis with upper lobe infiltrates, cavitation, and sputum production.
- Children with active Tuberculosis are often found to be smear and culture negative when clinical specimens (e.g., sputum, gastric aspirates, etc.) are examined; these children should be treated as having active disease, not culture-negative Tuberculosis. In such instances when an isolate from a pediatric case is not available, drug susceptibility results from the adult index case can be used to guide therapy.
- Drug-susceptible pulmonary disease is treated for 6 months: the initial (2-month) phase employs 3 drugs (INH, RIF, PZA) and the continuation (4-month) phase consists of INH and RIF. A fourth drug (usually EMB) is added to the initial regimen only if there are risk factors for drug resistance in the child or index case and is continued until drug susceptibility studies are known. Treat isolated hilar adenopathy with 6 months of INH and RIF alone; however, where drug resistance is a consideration, add PZA for the initial 2 months.
- Extrapulmonary disease is treated the same as pulmonary disease except for CNS or miliary Tuberculosis which is treated for 9-12 months. After expert consultation, this may involve adding a 4th drug (EMB, an aminoglycoside, or ethionamide) and steroids (indicated for CNS Tuberculosis and considered for severe miliary, endobronchial, and pericardial disease and pleural effusion). For skeletal Tuberculosis, orthopedic intervention and prolonged therapy may be indicated.
- Based on medication history and drug susceptibility results, treatment for MDR Tuberculosis (resistance to at least INH and RIF) must be individualized and prolonged.
- The clinical manifestations and radiographic appearance of Tuberculosis disease in children with HIV tend to be similar to those in immunocompetent children, but manifestations in these children can be more severe and unusual and can include extrapulmonary involvement. Optimal therapy has not been established; therapy should include at least 3 first-line drugs (INH, RIF, PZA) initially and be continued for at least 9 months.
- Treatment of Tuberculosis benefits both the community as a whole and the individual patient; thus, all public health programs and private providers not only must prescribe an appropriate regimen but also ensure adherence until treatment completion.
- All new and suspected cases of Tuberculosis should be reported to your state and local health departments so that index case or contact investigations can be conducted and case management provided.

Drug Resistant Tuberculosis

Explanation

When an initial culture is identified as positive for M. Tuberculosis, a drug susceptibility test is performed. In this test the organism is incubated in the presence of a panel of anti-Tuberculosis drugs. If the organism grows, then it is considered to be resistant to that drug. The test may take two to three weeks after the identification of M. Tuberculosis. It is crucial to identify drug resistance as early as possible to ensure appropriate treatment.

A person can either acquire a drug resistant strain of Tuberculosis from another person (primary resistance) or can develop resistance as a result of inadequate treatment (secondary resistance). Non-compliance with drug treatment plays a major role in the development of drug-resistant Tuberculosis.

Drug resistance presents difficult treatment problems. Treatment must be individualized and based on the patient's medication history and susceptibility studies. Clinicians who are unfamiliar with the treatment of drug-resistant Tuberculosis should consult with the Nebraska Tuberculosis Program Manager.

Isoniazid-Resistant Tuberculosis

When resistance to isoniazid is documented, the treatment regimen should be adjusted by discontinuing isoniazid and continuing rifampin, ethambutol and pyrazinamide. Adding a fluoroquinolone may strengthen the regimen for patients with extensive disease. A 6-month regimen has yielded >95% success rates, despite resistance to isoniazid, if 4 drugs were used in the initial phase and rifampin plus ethambutol was used throughout.

Multi-drug resistant Tuberculosis

Multi-drug resistant Tuberculosis (MDR Tuberculosis) is defined as resistance to at least isoniazid and rifampin. Patients with MDR Tuberculosis are at high risk for treatment failure and further acquired resistance. They must be referred immediately to a specialist or consultation obtained from specialized treatment centers.

Directly Observed Therapy (DOT)

Explanation/Definition

It is strongly recommended that patient-centered care be the initial management strategy, regardless of the source of supervision. This strategy should always include an adherence plan that emphasizes directly observed therapy (DOT), in which patients are observed to ingest each dose of anti-Tuberculosis medications, to maximize the likelihood of completion of therapy. Programs utilizing DOT as the central element in a comprehensive, patient-centered approach to case management (enhanced DOT) have higher rates of treatment completion than less intensive strategies. Each patient's management plan should be individualized to incorporate measures that facilitate adherence to the drug regimen. Such measures may include, for example, social service

support, treatment incentives and enablers, housing assistance, referral for treatment of substance abuse, and coordination of Tuberculosis services with those of other providers.

How to Obtain Directly Observed Therapy (DOT)

The Tuberculosis Program contracts with local public health agencies to provide DOT for patients with suspect/known active Tuberculosis. Billing requests must include date(s) of DOT visits and total amount requested, based on a standard rate per visit (see Forms & Tables section "Tuberculosis Program Rate Reimbursement" and "DOT Treatment Notes").

Directly Observed Therapy and Adherence

Directly observed therapy (DOT) is therefore the standard method of providing treatment to all persons with active Tuberculosis. In addition, DOT allows for the immediate detection of non-compliance so that actions can be taken to avoid treatment failure. Careful attention must be paid to ensure that ingestion of the medication is, in fact, observed. Health care providers must recognize that even with DOT, additional strategies and efforts are necessary for treatment success.

Medication/Treatment:

ATS Recommendations

The Tables marked "Figure 3" and "Figure 3 Continued" which are located in the tables and forms sections were extrapolated from MMWR Recommendations and Reports June 20, 2003 / 52(RR11);1-77 Treatment of Tuberculosis American Thoracic Society, CDC, and Infectious Diseases Society of America. This can also be found on the web at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm#tab3

How to Monitor for Side Effects

Side Effects Table

Please see Tuberculosis Medication Side Effects in the Forms & Tables Section.

Educate patients about possible side effects of treatment before beginning therapy and instruct them to notify the clinic if any symptoms present. Active hepatitis and end-stage liver disease are relative contraindications to the use of INH for treatment of LTBI. Use of these drugs in such patients must be undertaken with caution.

Baseline laboratory testing is NOT routinely indicated for all patients at the beginning of treatment for LTBI. Baseline hepatitis measurements of serum AST (SGOT) or ALT (SGPT) and total bilirubin are indicated for the following:

- Patients with an initial evaluation suggesting a liver disorder
- Patients with HIV infection

- Women who are pregnant or in the immediate postpartum period (within 3 months of delivery).
- Patients with a history of chronic liver disease (e.g. hepatitis B or C, alcoholic hepatitis or cirrhosis, persons who use alcohol regularly and others who are at risk of chronic liver disease)
- Patients who are taking medications for chronic medical conditions (considered on an individual basis)
- If client is taking anti-convulsants (e.g. Dilantin), refer client to Health Care provider for monitoring of anti-convulsant drug levels.

The Tuberculosis Program should evaluate patients receiving treatment of LTBI for the following:

1. Adherence to prescribed regimen
2. Signs and symptoms of active Tuberculosis disease
3. Signs and symptoms of hepatitis

Whenever any of these are present, consult with the patient's medical provider. Liver function tests may be indicated if signs or symptoms of hepatitis develop. In most cases, therapy should be stopped until laboratory results are reviewed.

Other laboratory testing (e.g. uric acid) should be considered for patients on treatment of LTBI and who develop symptoms of acute arthritis.

Adherence to Tuberculosis Treatment – Case Management

Motivating People to Comply with Therapy

Assuming appropriate drugs are prescribed, circumstances surrounding each Tuberculosis patient that may affect his/her ability to complete treatment becomes the most important consideration in completion of Tuberculosis treatment. Factors that interfere with adherence include cultural and linguistic barriers, life style differences, homelessness, substance abuse, and other conditions and circumstances that, for the patient, are priorities that compete with taking treatment for Tuberculosis. Effective Tuberculosis case management identifies the circumstances surrounding each patient and determines an appropriate care plan.

Poor adherence to Tuberculosis medication regimens leads to inadequate treatment. The consequences of inadequate and incomplete Tuberculosis treatment are serious:

- Prolonged illness and disability for the patient
- Infectiousness of the patient, causing continued transmission of Tuberculosis in the community
- Development of drug-resistant Tuberculosis
- Death

Adherence to a prescribed Tuberculosis mediation regimen will be more likely to succeed if the case manager(s):

- Learn as much as possible about your patient's health history, beliefs and attitudes about Tuberculosis, sources of social support, and barriers to treatment.

- Work with an interpreter or a person of the same cultural background as the patient, if possible.
- Look for early warning signs of future adherence problems (e.g., patient feels medicine is no longer needed because he/she is feeling well, difficulty in accessing health care).
- Designate a person to do DOT who does not have a strong emotional tie with the patient. Suitable designees might include school nurse/staff, employee health, public health, visiting nurse, work supervisor, clergy, or other responsible person.
- Provide effective education to patients and key individuals in the patient's social environment.
- Provide patient with needed health or social services or make referral to other health or social service agencies.
- Use a team of personnel whose members work together to assist each patient in completing treatment.
- Mutually agree on a time and location for DOT (be creative and flexible).
- Be aware of patients who may require techniques to assess for ingestion of medication (e.g., hiding pills in mouth, vomiting after pills swallowed).
- Encourage a social support system that enhances the patient's adherence to treatment.
- Use incentives and enablers.
- Contact Tuberculosis Program for further information and resources.

Compliance with Treatment

Monitoring

Health care providers often do not realize that patients are not following recommendations. It is very important for you to determine whether your patients are taking medications as prescribed and to have a high index of suspicion of non-compliance. There are several methods for assessing compliance.

- Ask the patient
- Communicate effectively
- Help the patient to remember
- Listen carefully: ask the patient to report any problem with taking the medications
- Monitor appointment keeping, medication refill, and pick-up
- Monitor pills (perform pill counts)
- Directly observe the patient swallowing each dose of medication

Community Tuberculosis Control

Transmission Prevention Precautions

Tuberculosis transmission prevention precautions must be followed for patients who are known or suspected of having active infectious Tuberculosis. Patients may be identified as having infectious Tuberculosis based on the patient's signs or symptoms of Tuberculosis, a history of incomplete Tuberculosis therapy, sputum smear and culture results, chest x-ray results, and/or the primary care provider's clinical diagnosis.

An effective Tuberculosis infection control program requires the early detection, isolation and treatment of persons with known or suspected infectious Tuberculosis. Tuberculosis precautions should be based on a careful assessment of risk for transmission of Tuberculosis in the facility or setting. The primary emphasis of the infection control plan should be on achieving these three goals through a hierarchy of control measures, including the following:

Assessing risk factors

Performing assessments of the risk for transmission of Tuberculosis in the particular setting or area and for a specific occupational group which should be based on the following:

1. The profile of Tuberculosis in the community
2. The number of infectious Tuberculosis patients admitted to the area or ward and/or the estimated number of infectious Tuberculosis patients to whom health care workers (HCWs) in an occupational group may be exposed
3. The results of analysis of HCW skin test conversions (where applicable) and possible person-to-person transmission of M. Tuberculosis

Use of administrative controls to reduce the risk of exposure to infectious Tuberculosis

Developing and implementing effective written policies and work practices to ensure the rapid identification, isolation, diagnostic evaluation, and treatment of persons likely to contract Tuberculosis. Protocols should include or (one of) the following Tuberculosis prevention precautions:

- Use triage to promptly identify patients who may have Tuberculosis.
- Promptly evaluate patients who have Tuberculosis symptoms.
- Place patient in a separate area apart from other patients and not in open waiting areas (ideally in a room or enclosure with special ventilation maintained under negative pressure).
- Give patient a surgical mask to wear until he/she can be transported to an appropriate isolation room or until he/she leaves the building.
- Give the patient a tissue and instruct them to cover their mouth and nose when coughing or sneezing.
- Schedule appointments to avoid exposing other patients, especially HIV infected or immunocompromised persons.
- Avoid performing a cough-inducing procedure (e.g. sputum inductions) on patients 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 Tuberculosis isolation.
- Allow enough time to pass before placing another patient in a room or area previously occupied by an infectious patient (requires airflow analysis by a qualified engineer to define the length of time needed to remove at least 99% of airborne contaminants).
- If the patient is placed in Tuberculosis isolation and is not wearing a mask, all persons entering the room must wear special respiratory protection which meets minimum. requirements for Tuberculosis transmission prevention (*see “Respiratory Protection

Guidelines" below). Tuberculosis transmission prevention precautions can be discontinued if the diagnosis of Tuberculosis is ruled out or if contagiousness is ruled out.

Educating, Training, and Counseling Health Care Workers about Tuberculosis

This includes basic education regarding Tuberculosis transmission, pathogenesis, diagnosis, differentiating of disease and therapy for latent Tuberculosis infection and disease, signs and symptoms of Tuberculosis, higher risk of disease associated with immunocompromised persons, prevalence of Tuberculosis in the community and facility, transmission prevention precautions, situations that increase risk for exposure, purpose of TST, significance of a positive TST result and recommended follow-up, disease reporting procedures, confidentiality, information regarding BCG vaccine, and options for work reassignments for immunocompromised HCWs.

Screening HCWs for Tuberculosis infection and disease

This includes developing and implementing a tuberculin skin-testing program for persons in the facility with the potential for exposure to Tuberculosis. Health care workers, including home health nurses, clinic workers and emergency medical technicians, should be included in a Tuberculosis testing and prevention program if the risk assessment indicates that they are at risk for exposure. This means a TST upon employment and at repeated intervals determined by their risk of exposure thereafter. Any worker who develops symptoms of Tuberculosis disease or whose TST result converts to positive should be evaluated promptly.

Screening also includes use of personal (particulate) respiratory protection, which has been certified by the National Institute for Occupational Safety and Health (NIOSH), including a respiratory protection program that teaches HCWs how and when to use the respirators.

Respiratory Protection Guidelines

In 1995, CDC's National Institute for Occupational Safety and Health (NIOSH) introduced a new classification scheme for particulate air-purifying respirators. Most health-care workers use type N95 half-mask filtering face piece respirators (i.e., N95 respirators) to prevent occupational transmission of Tuberculosis. Fit testing N95 respirators is essential in programs employing these respirators and can eliminate poorly fitting respirators, ensuring at least the expected level of protection. However, when fit tested first, a substantially greater level of protection than normally expected was obtained. Without fit testing, persons unknowingly may have poor face seals, resulting in excessive leakage and exposure.

It is the Policy of the State of Nebraska Tuberculosis Program to utilize and recommend N95 Respirators for all person(s) who will come into contact with a contagious or potentially contagious person(s). It is also the recommendation by our department that all N95 Respirators be fit tested to the current CDC and NIOSH standards and guidelines.

Tuberculosis Precautions in Hospitals and Other Inpatient Facilities

Explanation

Hospitals and other inpatient facilities must initiate isolation in a private isolation room with special ventilation maintained under negative pressure relative to other parts of the facility (air flow from the corridors into the isolation room). The room must be monitored daily while in use to assure that appropriate ventilation is maintained, the door must remain closed, and the patient should only leave the room for medically essential purposes.

Staff

For the safety of all workers, the isolation room must be clearly identified as housing a potentially infectious patient. When the patient must leave the room, the patient should wear a surgical mask that covers the nose and mouth at all times.

Patient(s)

Patients who are placed in isolation rooms should be educated about the transmission of Tuberculosis, the reasons for isolation, and the importance of staying in their rooms. The patient should also be instructed to cover his/her nose and mouth with a tissue when coughing or sneezing.

Visitor(s)

The number of persons entering the room should be limited and those entering the room must wear appropriate respiratory protective devices, i.e. N95 Respirator mask. These devices must adequately fit the worker or visitor.

Discharge Note

Patients evaluated at or admitted to an inpatient facility and determined to have suspected or known infectious Tuberculosis cannot be released until the state or local public health agency has made arrangements for appropriate follow up post discharge. 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 infectious.

Tuberculosis Precautions in Ambulatory-Care Settings and Emergency Departments

Some patients with suspected or known active Tuberculosis may be evaluated or treated in an outpatient setting under the supervision of or directly provided by the local public health agency. All ambulatory-care settings and emergency departments must develop, implement and update a Tuberculosis infection control plan in accordance with federal and state rules and/or recommendations.

Health Care Settings

Explanation

Contact the Tuberculosis Program for consultation regarding the appropriateness of home placement for individual patients. Patients 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. Healthcare workers or visitors must wear appropriate respiratory protection when visiting patients with confirmed or suspect Tuberculosis. Avoid performing cough-inducing procedures on patients who are infectious or use appropriate respiratory protection and perform in a well-ventilated area.

Home Care Settings

Explanation

Health care workers who provide medical services in the homes of patients who have suspected or confirmed infectious Tuberculosis should instruct such patients to cover their mouths and noses with a tissue when coughing or sneezing. Until such patients are no longer infectious, Health care workers should wear respiratory protection when entering these patients' homes. Precautions in the home may be discontinued when the patient is no longer infectious.

Health care workers who provide health-care services in the patient's homes can assist in preventing transmission of M. tuberculosis by educating their patients regarding the importance of taking their medications as prescribed and by administering DOT.

Cough inducing procedures by a health care worker should not be done in the patient's home, if diagnosed with infectious Tuberculosis. Cough inducing procedures should be performed on patients in a health care facility in a room or booth that has the recommended ventilation for such procedures.

Health care workers who provide services to patients who are at risk for developing pulmonary Tuberculosis should periodically remind the patient of the importance of having pulmonary symptoms evaluated for early detection and treatment of Tuberculosis disease.

As stated prior, all health care workers who will come into contact with people who are infected with Tuberculosis are to abide by the current NIOSH guidelines and be fit tested with a N95 Respirator.

Infectiousness

When is an Active case contagious?

Factors of contagiousness

Factors that correlate with the contagiousness of an active case follows:

1. Pulmonary or laryngeal Tuberculosis
2. Presence of cough or cough-inducing procedures

3. Failure of patient to cover his/her mouth and nose when coughing
4. Positive sputum AFB smear
5. Cavitation on chest radiograph
6. Inappropriate or short duration of treatment adequacy
7. Poor clinical response to treatment

Identifying those who are not contagious

Patients are not considered infectious if they meet ALL the following criteria:

1. They are on adequate therapy
2. They have significant clinical response to therapy (i.e., reduction in cough, resolution of fever)
3. They have three consecutive negative sputum smears collected on different days

Patients with extra-pulmonary Tuberculosis usually are not infectious unless they have pulmonary or laryngeal Tuberculosis in addition to their extra pulmonary disease or have an abscess or open lesion requiring treatment that may lead to aerosolization of wound drainage

Case Investigations/Suspected or Confirmed

Tuberculosis Program and Health Departments: Procedures

Upon notification of a suspected case of Tuberculosis, after the proper procedures have been followed and if the Patient(s) has all diagnostic/clinical requirements met, fill out CDC Reporting Form for Tuberculosis (see Forms & Tables section). Please fax the completed form to the State of Nebraska Tuberculosis Program at 402.471.1377.

Who to Notify Regarding Active/Suspect Tuberculosis

Communicable Diseases:
Tuberculosis Program Manager
301 Centennial Mall South
P.O. Box 95007
Lincoln, NE 68509-5007
(p) 402.471.6441
(f) 402.417.1377
Communicable Disease Operator
(p) 402.471.2937

All cases, suspect cases and positive laboratory results must be reported within 24 hours to the local health agency or the Tuberculosis Program. Options for reporting a case include the following.

Contact Investigation for Tuberculosis

Please refer to and complete ARPE form in the “Forms & Tables” Section

Explanation

Contact investigation is an integral part of any Tuberculosis program and one of the best ways to find people who have Tuberculosis disease. According to the Centers for Disease Control and Prevention, 7-8 cases of disease are found for every 1000 contacts that are evaluated. Finding infected contacts that do not yet have disease and offering treatment for latent Tuberculosis infection (LTBI) is important as well. On average, about 20% of contacts are found to have Tuberculosis infection, but in some contact investigations as many as 80-100% of the close contacts may be infected. Successful contact investigation requires skills in patient assessment, counseling, interviewing, and evaluation.

Purpose

- To identify persons who have Tuberculosis disease so that they can be given treatment and stop further transmission
- To identify persons who have LBTI and offer treatment to prevent progression to disease
- To identify persons who are at high risk of developing Tuberculosis disease and need treatment
- To identify the source of Tuberculosis disease transmission
- To identify environmental factors that may contribute to the transmission of Tuberculosis

Who is a Contact?

Contacts are persons exposed to someone with infectious Tuberculosis disease. Exposure to Tuberculosis 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 identifies contacts by interviewing the person with Tuberculosis and by visiting the places where that person spends time regularly.

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 Tuberculosis. In general, a contact investigation should be done whenever a patient is found to have or is suspected of having infectious Tuberculosis disease (e.g. symptoms and chest x-ray consistent with Tuberculosis disease). Infectiousness depends on a variety of factors, but is more likely when patients have the following:

- Cough
- Hoarseness
- Other symptoms of pulmonary or laryngeal Tuberculosis
- Positive AFB smear or culture results for M. tuberculosis (recent evidence suggests that transmission can occur in AFB sputum smear-negative cases as well)
- Cavity on chest x-ray
- Inadequate or no treatment

Children four years old or younger (< 4) with pulmonary Tuberculosis disease are rarely infectious, so a contact investigation is generally not conducted for them. However, young children with pulmonary Tuberculosis disease should be evaluated for infectiousness and contact investigation may be warranted. Contact the Tuberculosis program Manager if there are any questions.

In addition, a index case investigation (looking for the source of exposure) should be conducted to find the source of Tuberculosis transmission when recent transmission is likely. This is usually done when the following takes place:

- A child four years old or younger (< 4) is found to have Tuberculosis infection or disease
- A severely immunocompromised person who does not have a known history of Tuberculosis infection is found to have Tuberculosis disease
- A cluster of TST conversions is found in a high-risk institution (e.g. health care or correctional facility)

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

Nine Step Contact Investigation

Nine Step Procedures

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 9 basic steps:

1. Medical Record Review

    - Review of the Tuberculosis patient's medical record/information and information from the clinician to determine whether the patient has been infectious and if so when. Knowing when the patient was infectious helps to determine which contacts are at risk.
    - Information that should be collected includes site of disease, symptoms, approximate date of onset of symptoms, sputum smear and culture or other mycobacterial laboratory results (including dates of specimens and drug susceptibility results), chest x-ray results, Tuberculosis treatment information (medications, dosages, and dates of treatment), and method of treatment (e.g. DOT vs. self administered), and the period of infectiousness after a complete assessment of the information is available.

2. Patient Interview (Tuberculosis Case Interview)

The patient interview is one of the most critical parts of the contact investigation. If the interviewer does not communicate well enough with the patient to get accurate information about symptoms, places where patient spent time, and names of contacts, then people who need evaluation and treatment may be missed. The interviewer should keep in mind that the patient may first learn of his/her new Tuberculosis diagnosis during the initial interview. The patient may be overwhelmed, fearful of his/her diagnosis, or still very ill and unable or unwilling to participate fully in an interview. Thus, follow-up interviews should be scheduled to educate patients and to complete a thorough contact investigation. Good communication (ask open-ended questions), good listening skills, patient education, and establishing and maintaining a trusting relationship are essential during all interviews.

The initial interview should occur no more that 3 working days after the case is reported. During the interview, the Tuberculosis patient should be asked more about the following:

- Symptoms—type and onset; especially cough and sputum production
- Places where the patient 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

In addition, the patient should be asked about the characteristics of each place (room size, windows open or closed, time spent in each place, etc.) to help determine the risk that M. tuberculosis was transmitted in each place. Written educational materials regarding Tuberculosis should also be provided to the patient.

Some patients may be reluctant to identify some or all of their contacts. For example, a patient may not want to identify people who use illegal drugs with him/her. The interviewer should be sensitive to the patient's fears, explain the importance of testing the contacts, and assure the patient that all information will be kept confidential (including the patient's name). A patient interview checklist can assist the interviewer in obtaining the correct information.

3. Field investigation

A field investigation means visiting the Tuberculosis patient's home or shelter, workplace (if any), and other places where the patient 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 the following:

- Room size
- Crowding
- Ventilation
- Contacts (especially children) and their locating information
- Evidence of other contacts that may not be present (e.g. pictures of others who may live in the place, 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

- Receive a TST and arrange for reading of the results;
- Be educated about the purpose of the investigation, basic Tuberculosis transmission, risk of transmitting Tuberculosis to others, and the importance of testing, treatment, and follow-up for LTBI and disease;
- Be referred for medial evaluation, including chest x-ray and sputum collection if they have symptoms of Tuberculosis.

4. Risk Assessment for M. tuberculosis Transmission

The infectiousness of the Tuberculosis patient is dependent upon the duration of time when the patient was infectious and estimated degree of infectiousness. The degree of infectiousness is estimated from information regarding the patient's symptoms, sputum smear results, and other conditions identified during the medical record review and patient interview. The greater 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, crowding conditions, poor ventilation (no or little fresh air to dilute the droplet nuclei in a room), and lack of air cleaning systems increase the risk of transmission of M. Tuberculosis.

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

5. Prioritization of contacts

Contacts are prioritized based on risk of progression to Tuberculosis disease once infected and the risk of infection after exposure to an active pulmonary or laryngeal Tuberculosis case (e.g. close, regular, prolonged contact with the Tuberculosis patient while he/she was infectious, especially in small, poorly ventilated places). To use time and resources wisely, the contact investigation should be focused on the high-priority contacts.

Contacts at high risk of developing Tuberculosis, once infected, are considered high priority and should be evaluated first. This includes household contacts, contacts living in congregate settings, children less than 4 years of age, HIV-infected or other immunocompromised persons, and contacts with certain other medical conditions. Contact the Tuberculosis Program for assistance with identification of these contacts. Other contacts to an active pulmonary or laryngeal Tuberculosis case should be evaluated in the order of their risk of infection after exposure. Prioritization is as follows:

High priority - Contacts to a index case:

- who spend 8 hours or more in a small, poorly ventilated space
- who spend 16 or more hours in a small, well-ventilated space

- who spend 24 hours or more in a classroom size space
- who spend 100 hours or more in a large, open space

Medium priority—Contacts to a index case:

- who are 4 to 15 years of age
- who spend 4 or more hours in a small space
- who spend 8 or more hours in a classroom size space
- who spend 50 or more hours in a large, open space

Low priority – All other contacts.

- These contacts have less intense, less frequent or shorter durations of contact with the Tuberculosis patient and should be given lower priority for testing.

6. Evaluation of Contacts

Evaluation of Tuberculosis contacts includes at least a medical history and TST. Close contacts and high-priority contacts should be examined within 7 working days after the index case has been diagnosed. Contacts should be asked about their history or treatment of previous Tuberculosis infection or disease, documented previous TST, previous exposure to Tuberculosis, risk factors for developing Tuberculosis disease, and current symptoms of Tuberculosis. All high-priority contacts should be given a TST. A reaction of 5 mm or greater is considered positive for contacts. Contacts with a positive reaction should be further evaluated for Tuberculosis disease (see "Contact Investigation Guideline" Forms & Tables section). In some cases, sputum inductions are necessary to obtain an appropriate specimen.

Contacts that have a previously documented positive TST should not receive another test, but should be evaluated for symptoms of Tuberculosis disease. Depending on the results of the evaluation, some of these contacts may be candidates for treatment of LTBI or disease. A chest x-ray should be obtained and interpreted before initiating any treatment.

Because it takes between 2 weeks and three months after Tuberculosis infection for the body's immune system to react to tuberculin (window period), contacts that have a negative reaction on the initial TST should be retested 10 weeks after their last exposure to the infectious Tuberculosis patient.

Infants under 6 months of age may have a false-negative TST reaction because their immune systems are not yet able to react to tuberculin. Thus, infants need careful clinical evaluation.

Contacts who have Tuberculosis symptoms, are HIV-infected, have other immunosuppressive conditions, or are under 4 years of age should have a chest x-ray at the same time as the initial skin test to evaluate him/her for Tuberculosis disease. This is because of their high risk of developing Tuberculosis disease. In addition, these close contacts should be considered for treatment of latent Tuberculosis infection (LTBI) even if the initial TST reaction is negative during the window period.

Treatment may be discontinued if the 10-week follow-up TST is still negative and the contact is not at continued risk for exposure to infectious Tuberculosis.

Contacts who have an abnormal chest x-ray or symptoms of Tuberculosis disease should have three early-morning sputum specimens, collected on three different days, for smear and culture examination, regardless of his/her TST reaction.

7. Treatment and follow-up for contacts

The following contacts should be offered treatment for LTBI:

- Contacts with a positive TST reaction and no evidence of Tuberculosis disease
- High-priority contacts who have a negative TST reaction who may develop Tuberculosis disease quickly after infection (e.g. children under 4 years of age, HIV-infected people, contacts with other immunosuppressive conditions). Contacts recently infected with M. tuberculosis are a high-priority for treatment for LTBI because they are at high-risk of developing Tuberculosis disease (highest risk of developing Tuberculosis disease 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 skin test results, because of the possibility of a false-negative skin test result (inability to react to tuberculin due to a compromised immune system).
- Contacts that have positive sputum smear(s) or chest x-ray result suggestive of current Tuberculosis disease should begin treatment for Tuberculosis disease.
- Contacts that have started treatment for LTBI or Tuberculosis disease should be monitored to ensure compliance and completion of treatment. Contacts with LTBI and at high-risk for progressing to Tuberculosis disease should be considered for directly observed preventive treatment (e.g. children, HIV positive or immunosuppressed patients).

8. Decision about Whether to Expand Testing

After the highest-priority contact group has been evaluated for LTBI and Tuberculosis disease, the contact investigation staff should evaluate the results of testing for evidence of recent transmission. Evidence of recent transmission is indicated by any of the following factors:

- High infection rate among contacts as compared to the local community infection rate
- Infection in a young child
- A skin test conversion in a contact
- A secondary case of Tuberculosis disease

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

1. Determine the number of contacts with newly-identified positive skin tests.
2. 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.

3. Determine the infection rate. Divide the number of contacts with a new positive skin test by the total number of contacts without a documented previous positive skin test. Multiply by 100; the resulting percentage is the infection rate for that group of contacts.

When there is evidence of recent transmission of Tuberculosis in the first priority group of contacts tested, the likelihood that M. tuberculosis has also been transmitted to contacts with less exposure, increases. The testing should, therefore, be expanded to the next priority level of contacts. This should be done as soon as it becomes clear that transmission may have occurred. The decision about expanding contact investigation to the next group of contacts should be made by clinical and supervisory staff, based on an assessment of all available information.

If there is no evidence of recent M. tuberculosis transmission among high priority contacts, testing should not be expanded to the next group of contacts (e.g. new positive skin test rate among contacts is lower than or similar to the level of infection in the community, no young children have a positive skin test reaction, no contact skin test conversions have occurred, no contacts have Tuberculosis disease). Once the infection rate among the group being tested is the same as the infection rate in the local community and there are no other factors indicating recent transmission, testing can be stopped.

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 these factors:

- 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 Tuberculosis infection or disease?
- How many infected contacts completed a regimen of treatment for LTBI?
- Did all identified cases complete an adequate treatment regimen?

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

Algorithm

See Forms & Tables section for “Contact Investigation Algorithm

Specimen Collection

Specimens should be collected and submitted in sterile, leak proof, disposable, appropriately labeled, laboratory-approved containers. All specimens can be collected in the sterile collection tubes. Do not use waxed containers, as they may provide false-positive smear results. Specimens should be forwarded promptly to the laboratory after collection for optimal processing and result

turn-around time. 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.

Specimen Types

Explanation

Many different types of specimens may be submitted for mycobacterial culture. The majority of the specimens submitted are from the respiratory tract. Tissue, normally sterile body fluids, urine, and gastric aspirates are other commonly submitted specimens. Blood and stool specimens may also be submitted for mycobacterial culture. The quality of specimens collected and the proper transport of those specimens to the laboratory are critical to the successful isolation of AFB (acid-fast bacilli). There will be no charge for Tuberculosis testing submitted by local public health agencies for patients with signs or symptoms consistent with Tuberculosis. Nebraska Public Health Laboratory (NPHL) has been designated as the State of Nebraska Tuberculosis lab, and only those specimens that are submitted to NPHL will be at no cost.

Sputum

Sputum, both expectorated and induced, is the principal specimen obtained for the diagnosis of pulmonary Tuberculosis. Collect an early-morning specimen, preferably 5-10 ml, from a deep, productive cough on at least 3, but usually not more than 5 or 6 consecutive days (24 or more hours apart). Processing of additional specimens does not seem to improve recovery. For expectorated sputum, patients should be instructed to cough deeply to produce specimens distinct from saliva or nasopharyngeal discharge. The patient should also 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.

Bronchoalveolar Lavage Fluids and Bronchial Washings

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 patient to produce sputum spontaneously for several days after the procedure, and specimens collected a day or two after bronchoscopy enhance detection of mycobacteria.

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 three 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 introduced 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 with 4 hours, adjust fluid to neutral pH with 100 mg of sodium carbonate immediately following collection. Unneutralized specimens are not acceptable, as acid is detrimental to the mycobacteria.

Blood

Cultures for the isolation of mycobacteria from blood are usually reserved for immunocompromised patients. The BACTEC 13A bottle is specifically designed for the recovery of mycobacteria from blood (contains a lysing agent). The 13A medium can be directly inoculated with 5 ml 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 or blood that is coagulated is NOT acceptable.

Urine

Collect the first morning specimens, either by catheterization or midstream clean catch, into a sterile container on three 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 time are dilute and thus not optimal. A minimum of 40 ml of urine is usually required for culture.

Stools

Stool specimens (>1 g) 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.

Body Fluids

Body fluids (cerebrospinal--CSF, pleural, peritoneal, pericardial, etc.) are aseptically collected by aspiration or surgical procedures. Collect as much as possible (10-15 ml minimum) in a sterile container or syringe with a luer tip cap. CSF culture requires at least 2 ml.

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.

Specimen Storage

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.

Laboratory and Diagnostic Services

Chest Radiograph and Interpretation

Outpatient and inpatient facilities offering Tuberculosis treatment should have ready access to a sufficient quantity of radiology equipment and enough trained radiology technicians so that chest radiographs can be obtained each day during clinic hours for all patients needing them. Furthermore, the chest radiograph should be interpreted by a qualified person, and the report of the chest radiograph findings should be available within 24 hours.

Mycobacteriology Laboratory

To ensure that results of acid-fast examinations of specimens are available promptly (ideally, within 24 hours of specimen collection), Tuberculosis control programs should have access to adequate mycobacteriology laboratory services. Reports of isolation and identification of M. tuberculosis should be available within 10-14 days, and reports of drug-susceptibility tests should be available within 15-30 days of specimen collection. The Tuberculosis control program should work closely with the laboratory to ensure rapid delivery of specimens to the laboratory and prompt laboratory reporting of acid-fast bacilli smears, culture results, and results of drug-susceptibility tests to the clinician and health department. The laboratory should use rapid laboratory methods, including fluorescent acid-fast staining procedures, inoculation of a liquid medium as primary culture, nucleic acid probes to identify M. Tuberculosis, and, using radiometric (e.g., BACTEC (R)) or similar systems, testing of M. tuberculosis isolates for susceptibility to the first-line drugs. These mycobacteriology laboratory services also should be available to Tuberculosis control programs for monitoring bacteriologic response to therapy.

Diagnostic Services to Assess Drug Toxicity

The outpatient and inpatient facilities where Tuberculosis treatment is offered should provide, or have access to, diagnostic services for monitoring patients for potential adverse reactions to anti-Tuberculosis medications. At least monthly during therapy, patients receiving anti-Tuberculosis medications should be evaluated by a health-care professional (e.g., nurse, physician, or physician assistant) and questioned about possible adverse reactions. The facilities offering Tuberculosis treatment should be able to perform visual acuity and color vision evaluations on site. Blood tests for liver enzymes, blood urea nitrogen, creatinine, uric acid, complete blood count, and platelets may be performed at an outside laboratory; however, phlebotomy services should be available on site. Audiometry should be available on site or at another accessible location. Testing of serum levels for anti-tuberculosis should be available through a reference laboratory.

Specimen Transport and Shipping Procedures:

Specimens who are sent to the Nebraska Public Health Lab (NPHL) can be couriered at no cost. For pick up arrangements and times please contact the NPHL. For other diagnostic laboratories the proper collection standards and arrangements need to be made.

Make sure that the specimen is in the appropriate sterile specimen collection container. Seal the container and label appropriately. Place the sealed specimen container and an appropriate laboratory requisition form into a second shipping container with ice packs (except blood).

Some specimens must be shipped via NPHL ground courier or Federal Express. Call NPHL at 402.559.2440 or 866.290.1406 for pick up if there are any questions about shipping.

NPHL Address

Nebraska Public Health Laboratory
University of Nebraska Medical Center
Box 981180 600 South 42nd St.
Omaha, NE 68198-1180
Phone: 866-290-1406
Fax: (402) 559-9497

Genotyping

Explanation

The National Tuberculosis Genotyping and Surveillance Network was designed and implemented to systematically evaluate the role of genotyping technology in improving Tuberculosis prevention and control activities. Genotyping proved a useful adjunct to investigations of tuberculosis outbreaks, unusual clusters, and laboratory cross-contamination.

Tuberculosis Genotyping is now available through the Nebraska Public Health Laboratory. The Nebraska Public Health Laboratory (NPHL) has recently been approved by the Centers for Disease Control and Prevention (CDC) to participate in the CDC Tuberculosis Genotyping Program.

Our understanding of Tuberculosis (Tuberculosis) transmission dynamics has been refined by genotyping of Mycobacterium Tuberculosis strains. Genotyping methods at the molecular level will allow further classification of Mycobacterium Tuberculosis isolates, the causative agent of Tuberculosis, and will enhance the epidemiological capacity for the Tuberculosis Program. Genotyping can potentially determine the origin of a Tuberculosis strain. If two patients have isolates with the same genotype, they would be considered “linked epidemiologically” and most likely became infected from a common source. The recognized benefits of Tuberculosis genotyping are enhanced contact investigations, earlier outbreak detection, identifying false positive cultures, and the ability to share Tuberculosis data with neighboring state health departments.

Clinical Laboratory Tuberculosis Reporting Standards

Any clinical laboratory authorized to perform tests for Tuberculosis, including performance of cultures on clinical specimens for the isolation of mycobacterium, will adhere to the following guidelines set up by the State of Nebraska Department of Health and Human Services:

A portion of the initial culture or subculture from any specimen which M. tuberculosis complex has been isolated will be submitted to the Nebraska Public Health Laboratory for genotyping analysis and identification.

Mycobacterium Tuberculosis Complex Genotyping Collection and Transport

Specimen Collection

Total volume required is 2 mls of positive broth (e.g., MGIT, Bactec, converted blood culture instrument) in a screw-top vial with installed o-ring (e.g., cryovial), screw-top securely fastened, taped with adhesive tape (two 1 ml vials acceptable); or LJ slant with viable growth, securely closed and taped with adhesive tape. Transport at 20-25C.

Transportation to NPHL

Specimens sent for Tuberculosis genotyping require submission with NPHL Special Microbiology requisition. Please notify NPHL if requisition is needed. Specimens must be packaged in Infectious Shipping containers, according to IATA packaging instructions 602. Please call NPHL client services at 866-290-1406 for shipping instructions or courier pickup. More information can be found on the internet at www.nphl.org

Any Tuberculosis genotyping results will be reported to the Tuberculosis Program, not the submitting laboratory, unless isolates represent false-positive cultures. The database of positive results will then be kept by the Nebraska Tuberculosis Program and NPHL. All laboratories within the State of Nebraska and all reference laboratories performing cultures for Nebraska patients will be eligible and are encouraged to participate. Isolates must be sent to the NPHL for submission to the genotyping laboratory. The appropriate paperwork must be completed prior to shipment; this can be found at these sites:

Microbiological Request form: URL

http://www.hhs.state.ne.us/wnv/forms03/WNVnphltestrequisition.pdf.

Clinical description – Extracted from CDC

A chronic bacterial infection caused by *Mycobacterium tuberculosis*, characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs may be involved.

Clinical case definition

A case that meets the following criteria:

- A positive tuberculin skin test
- Other signs and symptoms compatible with tuberculosis (e.g., an abnormal, unstable [i.e., worsening or improving] chest radiographs, or clinical evidence of current disease)
- Treatment with two or more antituberculosis medications
- Completed diagnostic evaluation

Laboratory criteria for diagnosis

- Isolation of *M. tuberculosis* from a clinical specimen* or
- Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test,** or
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained

Case classification

Confirmed: a case that meets the clinical case definition or is laboratory confirmed

Comment

A case should not be counted twice within any consecutive 12-month period. However, cases in which the patients had previously had verified disease should be reported again if the patients were discharged from treatment. Cases also should be reported again if patients were lost to supervision for greater than 12 months and disease can be verified again. Mycobacterium diseases other than those caused by *M. tuberculosis* complex should not be counted in tuberculosis morbidity statistics unless there is concurrent tuberculosis. *Use of rapid identification techniques for M. tuberculosis (e.g., DNA probes and mycolic acids high-pressure liquid chromatography performed on a culture from a clinical specimen) are acceptable under this criterion. **Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert. Current FDA-approved NAA tests are only approved for smear-positive respiratory specimens.

What is Case Management?

There are many strategies that may be used to ensure that patients complete treatment. One strategy that may be used is case management. There are three elements in a case management system:

- Assignment of primary responsibility for the patient
- Systematic regular review of patient progress
- Plan to address any barriers to adherence

A health department employee (case manager) is assigned primary responsibility and is held accountable from ensuring

- Each patient is assessed and a treatment plan is established
- Each patient is educated about TB and its treatment

- Therapy is continuous
- Contacts are examined

Although one person is assigned primary responsibility, case management provides continuity of care by using a team of persons who work together to help each patient complete treatment. Some specific responsibilities such as the patient interview, directly observed therapy (DOT), and patient education may be assigned to other persons (e.g., clinical supervisors, outreach workers, health educators, and social workers).

Case management uses a combination of patient-focused services in which the case management team performs the following tasks:

- Assesses the patient and develops a treatment plan
- Provides DOT
- Provides effective education to patients and key individuals
- Establishes efficient clinic systems for scheduling appointments, keeping records, and providing pharmacy services
- Helps patients keep appointment
- Communicates effectively with patients whose cultural and language backgrounds are different from their own
- Offers incentives and enablers to encourage adherence
- Provides patients with needed health or social services, or makes referrals to other appropriate service agencies
- Establishes a trusting relationship with the patient

Goals of TB Prevention and Control

The three primary goals of TB prevention and control are to

- Identify and treat persons who have active TB disease
- Identify and evaluate exposed contacts, offering appropriate treatment as indicated
- Test populations at high risk for TB infection and disease in order to detect infected persons, and provide treatment of latent TB infection (LTBI) to prevent progression to active TB

State and local health departments have the primary responsibility for preventing and controlling TB. To meet this challenge successfully, TB control programs should be able to carry out the following core components:

- Identify TB cases
- Ensuring adequate therapy
- Identifying high-priority candidates for treatment of LTBI
- Collecting and analyzing data
- Conducting overall planning and policy development
- Providing laboratory and diagnostic services
- Providing training and education

Quarantine Procedures/State Statues

Nebraska State Statues Cited

The following is directly from Nebraska State Statue Title 173 Chapter 2.
Online at : http://statutes.unicam.state.ne.us/Corpus/statutes/chap71/R7136001.html
71-3601.01

Act, how cited.

Sections 71-3601 to 71-3614 shall be known and may be cited as the Tuberculosis Detection and Prevention Act.

71-3601

Terms, defined.

For purposes of the Tuberculosis Detection and Prevention Act:

(1) Communicable Tuberculosis means Tuberculosis manifested by a laboratory report of sputum or other body fluid or excretion found to contain tubercle bacilli or by chest X-ray findings interpreted as active Tuberculosis by competent medical authority;

(2) Department means the Department of Health and Human Services Regulation and Licensure;

(3) Facility means a structure in which suitable isolation for Tuberculosis can be given and which is approved by the department for the detention of recalcitrant Tuberculosis persons;

(4) Local health officer means (a) the health director of a local public health department as defined in section 71-1626 or (b) the medical advisor to the board of health of a county, city, or village;

(5) Recalcitrant tuberculous person means a person affected with Tuberculosis in an active stage who by his or her conduct or mode of living endangers the health and well-being of other persons, by exposing them to Tuberculosis, and who refuses to accept adequate treatment; and

(6) State health officer means the Director of Regulation and Licensure or the chief medical officer as described in section 81-3201.

71-3602

Rules, regulations, orders; violation; procedure.

When a person with communicable Tuberculosis violates the rules, regulations, or orders adopted and promulgated by the department and is thereby conducting himself or herself in such a way as to expose others to danger of infection, after having been ordered by the state health officer or a local health officer to comply, the state health officer or local health officer shall institute proceedings for commitment, returnable to the county court of the county in which the person resides or, if the person is a nonresident or has no permanent residence, in the county in which the person is found. Strictness of pleading is not required, and a general allegation that the public health requires commitment of the person is sufficient.

71-3603

Petition; hearing; notice; costs.

The county attorney of the county in which the proceedings are to be held as provided in section 71-3602 shall act for the department or local board of health. Either the state health officer or local health officer shall advise the county attorney in writing of the violation. Within three days of such notification, the county attorney shall file a petition with the county court.

Upon filing of the petition, the court shall set the matter for a hearing, which time shall be not less than five days nor more than ten days subsequent to filing. A copy of the petition together with a summons stating the time and place of hearing shall be served upon the person three days or more prior to the time set for the hearing.

Summons shall be served by the sheriff of the county in which the hearing is to be held, and return thereof shall be made as in other civil cases.

The court costs incurred in proceedings under the Tuberculosis Detection and Prevention Act, including medical examinations required by order of the court but excluding examinations procured by the person named in the petition, shall be borne by the county in which the proceedings are held.

71-3604

Hearing; procedure; order.

Upon the hearing set in the order, the person named in the order shall have a right to be represented by counsel, to confront and cross-examine witnesses against him, and to have compulsory process for the securing of witnesses and evidence in his own behalf.

Upon a consideration of the petition and evidence, if the court finds that the person named in the petition has communicable Tuberculosis and conducts himself in such a way as to be a danger to the public health, an order shall be issued committing the person named to a facility and directing the sheriff to take him into custody and deliver him to the facility. If the court does not so find, the petition shall be dismissed. The cost of transporting such person to the facility shall be paid from county general funds.

71-3605

Appeal; procedure.

Any person aggrieved by a final decision in a contested case, whether such decision is affirmative or negative in form, is entitled to judicial review under the provisions of sections 25-2728 to 25-2738.

71-3606

Commitment; length of time.

Upon commitment, the person shall be confined until such time as the responsible attending physician determines that the patient no longer has communicable Tuberculosis or that his discharge will not endanger public health.

71-3607

Commitment; release; procedure.

Any time beyond sixty days after commitment, the person or any friend or relative believing that the patient no longer has communicable Tuberculosis or that his discharge will not endanger public health may institute proceedings by petition in the county court of the county wherein the confinement exists, whereupon the court shall set the matter down for a hearing before him within fifteen days, requiring the physician in attendance to show cause on a day certain why the patient should not be released. The court shall also require that the patient be allowed the right to be examined prior to the hearing by a physician of his own choice, if so desired and at his own expense. Thereafter all proceedings shall be conducted the same as on proceedings for commitment with the right of appeal by either party; PROVIDED, such petition for discharge shall not be brought or renewed more often than once every ninety days.

71-3608

Commitment; voluntary hospitalization.

No person having communicable Tuberculosis who in his or her home or elsewhere obeys the rules, regulations, and orders of the department for the control of Tuberculosis or who voluntarily accepts hospitalization or treatment in a health care facility which is licensed and approved for such use under the Health Care Facility Licensure Act by the department and obeys the rules, regulations, and orders of the department for the control of communicable Tuberculosis shall be committed under the Tuberculosis Detection and Prevention Act.

71-3609

Commitment; medical or surgical treatment; consent required.

No person committed under the Tuberculosis Detection and Prevention Act shall be required to submit to medical or surgical treatment without his or her consent or, if incompetent, without the consent of his or her legal guardian, or, if a minor, without the consent of a parent or next of kin.

71-3610

Commitment; treatment; expenses; payment by state.

The expenses incurred in the care, maintenance, and treatment of patients committed under the Tuberculosis Detection and Prevention Act shall be paid from state funds appropriated to the

Department of Health and Human Services Finance and Support for the purpose of entering into agreements with qualified health care facilities so as to provide for the care, maintenance, and treatment of such patients and those other persons having communicable Tuberculosis who voluntarily agree to and accept care and treatment.

71-3611

Commitment; consent to leave hospital; violation; return; costs paid by county.

Any person committed under the Tuberculosis Detection and Prevention Act who leaves the facility without having been discharged by the attending physician or by court order shall be taken into custody and returned to the facility by the sheriff of any county where such person is found, upon an affidavit being filed with the sheriff by the administrator of the facility or duly authorized officer in charge thereof acting as the duly appointed agent and representative of the department in the matter. The costs of such transportation shall be paid from county general funds of the patient's county of residence. If the person is a nonresident of Nebraska or has no permanent residence, the costs shall be paid from county general funds of the county of commitment.

71-3612

Communicable Tuberculosis; examination required; expense; payment.

The state health officer and each local health officer shall use all available means to detect persons with communicable Tuberculosis in his or her jurisdiction. If he or she has reasonable grounds based upon medical science for believing that a person has communicable Tuberculosis and if this person refuses to submit to the examination necessary for determining the existence of communicable Tuberculosis, the state health officer or local health officer shall issue an order to the person to obtain the appropriate examination. Thereafter, if the person does not comply within seven days, the state health officer or local health officer may institute commitment procedures as described in sections 71-3601 to 71-3604, the purpose of commitment under this section being to determine whether or not the person has communicable Tuberculosis.

The costs of voluntary examination made upon request of the state health officer or local health officer and the cost of examination made upon order of the state health officer or local health officer shall be paid from county general funds of the person's county of residence. If the person is a nonresident or has no permanent residence, the costs shall be paid from the county general funds of the county of commitment. The costs of examination and maintenance while under commitment shall be paid from state funds appropriated to the department thereof. The costs of transportation under the commitment procedure for examination shall be paid from county general funds of the county of residence. If the person is not a resident of Nebraska or has no permanent residence, they shall be paid from the county general funds of the county of commitment.

71-3613

Department; powers and duties.

The department shall have and may exercise the following powers and duties in its administration of the Tuberculosis Detection and Prevention Act:

(1) To contract with qualified hospitals or other health care facilities which are licensed and approved for such use under the Health Care Facility Licensure Act by the department for the purpose of caring for, maintaining, and treating patients committed under the Tuberculosis Detection and Prevention Act, and for those other persons having communicable Tuberculosis who voluntarily agree to and accept care and treatment in such a health care facility on either an inpatient or an outpatient basis;

(2) To inspect and supervise to the extent necessary the facilities, operations, and administration of those health care facilities under contract to or otherwise receiving support from the department for the purpose of providing care, treatment, or maintenance for persons infected with communicable Tuberculosis;

(3) To provide visiting nursing services to those persons having communicable Tuberculosis who are being treated on an outpatient basis;

(4) To adopt rules and regulations, and issue orders based thereon, relative to reports and statistics on Tuberculosis from counties and the care, treatment, and maintenance of persons having Tuberculosis, especially of those in the communicable or contagious stage thereof; and

(5) To set standards by rule and regulation for the types and level of medical care and treatment to be used by those health care facilities caring for tuberculous persons and to set standards by rule and regulation governing contracts mentioned in subdivision (1) of this section dealing with such matters as program standards, maximum and minimum costs and rates, administrative procedures to be followed and reports to be made, and arbitration by third parties.

71-3614

Cost of patient care; transportation; payment.

(1) When any person who has communicable or contagious Tuberculosis and who has relatives, friends, or a private or public agency or organization willing to undertake the obligation to support him or her or to aid in supporting him or her in any other state or country, the department may furnish him or her with the cost of transportation to such other state or country if it finds that the interest of the State of Nebraska and the welfare of such person will be promoted thereby. The expense of such transportation shall be paid by the department out of funds appropriated to it for the purpose of carrying out the Tuberculosis Detection and Prevention Act.

(2) No funds appropriated to the department for the purpose of carrying out the act shall be used for meeting the cost of the care, maintenance, or treatment of any person who has communicable or contagious Tuberculosis in a health care facility on either an inpatient or an outpatient basis, or otherwise, or for transportation to another state or country, to the extent that such cost is covered by an insurer or other third-party payor or any other entity under obligation to such person by contract, policy, certificate, or any other means whatsoever. The department in no case shall expend any such funds to the extent that any such person is able to bear the cost of such care, maintenance, treatment, or transportation. The department shall determine the ability of a person to pay by consideration of the following factors: (a) The person's age, (b) the number of his or her dependents and their ages and physical condition, (c) the person's length of care, maintenance, or treatment, (d) his or her

liabilities, and (e) his or her assets. Pursuant to the Administrative Procedure Act, the department shall adopt and promulgate rules and regulations for making the determinations required by this subsection.

Forms & Tables:

Explanation

All forms and tables that are to be utilized by Nebraska Tuberculosis Case Managers and the Tuberculosis Program Manager are attached on the following pages.