Tuberculosis

Goals & Objectives

Course Description

"Tuberculosis" is an asynchronous online continuing education course for physical therapists and physical therapist assistants. This course presents updated information about tuberculosis including sections on epidemiology, screening, diagnosis, treatment, infection control, discharge considerations, confidentiality issues, and patient's rights.

Course Rationale

The purpose of this course is to present current information about tuberculosis. Physical therapists and physical therapist assistants will find this information pertinent and useful when addressing the challenges and needs specific to individuals who have been diagnosed with either tuberculosis infection or disease.

Course Goals and Objectives

Upon completion of this course, the participant will be able to:

1. recognize the pathogenesis and transmission modes of TB
2. identify risk factors for acquiring TB
3. define the procedures for TB screening and identify positive and negative TB results
4. recognize the diagnostic process for confirming TB disease
5. identify available treatments for TB infection and disease
6. define infection control procedures required for the care of individuals with TB
7. recognize the principles and practices of TB control
8. define the confidentiality issues that pertain to the care of individuals with TB
9. identify patient adherence issues associated with TB
10. define patient rights and due process for individuals with TB

Course Provider – Innovative Educational Services

Course Instructor - Michael Niss, DPT

Target Audience – Physical therapists and physical therapist assistants

Course Educational Level – Introductory / intermediate

Course Prerequisites – None

Method of Instruction/Availability – Online text-based course available continuously.

Criteria for issuance of CE Credits - A score of 70% or greater on the course post-test.

Continuing Education Credits – 5 hours

Continuing Education Credits - Mergener Formula: .9 x [-22.3+(0.00209 x 111,683) + (2.78 x 25) + (15.5 x 3)] = 300 minutes = 5.0 hours

Fees - $49.95

Conflict of Interest – No conflict of interest exists for the presenter or provider of this course.

Refund Policy - Unrestricted 100% refund upon request. The request for a refund by the learner shall be honored in full without penalty or other consideration of any kind. The request for a refund may be made by the learner at any time without limitations before, during, or after course participation.

Tuberculosis
Course Outline

Overview

History of TB

Tuberculosis — a disease also known as consumption, wasting disease, and the white plague — has affected humans for centuries. Until the mid-1800s, people thought that tuberculosis, or TB, was hereditary. They did not realize that it could be spread from person to person through the air. Also, until the 1940s and 1950s, there was no cure for TB. For many people, a diagnosis of TB was a slow death sentence.

In 1865 a French surgeon, Jean-Antoine Villemin, proved that TB was contagious, and in 1882 a German scientist named Robert Koch discovered the bacteria that caused TB. Yet half a century passed before drugs were discovered that could cure TB. Until then, many people with TB were sent to sanatoriums, special rest homes where they followed a prescribed routine every day. No one knows whether sanatoriums really helped people with TB; even so, many people with TB could not afford to go to a sanatorium, and they died at home.

A breakthrough came in 1943. An American scientist, Selman Waksman, discovered a drug that could kill TB bacteria. Between 1943 and 1952, two more drugs were found. After these discoveries, many people with TB were cured, and the death rate for TB in the United States dropped dramatically. Each year, fewer and fewer people got TB.

By the mid-1970s, most TB sanatoriums in the United States had closed. In the next two decades, people began to hope that TB could be eliminated from the United States, like polio and smallpox.

Since the mid-1980s, however, TB cases have started increasing again. Because of the increase in TB, health departments and other organizations are stepping up their efforts to prevent and control the disease. Even today, TB can be fatal if not treated.

Transmission

TB is caused by an organism called *Mycobacterium tuberculosis*. *M. tuberculosis* organisms are sometimes called tubercle bacilli.

M. tuberculosis is a type of mycobacteria**.** Mycobacteria can cause a variety of diseases. Some mycobacteria are called tuberculous mycobacteria because they cause TB or diseases similar to TB. These mycobacteria are *M. tuberculosis, M. bovis,* and *M. africanum*. Other mycobacteria are called nontuberculous mycobacteria because they do not cause TB. One common type of nontuberculous mycobacteria is *M. avium* complex. Nontuberculous mycobacteria are NOT usually spread from person to person.

TB is spread from person to person through the air. When a person with infectious TB disease coughs or sneezes, tiny particles containing *M. tuberculosis* may be expelled into the air. These particles, called droplet nuclei, are about 1 to 5 microns in diameter — less than 1/5000 of an inch. Droplet nuclei can remain suspended in the air for several hours, depending on the environment. If another person inhales air that contains these droplet nuclei, transmission may occur.

Not everyone who is exposed to an infectious TB patient becomes infected with *M. tuberculosis*. The probability that TB will be transmitted depends on three factors:

- How contagious is the TB patient?
- In what kind of environment did the exposure occur?
- How long did the exposure last?

Pathogenesis

When a person inhales air that contains droplets, most of the larger droplets become lodged in the upper respiratory tract (the nose and throat), where infection is unlikely to develop. However, the droplet nuclei may reach the alveoli where infection begins.

At first, the tubercle bacilli multiply in the alveoli and a small number enter the bloodstream and spread throughout the body. Bacilli may reach any part of the body, including areas where TB disease is more likely to develop. These areas include the upper portions of the lungs, as well as the kidneys, the brain, and bone. Within 2 to 10 weeks, however, the body's immune system usually intervenes, halting multiplication and preventing further spread.

TB Infection

TB infection means that tubercle bacilli are in the body but the body's immune system is keeping the bacilli under control. The immune system does this by producing special immune cells that surround the tubercle bacilli. The cells form a hard shell that keeps the bacilli contained and under control.

TB infection is detected by the tuberculin skin test. Most people with TB infection have a positive reaction to the tuberculin skin test.

People who have TB infection but not TB disease are NOT infectious. These people usually have a normal chest x-ray. It is important to remember that TB infection is not considered a case of TB. Major similarities and differences between TB infection and TB disease are shown in Table 1 below.

Table 1
TB Infection vs. TB Disease

TB Infection	TB Disease (in the lungs)
Tubercle bacilli in the body	
Tuberculin skin test reaction usually positive	
Chest x-ray usually normal	Sputum smears and cultures usually positive
Sputum smears and cultures negative	Chest x-ray usually abnormal
No symptoms	Symptoms such as cough, fever, weight loss
Not infectious	Often infectious before treatment
Not a case of TB	A case of TB

TB Disease

Some people with TB infection develop TB disease. TB disease develops when the immune system cannot keep the tubercle bacilli under control and the bacilli begin to multiply rapidly. The risk that TB disease will develop is higher for some people than for others.

TB disease can develop very soon after infection or many years after infection. In the United States, about 5% of the people who have recently been infected with *M. tuberculosis* will develop TB disease in the first year or two after infection. Another 5% will develop disease later in their lives. In other words, about 10% of all people who have TB infection will develop disease at some point**.** The remaining 90% will stay infected, but free of disease, for the rest of their lives.

Because about half the risk of developing TB disease is concentrated in the first 2 years after infection, it is important to detect new infection early. People with TB infection can be given treatment to prevent them from getting TB disease. Thus, detecting new infection early helps prevent new cases of TB.

Some conditions appear to increase the risk that TB infection will progress to disease. The risk may be about 3 times higher (as with diabetes) to more than 100 times higher (as with HIV infection) for people who have these conditions than for those who do not. Some of these conditions are

- Infection with HIV, the virus that causes AIDS
- Injection of illicit drugs
- Recent TB infection (within the past 2 years)

- Chest x-ray findings suggestive of previous TB
- Diabetes mellitus
- Silicosis
- Prolonged therapy with corticosteroids
- Immunosuppressive therapy
- Certain types of cancer (e.g., leukemia, Hodgkin's disease, or cancer of the head and neck)
- Severe kidney disease
- Certain intestinal conditions
- Low body weight (10% or more below ideal)

When the immune system is weakened, the body may not be able to control the multiplication and spread of tubercle bacilli. For this reason, people who are infected with both *M. tuberculosis* and HIV are much more likely to develop TB disease than people who are infected only with *M. tuberculosis.* Studies suggest that the risk of developing TB disease is 7% to 10% each year for people who are infected with both *M. tuberculosis* and HIV, whereas it is 10% over a lifetime for people infected only with *M. tuberculosis*.

In an HIV-infected person, TB disease can develop in either of two ways. First, a person who has TB infection can become infected with HIV and then develop TB disease as the immune system is weakened. Second, a person who has HIV infection can become infected with *M. tuberculosis* and then rapidly develop TB disease.

Sites of TB Disease

TB disease can occur in different places in the body. About 85% of TB cases are pulmonary. Most patients with pulmonary TB have a cough and an abnormal chest x-ray, and they should be considered infectious until they meet certain criteria.

Extrapulmonary TB occurs in places other than the lungs, such as the larynx, the lymph nodes, the pleura, the brain, the kidneys, or the bones and joints. Extrapulmonary TB occurs more often in people who are infected with HIV than in people who are not infected with HIV. In HIV-infected people, extrapulmonary TB is often accompanied by pulmonary TB. Most types of extrapulmonary TB are not considered infectious

Miliary TB occurs when tubercle bacilli enter the bloodstream and are carried to all parts of the body, where they grow and cause disease in multiple sites. This condition, which is rare but serious, is called miliary TB because the chest x-ray has the appearance of millet seeds scattered throughout the lung.

Classification System

Many systems have been used to classify people who have TB. The current classification system (Table 2) is based on the pathogenesis of TB. Many health departments and private health care providers use this system when describing patients. Thus, it is important for all health care workers to be familiar with this system. In particular, health care workers should be aware that any patient with a classification of 3 or 5 should be receiving treatment for TB, and the case or suspected case should be reported.

Table 2
Classification System for TB

Class	Type	Description
0	No exposure to TB Not infected	No history of exposure, negative reaction to the tuberculin skin test
1	Exposure to TB No evidence of infection	History of exposure, negative reaction to a tuberculin skin test given at least 10 weeks after exposure
2	TB infection No TB disease	Positive reaction to the tuberculin skin test, negative smears and cultures (if done), no clinical or x-ray evidence of TB disease
3	Current TB disease	Positive culture for *M. tuberculosis* (if done), **or** A positive reaction to the tuberculin skin test and clinical or x-ray evidence of current TB disease
4	Previous TB disease (not current)	Medical history of TB disease, **or** Abnormal but stable x-ray findings for a person who has a positive reaction to the tuberculin skin test, negative smears and cultures (if done), and no clinical or x-ray evidence of current TB disease
5	TB suspected	Signs and symptoms of TB disease, but evaluation not complete

Epidemiology of Tuberculosis

TB infection is one of the most common infections in the world. It is estimated that 30% to 60% of adults in developing countries have TB infection. Every year, about 8 million people develop TB disease and 3 million people die of the disease. In fact, among people older than 5 years of age, TB disease is the leading cause of death around the world.

In the United States, physicians and other health care providers are required by law to report TB cases to their state or local health department. Reporting is very important for TB control. When the health department learns about a new case of TB, it should take steps to ensure that the person receives appropriate treatment. The health department should also start a contact investigation. This means interviewing a person who has TB disease to determine who may have been exposed to TB. People who have been exposed to TB are screened for TB infection and disease.

State and some big-city health departments report TB cases to the federal Centers for Disease Control and Prevention (CDC) based on certain criteria. CDC reports the number of TB cases that occur each year in the United States.

In 1953, when nationwide TB reporting first began, there were more than 84,000 TB cases in the United States. From 1953 through 1984, the number of TB cases decreased by an average of 6% each year. In 1985, the number of TB cases reached an all-time low of 22,201. In 1986, however, there was an increase in TB cases, the first since 1953. From 1986 through 1993, the number of new cases increased by 14% — from 22,201 to 25,313. Fortunately, the number of new cases peaked in the mid 1990's and has since trended progressively downward. The number of new cases of TB in the U.S. in 2006 was 13,767.

Four primary factors contributed to the increase in TB cases during the 80's and 90's:

- The HIV epidemic
- Increased immigration from countries where TB is common
- The spread of TB in certain settings (for example, correctional facilities and homeless shelters)
- Inadequate funding for TB control and other public health efforts

The CDC has found that in certain groups, the rates of TB are higher than in others. These high-risk groups can be divided into two categories:

1. People who are more likely to be exposed to or infected with *M. tuberculosis*

    - Close contacts of people with infectious TB

- People born in areas of the world where TB is common (for example, Asia, Africa, or Latin America)
- Elderly people
- Low-income groups with poor access to health care, including homeless people
- People who inject illicit drugs
- People who live or work in residential facilities (for example, nursing homes or correctional facilities)
- Other people who may be exposed to TB on the job (for example, some health care workers)

2. People who are more likely to develop TB disease once infected

- People with HIV infection
- People with other medical conditions that appear to increase the risk for TB
- People recently infected with *M. tuberculosis* (within the past 2 years)
- People with chest x-ray findings suggestive of previous TB disease
- People who inject illicit drugs

People at Higher Risk for Exposure or Infection

In the United States, TB infection and disease occur often among people born in areas of the world where TB is common, such as Asia, Africa, and Latin America. In most cases, these foreign-born persons become exposed to and infected with *M. tuberculosis* in their country of birth.

All people who apply for immigration and refugee status are screened for TB disease before coming to the United States. Immigrants with TB disease who are infectious at the time of screening are required to receive treatment before they enter the United States. However, some immigrants have TB disease but are not infectious at the time of screening. Sometimes these immigrants become infectious after they enter the United States. Also, many immigrants have TB infection, but not TB disease, at the time of screening. These immigrants may develop TB disease years after they come to the United States. Finally, many people enter the United States without being screened for TB disease, such as students, tourists, and undocumented aliens.

TB is also more common among the elderly. Many elderly people were exposed to and infected with *M. tuberculosis* when they were younger and TB was more common than it is today. Because a larger proportion of elderly people have TB infection, this group is at higher risk for TB disease. Of all TB cases reported, 23% were in people 65 years of age and older, even though this age group makes up only 13% of the population. Elderly people living in nursing homes are at an even higher risk for TB.

Another risk group is low-income people. The average rate of TB cases is nearly eight times higher in zip code areas with the lowest household income as in areas with the highest household income. The reasons for this are not entirely clear, but some possible reasons are crowding, inadequate living conditions, malnutrition, and poor access to health care.

TB infection and disease are also more common among homeless people. Homeless people may be at higher risk of developing TB disease once infected because of malnutrition and poor access to health care. Moreover, in some areas they may be more likely than the general population to be infected with HIV.

People who inject illicit drugs are more likely to be exposed to or infected with *M. tuberculosis.* This may be because a large proportion of people in this risk group have other risk factors for exposure to TB, such as being in a low-income group and having poor access to health care. People who inject illicit drugs are also at high risk of developing TB disease once infected, perhaps because they are more likely to be HIV infected. Also, it is possible that injecting illicit drugs weakens the immune system.

Risk for Health-Care–Associated Transmission of *M. tuberculosis*

Transmission of *M. tuberculosis* is a risk in health-care settings. The magnitude of the risk varies by setting, occupational group, prevalence of TB in the community, patient population, and effectiveness of TB infection-control measures. Health-care–associated transmission of *M. tuberculosis* has been linked to close contact with persons with TB disease during aerosol-generating or aerosol-producing procedures, including bronchoscopy, endotracheal intubation, suctioning, other respiratory procedures, open abscess irrigation, autopsy, sputum induction, and aerosol treatments that induce coughing.

Of the reported TB outbreaks in health-care settings, multiple outbreaks involved transmission of TB strains to both patients and HCWs. The majority of the patients and certain HCWs were HIV-infected, and progression to TB was rapid. Factors contributing to these outbreaks included delayed diagnosis of TB disease, delayed initiation and inadequate airborne precautions, lapses in AII practices and precautions for cough inducing and aerosol-generating procedures, and lack of adequate respiratory protection. Multiple studies suggest that the decline in health-care–associated transmission observed in specific institutions is associated with the rigorous implementation of infection-control measures.

After the release of the 1994 CDC infection-control guidelines, increased implementation of recommended infection-control measures occurred. In a survey of approximately 1,000 hospitals, a TB screening program was present in nearly all sites, and 70% reported having an AII room. Other surveys have documented improvement in the proportion of AII rooms meeting CDC criteria and proportion of HCWs using CDC-recommended respiratory protection and

receiving serial TB screenings. A survey of New York City hospitals with high caseloads of TB disease indicated 1) a decrease in the time that patients with TB disease spent in EDs before being transferred to a hospital room, 2) an increase in the proportion of patients initially placed in AII rooms, 3) an increase in the proportion of patients started on recommended antituberculosis treatment and reported to the local or state health department, and 4) an increase in the use of recommended respiratory protection and environmental controls. Reports of increased implementation of recommended TB infection controls combined with decreased reports of outbreaks of TB disease in healthcare settings suggest that the recommended controls are effective in reducing and preventing health-care–associated transmission of *M. tuberculosis*.

Less information is available regarding the implementation of CDC-recommended TB infection-control measures in settings other than hospitals. One study identified major barriers to implementation that contribute to the costs of a TB screening program in health departments and hospitals, including personnel costs, HCWs' time off from work for TB screening administration and reading, and training and education of HCWs.

Outbreaks have occurred in outpatient settings (i.e., private physicians' offices and pediatric settings) where the guidelines were not followed.

Special Settings

In certain settings, such as nursing homes and correctional facilities, the risk of being exposed to TB is higher than in other places. This is because many people in these facilities are at risk for TB. The risk of exposure to TB is even higher if the facility is crowded.

For example, TB is a problem in nursing homes. The CDC found that the rate of TB disease was twice as high for elderly people living in nursing homes as for elderly people not living in nursing homes.

TB is also a problem in correctional facilities. A CDC study showed that there were four times as many TB cases in people living in correctional facilities as there were in people of the same age who did not live in correctional facilities. There are several reasons why rates of TB disease are higher in correctional facilities. First, many inmates already have TB infection and therefore are at higher risk of developing TB disease. Second, an increasing number of inmates are infected with HIV, which means that they are more likely to develop TB disease if they become infected with *M. tuberculosis*. Finally, some correctional facilities are crowded, which promotes the spread of TB.

Other settings where people at risk for TB are grouped together are homeless shelters and drug treatment centers. People who live or work in these settings are at higher risk of being exposed to TB.

People who work in health care facilities, such as clinics and hospitals, may be exposed to TB on the job. The risk of exposure depends on the number of TB patients in the facility, the employee's duties, and the effectiveness of the infection control procedures in the facility.

TB in Children

Approximately 7% of all reported TB cases are in children younger than 15 years old. TB is becoming more common in children; in fact, since 1983, the number of TB cases in children has increased by 36%.

Vaccination

BCG, or bacille Calmette-Guérin, is a vaccine for tuberculosis (TB) disease. BCG is used in many countries with a high prevalence of TB to prevent childhood tuberculous meningitis and miliary disease. However, BCG is not generally recommended for use in the United States because of the low risk of infection with *Mycobacterium tuberculosis*, the variable effectiveness of the vaccine against adult pulmonary TB, and the vaccine's potential interference with tuberculin skin test reactivity. The BCG vaccine should be considered only for very select persons who meet specific criteria and in consultation with a TB expert.

Children
BCG vaccination should only be considered for children who have a negative tuberculin skin test and who are continually exposed, and cannot be separated from, adults who

- Are untreated or ineffectively treated for TB disease (if the child cannot be given long-term treatment for infection); or
- Have TB caused by strains resistant to isoniazid and rifampin.

Health Care Workers.
BCG vaccination of health care workers should be considered on an individual basis in settings in which

- A high percentage of TB patients are infected with M. tuberculosis strains resistant to both isoniazid and rifampin;
- There is ongoing transmission of such drug-resistant M. tuberculosis strains to health care workers and subsequent infection is likely; or
- Comprehensive TB infection-control precautions have been implemented but have not been successful.

Health care workers considered for BCG vaccination should be counseled regarding the risks and benefits associated with both BCG vaccination and treatment of latent TB infection (LTBI).

Screening for Tuberculosis Infection

The Tuberculin Skin Test (TST)

The tuberculin skin test is used to determine whether a person has TB infection. In this test, a substance called tuberculin is injected into the skin. Tuberculin is protein derived from tubercle bacilli that have been killed by heating. In most people who have TB infection, the immune system will recognize the tuberculin because it is similar to the tubercle bacilli that caused infection. This will cause a reaction to the tuberculin.

Tuberculin testing is useful for

- Examining a person who is not sick but who may have TB infection**,** such as a person who has been exposed to someone who has TB. In fact, the tuberculin skin test is the only way to diagnose TB infection before the infection has progressed to TB disease.
- Screening groups of people for TB infection
- Examining a person who has symptoms of TB disease

Different types of tuberculin tests are available, such as the Mantoux tuberculin skin test and the multiple-puncture test. The Mantoux tuberculin skin test is the preferred type because it is the most accurate.

Mantoux Test

The Mantoux skin test is given by using a needle and syringe to inject 0.1 ml of 5 tuberculin units of liquid tuberculin intradermally, usually on the forearm.

The tuberculin used in the Mantoux skin test is also known as purified protein derivative, or PPD. For this reason, the tuberculin skin test is sometimes called a PPD skin test**.**

With the Mantoux skin test, the patient's arm is examined 48 to 72 hours after the tuberculin is injected. Most people with TB infection have a positive reaction to the tuberculin. The reaction is an area of induration (swelling that can be felt) around the site of the injection. The diameter of the indurated area is measured across the forearm; erythema around the indurated area is not measured, because the presence of erythema does not indicate that a person has TB infection.

Multiple-Puncture Test
Multiple-puncture tests (for example, the Tine test) are done by puncturing the skin of the forearm with a set of short prongs or tines coated with tuberculin. Multiple-puncture tests are easy to give, and they are convenient because they do not require a needle and syringe. However, in the multiple-puncture test the amount of tuberculin that actually enters the skin cannot be measured. Because the amount of tuberculin can always be measured during a Mantoux test, this type of test is more accurate, and it is the preferred method.

Positive reactions to multiple-puncture tests should always be confirmed with a Mantoux test (except when there is blistering at the site of the injection).

Classifying the Reaction

Whether a reaction to the tuberculin skin test is classified as positive depends on the size of the induration and the person's risk factors for TB.

An induration of 5 or more millimeters is considered a positive reaction for the following people:

- People with HIV infection
- Close contacts of people with infectious TB
- People with chest x-ray findings suggestive of previous TB disease
- People who inject illicit drugs and whose HIV status is unknown

An induration of 10 or more millimeters is considered a positive reaction for the following people:

- People born in areas of the world where TB is common (foreign-born persons)
- People who inject illicit drugs but who are known to be HIV negative
- Low-income groups with poor access to health care
- People who live in residential facilities (for example, nursing homes or correctional facilities)
- People with medical conditions that appear to increase the risk for TB (not including HIV infection), such as diabetes
- Children younger than 4 years old
- People in other groups likely to be exposed to TB, as identified by local public health officials

An induration of 15 or more millimeters is considered a positive reaction for people with no risk factors for TB. In most cases, people who have a very small reaction or no reaction probably do not have TB infection.

For people who may be exposed to TB 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 size of the induration
- The employee's individual risk factors for TB
- The risk of exposure to TB in the person's job

Therefore, in facilities where the risk of exposure to TB is very low, 15 or more millimeters of induration may be considered a positive reaction for employees with no other risk factors for TB. In facilities where TB patients receive care, 10 or more millimeters of induration may be considered a positive reaction for employees with no other risk factors for TB.

Most people who have a positive skin test reaction will have a positive reaction if they are skin 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.

False-Positive Reactions

The skin test is a valuable tool, but it is not perfect. Several factors can affect the skin test reaction. Two factors are infection with nontuberculous mycobacteria (mycobacteria other than *M. tuberculosis*) and vaccination with BCG. BCG (bacillus Calmette-Guérin) is a vaccine for TB 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. People who are infected with nontuberculous mycobacteria or who have been vaccinated with BCG may have a positive reaction to the tuberculin skin test even if they do not have TB infection. This is called a false-positive reaction.

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

- The reaction is large
- The person was vaccinated a long time ago
- The person comes from an area of the world where TB is common
- The person has been exposed to someone with infectious TB disease
- The person's family has a history of TB disease

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

False-Negative Reactions

Some people have a negative reaction to the tuberculin skin test even though they have TB infection. These are called false-negative reactions. False-negative reactions may be due to

- Anergy
- Recent TB infection (within the past 10 weeks)
- Very young age (younger than 6 months old)

The most common cause of false-negative reactions is anergy. Anergy is the inability to react to skin tests because of a weakened immune system. Many conditions, such as HIV infection, cancer, or severe TB disease itself, can weaken the immune system and cause anergy. HIV infection is a main cause of anergy.

Because of their risk for anergy and their risk for TB, HIV-infected people may be tested for anergy if they have a negative reaction to the tuberculin skin test. Anergy testing is done by giving skin tests using two substances other than tuberculin. The recommended substances for anergy testing are mumps, *Candida*, or tetanus extracts. Most healthy people will have a skin test reaction to one or more of these substances.

People who do not react to any of the substances, including tuberculin, after 48 to 72 hours (that is, people who have less than 3 millimeters of induration to all of the skin tests), are considered anergic. People who have a reaction (3 or more millimeters of induration) to any of the substances are not anergic. If a person being evaluated for anergy has a reaction of 5 or more millimeters of induration to tuberculin, he or she is considered to have TB infection, regardless of the reaction to the other substances.

Another cause of false-negative reactions is recent TB infection (infection within the past 10 weeks). It takes 2 to 10 weeks after TB infection for the body's immune system to be able to react to tuberculin. Therefore, after TB has been transmitted, it takes 2 to 10 weeks before TB infection can be detected by the tuberculin skin test. For this reason, close contacts of someone with infectious TB disease who have 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 TB disease.

A third cause of false-negative reactions is very young age. Because their immune systems are not yet fully developed, children younger than 6 months old may have a false-negative reaction to the tuberculin skin test.

A false-positive reaction or a false-negative reaction may occur when the tuberculin skin test is given incorrectly or the results are not measured properly.

Any patient with symptoms of TB should be evaluated for TB disease, regardless of his or her skin test reaction. In fact, people with symptoms of TB should be evaluated for TB disease right away, at the same time that the tuberculin skin test is given. The symptoms of pulmonary TB disease include coughing, pain in the chest when breathing or coughing, and coughing up sputum or blood. The general symptoms of TB disease (pulmonary or extrapulmonary) include weight loss, fatigue, malaise, fever, and night sweats.

TB Screening Programs and Two-Step Testing

Many residential facilities, health care facilities, and other settings have TB screening programs. This means that employees and residents are periodically given tuberculin skin tests. The purposes of the screening program are to

- Identify people who have TB infection and possibly TB disease, so that they can be given treatment as needed
- Determine whether TB is being transmitted in the facility

In a TB screening program, employees or residents are skin tested when they start their job or enter the facility. This is called the baseline skin test**.** If they have a negative skin test reaction, they may be retested at regular intervals thereafter. (For most employees, repeat testing should be done at least once a year.)

Employees or residents whose skin test reaction converts from negative to positive between screening intervals have probably become infected with *M. tuberculosis.* These skin test conversions may indicate that TB is being transmitted in the facility. People with skin test conversions are at high risk of developing TB disease because they were infected with *M. tuberculosis* relatively recently (within the past 2 years). In order to detect TB transmission and identify people who have skin test conversions, accurate information must be obtained for every employee's baseline skin test, as well as for additional skin tests.

One factor that can affect the accuracy of the baseline skin test is the booster phenomenon**.** The booster phenomenon happens because in some people who have TB infection, the ability to react to tuberculin lessens over time. When these people are skin tested many years after they became infected with *M. tuberculosis*, they may have a negative reaction. However, if they are tested again within a year of the first test, they may have a positive reaction. This is because the first skin test "jogged the memory" of the immune system, boosting its ability to react to tuberculin. It may appear that these people were infected between the first and second skin tests (recent TB infection). Actually, the second, positive reaction is a boosted reaction (due to TB infection that occurred a long time ago). The booster phenomenon occurs mainly among older adults.

The booster phenomenon can present a problem in TB screening programs. This is because a negative reaction to the baseline skin test, followed by a positive

reaction to a subsequent skin test that is given up to a year later, may be caused by either

- Recent TB infection in a person who was NOT infected at the time of the baseline skin test, or
- A boosted reaction in a person who WAS infected at the time of the baseline skin test

To avoid misinterpretation, a strategy has been developed for telling the difference between boosted reactions and reactions caused by recent infection. This strategy, called two-step testing, means that if a person has a negative reaction to an initial skin test, he or she is given a second test 1 to 3 weeks later.

- If the reaction to the second test is positive, it probably is a boosted reaction (due to TB infection that occurred a long time ago).
- If the reaction to the second test is negative, the person is considered uninfected. In this person, a positive reaction to a skin test given later on will probably be due to recent infection.

Thus, because it provides accurate information about each employee's baseline skin test reaction, two-step testing is used in many TB screening programs for skin testing employees when they start their job. In particular, two-step testing is often used in hospitals and nursing homes.

TB Screening Risk Classifications

The three TB screening risk classifications are low risk, medium risk, and potential ongoing transmission.

The classification of low risk should be applied to settings in which persons with TB disease are not expected to be encountered, and, therefore, exposure to *M. tuberculosis* is unlikely. This classification should also be applied to HCWs who will never be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis.*

The classification of medium risk should be applied to settings in which the risk assessment has determined that HCWs will or will possibly be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.

The classification of potential ongoing transmission should be temporarily applied to any setting (or group of HCWs) if evidence suggestive of person-to-person (e.g., patient-to patient, patient-to-HCW, HCW-to-patient, or HCW-to- HCW) transmission of *M. tuberculosis* has occurred in the setting during the preceding year. Evidence of person-to person transmission of *M. tuberculosis* includes 1) clusters of TST conversions, 2) HCW with confirmed TB disease, 3) increased

rates of TST conversions, 4) unrecognized TB disease in patients or HCWs, or 5) recognition of an identical strain of *M. tuberculosis* in patients or HCWs with TB disease identified by deoxyribonucleic acid (DNA) fingerprinting.

If uncertainty exists regarding whether to classify a setting as low risk or medium risk, the setting typically should be classified as medium risk.

TB Screening Procedures for Settings (or HCWs) Classified as Low Risk
All HCWs should receive baseline TB screening upon hire, using two-step TST or a single BAMT to test for infection with *M. tuberculosis*. After baseline testing for infection with *M. tuberculosis*, additional TB screening is not necessary unless an exposure to *M. tuberculosis* occurs. HCWs with a baseline positive or newly positive test result for *M. tuberculosis* infection or documentation of treatment for LTBI or TB disease should receive one chest radiograph result to exclude TB disease (or an interpretable copy within a reasonable time frame, such as 6 months). Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician.

TB Screening Procedures for Settings (or HCWs) Classified as Medium Risk
All HCWs should receive baseline TB screening upon hire, using two-step TST to test for infection with *M. tuberculosis*. After baseline testing for infection with *M. tuberculosis*, HCWs should receive TB screening annually (i.e., symptom screen for all HCWs and testing for infection with *M. tuberculosis* for HCWs with baseline negative test results). HCWs with a baseline positive or newly positive test result for *M. tuberculosis* infection or documentation of previous treatment for LTBI or TB disease should receive one chest radiograph result to exclude TB disease. Instead of participating in serial testing, HCWs should receive a symptom screen annually. This screen should be accomplished by educating the HCW about symptoms of TB disease and instructing the HCW to report any such symptoms immediately to the occupational health unit.

TB Screening Procedures for Settings (or HCWs) Classified as Potential Ongoing Transmission
Testing for infection with *M. tuberculosis* might need to be performed every 8–10 weeks until lapses in infection control have been corrected, and no additional evidence of ongoing transmission is apparent. The classification of potential ongoing transmission should be used as a temporary classification only. It warrants immediate investigation and corrective steps. After a determination that ongoing transmission has ceased, the setting should be reclassified as medium risk. Maintaining the classification of medium risk for at least 1 year is recommended.

Diagnosis of Tuberculosis Infection and Disease

Diagnosing TB Disease

Before clinicians can diagnose TB disease in a patient, they must think of the possibility of TB when they see a patient with symptoms of TB or abnormal chest x-ray findings. Because TB is not as common as it was many years ago, many clinicians do not consider the possibility of TB when making diagnoses for patients who have symptoms of TB. When this happens, the diagnosis of TB may be delayed or even overlooked, and the patient will remain ill and possibly infectious.

Anyone with symptoms of TB should be evaluated for TB disease. In addition, anyone found to have a positive tuberculin skin test reaction should be evaluated for TB disease.

There are four steps in diagnosing TB disease.

1. Medical History
2. Tuberculin Skin Test
3. Chest X-Rays
4. Bacteriological Exam

Medical History

A medical history is the part of a patient's life history that is important for diagnosing and treating the patient's medical condition. It includes social, family, medical, and occupational information about the patient. To obtain a medical history, the clinician should ask whether the patient has:

a. **Exposure to TB.** One important part of the medical history is asking the patient about his or her exposure to TB. Patients should be asked whether they have spent time with someone who has infectious TB. Some people may have been exposed to TB in the distant past, when they were children. Others may have been exposed more recently.

   Anyone who has been exposed to TB may have TB infection. Some people become infected with *M. tuberculosis* without knowing that they were exposed to it. The risk of being exposed to TB is higher for some occupations (for example, some health care workers) and in some residential facilities (for example, nursing homes or correctional facilities).

b. **Symptoms of TB disease.** Another important part of the medical history is checking for symptoms of TB disease. People with TB disease may or may not have symptoms. However, most patients with TB disease have one or more symptoms that led them to seek medical care. Occasionally,

TB is discovered during a medical examination for an unrelated condition (for example, when a patient is given a chest x-ray before undergoing surgery). Usually, when patients do have symptoms, the symptoms have developed gradually, and they have been present for weeks or even months.

Pulmonary TB disease usually causes one or more of the following symptoms:

- Coughing
- Pain in the chest when breathing or coughing
- Coughing up sputum (phlegm from deep in the lungs) or blood

The general symptoms of TB disease (pulmonary or extrapulmonary) include:

- Weight loss
- Fatigue
- Malaise
- Fever
- Night sweats

The symptoms of extrapulmonary TB disease depend on the part of the body that is affected by the disease. For example, TB of the spine may cause pain in the back**;** TB of the kidney may cause blood in the urine.

All of these symptoms may be caused by other diseases, but they should prompt the clinician to suspect TB disease.

c. **Previous TB infection or TB disease.** During the medical history, the clinician should ask the patient whether he or she has ever been diagnosed with or treated for TB infection or disease.
   - Patients known to have a positive skin test reaction probably have TB infection. If they were infected within the past 2 years, they are at high risk for TB disease.
   - Patients who have had TB disease before should be asked when they had the disease and how the disease was treated. If the regimen prescribed was inadequate or if the patient did not follow the recommended treatment, TB may recur, and it may be resistant to one or more of the drugs used.

d. **Risk factors for developing TB disease.** A fourth part of the medical history is checking for risk factors for developing TB disease. The following conditions appear to increase the risk that TB infection will progress to disease:
   - Infection with HIV, the virus that causes AIDS

- Alcohol abuse and drug injection
- Recent TB infection (within the past 2 years)
- Chest x-ray findings suggestive of previous TB
- Diabetes mellitus
- Silicosis
- Prolonged therapy with corticosteroids
- Immunosuppressive therapy
- Certain types of cancer (e.g., leukemia, Hodgkin's disease, or cancer of the head and neck)
- Severe kidney disease
- Certain intestinal conditions
- Low body weight (10% or more below ideal)

Clinicians should determine whether patients have any of these conditions. In particular, HIV infection greatly increases the risk that TB infection will progress to TB disease.

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

The Tuberculin Skin Test

Patients with symptoms of TB disease are often given a tuberculin skin test to detect exposure to and infection with TB. However, as many as 20% of patients found to have TB disease have a negative tuberculin skin test reaction. For this reason, patients with symptoms of TB disease should always be evaluated for TB disease, regardless of their skin test results**.**

Furthermore, for patients with symptoms of TB disease, clinicians should not wait for tuberculin skin test results (48 to 72 hours) before starting other diagnostic tests.

A tuberculin skin test is not necessary for patients known to have had a previous positive tuberculin skin test reaction.

The Chest X-Ray

The chest x-ray is useful for diagnosing TB disease because about 85% of TB patients have pulmonary TB. Usually, when a person has TB disease in the lungs, the chest x-ray appears abnormal. It may show infiltrates (collections of fluid and cells in the tissues of the lung) or cavities (hollow spaces within the lung that may contain many tubercle bacilli).

The purposes of the chest x-ray are to

- Help rule out the possibility of pulmonary TB disease in a person who has a positive reaction to the tuberculin skin test
- Check for lung abnormalities in people who have symptoms of TB disease

However, the results of a chest x-ray cannot confirm that a person has TB disease. A variety of illnesses may produce abnormalities whose appearance on a chest x-ray resembles TB. Although an abnormality on a chest x-ray may lead a clinician to suspect TB, only a bacteriologic culture that is positive for *M. tuberculosis* proves that a patient has TB disease**.** Moreover, a chest x-ray cannot detect TB infection.

In patients who are infected with HIV, pulmonary TB disease may have an unusual appearance on the chest x-ray. The chest x-ray may even appear entirely normal.

The Bacteriologic Examination

The next step in diagnosing TB disease is the bacteriologic examination. This is done in a laboratory that specifically deals with *M. tuberculosis* and other mycobacteria. There are four parts to a bacteriologic examination:

a. **Obtaining a specimen.** Specimens that will be sent to the laboratory can be obtained in several ways. Usually, patients who are suspected of having pulmonary TB disease simply cough up sputum into a sterile container for processing and examination. This is the cheapest and easiest procedure.

   If a patient cannot cough up sputum on his or her own, other techniques can be used to obtain a specimen. An induced sputum sample can be obtained by having the patient inhale a saline mist, which causes the patient to cough deeply. This procedure is easily done, and it should be used to help patients cough up sputum if they cannot do so on their own. Induced specimens are often clear and watery, so they should be labeled "induced specimen" so that they will not be confused with saliva.

   Another procedure, bronchoscopy, can be used to obtain pulmonary secretions or lung tissue. In this procedure, a bronchoscope is passed through the mouth directly into the diseased portion of the lung, and some sputum or lung tissue is removed. Bronchoscopy should be used only when patients cannot cough up sputum on their own and an induced specimen cannot be obtained.

   A fourth procedure, gastric washing**,** involves inserting a tube through the patient's nose and passing it into the stomach. The idea is to get a sample of sputum that has been coughed into the throat and then swallowed. Gastric washings are done in the morning because patients usually

swallow sputum during the night. This procedure is usually used only when patients cannot cough up sputum on their own, an induced specimen cannot be obtained, and bronchoscopy cannot be done. However, gastric washings are often used for obtaining sputum from children. Most children produce little or no sputum when they cough.

b. **Examining the specimen under a microscope.** Before the specimen is examined under a microscope, it is smeared onto a glass slide and stained with a dye. This is called a smear. Then laboratory personnel use the microscope to look for acid-fast bacilli (AFB) on the smear. AFB are mycobacteria that stay stained even after they have been washed in an acid solution. Tubercle bacilli are one kind of AFB.

   There is a system for reporting the number of AFB that are seen at a certain magnification. According to the number of AFB seen, the smears are classified as 4+, 3+, 2+, or 1+. (Table 3) In smears classified at 4+, 10 times as many AFB were seen as in smears classified as 3+; in 3+ smears, 10 times as many as in 2+ smears; and in 2+ smears, 10 times as many as in 1+ smears.

   Smears that are classified as 4+ and 3+ are considered strongly positive; 2+ and 1+ smears are considered moderately positive. If very few AFB are seen, the smear is classified by the actual number of AFB seen (no plus sign).

   It takes only a few hours to prepare and examine a smear. Therefore, the results of the smear examination should be available to the clinician within 1 day.

   The results of the smear examination can be used to help determine the infectiousness of the patient. Patients who have many tubercle bacilli in their sputum have a positive smear. Patients who have positive smears are considered infectious because they can cough many tubercle bacilli into the air. However, because AFB are not always tubercle bacilli, patients who have positive smears do not necessarily have TB. Furthermore, as mentioned previously, patients who have negative smears may have TB.

Table 3: Smear Classifications and Results

Classification of Smear	Smear Result	Infectiousness of Patient
4+	Strongly positive	Probably very infectious

3+	Strongly positive	Probably very infectious
2+	Moderately positive	Probably infectious
1+	Moderately positive	Probably infectious
Actual number of AFB seen (no plus sign)	Weakly positive	Probably infectious
No AFB seen	Negative	May not be infectious

Treatment of Tuberculosis Infection and Disease

Treatment of TB Infection (Preventive Therapy)

Preventive therapy is medication that is given to people who have TB infection to prevent them from developing TB disease.

Some groups of people are at higher risk for TB than others. These groups are either

- More likely to be exposed to or infected with *M. tuberculosis*, or
- More likely to develop TB disease once infected

People in these groups should receive high priority for preventive therapy if they have a positive tuberculin skin test reaction (table 4).

Table 4: High-Priority Candidates for Preventive Therapy

People in these groups should be given high priority for preventive therapy if they have a positive skin test reaction, regardless of their age:	People in these groups should be given high priority for preventive therapy if they have a positive skin test reaction and they are younger than 35:
People with HIV infection Close contacts of people with infectious TB disease People whose skin test reaction converted from	People born in areas of the world where TB is common (for example, Asia, Africa, or Latin America) Low-income groups with poor access to health care

negative to positive within the past 2 years People with chest x-ray findings suggestive of previous TB disease People who inject illicit drugs People with medical conditions that appear to increase the risk for TB disease	People who live in residential facilities (for example, nursing homes or correctional facilities) Children younger than 4 years old People in other groups as identified by local public health officials

People with no risk factors should be evaluated for preventive therapy if their tuberculin skin test reaction is 15 mm or larger and they are younger than 35 years old.

People who may be exposed to TB on the job (for example, health care workers and staff of nursing homes or correctional facilities) should be evaluated for preventive therapy if they have a positive skin test reaction.

Sometimes preventive therapy is given to people who have a negative tuberculin skin test reaction. For example, some close contacts may start taking preventive therapy if they have a negative skin test reaction but less than 10 weeks have passed since they were last exposed to TB. These contacts include

- High-risk contacts who have a negative skin test reaction (including contacts who are anergic). High-risk contacts are young children, adolescents, HIV-infected people, and others who may develop TB very quickly after infection.
- Close contacts who have a negative skin test reaction, if many other close contacts have a positive skin test reaction

Because less than 10 weeks have passed since they were last exposed to TB, these contacts may be infected with *M. tuberculosis* but have a false-negative skin test reaction. They should start preventive therapy to prevent them from rapidly developing TB disease. These contacts should be retested 10 weeks after they were last exposed to TB. If they have a negative skin test reaction, they can stop taking preventive therapy**.** (HIV-infected contacts may be given a full course of preventive therapy, regardless of their skin test results.) If they have a positive skin test reaction, they should continue to take preventive therapy.

Evaluation for Preventive Therapy

All people being considered for preventive therapy should receive a medical evaluation. One reason for this evaluation is to exclude the possibility of TB

disease, because treating TB disease with a preventive therapy regimen (usually a single drug) can lead to drug resistance. To rule out the possibility of TB disease, clinicians should determine whether the patient has symptoms of TB disease, and they should evaluate the patient with a chest x-ray. People with symptoms of TB disease or chest x-ray findings suggestive of TB disease should be given treatment for TB disease, not TB infection.

Another reason for the medical evaluation is to determine whether the patient has ever been treated for TB infection or disease**.** People who have been adequately treated should not be treated again. The tuberculin skin test cannot be used to determine whether a patient has received treatment for TB infection or disease. This is because most people who have a positive skin test reaction will have a positive reaction if they are skin tested later in their lives, regardless of whether they have received treatment.

A third reason for the medical evaluation is to find out whether the patient has any medical problems that may complicate therapy or require more careful monitoring (for example, liver disease or alcoholism).

Regimens for Preventive Therapy

The usual regimen for preventive therapy is a drug called isoniazid given daily for 6 months. Six months of isoniazid preventive therapy is very effective in preventing the development of TB disease in people not infected with HIV. Because isoniazid preventive therapy is not always effective when it is given for less than 6 months, every effort must be made to ensure that patients receive preventive therapy for at least 6 months.

Some groups of people should receive isoniazid preventive therapy for longer than 6 months. For example, children should receive at least 9 months of isoniazid preventive therapy. HIV-infected people should receive 12 months of isoniazid preventive therapy. In addition, people with chest x-ray findings suggestive of silicosis or previous TB disease should receive a 12-month regimen of isoniazid preventive therapy or a 4-month regimen of isoniazid and another drug, rifampin.

For most pregnant women with TB infection, preventive therapy should be delayed until after delivery, even though isoniazid has NOT been shown to have harmful effects on the fetus. However, pregnant women who have certain conditions should receive preventive therapy right away if they are found to have TB infection. These conditions include HIV infection, recent TB infection, and other conditions that appear to increase the risk for TB disease. The preventive therapy regimen for pregnant women is the same as the usual preventive therapy regimen -- isoniazid given daily for 6 months.

Alternative Regimens for Preventive Therapy

In some situations, drugs other than isoniazid may be used for preventive therapy. For example, preventive therapy with rifampin is recommended for people with a positive skin test reaction who have been exposed to isoniazid-resistant TB. Preventive therapy with rifampin should be given for 6 months in adults and 9 months in children.

No preventive therapy regimens have been studied for persons exposed to TB resistant to both isoniazid and rifampin. Persons at high risk of developing TB disease (for example, HIV-infected people) who are likely to be infected with multidrug-resistant organisms may be given an alternative preventive therapy regimen. This regimen should consist of two drugs to which the infecting organism is known to be susceptible. Two suggested regimens are ethambutol and pyrazinamide or pyrazinamide and a quinolone.

Adverse Reactions to Isoniazid
Sometimes medications cause adverse reactions, or negative side effects. Isoniazid may cause hepatitis, or damage to the liver. Hepatitis prevents the liver from functioning normally, causing symptoms such as:

- Nausea
- Vomiting
- Abdominal pain
- Fatigue
- Dark urine

Many things can cause hepatitis, including various viruses and medications.

Isoniazid can cause hepatitis in anyone. In fact, as many as 20% of people treated with isoniazid have some abnormality of liver function tests during treatment with isoniazid. In most people, these test results return to normal even when isoniazid treatment is continued.

In some people, however, there is a greater risk that isoniazid will cause serious hepatitis. Age is one factor; older persons are at higher risk for hepatitis. This is why preventive therapy is not recommended for people 35 years and older, unless their risk of developing TB disease is very high. Alcoholism, previous or current liver disease, drug injection, and the use of certain medications are other factors. In addition, some evidence suggests that women, particularly black and Hispanic women, are at increased risk for fatal hepatitis associated with isoniazid. This risk may be even greater for women who have recently given birth. However, fatal hepatitis is very rare.

Monitoring for Adverse Reactions
First, all patients taking preventive therapy should be educated about the symptoms that are caused by adverse reactions to isoniazid. These patients should be instructed to stop taking the medication and seek medical attention immediately if these symptoms occur. Second, all persons receiving preventive therapy should be evaluated at least monthly during therapy for signs and symptoms of adverse reactions**.** During each monthly evaluation, clinicians should ask patients whether they have nausea, abdominal pain, or any of the other symptoms that may be caused by adverse reactions. In addition, they should examine patients for signs of these adverse reactions.

People at greatest risk for hepatitis should have liver function tests before starting isoniazid preventive therapy and every month during therapy. This includes:

- People 35 years of age and older
- People with a history of liver disease
- People who abuse alcohol
- People who inject illicit drugs
- People who are taking other medications that may increase the risk of hepatitis

In addition, more careful monitoring -- and possibly more liver function tests -- should be considered for black and Hispanic women because they may be at increased risk for isoniazid-associated hepatitis. For all patients, isoniazid should be stopped if the results of liver function tests are much higher than the upper limit of the normal range.

Treatment of TB Disease

Treating TB disease benefits both the person who has TB and the community. It helps the patient because it prevents disability and death and restores health; it benefits the community because it prevents the further transmission of TB.

TB disease must be treated for at least 6 months; in some cases, treatment lasts even longer. Most of the tubercle bacilli are killed during the first 8 weeks of treatment (the initial phase). However, a few bacilli become dormant, and they can remain dormant for a long time. The drugs used to treat TB do not work as well against dormant bacilli as they do against bacilli that are growing (active). Therefore, treatment must be continued for several more months to kill these few remaining bacilli (the continuation phase). If treatment is not continued for a long enough time, some bacilli may survive and cause TB disease at a later time (relapse).

In most areas of the country, the initial regimen for treating TB disease should include four drugs:

- Isoniazid (INH)
- Rifampin (RIF)
- Pyrazinamide (PZA)
  and either
- Ethambutol (EMB) or streptomycin (SM)

When the drug susceptibility results are available, clinicians may change the regimen accordingly. In areas where less than 4% of cases are resistant to isoniazid (first drug susceptibility test only), three drugs (INH, RIF, and PZA) may be adequate for the initial regimen.

Preventing Drug Resistance
Drug resistance can develop when patients are prescribed an inappropriate regimen for treatment. TB disease must be treated with at least two drugs to which the bacilli are susceptible. Using only one drug to treat TB disease can create a population of tubercle bacilli that is resistant to that drug. When two or more drugs are used together, each drug helps prevent the emergence of bacilli that are resistant to the other drugs. When a patient is not improving in response to a prescribed regimen, adding a single drug to that regimen may have the same effect as using only one drug for treatment: it can lead to drug resistance.

Drug resistance can also develop when patients do not follow treatment regimens as prescribed -- in other words, if they do not take all of their pills, if they do not take their pills as often as prescribed, or both. When this happens, the patients may expose the bacilli to a single drug.

Adherence to Treatment
Treatment for TB disease lasts longer and requires more drugs than treatment for other infectious diseases. In order to cure TB and prevent drug resistance, patients with TB must follow the recommended course of treatment. This is called adhering to treatment. However, ensuring that patients adhere to treatment can be difficult, because many patients are reluctant to take several different medications for many months.

There are many ways to encourage patients to adhere to treatment. The most effective strategy is **directly observed therapy (DOT).** DOT means that a health care worker or another designated person watches the TB patient swallow each dose of the prescribed drugs. This method of treatment should be considered for all patients because there is no way to predict reliably which patients will adhere to treatment.

Another way to improve patient adherence is to offer incentives or enablers**.** Incentives are small rewards given to patients to encourage them to take their

own medicines or to keep their DOT or clinic appointments. For example, patients may be given food, restaurant coupons, clothing, or other items as an incentive. Enablers are things that help the patient receive treatment, such as bus tokens to get to the clinic. Incentives and enablers should be chosen according to the patient's needs, and they are frequently offered along with DOT.

An important part of helping patients take their medicine is to educate them about TB. This means talking to them about the cause of TB, the way TB is spread, the methods of diagnosing TB, and the specific treatment plan. Patients who understand these concepts are more likely to adhere to treatment.

In summary, in order to prevent relapse and drug resistance, clinicians must prescribe an adequate regimen and make sure that patients adhere to treatment.

Monitoring for Adverse Reactions

Before starting treatment, adult patients should have certain blood tests and vision tests to help detect any abnormalities that may complicate treatment. For children, only vision tests are necessary unless there are other medical conditions that may complicate treatment. Follow-up tests should be done periodically if the results of the baseline tests indicate abnormalities or if the patient has symptoms that may be due to adverse reactions.

As with patients receiving preventive therapy, all patients being treated for TB disease should be educated about the symptoms that are caused by adverse reactions to the drugs they are taking. The patients should be warned about the symptoms of insignificant side effects, such as the orange discoloration of the urine from rifampin, as well as the symptoms of potentially serious side effects, such as vomiting or abdominal pain. Patients should be instructed to seek medical attention immediately if they have symptoms of a serious side effect.

All patients should be seen by a physician at least monthly during treatment and evaluated for possible adverse reactions. During this evaluation, the doctor should ask patients whether they have any of the symptoms that may be due to adverse reactions and examine patients for signs of possible adverse reactions. Also, health care workers who have regular contact with patients should ask patients about adverse reactions at every visit. If a patient has symptoms of an adverse reaction, the health care worker should

- Instruct the patient to stop the medication if the symptoms are serious (before working with TB patients, health care workers should be educated about which symptoms are serious)
- Report the situation to a physician and arrange for a medical evaluation right away
- Note the symptoms on the patient's form

Table 5: Common Adverse Reactions to TB Drugs

Caused by	Adverse Reaction	Signs and Symptoms
Any drug	Allergic reactions	Skin rash
Ethambutol	Eye damage	Blurred or changed vision Changed color vision
Isoniazid **Pyrazinamide** **Rifampin**	Hepatitis	Abdominal pain Abnormal liver function test results Dark urine Fatigue Fever for 3 or more days Flulike symptoms Lack of appetite Nausea Vomiting Yellowish skin or eyes
Isoniazid	Nervous system damage	Dizziness Tingling or numbness around the mouth
	Peripheral neuropathy	Tingling sensation in hands and feet
Pyrazinamide	Stomach upset	Stomach upset, vomiting, lack of appetite
	Increased uric acid	Abnormal uric acid level Joint aches Gout (rare)
Rifampin	Bleeding problems	Easy bruising Slow blood clotting
	Discoloration of body fluids	Orange urine, sweat, or tears Permanently stained soft contact lenses
	Drug interactions	Interferes with certain medications, such as birth control pills, birth control implants, and methadone treatment
	Sensitivity to the sun	Frequent sunburn
Streptomycin	Ear damage	Balance problems Hearing loss Ringing in the ears
	Kidney damage	Abnormal kidney function test results

Monitoring Patients' Adherence to Therapy

Patients who are not receiving directly observed therapy should be monitored carefully for adherence to treatment. This can be done in at least three ways:

- Check to see whether the patient is reporting to the clinic as scheduled

- Ask the patient to bring the prescribed medications to each therapy visit and count the number of pills to determine how many have been taken
- Assess the patient's clinical response to treatment

None of these methods can be used to prove that a patient is taking every dose of the prescribed medication. The best way to ensure adherence to treatment is to use directly observed therapy**.**

Evaluating Patients' Response to Treatment

Clinicians use three methods to determine whether a patient is responding to treatment. First, they can check to see whether the patient still has symptoms of TB (clinical evaluation). Although each patient responds to treatment at a different pace, all patients' TB symptoms should gradually improve and eventually go away. Patients whose symptoms do not improve during the first 2 months of treatment, or whose symptoms worsen after improving initially, should be reevaluated.

Health care professionals who have regular contact with patients should pay attention to the patients' improvement. If a patient has symptoms of TB (or of adverse reactions), they should report the situation to the physician and arrange for a medical evaluation right away. They should also note the symptoms on the patient's forms.

Second, a patient's response to treatment is monitored by doing a bacteriologic examination of the sputum or other specimens. Specimens should be examined at least every month until the culture results have converted from positive to negative. For more than 85% of patients who are treated with isoniazid and rifampin, cultures will convert to negative after the patient has received 2 months of treatment. After conversion is documented, patients should have at least one more smear examination and culture at the end of treatment. Any patient whose culture results have not become negative after 2 months of treatment, or whose culture results become positive after being negative, should be carefully reevaluated.

Third, clinicians can use x-rays to monitor a patient's response to treatment. Repeated x-rays are not as important as monthly bacteriologic and clinical evaluations. However, patients should have an x-ray at the end of treatment. This x-ray can be compared with any x-rays given later on. X-rays are also useful for patients who have negative culture results before treatment or who have certain types of extrapulmonary TB, such as bone and joint TB. In these patients, the bacteriological response may be difficult to assess, and the clinician may have to rely on the clinical and x-ray responses.

The tuberculin skin test cannot be used to determine whether a patient is responding to treatment. This is because most people who have a positive skin

test reaction will have a positive reaction if they are skin tested later in their lives, regardless of whether they have received treatment.

Reevaluating Patients Who Do Not Respond to Treatment or Who Relapse
Patients should be reevaluated promptly if:

- Symptoms do not improve during the first 2 months of therapy
- Symptoms worsen after improving initially
- Culture results have not become negative after 2 months of treatment
- Culture results become positive after being negative

Reevaluating the patient means checking for drug resistance by repeating the drug susceptibility tests and assessing whether the patient has been taking medication as prescribed.

The treatment of TB can be complicated, especially in patients who fail to respond to treatment, who relapse, or who have drug-resistant TB or adverse reactions to medications. A new regimen may be required, and treatment may last longer. Clinicians who do not have experience with these situations should consult a medical expert.

Multidrug Resistant Tuberculosis (MDR-TB)

Multidrug-resistant tuberculosis (MDR-TB) is a type of tuberculosis that often develops in patients who do not adhere to or complete the proper treatment for standard tuberculosis. This can occur when a physician does not prescribe a proper treatment regimen, or when a patient is unable to, or refuses to, complete the lengthy therapy.

The World Health Organization has reported that in several regions around the world there is an MDR-TB prevalence of greater than 3 percent among newly diagnosed TB cases.

There are many challenges associated with the treatment of MDR-TB.

MDR-TB patients respond poorly to treatment with first line drugs (isoniazid and rifampicin) typically used for standard TB. MDR-TB requires a complex diagnosis, the use of second line drugs (capreomycin, kanamycin, and amikacin), and a much longer time commitment for treatment (typically up to 24 months, compared to 6 to 9 months for regular TB). Second line drugs are more expensive, and have more side effects. Additional barriers include extensive laboratory requirements to conduct culture and drug-susceptibility testing. This is why many programs choose hospitalization, at least for the initial portion of the

therapy. Hospitalization, however, greatly increases the risk of transmission of MDR-TB to both staff and patients, especially those infected with HIV.

Extensively Drug Resistant Tuberculosis (XDR-TB)

Recently, the Centers for Disease Control and the World Health Organization announced the worldwide emergence of XDR-TB—extensively drug-resistant tuberculosis. XDR-TB is tuberculosis that is resistant to first line drugs, any fluoroquinolone and at least one of three injectable second line drugs (capreomycin, kanamycin, and amikacin).

In Eastern Europe, 14 percent of MDR-TB patients have been diagnosed with XDR-TB. The phenomenon of XDR-TB gained international attention with the October 2006 outbreak in South Africa.

Infectiousness and Infection Control

Infectiousness

The infectiousness of a TB patient is directly related to the number of tubercle bacilli that he or she expels into the air. Patients who expel many tubercle bacilli are more infectious than patients who expel few or no bacilli. The number of tubercle bacilli expelled by a TB patient depends on the following factors.

Usually, only people with pulmonary or laryngeal TB are infectious. This is because these people may be coughing and expelling tubercle bacilli into the air. People with extrapulmonary TB only (no pulmonary TB) generally are not infectious. This is because tubercle bacilli usually cannot be expelled into the air from an extrapulmonary site.

Because there are many tubercle bacilli in a cavity, patients who have a cavity in the lung may be expelling tubercle bacilli if they are coughing.

Patients expel more tubercle bacilli if they have a cough that produces a lot of sputum. Also, they may expel tubercle bacilli if they are undergoing medical procedures that cause them to cough (cough-inducing procedures).

Patients who do not cover their mouth when they cough are more likely to expel tubercle bacilli.

The presence of acid-fast bacilli on a sputum smear indicates that the patient may be expelling tubercle bacilli.

Patients who have NOT been receiving adequate treatment are much more likely to be infectious than patients who have been receiving adequate treatment for 2 to 3 weeks or longer. Patients who have been receiving adequate treatment usually respond to treatment; in other words, their symptoms improve and eventually go away.

Also, patients who have drug-resistant TB are more likely to be infectious than patients who have drug-susceptible TB. This is because patients with drug-resistant TB may not respond to the initial drug regimen, and they may remain infectious until they receive proper drugs.

These factors are summarized in Table 6

Table 6: Infectiousness of TB Disease

Factors Associated with Infectiousness	Factors Associated with Non-infectiousness
TB of the lungs or larynx	Most extrapulmonary TB
Cavity in the lung	No cavity in the lung
Cough or cough-inducing procedures	No cough or cough-inducing procedures
Patient not covering mouth when coughing	Patient covering mouth when coughing
Acid-fast bacilli on sputum smear	No acid-fast bacilli on sputum smear
Not receiving adequate treatment	Receiving adequate treatment for 2-3 weeks

Young children with pulmonary or laryngeal TB disease are much less likely than adults to be infectious. This is because children generally do not produce sputum when they cough. However, it is possible for children to transmit TB to others.

Infectiousness appears to decline very rapidly after adequate treatment is started, but how quickly it declines varies from patient to patient. Some patients may stop being infectious on the day they begin treatment. Others may remain infectious for weeks or even months. Patients with drug-resistant TB may not respond to the initial drug regimen, and they may remain infectious until they receive proper drugs.

Patients can be considered noninfectious when they meet all of the following criteria:

- They have been receiving adequate treatment for 2 to 3 weeks
- Their symptoms have improved (for example, coughing less and no longer have a fever)
- They have THREE consecutive negative sputum smears from sputum collected on different days

Infection Control

TB is a communicable disease. It can be spread in many places, such as homes or worksites. On average, about 30% of people who spend a lot of time with someone who has infectious TB disease (close contacts) become infected with *M. tuberculosis*. However, TB patients vary in their infectiousness; some infect most or all their close contacts, whereas others infect few or none of their contacts.

TB can also be transmitted in health care facilities, such as hospitals and clinics. TB is most likely to be transmitted when health care workers and patients come in contact with patients who have unsuspected TB disease, who are not receiving adequate treatment, and who have not been isolated from others. Several recent outbreaks of TB in health care facilities, including outbreaks of multidrug-resistant TB, have heightened concern about the spread of TB in these facilities. The transmission of TB to HIV-infected people is of particular concern because these persons are at high risk of developing TB disease if infected. All health care facilities should take measures to prevent the spread of TB.

Parts of an Effective TB Infection Control Program

The main goal of an infection control program is to detect TB disease early and to promptly isolate and treat people who have TB disease. The infection control program should involve three types of controls:

- Administrative controls
- Engineering controls
- Personal respiratory protection

Administrative controls

Administrative controls mean establishing and following guidelines for

- Promptly detecting patients who have TB disease
- Placing these patients in an area away from other patients and giving them a diagnostic evaluation
- Treating patients who are likely to have TB disease

Other administrative control measures include

- Making sure that health care workers are following guidelines for preventing the spread of TB
- Educating, training, and counseling health care workers about TB
- Screening health care workers for TB infection and disease

To detect patients who have TB disease as soon as possible, clinicians and other health care workers should suspect TB disease in a patient who has any of these symptoms:

- A persistent cough
- Bloody sputum
- Weight loss or loss of appetite
- Fever
- Night sweats

In areas where TB is very common, staff of local health care facilities should be especially alert for TB. Health care workers who admit patients to the facility should be trained to ask appropriate questions to help detect patients who have signs or symptoms of TB disease.

Patients who have signs or symptoms of TB disease should be placed in an area away from other patients (preferably in a TB isolation room) and promptly given a diagnostic evaluation. These patients should be given a surgical mask and instructed to keep it on. They should also be given tissues and asked to cover their nose and mouth when coughing or sneezing, even when in an area away from others.

In hospitals and other inpatient settings, patients known to have TB disease or suspected of having TB disease should be placed in a special TB isolation room (AII) right away. TB isolation rooms are rooms in the facility that have special characteristics to prevent the spread of droplet nuclei expelled by a TB patient. One characteristic of TB isolation rooms is that they are at negative pressure relative to other parts of the facility. Negative pressure means that air flows from the corridors into the isolation room. This way, contaminated air cannot escape from the isolation room to other parts of the facility. Air from the isolation room can be exhausted directly to the outdoors, where any infectious droplet nuclei will be diluted in the outdoor air and killed by the sunlight. Alternatively, the air can be passed through a special filter that removes all of the droplet nuclei before the air is returned to the general circulation The room should have at least six air changes per hour. The door must be kept closed in order to maintain negative pressure, and the room must be checked periodically to make sure that it remains at negative pressure.

Patients suspected of having TB disease should be given a diagnostic evaluation as soon as possible. This means a medical history, a tuberculin skin test, a chest x-ray, and the collection of specimens for a bacteriologic examination. It is

important that laboratories use the most rapid diagnostic methods available. In outpatient settings where a diagnostic evaluation cannot be completed, patients who have symptoms of TB should be referred to a facility capable of doing the evaluation.

Patients who are likely to have TB should start appropriate treatment at once.

Patients should be educated about the transmission of TB, the reason for TB isolation, and the importance of staying in their room. Every effort should be made to help the patient follow the isolation policy — including the use of incentives, such as providing telephones or televisions or allowing special dietary requests. As few people as possible should be allowed to enter the TB isolation room, and anyone entering should wear respiratory protection.

Training and education. All health care workers should be educated about the basic concepts of TB transmission and pathogenesis, infection control practices, the signs and symptoms of TB, and the importance of participating in the skin testing program for health care workers.

TB screening for health care workers. Health care workers who may be exposed to TB should be included in a TB screening and prevention program. This means two-step tuberculin skin testing upon employment and at least once a year thereafter. Any worker who develops symptoms of TB disease or whose tuberculin skin test reaction converts to positive should be evaluated promptly.

Engineering controls

Three types of engineering controls are used to prevent the transmission of TB in health care facilities:
1. ventilation
2. high-efficiency particulate air (HEPA) filtration
3. ultraviolet germicidal irradiation.

In isolation (AII) rooms, ventilation systems are necessary to maintain negative pressure and to exhaust the air properly. These systems can also be designed to minimize the spread of TB in other areas of the health care facility. HEPA filters are special filters that can be used in ventilation systems to help remove droplet nuclei from the air. Ultraviolet germicidal irradiation (UVGI), or the use of special lamps that give off ultraviolet light, is used to kill the tubercle bacilli contained in droplet nuclei. However, exposure to ultraviolet light can be harmful to the skin and eyes of humans, so the lamps must be installed in the upper part of rooms or corridors or placed in exhaust ducts. HEPA filters and UVGI should be used in conjunction with other infection control measures.

Personal Respiratory Protection

In some settings, administrative and engineering controls may not fully protect health care workers from infectious droplet nuclei. These settings include

- TB isolation (AII) rooms
- Rooms where cough-inducing procedures are done
- Ambulances and other vehicles transporting infectious TB patients
- The homes of infectious TB patients

Health care workers should use personal respirators, or special masks designed to filter out droplet nuclei, in these settings. Health care workers should be taught how and when to use personal respirators.

Considerations for Selection of Respirators
The overall effectiveness of respiratory protection is affected by 1) the level of respiratory protection selected (e.g., the assigned protection factor), 2) the fit characteristics of the respirator model, 3) the care in donning the respirator, and 4) the adequacy of the fit-testing program. Although data on the effectiveness of respiratory protection from various hazardous airborne materials have been collected, the precise level of effectiveness in protecting HCWs from *M. tuberculosis* transmission in health-care settings has not been determined. Information on the transmission parameters of *M. tuberculosis* is also incomplete. Neither the smallest infectious dose of *M. tuberculosis* nor the highest level of exposure to *M. tuberculosis* at which transmission will not occur has been defined conclusively. In addition, the size distribution of droplet nuclei and the number of particles containing viable *M. tuberculosis* organisms that are expelled by patients with infectious TB disease have not been adequately defined, and accurate methods of measuring the concentration of infectious droplet nuclei in a room have not been developed. Nonetheless, in certain settings (e.g., AII rooms and ambulances during the transport of persons with suspected or confirmed infectious TB disease), administrative and environmental controls alone might not adequately protect HCWs from infectious airborne droplet nuclei.

Types of Respiratory Protection for TB
Respirators encompass a range of devices that vary in complexity from flexible masks covering only the nose and mouth, to units that cover the user's head (e.g., loose-fitting or hooded PAPRs), and to those that have independent air supplies (e.g., airline respirators). Respirators must be selected from those approved by CDC/NIOSH under the provisions of 42 CFR, Part 84.

Nonpowered air-purifying respirators. Nine classes of nonpowered, air-purifying, particulate-filter respirators are certified under 42 CFR 84. These include N-, R-, and P-series respirators of 95%, 99%, and 100% (99.7%) filtration efficiency when challenged with 0.3 μm particles (filters are generally least efficient at this size) The N, R, and P classifications are based on the capacity of

the filter to withstand exposure to oil. All of these respirators meet or exceed CDC's filtration efficiency performance criteria during the service life of the filter. Nonpowered air-purifying respirators work by drawing ambient air through the filter during inhalation. Inhalation causes negative pressure to develop in the tight-fitting facepiece and allows air to enter while the particles are captured on the filter. Air leaves the facepiece during exhalation because positive pressure develops in the facepiece and forces air out of the mask through the filter (disposable) or through an exhalation valve (replaceable and certain ones are disposable). The classes of certified nonpowered air-purifying respirators include both filtering facepiece (disposable) respirators and elastomeric (rubber-like) respirators with filter cartridges. The certification test for filtering facepieces and filter cartridges consists only of a filter performance test. It does not address respirator fit. Although all N-, R-, and P-series respirators are recommended for protection against *M. tuberculosis* infection in health-care settings and other workplaces that are usually free of oil aerosols that could degrade filter efficiency, wellfitting N-series respirators are usually less expensive than Rand P-series respirators. All respirators should be replaced as needed, based on hygiene considerations, increased breathing resistance, time-use limitations specified in the CDC/NIOSH approval guidelines, and respirator damage, in accordance with manufacturer specifications.

Powered Air Purifying Respirator (PAPRs). PAPR uses a blower that draws air through the filters into the facepiece. PAPRs can be equipped with a tightfitting or loose-fitting facepiece, a helmet, or a hood. A hooded PAPR high efficiency filter meets the N100, R100, and P100 criteria at the beginning of their service life. No loading tests using 0.3 μm particles are conducted as part of certification. PAPRs can be useful for persons with facial hair or other conditions that prevent an adequate face to facepiece seal. Data on the effectiveness of respiratory protection against hazardous airborne materials are based on experience in the industrial setting; data on protection against transmission of *M. tuberculosis* in health-care settings are not available. The parameters used to determine the effectiveness of a respiratory protective device are face-seal efficacy and filter efficiency.

Face-seal leakage. Face-seal leakage is the weak link that limits a respirator's protective ability. Excessive face-seal leakage compromises the ability of particulate respirators to protect HCWs from airborne materials. A proper seal between the respirator's sealing surface and the face of the person wearing the respirator is essential for the effective and reliable performance of any tight-fitting, negative-pressure respirator. For tight-fitting, negative-pressure respirators (e.g., N95 disposable respirators), the amount of face-seal leakage is determined by 1) the fit characteristics of the respirator, 2) the care in donning the respirator, and 3) the adequacy of the fit-testing program. Studies indicate that a well-fitting respirator and a fit test produce better results than a well-fitting respirator without a fit test or a poor-fitting respirator with a fit test. Increased face-seal leakage can result from additional factors, including incorrect facepiece size, failure to follow

the manufacturer's instructions at each use, beard growth, perspiration or facial oils that can cause facepiece slippage, improper maintenance, physiological changes of the HCW, and respirator damage. Face-seal leakage is inherent in tight-fitting negative pressure respirators. Each time a person wearing a non-powered particulate respirator inhales, negative pressure (relative to the workplace air) is created inside the face piece. Because of this negative pressure, air containing contaminants can leak into the respirator through openings at the face-seal interface and avoid the higher-resistance filter material. A half-facepiece respirator, including an N95 disposable respirator, should have <10% leakage. Full facepiece, nonpowered respirators have the same leakage (<2%) as PAPRs with tight-fitting full facepieces.

Infection Control in Residential Facilities

All residential facilities where TB patients receive care should establish and follow an infection control program. These residential facilities may include nursing homes, correctional facilities, homeless shelters, drug treatment centers, and other places. As in health care facilities, the main goal of the infection control program should be to detect TB disease early and arrange for the isolation and treatment of suspected TB patients.

AII Room Practices

AII rooms should be single-patient rooms in which environmental factors and entry of visitors and HCWs are controlled to minimize the transmission of *M. tuberculosis*. All HCWs who enter an AII room should wear at least N95 disposable respirators. Visitors may be offered respiratory protection (i.e., N95) and should be instructed by HCWs on the use of the respirator before entering an AII room. AII rooms have specific requirements for controlled ventilation, negative pressure, and air filtration. Each inpatient AII room should have a private bathroom.

Health-care personnel settings with AII rooms should:

- Keep doors to AII rooms closed except when patients, HCWs, or others must enter or exit the room;
- Maintain enough AII rooms to provide airborne precautions of all patients who have suspected or confirmed TB disease.
- Monitor and record direction of airflow (i.e., negative pressure) in the room on a daily basis, while the room is being used for TB airborne precautions. Record results in an electronic or readily retrievable document;

- Consider grouping AII rooms in one part of the healthcare setting to limit costs, reduce the possibility of transmitting *M. tuberculosis* to other patients, facilitate the care of TB patients, and facilitate the installation and maintenance of optimal environmental controls (particularly ventilation). Depending on the architecture and the environmental control systems of a particular setting, AII rooms might be grouped either horizontally (e.g., a wing of a facility) or vertically (e.g., the last few rooms of separate floors of a facility);

- Perform diagnostic and treatment procedures (e.g., sputum collection and inhalation therapy) in an AII room.

- Ensure patient adherence to airborne precautions. In their primary language, with the assistance of a qualified medical interpreter, if necessary, educate patients (and family and visitors) who are placed in an AII room about *M. tuberculosis* transmission and the reasons for airborne precautions.

- Ensure that patients with suspected or confirmed infectious TB disease who must be transported to another area of the setting or to another setting for a medically essential procedure bypass the waiting area and wear a surgical or procedure mask, if possible. Drivers, HCWs, and other staff who are transporting persons with suspected or confirmed infectious TB disease might consider wearing an N95 respirator. Schedule procedures on patients with TB disease when a minimum number of HCWs and other patients are present and as the last procedure of the day to maximize the time available for removal of airborne contamination.

Cleaning, Disinfecting, and Sterilizing Patient-Care Equipment and Rooms

Medical instruments and equipment, including medical waste, used on patients who have TB disease are usually not involved in the transmission of *M. tuberculosis*. However, transmissions of *M. tuberculosis* and pseudo-outbreaks (e.g., contamination of clinical specimens) have been linked to inadequately disinfected bronchoscopes contaminated with *M. tuberculosis*.
The rationale for cleaning, disinfecting, or sterilizing patient care instruments and equipment can be understood more readily if medical devices, equipment, and surgical materials are divided into three general categories. The categories are critical, semicritical, and noncritical and are based on the potential risk for infection if an item remains contaminated at the time of use.

Critical Medical Instruments
Instruments that are introduced directly into the bloodstream or other normally sterile areas of the body (e.g., needles, surgical instruments, cardiac catheters,

and implants) are critical medical instruments. These items should be sterile at the time of use.

Semicritical Medical Instruments
Instruments that might come into contact with mucous membranes but do not ordinarily penetrate body surfaces (e.g., noninvasive flexible and rigid fiberoptic endoscopes or bronchoscopes, endotracheal tubes, and anesthesia breathing circuits) are semicritical medical instruments. Although sterilization is preferred for these instruments, high-level disinfection that destroys vegetative microorganisms, the majority of fungal spores, mycobacteria (including tubercle bacilli), and small nonlipid viruses can be used. Meticulous cleaning of such items before sterilization or high-level disinfection is essential. When an automated washer is used to clean endoscopes and bronchoscopes, the washer must be compatible with the instruments to be cleaned. High-level disinfection can be accomplished with either manual procedures alone or use of an automated endoscope reprocessor with manual cleaning. In all cases, manual cleaning is an essential first-step in the process to remove debris from the instrument.

Non-critical Medical Instruments or Devices
Instruments or devices that either do not ordinarily touch the patient or touch only the patient's intact skin (e.g., crutches, bed boards, and blood pressure cuffs) are non-critical medical instruments. These items are not associated with transmission of *M. tuberculosis*. When non-critical instruments or equipment are contaminated with blood or body substances, they should be cleaned and then disinfected with a hospital-grade, Environmental Protection Agency (EPA)-registered germicide disinfectant with a label claim for tuberculocidal activity (i.e., an intermediate-level disinfectant). Tuberculocidal activity is not necessary for cleaning agents or low-level disinfectants that are used to clean or disinfect minimally soiled noncritical items and environmental surfaces (e.g., floors, walls, tabletops, and surfaces with minimal hand contact).

Disinfection

The rationale for use of a disinfectant with tuberculocidal activity is to ensure that other potential pathogens with less intrinsic resistance than that of mycobacteria are killed. A common misconception in the use of surface disinfectants in health care relates to the underlying purpose of products labeled as tuberculocidal germicides. Such products will not interrupt and prevent transmission of *M. tuberculosis* in health-care settings, because TB is not acquired from environmental surfaces. The tuberculocidal claim is used as a benchmark by which to measure germicidal potency. Because mycobacteria have the highest intrinsic level of resistance among the vegetative bacteria, viruses, and fungi, any germicide with a tuberculocidal claim on the label (i.e., an intermediate-level disinfectant) is considered capable of inactivating many pathogens, including much less resistant organisms such as the bloodborne pathogens (e.g., hepatitis

B virus, hepatitis C virus, and HIV). Rather than the product's specific potency against mycobacteria, a germicide that can activate many pathogens is the basis for protocols and regulations indicating the appropriateness of tuberculocidal chemicals for surface disinfection. Policies of health-care settings should specify whether cleaning, disinfecting, or sterilizing an item is necessary to decrease the risk for infection. Decisions regarding decontamination processes should be based on the intended use of the item, not on the diagnosis of the condition of the patient for whom the item is used. Selection of chemical disinfectants depends on the intended use, the level of disinfection required, and the structure and material of the item to be disinfected. The same cleaning procedures used in other rooms in the health-care setting should be used to clean AII rooms. However, personnel should follow airborne precautions while cleaning these rooms when they are still in use. Personal protective equipment is not necessary during the final cleaning of an AII room after a patient has been discharged if the room has been ventilated for the appropriate amount of time

Discharge Considerations

If a hospitalized patient who has suspected or confirmed TB disease is deemed medically stable (including patients with positive AFB sputum smear results indicating pulmonary TB disease), the patient can be discharged from the hospital before converting the positive AFB sputum smear results to negative AFB sputum smear results, if the following parameters have been met:

- a specific plan exists for follow-up care with the local TB-control program;
- the patient has been started on a standard multidrug antituberculosis treatment regimen, and DOT has been arranged;
- no infants and children aged <4 years or persons with immunocompromising conditions are present in the household;
- all immunocompetent household members have been previously exposed to the patient; and
- the patient is willing to not travel outside of the home except for health-care–associated visits until the patient has negative sputum smear results.

Patients with suspected or confirmed infectious TB disease should not be released to health-care settings or homes in which the patient can expose others who are at high risk for progressing to TB disease if infected (e.g., persons infected with HIV or infants and children aged <4 years). Coordination with the local health department TB program is indicated in such circumstances.

Infection Control in the Home

Health care workers who visit TB patients at home should take these precautions to protect themselves from the spread of TB:

- Instruct patients to cover their mouth and nose with a tissue when coughing or sneezing
- Wear a personal respirator when visiting the home of an infectious TB patient or when transporting an infectious TB patient in a vehicle
- When it is necessary to collect a sputum specimen in the home, collect the specimen in a well-ventilated area, away from other household members; if possible, the specimen should be collected outdoors
- Participate in a TB screening and prevention program

Principles and Practice of TB Control

Basic Principles of TB Control

The goal of TB control in the United States is to reduce morbidity and mortality caused by TB by 1) preventing transmission of *M. tuberculosis* from persons with contagious forms of the disease to uninfected persons and 2) preventing progression from LTBI to TB disease among persons who have contracted *M. tuberculosis* infection.

Four fundamental strategies are used to achieve this goal as follows:

1. Early and accurate detection, diagnosis, and reporting of TB cases leading to initiation and completion of treatment.
Detecting and reporting suspected cases of TB is the key step in stopping transmission of *M. tuberculosis* because it leads to prompt initiation of effective multiple-drug treatment, which rapidly reduces infectiousness. Completion of a full course of standard therapy is essential to prevent treatment failure, relapse, and the acquisition of drug resistance. TB is commonly diagnosed when a person seeks medical attention for symptoms caused by the disease or a concomitant medical condition. Thus, health-care providers, particularly those providing primary health-care to populations at high risk, are key contributors to TB case detection. A suspected or confirmed case of TB should be reported immediately to the jurisdictional public health agency. Reporting of new cases is essential to initiate public health responses, including institution of a treatment plan, case-management services, and evaluation of contacts, and for surveillance purposes.

2. Identification of contacts of patients with infectious TB and treatment of those at risk with an effective drug regimen.
The evaluation of contacts of cases of infectious TB is one of the most productive methods of identifying adults and children with LTBI at high risk for progression to TB disease and persons in the early stages of TB disease. Contact investigations therefore serve as an important means of detecting tuberculosis cases and at the same time identify persons in the early stage of LTBI, when the risk for progression to TB disease is high and the benefit of treatment is greatest.

3. Identification of other persons with LTBI at risk for progression to TB disease and treatment of those persons with an effective drug regimen. Targeted testing is intended to identify persons other than TB contacts who have an increased risk for acquiring TB and to offer such persons diagnostic testing for *M. tuberculosis* infection and treatment, if indicated, to prevent subsequent progression to TB disease. This approach is critical to the eventual elimination of TB in the United States, because it is the only means of preventing TB in the substantial pool of persons with LTBI at high risk for progression to TB disease. Targeted testing and treatment of LTBI is also a primary means of controlling TB among foreign-born persons at high risk residing in the United States because genotyping surveys have consistently demonstrated that the majority of TB cases in that population are attributable to progression from LTBI. Targeted testing and treatment of LTBI is best accomplished through cost-effective programs aimed at patients and populations identified on the basis of local surveillance data as being at increased risk for TB.

4. Identification of settings in which a high risk exists for transmission of *M. tuberculosis* and application of effective infection-control measures. For the rising burden of TB from recent transmission of *M. tuberculosis* to be reduced, settings at high risk for transmission should be identified, and effective infection-control measures should be taken to reduce the risk. TB outbreaks associated with person-to-person spread occur in different venues, most prominently in health-care facilities. Institutional infection-control measures have been highly successful in health-care facilities, but other high-risk settings (e.g., correctional facilities, homeless shelters, bars, and social settings that extend beyond single venues present challenges to effective infection control.

Deficiencies in TB Control

Because TB control is a complex undertaking that involves multiple participants and processes, mistakes often occur, with adverse consequences. Common errors include 1) delays among persons with active TB obtaining health care; 2) delayed detection and diagnosis of active TB; 3) failed or delayed reporting of TB; 4) failure to complete an effective course of treatment for TB; 5) missed opportunities to prevent TB among children; and 6) deficiencies in conducting contact investigations and in recognizing and responding to outbreaks.

Delays in Obtaining Health Care
Homeless patients with TB symptoms often delay seeking care or experience delays in gaining access to care, and fear of immigration authorities has been associated with patient delay among foreign-born persons. Patients who speak languages other than English or who are aged 55--64 years are more likely than others to delay seeking care.

Cultural factors that might affect health-seeking behavior by foreign-born persons include misinterpretation or minimization of symptoms, self-care by using over-

the-counter or folk medicines, and the social stigma associated with TB. In certain societies, women with TB are less likely to take advantage of health-care services, perhaps because of stigma associated with the diagnosis, including a lower likelihood of marriage. Even in areas with open access to public health clinical services, persons at risk for TB might not seek evaluation and treatment because they are not aware that these resources are available for persons with limited financial means.

Delayed Detection and Diagnosis of Active TB
Delayed detection of a case of TB and resulting delays in initiation of treatment can occur if the clinician does not suspect the diagnosis. Asians and homeless persons were more likely to encounter delays in receiving a diagnosis than non-Asians and persons with stable housing. Persons without cough who had AFB smear-negative TB or who did not have a chest radiograph at their initial visit also experienced delays.

These problems reflect the increasing difficulty in maintaining clinical expertise in the recognition of TB in the face of declining disease incidence. Recognition of TB among patients with AFB-negative sputum smear results is a challenge for practitioners and has been associated with delays in reporting and treatment.

Delayed Reporting of TB
Failure to promptly report a new TB case delays public health responses (e.g., institution of a treatment plan, case-management services, and protection of contacts). Although TB cases in the United States rarely remain unreported, timeliness of reporting varies (median: 7--38 days).

Failure to Receive and Complete Treatment for Active TB
Failure to receive and complete a standard course of treatment for TB has adverse consequences; including treatment failure, relapse, increased TB transmission, and the emergence of drug-resistant TB. At least two reasons exist for failure to complete standard treatment. Patients frequently fail to adhere to the lengthy course of treatment. Poor adherence to treatment regimens might result from difficulties with access to the health-care system, cultural factors, homelessness, substance abuse, lack of social support, rapid clearing of symptoms, or forgetfulness. Also, as TB has become less common, clinicians might fail to use current treatment regimens. These adverse outcomes are preventable by case-management strategies provided by TB-control programs, including use of DOT.

Deficiencies in Conducting Contact Investigations and in Recognizing and Responding to Outbreaks
Deficiencies in contact investigations and failure to recognize and respond to TB outbreaks are among the most important challenges to optimal control of TB in the United States.

Confidentiality in Tuberculosis Control

Confidentiality

Confidentiality involves the protection of information revealed during patient-health care worker encounters, including all written or electronic records of these encounters. Confidentiality is an essential issue in many different aspects of TB control. Health care workers need to be aware of confidentiality issues that are relevant to patient-health care worker encounters, as well as to the collection, management, and sharing of information gathered on TB patients.

Health care workers should keep patient information in confidence and only divulge it with the permission of the patient except as otherwise required by law. It is the responsibility of the health care worker to protect the patient's private information and ensure that only those persons who need to know information have access to patient records. Only persons directly involved in patient care or public health activities should have access to patient information. Safeguarding patient information should be a priority for all members of the health care team.

Confidentiality is a very important issue in TB control because the diagnosis of TB disease is potentially damaging to patients. For some patients, a diagnosis of TB can lead to stigmatization or rejection by family, friends, and coworkers; the loss of a job; and possibly eviction from housing. There are some specific confidentiality issues that require special attention by health care workers working with TB patients:

- The TB patient has certain rights that must be respected and are often protected by legislation
- The health department has a responsibility to protect the public's health using certain effective TB control strategies
- In the course of conducting TB control activities, some patient rights may be overridden in the interest of protecting the public's health (for example, an uncooperative, infectious patient may be quarantined until noninfectious)
- Great care must be taken to ensure that patient rights -- especially the right to privacy -- are protected to the fullest extent possible so the patient-health care worker relationship is not compromised; this relationship must be strong enough to last throughout the time it takes a TB patient to complete therapy

Identifying and Managing TB Cases

Most persons who have TB disease are diagnosed when they seek medical care for symptoms caused by TB or other medical conditions. Reports of suspected or confirmed TB cases are required to be submitted to public health authorities.

Cases of TB are reported to federal, state, or local health authorities based upon laws governing the locality. Because TB is considered a significant threat to the public's health, the disclosure of the patient information from the health care worker to a designated public health authority is allowed for the purpose of TB control. In addition to routine case reporting, some TB control programs conduct active surveillance to identify TB cases through laboratory or pharmacy records. Health departments are required to protect the confidentiality of all TB case reports.

Once the information about a suspected or confirmed TB case is transmitted to or obtained by the health department, health care workers use this information to ensure that the necessary steps are taken to treat the patient and halt the spread of disease.

When a TB case report has been submitted, the health care worker should check the TB program database to see if the case has been reported previously. If so, he or she should obtain information about the patient's past clinic visits, chest x-ray reports, adherence history, bacteriology and susceptibility results, and medication history, including the administration of directly observed therapy (DOT). It is crucial that this information be given immediately to the health care worker managing the case to ensure appropriate medical treatment. As confidentiality laws permit, this information may also be shared with others providing direct care to the patient.

If a patient travels or moves from one health jurisdiction to another, the health department of the patient's home jurisdiction should notify the health department for the area to which the patient is moving. It is important that as much information as possible be relayed to the receiving jurisdiction, within the limitations of current laws and regulations governing the confidentiality of records. Health care workers should be aware that legal obligations of confidentiality may vary widely from state to state.

Although sharing necessary information between health care workers, health departments, and health jurisdictions is encouraged to protect the health of the patient and the public, information should be shared only on a need-to-know basis. In addition, when sending or faxing information, measures should be taken to ensure confidentiality. For example, any materials sent through the mail should be sent by way of secure mail to the care of a specific person. Health care workers should never fax patient information if they are not sure if the receiving fax machine is in a secure area. Furthermore, all information sent by fax should be sent to a specific person and should be labeled confidential.

Contact investigations and targeted screening for TB are additional ways to identify TB cases. Both these activities require the health care worker to practice confidentiality.

Ensuring Adequate Therapy

When a suspected or confirmed TB case has been identified, a treatment plan is made for the patient and the patient's informed consent is obtained. The treatment plan usually includes information on

- The prescribed regimen
- Monitoring for adverse reactions and response to treatment
- Ensuring adherence to the regimen, which may involve giving directly observed therapy and various incentives and enablers

It should be made clear from the beginning of treatment that confidentiality of the patient's personal information is an important priority. Health care workers should discuss confidentiality with the patient and determine who, if anyone, will be allowed to know about the patient's care or to participate in decision-making. A trusted family member or close friend can be very valuable in supporting the patient during his or her care; however, in no case should such a person be "recruited" to assist without the patient's request and prior knowledge.

In some cases, the plan for ensuring adherence to the regimen may involve self-administered therapy with occasional visits to the health care worker for monitoring. More often, however, directly observed therapy (DOT) is offered to ensure that the patient receives adequate therapy and completes a recommended regimen. DOT involves frequent encounters between the patient and a health care worker, which may take place at sites in the community (for example, the patient's home, workplace, or other locations). Health care workers should make sure that the patient's confidentiality is protected during these encounters. This means that

- The location chosen should allow private conversations
- No other persons should be present without the patient's permission
- Any documents or materials brought to such encounters should be protected from access by unauthorized persons

Occasionally, a TB patient may decide not to cooperate with the health care worker in completing an adequate regimen. When this happens, the health care worker has a responsibility to

- Review the causes of the patient's nonadherence
- Identify potential solutions
- Try to meet the patient's needs to the extent possible to facilitate completion of therapy

If these measures fail, the patient may be required to continue treatment under a court order or even be confined for the duration of treatment. Because the threat to the public's health is serious, an uncooperative TB patient can be quarantined

until noninfectious or, in some jurisdictions, committed to a treatment facility. This is a very rare event, which is fortunate because it involves a serious breach of the patient's right to autonomy.

In such a situation, maintaining the confidentiality of patient information is critical. Although disclosure of patient information is necessary to obtain a court order or an order for confinement, such disclosure should be strictly limited to the appropriate government authorities who need the information. Any health department or law enforcement officials who become involved in enforcing such orders should take great care to protect the patient's right to privacy. A breach of confidentiality in these circumstances can further undermine the patient-health care worker relationship and lead to continued resistance to adherence-promoting measures.

Identifying High-Priority Candidates for Treatment for Latent TB Infection (LTBI)

When a reported case of TB is potentially infectious, a contact investigation is conducted to identify persons who may have TB disease, as well as those who are newly infected with *M. tuberculosis*. These newly infected persons are high-priority candidates for treatment for LTBI.

When a contact investigation is conducted for a reported TB patient, a public health care worker will

- Interview the patient
- Explain the goals of the investigation
- Explain why it is important to know the names of contacts
- Tell the patient about his or her right to privacy
- Explain the measures that will be taken to maintain confidentiality

Contact Investigations and Confidentiality. Contact investigations pose some unique challenges to maintaining patient confidentiality. Whenever possible, the health care worker should ensure that patient interviews take place under conditions that are private and maintain confidentiality. The patient should be told about his or her rights to privacy and reassured of the measures that will be taken to maintain confidentiality.

The health care worker should be aware that 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 or her, or the patient simply may not want his or her friends to know that he or she has TB. In addition, if the patient has contacts who are in the country illegally, the patient may be reluctant to identify contacts for fear they will be reported to immigration authorities. The health care worker should

- Be sensitive to the patient's fears
- Explain the importance of screening the contacts
- Assure the patient that all information, including the patient's name, will be kept confidential and will not be shared with authorities

The health care worker and the patient should decide who will notify the contacts and make appointments for them to receive TB testing at the health department. Some TB patients prefer to notify their contacts themselves, especially when the contacts are family members or close friends. Others prefer that the health worker notify the contacts to protect their privacy; in this instance, the patient should be assured that the contacts they name will not be told who identified them as a contact.

Public health investigators should conduct contact investigations without jeopardizing the TB patient's confidentiality. The health care worker should be careful not to inadvertently reveal clues about the TB patient (index case) during contact follow-up. Health care workers can use the following strategies to protect the confidentiality of the patient when conducting a contact follow-up during contact investigations:

- Gender-neutral language should be used (even if it requires using bad grammar). For example, "Somebody was diagnosed with TB and they were [or "that person was"] concerned about you" instead of "A woman was diagnosed with TB and she was concerned about you."
- The index case's health care worker, place and dates of diagnosis, or hospitalization should not be mentioned
- The environment in which the exposure occurred should not be mentioned. For example, "You have been around somebody who has TB" instead of "You have been around somebody at work who has TB."
- The dates of exposure should not be specified
- When following-up on interjurisdictional referrals, the county or state that initiated the referral should not be mentioned
- Confidentiality should not be violated even if contacts refuse to be evaluated until they have been told the index patient's identity

In addition, HIV/AIDS programs conduct partner notification to identify and counsel the sexual and needle-sharing contacts of HIV-infected persons; this notification is confidential and depends on the voluntary cooperation of the patient. When an HIV-infected person is diagnosed with TB disease, health care workers should explain what a contact is for the purpose of TB investigations and assure the patient that his or her name and HIV status will be kept confidential.

In a situation where an outbreak of TB has occurred or when a contact investigation is conducted in a work site or institutional setting in which numerous contacts may have been infected, maintaining confidentiality is challenging. Sometimes, a contact guesses the identity of the source case and it becomes

difficult to contain rumors. In addition, a friend, family member, or co-worker of the patient may divulge information about the patient to others. Patients should be counseled that despite the health care worker's best efforts, sometimes confidentiality is not preserved. The patient and the health care worker should discuss this possibility and be prepared to address this issue in the event that patient confidentiality is not maintained. To prevent breaches in confidentiality, patients should be counseled to inform only persons they trust about their diagnosis and to ask these persons to safeguard that information.

Testing and Confidentiality. Testing for TB infection may be mandatory for specific groups of people. In health-care facilities or other institutional settings (for example, homeless shelters, correctional facilities, drug-treatment centers, AIDS clinics or hospices, homes for the mentally ill), residents and employees may be required to participate in an ongoing tuberculin skin-testing program. In such situations, testing procedures should be designed and records maintained in such a way that confidentiality is protected. It should not be obvious to other residents or patients that a person is being evaluated because of a positive skin-test reaction.

Confidentiality measures are not only important in testing high-priority candidates for LTBI, but are also relevant in providing and monitoring treatment for LTBI. Treatment for LTBI should be offered to persons with a positive skin-test reaction or a high likelihood of infection with *M. tuberculosis* according to current guidelines and recommendations.

Confidentiality and Conducting Other Core Activities

In addition to identifying TB cases, ensuring adequate therapy, and identifying high-priority candidates for treatment for LTBI, TB programs are responsible for

- Collecting and analyzing data
- Conducting overall planning and policy development
- Providing laboratory and diagnostic services
- Providing training and education

Confidentiality is important in several of these core activities, including collecting and analyzing data with patient-identifiable information. TB control programs develop specific policies to ensure the security and confidentiality of TB records and should train staff members in procedures for maintaining and carrying out these policies. Policies and procedures should be in place to protect all TB reports, records, and files containing patient names or other identifying information.

Local policies regarding the security and confidentiality of such information, especially HIV test results, must adhere to all laws applicable in state and local jurisdictions. These protections should include the use of TB surveillance

databases such as CDC's Tuberculosis Information Management System (TIMS). These databases are encrypted to protect information during transfers of data for reporting purposes. Although such databases allow for the collection and storage of personal identifiers such as names and street addresses for local and state TB surveillance purposes, these identifiers are not transmitted to CDC. In general, any surveillance information sent through the mail should be stamped "confidential," addressed to a specific person (or sent to that person's attention), and sent by secure mail. These precautions will help to limit unauthorized access to surveillance information.

Because HIV infection and AIDS can have serious implications for TB control, some health jurisdictions have specific rules and regulations for the sharing of information between TB and HIV/AIDS programs. AIDS is a reportable disease in every state. The requirements for reporting HIV infection differ from state to state, and health care workers should be familiar with local reporting requirements. HIV reports are held in strictest confidence and in many jurisdictions are protected by statute from subpoena. For clinical care purposes, HIV-related information should be shared between TB health care workers and other health care workers in accordance with state and local laws.

The sharing of surveillance information between HIV/AIDS programs and TB programs within the same health department is necessary to conduct both TB and HIV/AIDS surveillance programs and to allow for adequate investigation of TB and HIV/AIDS cases. In general, TB surveillance programs and staff should adhere to the same confidentiality standards as HIV/AIDS surveillance programs and should work with local HIV/AIDS programs to establish equivalent data confidentiality systems. Sharing information on HIV serostatus with persons outside the HIV/AIDS and TB surveillance programs of the same health department should only be done with the informed consent of the patient.

Program evaluation reports serve as a basis for policy development and are often shared with appropriate public, private, and community groups. TB programs collect and analyze

- Morbidity rates
- Trends
- Demographic characteristics of the TB patient population in the area

They also assess program performance by determining the rates for

- Completion of therapy
- Contact identification
- Initiation and completion of treatment for LTBI

Program evaluation reports should never include patient-identifiable information, such as names, addresses, or even detailed demographic information if such information allows the determination of a patient's identity.

Patient Adherence to Tuberculosis Treatment

Patient Adherence to TB Treatment

Adherence to treatment means that a patient is following the recommended course of treatment by taking all the prescribed medications for the entire length of time necessary. Adherence is important because TB is nearly always curable if patients adhere to their TB treatment regimen.

Nonadherence is the patient's inability or refusal to take TB drugs as prescribed. When medical treatment is complicated or lasts for a long time, as in the treatment for TB disease, patients often do not take their medication as instructed. This behavior is one of the biggest problems in TB control and can lead to serious consequences. A nonadherent patient with TB disease may

- Remain sick longer or have more severe illness
- Spread TB to others
- Develop and spread drug-resistant TB
- Die as the result of interrupted treatment

It is also important that persons with latent TB infection (LTBI) who are prescribed a regimen for LTBI adhere to the regimen. Completion of therapy for LTBI can prevent people with TB infection from developing TB disease.

Reasons for Non-adherence

There are many reasons why a person might have trouble completing a regimen of TB drugs. Here are a few examples:

- Once patients no longer feel sick, they often think it is all right to discontinue taking their TB drugs. TB symptoms can improve dramatically during the initial phase of treatment (the first 8 weeks). However, unless patients continue treatment for at least 6 months, some tubercle bacilli may survive, putting patients at risk for a relapse of TB disease and the development of drug-resistant organisms.
- Patients sometimes do not fully understand the treatment regimen, how to take their drugs, or the reasons for the long duration of TB treatment. This lack of knowledge can lead to an inability or lack of motivation to complete a regimen.
- Some patients have strong personal or cultural beliefs about TB disease, how it should be treated, and who they can turn to for help. When TB

treatment conflicts with these beliefs, patients can become fearful, anxious, or alienated from their health care workers.

- Certain patients lack skills necessary for following a health care worker's instructions and adhering to a prescribed regimen. Elderly patients with limited mobility or manual dexterity, patients with substance abuse or mental health problems, and young children are particularly at risk for problems with adherence.
- Lack of access to health care can also be a significant barrier to successfully completing a TB regimen. Special efforts must be made to reach and provide care to patients without a permanent address or a means of transportation. Patients with jobs may have work schedules that conflict with clinic hours. Immigrants and refugees, as well as persons who inject illicit drugs, may need reassurance that their TB disease and treatment will be kept confidential and should not cause them legal problems.
- Some patients, especially recent immigrants, may not be able to find a health care worker who speaks their language. When a patient speaks little or no English, this language barrier can present significant problems for adherence, as patient education and support services can have little effect. Unless a good interpreter is found, such patients may be unable to continue treatment.
- Some patients have poor relationships with health care workers**.** When patients and health care workers fail to establish a trusting relationship, this lack of relationship can influence patient adherence. If a patient trusts or has confidence in his or her health care worker, he or she is more likely to follow instructions and advice and to cooperate with the health care worker. Patients may also be more likely to bring questions and concerns regarding adherence to the health care worker's attention.
- Finally, some patients may have a lack of motivation to adhere to a TB regimen. If patients have many competing priorities in their lives such as substance abuse, homelessness, sickness from other diseases (e.g., HIV), taking TB medication may not be considered a priority by the patient.

Each patient is unique and may have his or her own reasons for nonadherence. One of the best predictors of adherence is a patient's past adherence. If a patient was nonadherent in the past, it is likely that he or she will encounter similar problems with the current treatment regimen. However, it is important to keep in mind that any patient can have problems with adherence. Barriers are anything that can prevent a patient from being able to adhere to a TB treatment regimen. Many health care workers think they can tell which patients will be adherent, but research shows they are correct only about half the time (that is, their predictions are no better than flipping a coin). Although adherence is hard to predict, the more the health care worker knows about the patient, the better he or she will be able to understand and address the patient's problems.

Patients and health care workers are both responsible for ensuring patients' adherence. Patients must decide every day or week whether or not to take their medicine. What they decide often depends on how much help they get from the health care workers they see.

Directly Observed Therapy (DOT)

A component of case management that helps to ensure that patients adhere to treatment is directly observed therapy (DOT). DOT is the most effective strategy for making sure patients take their medicines. DOT means that a health care worker or other designated individual watches the patient swallow every dose of the prescribed drugs. DOT should be considered for all patients because it is difficult to reliably predict which patients will be adherent. Even patients who intend to take their medicine might have trouble remembering to take their pills every time. All DOT visits should be documented. In many health departments, DOT is the standard of care.

Many TB programs use their area treatment completion rates to decide how to implement DOT. If the percentage of patients who finish therapy within 12 months is less than 90%, or is unknown, programs will often increase the use of DOT. Many programs have substantially improved completion rates after deciding to make DOT the standard of care for TB treatment.

All patients should be considered for DOT. However, there are certain groups of patients for whom DOT is often the best option, regardless of local treatment completion rates. These groups include

- Patients with drug-resistant TB
- Patients receiving intermittent therapy
- Persons at high risk for nonadherence, such as
    - Homeless or unstably housed persons
    - Persons who abuse alcohol or illicit drugs
    - Persons who are unable to take pills on their own due to mental, emotional, or physical disabilities
    - Children and adolescents
    - Persons with a history of nonadherence

DOT for Latent TB Infection (LTBI)

In addition, more and more TB programs are using directly observed treatment for latent TB infection (LTBI). DOT for LTBI is for persons who are at especially high risk of developing TB disease such as young children, and HIV-infected and other immunosuppressed persons.

DOT for LTBI is appropriate in institutions and facilities where pill ingestion can be observed by a staff member or for household contacts of a TB patient who is on DOT. Because persons taking treatment for LTBI have no symptoms of TB

disease, it is very important that they understand the need for medication so that they are motivated to start and finish DOT for LTBI.

Recent data indicate low completion rates among patients on regimens for treatment for LTBI. The use of DOT for LTBI is one strategy that can improve patients' adherence to treatment for LTBI. However, if resources are limited, DOT for TB disease should be the priority over DOT for LTBI.

Different Health Beliefs

Sometimes cultural, religious, or other personal beliefs affect a patient's TB treatment. It is important for the health care worker to sincerely respect the beliefs of the patient. Sometimes patients seek medical advice from folk healers or alternative practitioners. The health care worker may encounter patients who use folk remedies along with their prescribed medications. For example, in some Asian cultures, TB medicines are considered "hot" and need to be countered with something "cold," such as green leafy vegetables.

Take the time to learn about the patient's cultural beliefs. If the patient thinks that the health care worker does not respect his or her beliefs, it could cause the patient to distrust the health care worker. A patient may come from a background that includes the use of alternative medicine (health care other than conventional, scientifically tested, medicinal treatment including herbal remedies, yoga, meditation, acupuncture, and other practices intended to maintain or improve health). Likewise, the patient may practice folk medicine (medicinal beliefs, knowledge, and practices associated with a particular culture or ethnic group. Folk medicine is usually handed down by cultural tradition and practiced by health care workers specially trained in that tradition; not all members of a given culture or ethnic group will use its folk medicine practices). The health care worker should find out if there are barriers to the acceptance of conventional medical practices. A discussion about the patient's beliefs and health practices may help the health care worker to individualize treatment so that it is acceptable to the patient.

When folk or alternative practices are safe, health care workers should consider including them in the treatment plan. For example, some people believe in the healing power of prayer. These persons may be more willing to take medications after saying a brief prayer, so accepting their belief in prayer is an important aspect of treatment. If a patient is taking an herbal remedy, the health care worker should check with the patient's physician or pharmacist to be sure it will not cause side effects or interact adversely with the patient's TB drugs. He or she should ask patients who have concerns about nutrition supplements or interactions with TB drugs to discuss this with their clinician.

While it is important to respect the patient's beliefs, it is just as important for the health care worker to clearly present the rationale for taking TB drugs for a full

course of treatment**.** The health care worker can do a great deal to help the patient adhere and incorporate his or her beliefs into the treatment, but it is crucial that both come to an agreement about taking TB medication.

Patients' Rights and Due Process of Law

As a general rule, individuals have the right to ignore a doctor's advice or refuse treatment if they wish. However, persons with infectious TB may lose that right if health officials believe these persons risk infecting others by not taking their prescribed medicine. Patients who are unwilling or unable to adhere to treatment may be required to do so by law or may be quarantined or isolated until noninfectious. State governments have legal responsibility for TB control activities, including treatment protocols for nonadherent patients.

The Advisory Council for the Elimination of Tuberculosis (ACET) defines non-adherent behavior as an inability or unwillingness to follow a prescribed treatment regimen. Examples of nonadherent behavior include

- Taking medication inconsistently
- Missing clinic appointments
- Consistently failing to report for DOT
- Refusing medications

Health care workers should notify the appropriate supervisory clinical and management staff when patients are nonadherent. The health official or a representative should find out why the patient is nonadherent and begin strategies that will help the patient finish treatment. Before legal measures are taken against a patient who has been taking TB drugs on a self-administered basis, DOT should be offered to the patient.

Progressive Interventions

ACET recommends that before a court orders involuntary confinement, state and local TB control programs should have a treatment plan that goes step-by-step from voluntary participation to involuntary confinement as a last resort plan should begin with learning the possible reasons for nonadherence and addressing the identified problems using methods such as DOT, incentives, and enablers. The patient should be told orally and in writing of the importance of adhering to treatment, the consequences of failing to do so, and the legal actions that will have to be taken if the patient refuses to take medication. If the patient does not adhere to DOT voluntarily, the next step may be DOT that is court-ordered. Court-ordered DOT is DOT that is administered to a patient by order of a public health official or a court with the appropriate authority. It is used when patients have been nonadherent despite the best efforts of TB program staff. It

can be successful in convincing a patient that his or her TB treatment is an important public health priority.

TB control programs should not begin procedures for confining patients to a treatment facility until after the patient has shown that he or she is unable or unwilling to follow a treatment regimen implemented outside such a facility. Involuntary confinement or isolation for inpatient treatment should be viewed as the last step. However, when a patient with infectious TB refuses treatment and voluntary isolation, emergency detention to isolate the person is appropriate. Confinement can be either in a hospital or in some other institution with TB isolation facilities.

Throughout the process, there must be detailed documentation of the patient's nonadherence and the steps taken to address it. Although nonadherence laws are available in some areas, they may be hard to enforce and should be used only when all other measures have failed. When legal steps are taken, the health care worker must make sure that the patient's rights are protected; patients undergoing these procedures should have legal counsel.

Criteria for Determining the Need for Involuntary Confinement

When deciding whether to legally confine a TB patient to protect the public, local health officials must decide whether the person is at real risk of infecting others (now or in the future). To determine this risk, these factors are considered:

- Laboratory results (acid-fast bacilli smears and cultures)
- Clinical signs and symptoms of infectious TB
- An abnormal chest radiograph, especially if cavities are present
- A history of nonadherence (not caused by factors outside patient's control)
- The opportunity to infect others

An order to confine a patient should require that he or she be isolated until no longer a public health threat. This decision should be based on

- The patient becoming asymptomatic, with documentation of at least three negative sputum smears taken on different days
- The local health officer's decision that the person has completed therapy according to the most recent American Thoracic Society/CDC treatment recommendations

The patient should be ordered to receive treatment in a proper facility until cured, unless it is certain that the person will voluntarily complete therapy at home once noninfectious. If the patient refuses the ordered treatment, the health officer should have the authority to extend the confinement order as needed.

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Tuberculosis

Post-Test

1. Tuberculosis is caused by a _____. (p. 3)
   A. Virus
   B. Fungus
   C. Mycobacteria
   D. Prion

2. After a person with infectious TB sneezes, droplet nuclei may remain suspended in the air for several _____. (p. 4)
   A. seconds
   B. minutes
   C. hours
   D. days

3. Infection begins when the droplet nuclei reaches the _____. (p. 4)
   A. nasal mucosa
   B. bronchioles
   C. bloodstream
   D. alveoli

4. A person with TB infection is not infectious. (p. 5) A. True B. False

5. TB occurs in places other than the lungs, such as the larynx, the lymph nodes, the pleura, the brain, the kidneys, or the bones and joints. (p. 6) A. True B. False

6. A patient demonstrates the following: positive skin test, negative smears, negative clinical TB signs, and negative x-ray evidence. This patient would be best classified as _____. (p. 7)
   A. Class 1 (exposure to TB, no evidence of infection)
   B. Class 2 (TB infection, no TB disease)
   C. Class 3 (current TB disease)
   D. Class 4 (previous TB disease)

7. In the United States, physicians and other health care providers are required by law to report TB cases to their state or local health department. (p. 8) A. True B. False

8. The risk of being exposed to TB is higher in nursing homes and correctional facilities than in other places. (p. 11) A. True B. False

9. In the United States, all health care workers are required to have the BCG vaccination for tuberculosis. (p. 12) A. True B. False

10. Which of the following would be considered a positive TB skin test reaction? (p. 14)
    A. heroin addict with a 4 mm induration
    B. prisoner with a 6 mm induration
    C. diabetic with a 10 mm induration
    D. therapist with a 3 mm induration

11. Which of the following is NOT one of the four steps for diagnosing TB disease? (p. 20)
    A. Medical history
    B. Chest x-rays
    C. Lung biopsy
    D. Bacteriological exam

12. As many as 20% of patients found to have TB disease have a negative tuberculin skin test reaction. (p. 22) A. True B. False

13. Bronchoscopy is the easiest and least expensive method to obtain a specimen for bacteriological examination. (p. 23) A. True B. False

14. The usual regimen for preventive therapy is ____ given daily for_____. (p. 27)
    A. thalsamid; 3 weeks
    B. wersalan; 8 months
    C. isoniazid; 6 months
    D. phazolamide; 10 weeks

15. TB disease must be treated with at least two drugs to which the bacilli are susceptible. (p. 30) A. True B. False

16. What is the most effective strategy to ensure that individuals with tuberculosis adhere to their treatment? (p. 30)
    A. Directly Observed Therapy (DOT)
    B. Incentives and enablers
    C. Patient education
    D. Patient confinement

17. Multidrug-resistant tuberculosis (MDR-TB) often develops in patients who do not adhere to or complete the proper treatment for standard tuberculosis. (P. 34) A. True B. False

18. Treatment of MDR-TB requires the use of at least three different first line drugs. (p. 34) A. True B. False

19. Usually, only people with pulmonary or laryngeal TB are infectious. (p. 35) A. True B. False

20. Which of the following is NOT a component of an effective TB infection control program? (p. 37)
    A. Administrative controls
    B. Engineering controls
    C. Personal respiratory protection
    D. Prophylactic systems

21. All health care workers who enter an AII room should wear at least an _____ respirator. (p. 42)
    A. N75 disposable
    B. N95 disposable
    C. N75 PAPR
    D. N95 PAPR

22. What is the recommended method used to clean a soiled blood pressure cuff used on a patient with TB? (p. 44)
    A. Autoclave sterilization
    B. High level disinfection with automated washer
    C. Disinfection with hospital grade, intermediate level disinfectant
    D. Disinfection with a low-level disinfectant

23. Some patient rights may be overridden in the interest of protecting the public's health (for example, an uncooperative, infectious patient may be quarantined until noninfectious) (p. 49) A. True B. False

24. Adherence is important because TB is nearly always curable if patients adhere to their TB treatment regimen. (p. 56) A. True B. False

25. Who has legal responsibility for TB control activities including treatment protocols for non-adherent patients? (p. 60)
    A. The Center for Disease Control (CDC)
    B. National Institute of Health (NIH)
    C. The patient's physician
    D. State government

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