Indiana State Department of Health

TUBERCULOSIS PROGRAM MANUAL

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ABREVIATIONS IN TABLE OF CONTENTS

TB – TUBERCULOSIS

LTBI – LATENT TUBERCULOSIS INFECTION

Introduction

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About the Indiana Tuberculosis Program Manual

Purpose

The purpose of the Indiana State Department of Health (ISDH) TB Control Program is to reduce the incidence of TB in the state by providing effective prevention, detection, treatment and educational services.

This manual is designed to present the key steps and crucial information needed to perform tuberculosis (TB) control tasks in states in which TB occurs with a low incidence—defined by the Centers for Disease Control and Prevention (CDC) as less than 3.5 cases/100,000 population/year.[1] Where additional or more detailed information is available, hyperlinks to CDC guidelines and other resources are provided.

The *Indiana Tuberculosis Program Manual* is based on a template created by an advisory group convened during CDC Task Order #6.

Audience

NOTE: This manual contains technical terms not well understood by the general public.

The audience for this manual includes:

- Public Health Nurses (City, County, Regional)
- Nurse Case Managers and other State TB Program staff
- Physicians and Physician consultants
- Outreach Workers (DOT workers, Firemen, School Nurses, etc.)
- Infection Control Nurses in hospitals, clinics, long-term care and other facilities
- State Epidemiologists
- HIV/STD Division staff (HIV Counselors, Case Managers, Out Reach Workers, etc.)

How to Use This Manual

Portable Document Format

This manual is available electronically as a portable document format (PDF) file. To view the PDF file, you will need the free Adobe Reader, available at this hyperlink: http://www.adobe.com/products/acrobat/readstep2.html .

Hyperlinks

When viewing this manual online with an Internet connection, you can go directly to underlined Web addresses by clicking on them.

Cross-References

When viewing this manual electronically, you can go directly to other sections or topics in the manual by clicking on text next to this icon:

Forms

Required and recommended forms are available on the Indiana State Department of Health – TB Control Program *Online TB Reporting Forms* page at http://www.in.gov/isdh/19682.htm . This icon alerts you that forms are available:

Information specific to Indiana

Information that is specific for Indiana for quick reference will be noted in text boxes with a bold outline, see example below:

INDIANA

It is the duty of the physician and administrator (or administrator's representative) of a hospital to report all cases and suspected cases of *Mycobacterium tuberculosis* to the local health department within 72 hours.

Labs shall submit all isolates of *Mycobacterium tuberculosis* to the ISDH Lab for further evaluation within 5 business days of isolation.

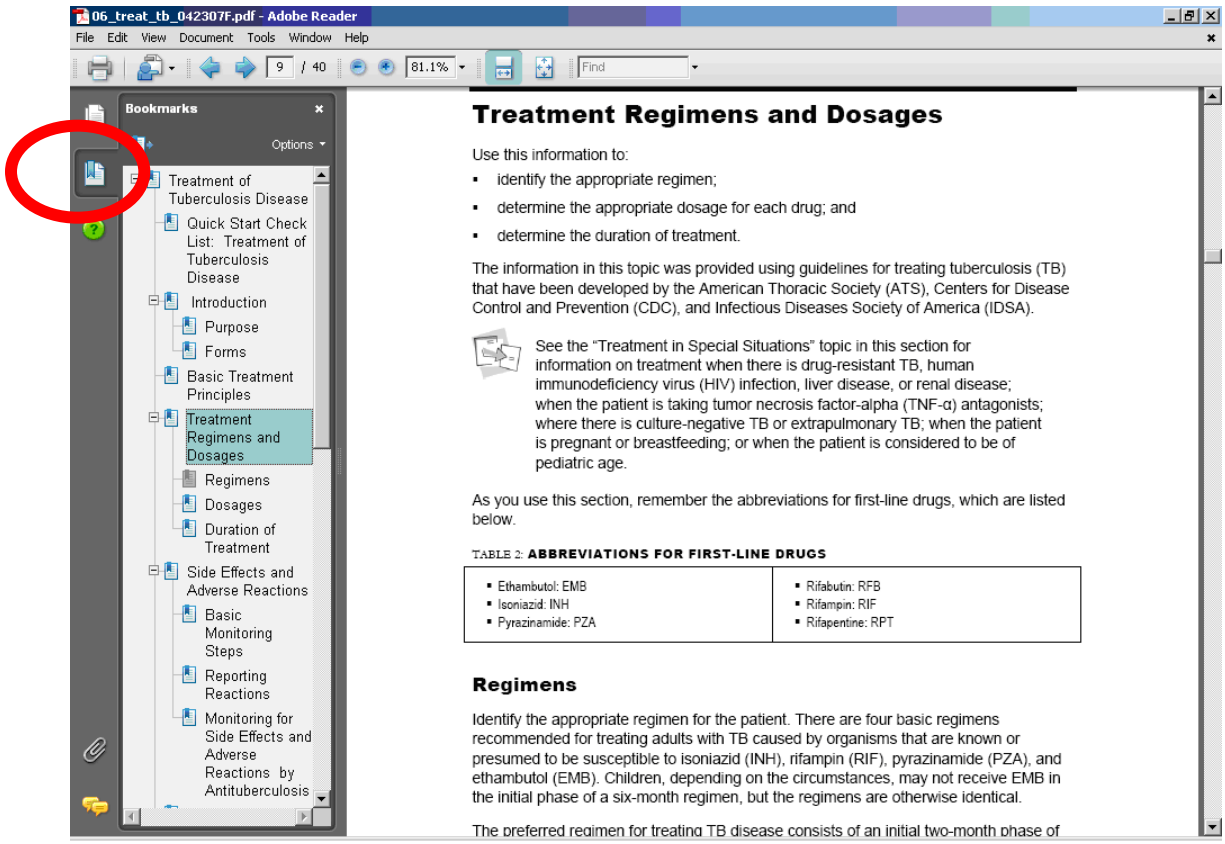
Bookmarks

In PDF files, you can use bookmarks to go quickly to a section or topic. If the bookmarks are not visible on the left, click the Bookmarks icon or tab on the left of the window.

To view sections and topics in the bookmarks list:

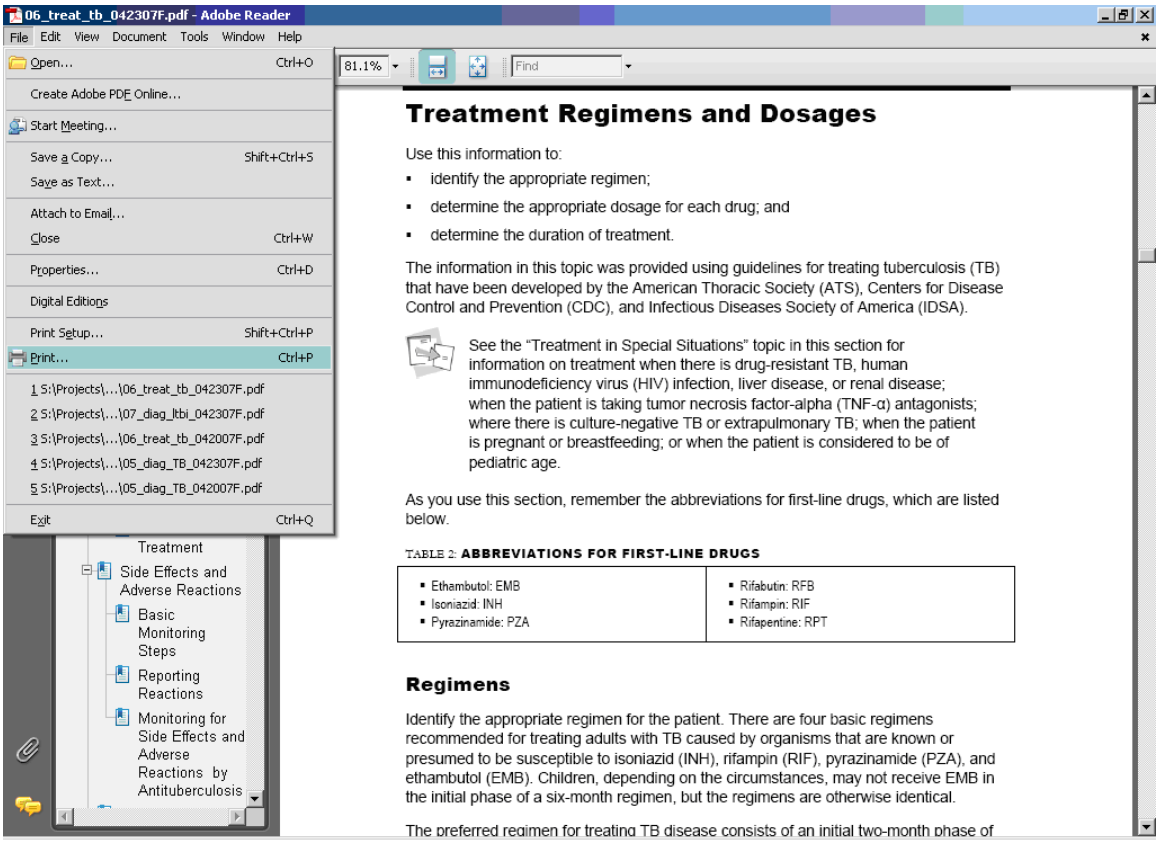
- Click + to see a more detailed list.
- Click – to hide the more detailed list.

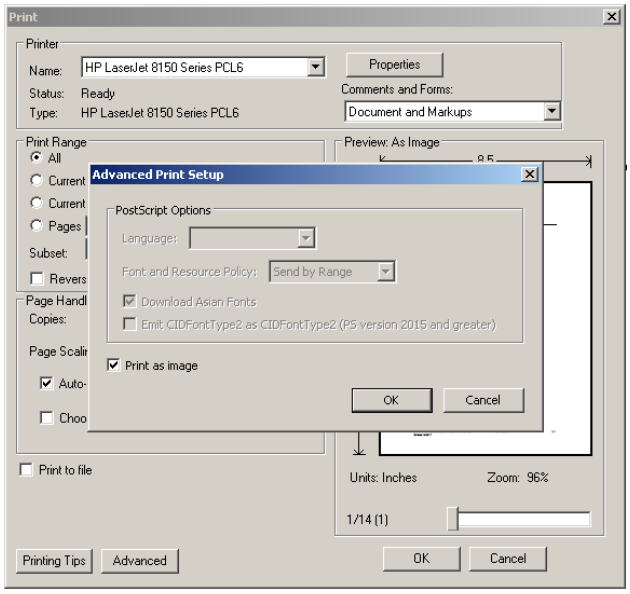
To go to a section or topic in the bookmarks list, point to its name and left-click.



Printing

To access the print dialog box, click the File drop-down menu, click Print, and then make your selections in the Print dialog box.





Some printers have older printer drivers that cause spaces to appear in the middle of words. To avoid this problem, select File/Print, click the Advanced button, check Print as Image, and then click OK. If you need further assistance with printing, call the ISDH TB/Refugee Health Division at 317-233-7434.

Icons

Throughout the manual, these icons quickly cue you into important information and other resources:

This warns about high-consequence information you must understand when performing the task.

This signals when you should call to report or to consult on the task.

This highlights special considerations for pediatric patients.

This suggests another relevant area in the manual or another resource that you may want to review.

This alerts you that a form is available for the task.

Abbreviations

Refer to the list below for abbreviations used in the manual.

ACET	Advisory Council for the Elimination of Tuberculosis
ACH	air changes per hour
AFB	acid-fast bacilli
AIDS	acquired immunodeficiency syndrome
AII	airborne infection isolation
ALT	alanine aminotransferase
ARPE	*Aggregate Report for Program Evaluation*
ART	antiretroviral therapy
AST	aspartate aminotransferase
ATS	American Thoracic Society
BAMT	blood assay for *Mycobacterium tuberculosis*
BCG	bacille Calmette-Guérin
CDC	Centers for Disease Control and Prevention
CT	computed tomography
CXR	chest radiograph
DNA	deoxyribonucleic acid
DOT	directly observed therapy
DGMQ	(CDC) Division of Global Migration and Quarantine
DTBE	Division of Tuberculosis Elimination
DTH	delayed-type hypersensitivity
ED	emergency department
EDN	electronic data notification
EMB	ethambutol

EMS	emergency medical service
ESRD	end-stage renal disease
FDA	U.S. Food and Drug Administration
HAART	highly active antiretroviral therapy
HCW	healthcare worker
HEPA	high-efficiency particulate air
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
IAC	Indiana Administrative Code
IC	Indiana (Administrative) Code
IDSA	Infectious Diseases Society of America
IGRA	interferon gamma release assay
INH	isoniazid
ISDH	Indiana State Department of Health
LAB	Laboratory
LHD	Local Health Department
LTBI	latent tuberculosis infection
mm	millimeter
M. tuberculosis	*Mycobacterium tuberculosis*
MAB	Medical Advisory Board
MDR-TB	multidrug-resistant tuberculosis
MIRU	mycobacterial interspersed repetitive units
MOTT	mycobacterium other than tuberculosis
NAA	nucleic acid amplification
NIOSH	National Institute for Occupational Safety and Health
NNRTI	nonnucleoside reverse transcriptase inhibitors
NTCA	National Tuberculosis Controllers Association

NTM	nontuberculous mycobacteria
NTNC	National Tuberculosis Nurse Coalition
OSHA	Occupational Safety and Health Administration
PAPR	powered air-purifying respirator
PCR	polymerase chain reaction
PI	protease inhibitor
PPD	purified protein derivative
PZA	pyrazinamide
QA	quality assurance
QFT	QuantiFERON®-TB test
QFT-G	QuantiFERON®-TB Gold test
QFT-GIT	QuantiFERON®-TB Gold test **In Tube**
RFB	rifabutin
RFLP	restriction fragment length polymorphism
RIPE	Four (4) Drug Regimen of rifampin, isoniazid, pyrazinamide, and ethambutal
RIF	rifampin
RNA	ribonucleic acid
RPT	rifapentine
RTMCC	Regional Training and Medical Consultation Center
RVCT	*Report of Verified Case of Tuberculosis*
RZ	rifampin and pyrazinamide
SWIMSS	State Wide Investigating Monitoring Surveillance System
TB	tuberculosis
TIMS	Tuberculosis Information Management System
TNF-α	tumor necrosis factor-alpha
T-Spot	T-Spot®.TB

TST	tuberculin skin test
TU	tuberculin units
US	United States
USCIS	U.S. Citizenship and Immigration Services
UVGI	ultraviolet germicidal irradiation
VDOT	Videophone directly observed therapy
WHO	World Health Organization
XDR-TB	extremely drug-resistant tuberculosis

Mycobacterium tuberculosis (TB) Infections

TB is divided into 2 types: active and latent, depending on whether or not the person exposed to the TB bacteria has developed the actual disease.

Clinical Description

Tuberculosis (TB) is a disease caused by the bacteria Mycobacterium tuberculosis. Although TB usually infects the lungs, the disease can also affect other parts of the body such as the kidneys or spine. Without proper treatment, TB can be fatal.

Symptoms of active TB disease of the lungs include:

• a bad cough that lasts 3 weeks or longer • pain in the chest • coughing up blood (hemoptysis) • weight loss • night sweats • weakness or fatigue • fever • chills

People with latent TB infection (LTBI) have TB bacteria in their bodies; however, because the bacteria are not active, these individuals are not sick. People with LTBI have no symptoms of active TB disease, and they cannot spread the bacteria to others. However, they may develop active TB disease in the future.

Incubation Period

Eight to ten weeks for a positive TST or IGRA. Progression to active disease is greatest in the first 2 years after infection, but may not occur for decades.

Mode of Transmission: Airborne

People with active TB disease of the lungs can release TB bacteria into the air when they cough, sneeze, speak, or sing. These bacteria can stay in the air for several hours. Persons who breathe in the air that contains these TB bacteria can become infected if the bacteria reach their lungs. Transmission from children younger than 10 years is unusual.

Period of Communicability

A person is able to spread TB from an assigned date of 3 months prior to symptom onset or a positive lab report. An individual is considered no longer communicable after effective treatment has been demonstrated for $\geq$ 2 weeks causing a significant reduction in symptoms.

Exclusion/Attendance

Active pulmonary tuberculosis cases and suspects who are sputum-smear negative, are not coughing, are clinically improving, and are known to be on adequate tuberculosis chemotherapy are defined as noninfectious. All other pulmonary tuberculosis cases and suspects must be isolated until no longer infectious. Infectious persons are excluded from work/school.

Prevention/Care

• Avoid close contact or spending prolonged time with known active TB patients while infectious.

• Treatment of LTBI reduces the risk that TB infection will progress to active TB disease. Immunocompromised persons and children <5 years old are at high risk for developing active TB disease once infected. Every effort should be made to begin and complete appropriate treatment for LTBI.

Reference

Excerpt from the ISDH "Communicable Disease Reference Guide for Schools: 2009 Edition."
http://www.in.gov/isdh/files/Communicable_Disease_Reference_Guide_2009_2.16.09.pdf

Non-tuberculous Mycobacterial (NTM) Infections

INDIANA

LAB: ISDH provides laboratory support for TB control and prevention by isolating, identifying, and performing susceptibility testing on clinical specimens from submitters pre-approved by our TB program. The lab also performs TB rule in/out testing on mycobacterium isolates from laboratories lacking this capability. However, speciation on non-tuberculosis (NTM) isolates will not be performed.

MEDICATION: If a TB suspect turns out to be a case of Non-TB, the standard TB medication regimen would be inappropriate therapy. The patient's need for drug therapy would need to be re-assessed by their physician because in some instances drug therapy is not recommended. If Non-TB drug therapy is indicated it depends on the species, HIV status and susceptibility testing. **Drug therapy for: 1) Non-TB cases and 2) BCG induced cases are NOT covered by ISDH.**

Non-Tuberculous mycobacterial (NTM) infections are caused by a group of microorganisms known by several different names including MOTT (mycobacteria other than tuberculosis), atypical mycobacteria, and environmental mycobacteria. Unlike TB which is spread from person to person, these organisms are usually acquired from water or soil. Currently there are more than 125 NTM species that have been identified.

These infections are often difficult to diagnose and challenging to treat because they require multiple antibiotics for extended periods, usually months to years. In some cases surgery may be required to control or cure the infection. The NTM most frequently causes lung infections but can involve soft tissues, bones or lymph nodes.

What is the Difference Between TB and NTM?

NTM refers to all species in the family of mycobacteria that may cause human disease, but do not cause tuberculosis (TB). Every year in the United States approximately two people per 100,000 population develop infections caused by these lesser-known "cousins" of TB and leprosy. In fact, for unknown reasons, data suggest that there may be rising numbers of cases in certain parts of the country.

NTM infections are not considered contagious. There is no evidence that the infection can be transmitted from one person to another. Just how and why people become infected with NTM is not clear. Although the germs are found easily in water and soil, they do not affect most people. Doctors believe that some people who become infected have an unknown defect in their lung structure or function or in their immune systems. People who have damaged lung tissue from diseases such as emphysema, bronchiectasis, adult cystic

fibrosis or previous TB infection appear to be at greater risk for developing an NTM infection. People who are immunocompromised (such as those with AIDS or those who receive strong immunosuppressant medications such as prednisone or remicaid) have a greater risk of developing a NTM infection that affects all organs of the body, not only the lungs.

What are the Different Types of NTM?

Under the microscope, NTM and TB appear quite similar. Careful lab studies must be performed to tell them apart. Most labs are capable of carrying the testing process far enough to determine whether they are dealing with an NTM. Fewer labs are equipped to determine exactly which organism it might be and what its susceptibility is to drugs.

The importance of identifying the exact organism can be illustrated with two of the organisms, *M. gordonae* and *M. scrofulaceum*. These two are very similar and react the same way in many lab tests. However, they react in different ways in the human body. One organism causes disease; the other organism does not cause disease. In this case, if the organism turns out to be *M. gordonae*, treatment is seldom indicated. *M. gordonae* is often a lab contaminant and not a cause of human disease. In fact, *M. gordonae* is found in water supplies so often that it is nicknamed the “tap water bacillus”. *M. scrofulaceum*, on the other hand, is known to cause disease and may require specific forms of treatment.

Other NTM infections that require treatment include: *M. avium, M. intracellulare, M. kansasii, M. abscessus, M. chelonae, M. fortuitum, M. terrae, M. xenopi, and M. simiae.*

What are the Symptoms of an NTM Infection?

Like TB, an NTM infection affects the lungs so the symptoms are similar. Most NTM infections and resulting symptoms progress slowly. Symptoms may include: fever, weight loss, cough, lack of appetite, night swears, blood in the sputum, and loss of energy.

How is NTM Infection Diagnosed?

An NTM infection can be more difficult to diagnose than TB. It is important to determine if the infection is TB or NTM (if NTM, the specific type of NTM is important). In addition, it is important for the healthcare provider to determine whether the NTM infection requires treatment. Some people harbor the germs and remain well. They may need to be observed without treatment. Others have or may be developing serious and progressive illness. A diagnosis is often based on medical history, chest CT scan, sputum culture (several sputum cultures are often necessary and must be done at specialized labs, one positive test does not always mean disease is present). Other diagnostic procedures, such as a bronchoscopy, may be required in certain cases.

What is the Treatment of NTM?

If medication therapy is indicated it depends on the species and the HIV status of the patient. Most of the NTM infections are naturally resistant to many common antibiotics. It is often necessary to use some of the same medications that are used to treat TB. In order to overcome drug resistance it is necessary to take several different anti-TB medications at the same time. Because many of these medications have side effects, close monitoring is important. Treatment may be necessary for as long as two years. Sometimes treatment is ongoing, depending on the severity of the disease.

The most common organisms involved in human infection are *M. kansasii, M. avium, M. intracellulare, M. chelonae and M. abscessus. M. kansasii* is easier to treat and often can be killed with only three anti-TB medications. On the other hand, organisms such as *M. avium, M chelonae* and *M. abscessus* are among the most stubborn germs and are more difficult to treat. Three to five medications may be needed. Depending on how localized the disease is, surgery also may be helpful.

Refer to references below for more detailed information on NTM:

National Jewish Medical and Research Center, Conditions, Nontuberculous Mycobacteria (NTM), September 2009, http://www.nationaljewish.org/healthinfo

The Official ATS/IDSA Statement: Diagnosis, Treatment, and Prevention of Nontuberculous Mycobacterial Diseases, [Am J Respir Crit Care Med, Vol 175. pp 367-416, 2007]
http://www.thoracic.org/sections/publications/statements/pages/mtpi/nontuberculous-mycobacterial-diseases.html

Purpose of Tuberculosis Control

The goal of TB control in the United States is to reduce TB morbidity and mortality by doing the following:

- Preventing transmission of *M. tuberculosis* from persons with contagious forms of the disease to uninfected persons
- Preventing progression from latent TB infection (LTBI) to active TB disease among persons who have contracted *M. tuberculosis* infection[2]

The four fundamental strategies to reduce TB morbidity and mortality include the following:

1. Early and accurate detection, diagnosis, and reporting of TB cases, leading to initiation and completion of treatment
2. Identification of contacts of patients with infectious TB and treatment of those at risk with an effective drug regimen
3. Identification of other persons with latent TB infection at risk for progression to TB disease and treatment of those persons with an effective drug regimen
4. Identification of settings in which a high risk exists for transmission of *M. tuberculosis* and application of effective infection control measures[3]

For more information on these strategies and the thinking behind them, see "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America" (*MMWR* 2005;54[No. RR-12]) at this hyperlink: http://www.cdc.gov/MMWR/PDF/rr/rr5412.pdf .

Indiana Laws and Rules on TB Control

Indiana laws and rules on tuberculosis (TB) are located in the

Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories, 410 IAC 1-2-3, Effective December 12, 2008, Indiana State Department of Health at http://www.in.gov/isdh/files/comm_dis_rule.pdf

See next page for an abbreviated Index for TB related information in the ***Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories***

Additional **Indiana** Communicable Disease Laws related to TB are listed on:

Pages 1.19 through 1.49 (for Index see page 1.19)

Contact the ISDH TB/Refugee Health Division at 317.233.7434 for assistance with interpreting laws and rules regarding TB control.

INDIANA

Reporting

It is the duty of the physician and administrator (or administrator's representative) of a hospital to report all cases and suspected cases of *Mycobacterium tuberculosis* to the local health department within 72 hours.

Labs shall report at least weekly AND shall submit all isolates of *Mycobacterium tuberculosis* to the ISDH Lab for further evaluation within 5 business days of isolation.

Refer to Section 2 – Surveillance AND the ***Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories*** for detailed information on reporting requirements.

Confidentiality

Please note that HIPAA regulations [section 1178 (b)] do not affect the legal requirements in the Indiana Administrative Code (IAC) for physicians and hospital administrators to report all cases and suspected cases of tuberculosis to the local health officer. In addition, "Covered entities" (e.g. hospitals, physicians) may disclose protected health information without an individual's authorization. [45 CFR 164.512 (b)(1)(i)].

Refer to Section 13 – Confidentiality for more detailed information.

Questions regarding access to Confidential Information? - contact the ISDH Privacy Officer at PrivacyOfficer@isdh.in.gov

Abbreviated Index, TB related info, **Indiana *Communicable Disease Reporting Rule***

INDIANA

The excerpts that follow contain references to the Indiana Communicable Disease and other TB related Indiana Laws (in addition to the ***Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories*** listed on the previous page).

Indiana Communicable Disease Laws: http://www.in.gov/legislative/ic/code/title16/ar41/

INDEX:

⌘ Terms *(defined)*:

IC 16-18-2-49 Carrier

Sec. 49. "Carrier", for purposes of IC 16-41, means a person who has:
(1) tuberculosis in a communicable stage; or
(2) another dangerous communicable disease.

IC 16-18-2-93 Designated Health Official

Sec. 93. "Designated health official", for purposes of IC 16-41, means:
(1) the state health commissioner;
(2) an assistant state health commissioner; or
(3) a person designated by the state health commissioner or assistant state health commissioner to implement IC 16-41 in a specific situation.

IC 16-18-2-166 Health directive

Sec. 166. "Health directive", for purposes of IC 16-41, means:
(1) a written statement; or
(2) in an emergency, an oral statement followed by a written statement within seventy-two (72) hours;
to a carrier issued by a designated health official under IC 16-41.

IC 16-20-1-19 Enforcement

Sec. 19. Local health officers shall enforce the health laws, ordinances, orders, rules, and regulations of the officer's own and superior boards of health.

IC 16-20-1-21 Communicable disease control; powers

Sec. 21. Each local health board has the responsibility and authority to take any action authorized by statute or rule of the state department to control communicable diseases. The board of each local health department or a designated representative may make sanitary and health inspections to carry out this chapter and IC 16-20-8.

IC 16-41-2-2 Reporting of required information

Sec. 2. Each:
(1) licensed physician;
(2) administrator of a hospital licensed under IC 16-21-2 or the administrator's representative; or
(3) director of a medical laboratory or the director's representative;
shall report to the local or state health officer designated by the state department the information required to be reported by the rules adopted under section 1 of this chapter.

IC 16-41-2-4 Waiver of physician-patient privilege

Sec. 4. A patient's privilege with respect to a physician under IC 34-46-3-1 is waived regarding information reported to a local or state health officer under this chapter.

IC 16-41-5-2 Investigations of carriers; intervention

Sec. 2. The health officer may make an investigation of each carrier of a dangerous communicable disease to determine whether the environmental conditions surrounding the carrier or the conduct of the carrier requires intervention by the health officer or designated health official to prevent the spread of disease to others.

IC 16-41-6-2 Informed consent; court-ordered examinations

Sec. 2. (a) As used in this section, "informed consent" means authorization for physical examination, made without undue inducement or any form of force, fraud, constraint, deceit, duress, or coercion after the following:
(1) A fair explanation of the examination, including the purpose, potential uses, limitations, and the fair meaning of the examination results.
(2) A fair explanation of the procedures to be followed, including the following:
(A) The voluntary nature of the examination.
(B) The right to withdraw consent to the examination process at any time.
(C) The right to anonymity to the extent provided by law with respect to participation in the examination and disclosure of examination results.
(D) The right to confidential treatment to the extent provided by law of information identifying the subject of the examination and the results of the examination.
(b) If the state health commissioner, the state health commissioner's legally authorized agent, or local health official has reasonable grounds to believe that an individual may have a communicable disease or other disease that is a danger to health, the state health commissioner, the state health commissioner's legally authorized agent, or local health officer may ask the individual for written informed consent to be examined to prevent the transmission of the disease to other individuals.
(c) If the individual, when requested, refuses such an examination, the state health commissioner, the state health commissioner's legally authorized agent, or local health officer may compel the examination only upon a court order based on clear and convincing evidence of a serious and present health threat to others posed by the individual.
(d) A hearing held under this section shall be held in camera at the request of the individual.

IC 16-41-6-3 Violations

Sec. 3. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.
(b) Each day a violation continues constitutes a separate offense.

IC 16-41-7-2 Reporting of persons posing serious and present danger or being at risk

Sec. 2. (a) A carrier is a "serious and present danger to the health of others" under the following conditions:
(1) The carrier engages repeatedly in a behavior that has been demonstrated epidemiologically (as defined by rules adopted by the state department under IC 4-22-2) to transmit a dangerous communicable disease or that indicates a careless disregard for the transmission of the disease to others.
(2) The carrier's past behavior or statements indicate an imminent danger that the carrier will engage in behavior that transmits a dangerous communicable disease to others.
(3) The carrier has failed or refused to carry out the carrier's duty to warn under section 1 of this chapter.
(b) A person who has reasonable cause to believe that a person:
(1) is a serious and present danger to the health of others as described in subsection (a);
(2) has engaged in noncompliant behavior; or
(3) is suspected of being a person at risk (as described in section 1 of this chapter);
may report that information to a health officer.
(c) A person who makes a report under subsection (b) in good faith is not subject to liability in a civil, an administrative, a disciplinary, or a criminal action.
(d) A person who knowingly or recklessly makes a false report under subsection (b) is civilly liable for actual damages suffered by a person reported on and for punitive damages.

IC 16-41-7-3 Notification by physician

Sec. 3. (a) A licensed physician who diagnoses, treats, or counsels a patient with a dangerous communicable disease shall inform the patient of the patient's duty under section 1 of this chapter.
(b) A physician described in subsection (a) may notify the following:
(1) A health officer if the physician has reasonable cause to believe that a patient:
(A) is a serious and present danger to the health of others as described in section 2(a) of this chapter;
(B) has engaged in noncompliant behavior; or
(C) is suspected of being a person at risk (as defined in section 1 of this chapter).
(2) A person at risk (as defined in section 1 of this chapter) or a person legally responsible for the patient if the physician:
(A) has medical verification that the patient is a carrier;
(B) knows the identity of the person at risk;
(C) has a reasonable belief of a significant risk of harm to the identified person at risk;
(D) has reason to believe the identified person at risk has not been informed and will not be informed of the risk by the patient or another person; and
(E) has made reasonable efforts to inform the carrier of the physician's intent to make or cause the state department of health to make a disclosure to the person at risk.
(c) A physician who notifies a person at risk under this section shall do the following:

(1) Identify the dangerous communicable disease.
(2) Inform the person of available health care measures such as counseling and testing.
(d) A physician who in good faith provides notification under this section is not subject to liability in a civil, an administrative, a disciplinary, or a criminal action.
(e) A patient's privilege with respect to a physician under IC 34-46-3-1 is waived regarding:
(1) notification under subsection (b); and
(2) information provided about a patient's noncompliant behavior in an investigation or action under this chapter, IC 16-41-2, IC 16-41-3, IC 16-41-5, IC 16-41-6, IC 16-41-8, IC 16-41-9, IC 16-41-13, IC 16-41-14, and IC 16-41-16.
(f) A physician's immunity from liability under subsection (d) applies only to the provision of information reasonably calculated to protect an identified person who is at epidemiological risk of infection.
(g) A physician who notifies a person under this section is also required to satisfy the reporting requirements under IC 16-41-2-2 through IC 16-41-2-8.

⌘ IC 16-41-8 Communicable Disease: Confidentiality Requirements

IC 16-41-8-1"Potentially disease transmitting offense"

Sec. 1. (a) As used in this chapter, "potentially disease transmitting offense" means any of the following:

(1) Battery by body waste (IC 35-42-2-6).

(2) An offense relating to a criminal sexual act (as defined in IC 35-41-1-19.3), if sexual intercourse or deviate sexual conduct occurred.

The term includes an attempt to commit an offense, if sexual intercourse or deviate sexual conduct occurred, and a delinquent act that would be a crime if committed by an adult.

(b) Except as provided in this chapter, a person may not disclose or be compelled to disclose medical or epidemiological information involving a communicable disease or other disease that is a danger to health (as defined under rules adopted under IC 16-41-2-1). This information may not be released or made public upon subpoena or otherwise, except under the following circumstances:

(1) Release may be made of medical or epidemiologic information for statistical purposes if done in a manner that does not identify an individual.

(2) Release may be made of medical or epidemiologic information with the written consent of all individuals identified in the information released.

(3) Release may be made of medical or epidemiologic information to the extent necessary to enforce public health laws, laws described in IC 31-37-19-4 through IC 31-37-19-6, IC 31-37-19-9 through IC 31-37-19-10, IC 31-37-19-12 through IC 31-37-19-23, IC 35-38-1-7.1, and IC 35-42-1-7, or to protect the health or life of a named party.

(4) Release may be made of the medical information of a person in accordance with this chapter.

(c) Except as provided in this chapter, a person responsible for recording, reporting, or maintaining information required to be reported under IC 16-41-2 who recklessly, knowingly, or intentionally discloses or fails to protect medical or epidemiologic

information classified as confidential under this section commits a Class A misdemeanor.

(d) In addition to subsection (c), a public employee who violates this section is subject to discharge or other disciplinary action under the personnel rules of the agency that employs the employee.

(e) Release shall be made of the medical records concerning an individual to:

(1) the individual;

(2) a person authorized in writing by the individual to receive the medical records; or

(3) a coroner under IC 36-2-14-21.

(f) An individual may voluntarily disclose information about the individual's communicable disease.

(g) The provisions of this section regarding confidentiality apply to information obtained under IC 16-41-1 through IC 16-41-16.

IC 16-41-8-2 Voluntary contact notification program information; use as evidence; release

Sec. 2. (a) Identifying information voluntarily given to the health officer or an agent of the health officer through a voluntary contact notification program may not be used as evidence in a court proceeding to determine noncompliant behavior under IC 16-41-1 through IC 16-41-16.

(b) A court may release to:

(1) an individual; or

(2) a representative designated in writing by the individual;

information or records relating to the individual's medical condition if the individual is a party in a pending action involving restriction of the individual's actions under IC 16-41-1 through IC 16-41-16. A person who obtains information under this subsection is subject to section 1 of this chapter.

IC 16-41-8-3 Violations

Sec. 3. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.

IC 16-41-8-4 Procedure for obtaining medical information concerning a person charged with certain offenses

Sec. 4. (a) This section applies to the release of medical information that may be relevant to the prosecution or defense of a person who has been charged with a potentially disease transmitting offense.

(b) A:

(1) prosecuting attorney may seek to obtain access to a defendant's medical information if the defendant has been charged with a potentially disease causing offense; and

(2) defendant who has been charged with a potentially disease causing offense may seek access to the medical information of another person if the medical information

would be relevant to the defendant's defense;
by filing a verified petition for the release of medical information with the court.

(c) The prosecuting attorney or defendant who files a petition under subsection (b) shall serve a copy of the petition on:

(1) the person whose medical information is sought;

(2) the guardian, guardian ad litem, or court appointed special advocate appointed for a minor, parent, or custodian of a person who is incompetent, if applicable; and

(3) the provider that maintains the record, or the attorney general if the provider is a state agency;

at the time of filing in accordance with Indiana Trial Rule 4.

(d) The court shall set the matter for hearing not later than twenty (20) days after the date of filing.

(e) If, following a hearing for release of a person's medical information, the court finds probable cause to believe that the medical information may be relevant to the prosecution or defense of a person who has been charged with a potentially disease transmitting offense, the court shall order the person having custody of the person's medical information to release the medical information to the court.

(f) The court shall examine the person's medical information in camera. If, after examining the medical information in camera and considering the evidence presented at the hearing, the court finds probable cause to believe that the medical information is relevant to the prosecution or defense of a person who has been charged with a potentially disease transmitting offense, the court may order the release of a person's medical information to the petitioner.

(g) In an order issued under subsection (f), the court shall:

(1) permit the disclosure of only those parts of the person's medical information that are essential to fulfill the objective of the order;

(2) restrict access to the medical information to those persons whose need for the information is the basis of the order; and

(3) include in its order any other appropriate measures to limit disclosure of the medical information to protect the right to privacy of the person who is the subject of the medical information.

(h) A hearing for the release of a person's medical information may be closed to the public. The transcript of the hearing, the court's order, and all documents filed in connection with the hearing are confidential. In addition, if a person's medical information is disclosed in a legal proceeding, the court shall order the record or transcript of the testimony to be preserved as a confidential court record.

(i) This section does not prohibit the application to medical information of any law concerning medical information that is not addressed by this section.

IC 16-41-8-5 Medical screening of a person charged with certain offenses

Sec. 5. (a) The following definitions apply throughout this section:

(1) "Bodily fluid" means blood, human waste, or any other bodily fluid.

(2) "Dangerous disease" means any of the following:

(A) Chancroid.

(B) Chlamydia.

(C) Gonorrhea.
(D) Hepatitis.
(E) Human immunodeficiency virus (HIV).
(F) Lymphogranuloma venereum.
(G) Syphilis.
(H) Tuberculosis.

(3) "Offense involving the transmission of a bodily fluid" means any offense (including a delinquent act that would be a crime if committed by an adult) in which a bodily fluid is transmitted from the defendant to the victim in connection with the commission of the offense.

(b) This subsection applies only to a defendant who has been charged with a potentially disease transmitting offense. At the request of an alleged victim of the offense, the parent, guardian, or custodian of an alleged victim who is less than eighteen (18) years of age, or the parent, guardian, or custodian of an alleged victim who is an endangered adult (as defined in IC 12-10-3-2), the prosecuting attorney shall petition a court to order a defendant charged with the commission of a potentially disease transmitting offense to submit to a screening test to determine whether the defendant is infected with a dangerous disease. In the petition, the prosecuting attorney must set forth information demonstrating that the defendant has committed a potentially disease transmitting offense. The court shall set the matter for hearing not later than forty-eight (48) hours after the prosecuting attorney files a petition under this subsection. The alleged victim, the parent, guardian, or custodian of an alleged victim who is less than eighteen (18) years of age, and the parent, guardian, or custodian of an alleged victim who is an endangered adult (as defined in IC 12-10-3-2) are entitled to receive notice of the hearing and are entitled to attend the hearing. The defendant and the defendant's counsel are entitled to receive notice of the hearing and are entitled to attend the hearing. If, following the hearing, the court finds probable cause to believe that the defendant has committed a potentially disease transmitting offense, the court may order the defendant to submit to a screening test for one (1) or more dangerous diseases. If the defendant is charged with committing battery by body waste (IC 35-42-2-6), the court may limit testing under this subsection to a test only for human immunodeficiency virus (HIV). However, the court may order additional testing for human immunodeficiency virus (HIV) as may be medically appropriate. The court shall take actions to ensure the confidentiality of evidence introduced at the hearing.

(c) This subsection applies only to a defendant who has been charged with an offense involving the transmission of a bodily fluid.

At the request of an alleged victim of the offense, the parent, guardian, or custodian of an alleged victim who is less than eighteen (18) years of age, or the parent, guardian, or custodian of an alleged victim who is an endangered adult (as defined in IC 12-10-3-2), the prosecuting attorney shall petition a court to order a defendant charged with the commission of an offense involving the transmission of a bodily fluid to submit to a screening test to determine whether the defendant is infected with a dangerous disease. In the petition, the prosecuting attorney must set forth information demonstrating that:

(1) the defendant has committed an offense; and

(2) a bodily fluid was transmitted from the defendant to the victim in connection with the commission of the offense.

The court shall set the matter for hearing not later than forty-eight (48) hours after the prosecuting attorney files a petition under this subsection. The alleged victim of the offense, the parent, guardian, or custodian of an alleged victim who is less than eighteen (18) years of age, and the parent, guardian, or custodian of an alleged victim who is an endangered adult (as defined in IC 12-10-3-2) are entitled to receive notice of the hearing and are entitled to attend the hearing. The defendant and the defendant's counsel are entitled to receive notice of the hearing and are entitled to attend the hearing. If, following the hearing, the court finds probable cause to believe that the defendant has committed an offense and that a bodily fluid was transmitted from the defendant to the alleged victim in connection with the commission of the offense, the court may order the defendant to submit to a screening test for one (1) or more dangerous diseases. If the defendant is charged with committing battery by body waste (IC 35-42-2-6), the court may limit testing under this subsection to a test only for human immunodeficiency virus (HIV). However, the court may order additional testing for human immunodeficiency virus (HIV) as may be medically appropriate. The court shall take actions to ensure the confidentiality of evidence introduced at the hearing.

(d) The testimonial privileges applying to communication between a husband and wife and between a health care provider and the health care provider's patient are not sufficient grounds for not testifying or providing other information at a hearing conducted in accordance with this section.

(e) A health care provider (as defined in IC 16-18-2-163) who discloses information that must be disclosed to comply with this section is immune from civil and criminal liability under Indiana statutes that protect patient privacy and confidentiality.

(f) The results of a screening test conducted under this section shall be kept confidential if the defendant ordered to submit to the screening test under this section has not been convicted of the potentially disease transmitting offense or offense involving the transmission of a bodily fluid with which the defendant is charged. The results may not be made available to any person or public or private agency other than the following:

(1) The defendant and the defendant's counsel.

(2) The prosecuting attorney.

(3) The department of correction or the penal facility, juvenile detention facility, or secure private facility where the defendant is housed.

(4) The alleged victim or the parent, guardian, or custodian of an alleged victim who is less than eighteen (18) years of age, or the parent, guardian, or custodian of an alleged victim who is an endangered adult (as defined in IC 12-10-3-2), and the alleged victim's counsel.

The results of a screening test conducted under this section may not be admitted against a defendant in a criminal proceeding or against a child in a juvenile delinquency proceeding.

(g) As soon as practicable after a screening test ordered under this section has been conducted, the alleged victim or the parent, guardian, or custodian of an alleged victim who is less than eighteen (18) years of age, or the parent, guardian, or custodian of an alleged victim who is an endangered adult (as defined in IC 12-10-3-2), and the victim's counsel shall be notified of the results of the test.

(h) An alleged victim may disclose the results of a screening test to which a defendant is ordered to submit under this section to an individual or organization to protect the

health and safety of or to seek compensation for:

(1) the alleged victim;

(2) the alleged victim's sexual partner; or

(3) the alleged victim's family.

(i) The court shall order a petition filed and any order entered under this section sealed.

(j) A person that knowingly or intentionally:

(1) receives notification or disclosure of the results of a screening test under this section; and

(2) discloses the results of the screening test in violation of this section;

commits a Class B misdemeanor.

⌘ IC 16-41-9 Communicable Disease: Imposition of Restrictions on Individuals With Certain Communicable or Dangerous Communicable Diseases

IC 16-41-9-1.5 Isolation; quarantine; notice; hearing; orders; renewal; crime; rules

Sec. 1.5. (a) If a public health authority has reason to believe that:

(1) an individual:

(A) has been infected with; or

(B) has been exposed to;

a dangerous communicable disease or outbreak; and

(2) the individual is likely to cause the infection of an uninfected individual if the individual is not restricted in the individual's ability to come into contact with an uninfected individual;

the public health authority may petition a circuit or superior court for an order imposing isolation or quarantine on the individual. A petition for isolation or quarantine filed under this subsection must be verified and include a brief description of the facts supporting the public health authority's belief that isolation or quarantine should be imposed on an individual, including a description of any efforts the public health authority made to obtain the individual's voluntary compliance with isolation or quarantine before filing the petition.

(b) Except as provided in subsections (e) and (k), an individual described in subsection (a) is entitled to notice and an opportunity to be heard, in person or by counsel, before a court issues an order imposing isolation or quarantine. A court may restrict an individual's right to appear in person if the court finds that the individual's personal appearance is likely to expose an uninfected person to a dangerous communicable disease or outbreak.

(c) If an individual is restricted from appearing in person under subsection (b), the court shall hold the hearing in a manner that allows all parties to fully and safely participate in the proceedings under the circumstances.

(d) If the public health authority proves by clear and convincing evidence that:

(1) an individual has been infected or exposed to a dangerous communicable disease or outbreak; and

(2) the individual is likely to cause the infection of an uninfected individual if the individual is not restricted in the individual's ability to come into contact with an uninfected individual;

the court may issue an order imposing isolation or quarantine on the individual. The court shall establish the conditions of isolation or quarantine, including the duration of isolation or quarantine. The court shall impose the least restrictive conditions of isolation or quarantine that are consistent with the protection of the public.

(e) If the public health authority has reason to believe that an individual described in subsection (a) is likely to expose an uninfected individual to a dangerous communicable disease or outbreak before the individual can be provided with notice and an opportunity to be heard, the public health authority may seek in a circuit or superior court an emergency order of quarantine or isolation by filing a verified petition for emergency quarantine or isolation. The verified petition must include a brief description of the facts supporting the public health authority's belief that:

(1) isolation or quarantine should be imposed on an individual; and

(2) the individual may expose an uninfected individual to a dangerous communicable disease or outbreak before the individual can be provided with notice and an opportunity to be heard.

The verified petition must include a description of any efforts the public health authority made to obtain the individual's voluntary compliance with isolation or quarantine before filing the petition.

(f) If the public health authority proves by clear and convincing evidence that:

(1) an individual has been infected or exposed to a dangerous communicable disease or outbreak;

(2) the individual is likely to cause the infection of an uninfected individual if the individual is not restricted in the individual's ability to come into contact with an uninfected individual; and

(3) the individual may expose an uninfected individual to a dangerous communicable disease or outbreak before the individual can be provided with notice and an opportunity to be heard;

the court may issue an emergency order imposing isolation or quarantine on the individual. The court shall establish the duration and other conditions of isolation or quarantine. The court shall impose the least restrictive conditions of isolation or quarantine that are consistent with the protection of the public.

(g) A court may issue an emergency order of isolation or quarantine without the verified petition required under subsection (e) if the court receives sworn testimony of the same facts required in the verified petition:

(1) in a nonadversarial, recorded hearing before the judge;

(2) orally by telephone or radio;

(3) in writing by facsimile transmission (fax); or

(4) through other electronic means approved by the court.

If the court agrees to issue an emergency order of isolation or quarantine based upon information received under subdivision (2), the court shall direct the public health authority to sign the judge's name and to write the time and date of issuance on the proposed emergency order. If the court agrees to issue an emergency order of isolation or quarantine based upon information received under subdivision (3), the court shall direct the public health authority to transmit a proposed emergency order to the court, which the court shall sign, add the date of issuance, and transmit back to the public health authority. A court may modify the conditions of a proposed emergency order.

(h) If an emergency order of isolation or quarantine is issued under subsection (g)(2), the court shall record the conversation on audiotape and order the court reporter to type or transcribe the recording for entry in the record. The court shall certify the audiotape, the transcription, and the order retained by the judge for entry in the record.

(i) If an emergency order of isolation or quarantine is issued under subsection (g)(3), the court shall order the court reporter to retype or copy the facsimile transmission for entry in the record. The court shall certify the transcription or copy and order retained by the judge for entry in the record.

(j) The clerk shall notify the public health authority who received an emergency order under subsection (g)(2) or (g)(3) when the transcription or copy required under this section is entered in the record. The public health authority shall sign the typed, transcribed, or copied entry upon receiving notice from the court reporter.

(k) The public health authority may issue an immediate order imposing isolation or quarantine on an individual if exigent circumstances, including the number of affected individuals, exist that make it impracticable for the public health authority to seek an order from a court, and obtaining the individual's voluntary compliance is or has proven impracticable or ineffective. An immediate order of isolation or quarantine expires after seventy-two (72) hours, excluding Saturdays, Sundays, and legal holidays, unless renewed in accordance with subsection (l). The public health authority shall establish the other conditions of isolation or quarantine. The public health authority shall impose the least restrictive conditions of isolation or quarantine that are consistent with the protection of the public. If the immediate order applies to a group of individuals and it is impracticable to provide individual notice, the public health authority shall post a copy of the order where it is likely to be seen by individuals subject to the order.

(l) The public health authority may seek to renew an order of isolation or quarantine or an immediate order of isolation or quarantine issued under this section by doing the following:

(1) By filing a petition to renew the emergency order of isolation or quarantine or the immediate order of isolation or quarantine with:

(A) the court that granted the emergency order of isolation or quarantine; or

(B) a circuit or superior court, in the case of an immediate order.

The petition for renewal must include a brief description of the facts supporting the public health authority's belief that the individual who is the subject of the petition should remain in isolation or quarantine and a description of any efforts the public health authority made to obtain the individual's voluntary compliance with isolation or quarantine before filing the petition.

(2) By providing the individual who is the subject of the emergency order of isolation or quarantine or the immediate order of isolation or quarantine with a copy of the petition and notice of the hearing at least twenty-four (24) hours before the time of the hearing.

(3) By informing the individual who is the subject of the emergency order of isolation or quarantine or the immediate order of isolation or quarantine that the individual has the right to:

(A) appear, unless the court finds that the individual's personal appearance may expose an uninfected person to a dangerous communicable disease or outbreak;

(B) cross-examine witnesses; and

(C) counsel, including court appointed counsel in accordance with subsection (c).

(4) If:

(A) the petition applies to a group of individuals; and

(B) it is impracticable to provide individual notice;

by posting the petition in a conspicuous location on the isolation or quarantine premises.

(m) If the public health authority proves by clear and convincing evidence at a hearing under subsection (l) that:

(1) an individual has been infected or exposed to a dangerous communicable disease or outbreak; and

(2) the individual is likely to cause the infection of an uninfected individual if the individual is not restricted in the individual's ability to come into contact with an uninfected individual;

the court may renew the existing order of isolation or quarantine or issue a new order imposing isolation or quarantine on the individual. The court shall establish the conditions of isolation or quarantine, including the duration of isolation or quarantine. The court shall impose the least restrictive conditions of isolation or quarantine that are consistent with the protection of the public.

(n) Unless otherwise provided by law, a petition for isolation or quarantine, or a petition to renew an immediate order for isolation or quarantine, may be filed in a circuit or superior court in any county. Preferred venue for a petition described in this subsection is:

(1) the county or counties (if the area of isolation or quarantine includes more than one (1) county) where the individual, premises, or location to be isolated or quarantined is located; or

(2) a county adjacent to the county or counties (if the area of isolation or quarantine includes more than one (1) county) where the individual, premises, or location to be isolated or quarantined is located.

This subsection does not preclude a change of venue for good cause shown.

(o) Upon the motion of any party, or upon its own motion, a court may consolidate cases for a hearing under this section if:

(1) the number of individuals who may be subject to isolation or quarantine, or who are subject to isolation or quarantine, is so large as to render individual participation impractical;

(2) the law and the facts concerning the individuals are similar; and

(3) the individuals have similar rights at issue.

A court may appoint an attorney to represent a group of similarly situated individuals if the individuals can be adequately represented. An individual may retain his or her own counsel or proceed pro se.

(p) A public health authority that imposes a quarantine that is not in the person's home:

(1) shall allow the parent or guardian of a child who is quarantined under this section; and

(2) may allow an adult;

to remain with the quarantined individual in quarantine. As a condition of remaining with the quarantined individual, the public health authority may require a person described in subdivision (2) who has not been exposed to a dangerous communicable disease to

receive an immunization or treatment for the disease or condition, if an immunization or treatment is available and if requiring immunization or treatment does not violate a constitutional right.

(q) If an individual who is quarantined under this section is the sole parent or guardian of one (1) or more children who are not quarantined, the child or children shall be placed in the residence of a relative, friend, or neighbor of the quarantined individual until the quarantine period has expired. Placement under this subsection must be in accordance with the directives of the parent or guardian, if possible.

(r) State and local law enforcement agencies shall cooperate with the public health authority in enforcing an order of isolation or quarantine.

(s) The court shall appoint an attorney to represent an indigent individual in an action brought under this chapter or under IC 16-41-6. If funds to pay for the court appointed attorney are not available from any other source, the state department may use the proceeds of a grant or loan to reimburse the county, state, or attorney for the costs of representation.

(t) A person who knowingly or intentionally violates a condition of isolation or quarantine under this chapter commits violating quarantine or isolation, a Class A misdemeanor.

(u) The state department shall adopt rules under IC 4-22-2 to implement this section, including rules to establish guidelines for:

(1) voluntary compliance with isolation and quarantine;

(2) quarantine locations and logistical support; and

(3) moving individuals to and from a quarantine location. The absence of rules adopted under this subsection does not preclude the public health authority from implementing any provision of this section.

IC 16-41-9-1.6 Actions of public health authority in event of quarantine

Sec. 1.6. (a) A public health authority may impose or petition a court to impose a quarantine and do the following:

(1) Distribute information to the public concerning:

(A) the risks of the disease;

(B) how the disease is transmitted;

(C) available precautions to reduce the risk of contracting the disease;

(D) the symptoms of the disease; and

(E) available medical or nonmedical treatments available for the disease.

(2) Instruct the public concerning social distancing.

(3) Request that the public inform the public health authority or a law enforcement agency if a family member contracts the disease.

(4) Instruct the public on self quarantine and provide a distinctive means of identifying a home that is self quarantined.

(5) Instruct the public on the use of masks, gloves, disinfectant, and other means of reducing exposure to the disease.

(6) Close schools, athletic events, and other nonessential situations in which people gather.

If a quarantine is imposed under section 1.5 of this chapter, the public health authority

shall ensure that, to the extent possible, quarantined individuals have sufficient supplies to remain in their own home.

(b) If an out of home, nonhospital quarantine is imposed on an individual, the individual shall be housed as close as possible to the individual's residence.

(c) In exercising the powers described in this section or in section 1.5 of this chapter, the public health authority may not prohibit a person lawfully permitted to possess a firearm from possessing one (1) or more firearms unless the person is quarantined in a mass quarantine location. The public health authority may not remove a firearm from the person's home, even if the person is quarantined in a mass quarantine location.

(d) This section does not prohibit a public health authority from adopting rules and enforcing rules to implement this section if the rules are not inconsistent with this section.

IC 16-41-9-1.7 Immunization programs

Sec. 1.7. (a) An immunization program established by a public health authority to combat a public health emergency involving a dangerous communicable disease must comply with the following:

(1) The state department must develop and distribute or post information concerning the risks and benefits of immunization.

(2) No person may be required to receive an immunization without that person's consent. No child may be required to receive an immunization without the consent of the child's parent, guardian, or custodian. The state department may implement the procedures described in section 1.5 of this chapter concerning a person who refuses to receive an immunization or the child of a parent, guardian, or custodian who refuses to consent to the child receiving an immunization.

(b) The state department shall adopt rules to implement this section. The absence of rules adopted under this subsection does not preclude the public health authority from implementing any provision of this section.

IC 16-41-9-3 Infected students; exclusion from school

Sec. 3. (a) The local health officer may exclude from school a student who has a dangerous communicable disease that:

(1) is transmissible through normal school contacts; and

(2) poses a substantial threat to the health and safety of the school community.

(b) If the local health officer subsequently determines that a student who has been excluded from school under subsection (a) does not have a dangerous communicable disease that:

(1) is transmissible through normal school contacts; and

(2) poses a substantial threat to the health and safety of the school community;

the local health officer shall issue a certificate of health to admit or readmit the student to school.

(c) A person who objects to the determination made by the local health officer under this section may appeal to the executive board of the state department, which is the ultimate authority. IC 4-21.5 applies to proceedings under this section.

IC 16-41-9-5 Mentally ill and dangerous or gravely disabled carriers; detention; reports

Sec. 5. (a) If a designated health official determines that a carrier has a dangerous communicable disease and has reasonable grounds to believe that the carrier is mentally ill and either dangerous or gravely disabled, the designated health official may request:

(1) immediate detention under IC 12-26-4; or

(2) emergency detention under IC 12-26-5;

for the purpose of having the carrier apprehended, detained, and examined. The designated health official may provide to the superintendent of the psychiatric hospital or center or the attending physician information about the carrier's communicable disease status. Communications under this subsection do not constitute a breach of confidentiality.

(b) If the written report required under IC 12-26-5-5 states there is probable cause to believe the carrier is mentally ill and either dangerous or gravely disabled and requires continuing care and treatment, proceedings may continue under IC 12-26.

(c) If the written report required under IC 12-26-5-5 states there is not probable cause to believe the carrier is mentally ill and either dangerous or gravely disabled and requires continuing care and treatment, the carrier shall be referred to the designated health official who may take action under this article.

IC 16-41-9-6 Detained carriers; isolation; unauthorized absences

Sec. 6. (a) The chief medical officer of a hospital or other institutional facility may direct that a carrier detained under this article be placed apart from the others and restrained from leaving the facility. A carrier detained under this article shall observe all the rules of the facility or is subject to further action before the committing court.

(b) A carrier detained under this article who leaves a tuberculosis hospital or other institutional facility without being authorized to leave or who fails to return from an authorized leave without having been formally discharged is considered absent without leave.

(c) The sheriff of the county in which a carrier referred to in subsection (b) is found shall apprehend the carrier and return the carrier to the facility at which the carrier was being detained upon written request of the superintendent of the facility. Expenses incurred under this section are treated as expenses described in section 13 of this chapter.

IC 16-41-9-7 Voluntarily admitted carriers; unauthorized absences; prevention of health threat

Sec. 7. (a) A carrier who:

(1) poses a serious and present danger to the health of others;

(2) has been voluntarily admitted to a hospital or other facility for the treatment of tuberculosis or another dangerous communicable disease; and

(3) who leaves the facility without authorized leave or against medical advice or who fails to return from authorized leave;

shall be reported to a health officer by the facility not more than twenty-four (24) hours

after discovery of the carrier's absence.

(b) If a health officer fails or refuses to institute or complete necessary legal measures to prevent a health threat (as defined in IC 16-41-7-2) by the carrier, the case shall be referred to a designated health official for appropriate action under this article.

IC 16-41-9-8 Discharge reports; release orders

Sec. 8. (a) A local health officer may file a report with the court that states that a carrier who has been detained under this article may be discharged without danger to the health or life of others.

(b) The court may enter an order of release based on information presented by the local health officer or other sources.

IC 16-41-9-9 Release of carriers from state penal institutions; advanced reports; jurisdiction of health officers

Sec. 9. (a) Not more than thirty (30) days after the proposed release from a state penal institution of a prisoner who is known to have:

(1) tuberculosis in a communicable stage; or

(2) other dangerous communicable disease;

the chief administrative officer of the penal institution shall report to the state department the name, address, age, sex, and date of release of the prisoner.

(b) The state department shall provide the information furnished the state department under subsection (a) to the health officer having jurisdiction over the prisoner's destination address.

(c) Each health officer where the prisoner may be found has jurisdiction over the released prisoner.

IC 16-41-9-10 Nonresident indigent carriers; transfer to legal residences

Sec. 10. (a) The administrator of a hospital or other facility for the treatment of tuberculosis or other dangerous communicable disease may transfer or authorize the transfer of a nonresident indigent carrier to the carrier's state or county of legal residence if the carrier is able to travel. If the carrier is unable to travel, the administrator may have the carrier hospitalized until the carrier is able to travel.

(b) Costs for the travel and hospitalization authorized by this section shall be paid by the: (1) carrier under section 13 of this chapter; or

(2) state department if the carrier cannot pay the full cost.

IC 16-41-9-12 Refusal of admission to facilities; actions against persons and licensed facilities

Sec. 12. (a) The superintendent or the chief executive officer of the facility to which a carrier has been ordered under this chapter may decline to admit a patient if the superintendent or chief executive officer determines that there is not available adequate space, treatment staff, or treatment facilities appropriate to the needs of the patient.

(b) The state department may commence an action under IC 4-21.5-3-6 or IC 4-21.5-4 for issuance of an order of compliance and a civil penalty not to exceed one thousand dollars ($1,000) per violation per day against a person who:

(1) fails to comply with IC 16-41-1 through IC 16-41-3, IC 16-41-5 through IC 16-41-9, IC 16-41-13, IC 16-41-14, or IC 16-41-16 or a rule adopted under these chapters; or

(2) interferes with or obstructs the state department or the state department's designated agent in the performance of official duties under IC 16-41-1 through IC 16-41-3, IC 16-41-5 through IC 16-41-9, IC 16-41-13, IC 16-41-14, or IC 16-41-16 or a rule adopted under these chapters.

(c) The state department may commence an action against a facility licensed by the state department under either subsection (b) or the licensure statute for that facility, but the state department may not bring an action arising out of one (1) incident under both statutes.

IC 16-41-9-13 Costs of care or treatment

Sec. 13. (a) The court shall determine what part of the cost of care or treatment ordered by the court, if any, the carrier can pay and whether there are other available sources of public or private funding responsible for payment of the carrier's care or treatment. The carrier shall provide the court documents and other information necessary to determine financial ability. If the carrier cannot pay the full cost of care and other sources of public or private funding responsible for payment of the carrier's care or treatment are not available, the county is responsible for the cost. If the carrier:

(1) provides inaccurate or misleading information; or

(2) later becomes able to pay the full cost of care;

the carrier becomes liable to the county for costs paid by the county.

(b) Except as provided in subsections (c) and (d), the costs incurred by the county under this chapter are limited to the costs incurred under section 1.5 of this chapter.

(c) However, subsection (b) does not relieve the county of the responsibility for the costs of a carrier who is ordered by the court under this chapter to a county facility.

(d) Costs, other than costs described in subsections (b) and (c) that are incurred by the county for care ordered by the court under this chapter, shall be reimbursed by the state under IC 16-21-7 to the extent funds have been appropriated for reimbursement.

IC 16-41-9-15 Cooperation to implement least restrictive but medically necessary procedures to protect public health

Sec. 15. In carrying out its duties under this chapter, a public health authority shall attempt to seek the cooperation of cases, carriers, contacts, or suspect cases to implement the least restrictive but medically necessary procedures to protect the public health.

⌘ Immunization Requirements – Postseconday Level *(NOTE: the Definition of matriculate: to register or enroll in a college or university)*

IC 20-12-71-12 Form of documentation; effect of noncompliance

Sec. 12. (a) Before matriculating in a residential campus of a postsecondary institution, each student shall provide the postsecondary institution with one (1) of the following documents:

(1) A certificate of immunity.

(2) Documentation of exemption as described in sections 13 and 14 of this chapter.

(b) Before matriculating in a residential campus of a postsecondary institution, a student that is not a citizen or resident of the United States shall provide the postsecondary institution with:

(1) medical documentation that the student has been tested for tuberculosis in the United States;

(2) the date on which the tuberculosis test was taken; and

(3) the results of the tuberculosis test.

(c) If a student fails to comply with subsection (a) or subsection (b) by the beginning of the student's second academic term, the postsecondary institution shall prohibit the student from matriculating in the campus of the postsecondary institution, where applicable, until the requirements are met.

⌘ Health Facilities

410 IAC 16.2-3.1-18 Infection Control Program [Licensing and Operational Standards]

Sec. 18. (a) The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of diseases and infection.

(b) The facility must establish an infection control program under which it does the following:

(1) Investigates, controls, and prevents infections in the facility, including, but not limited to, a surveillance system to:

(A) monitor, investigate, document, and analyze the occurrence of nosocomial infection;

(B) recommend corrective action; and

(C) review findings at least quarterly.

The system shall enable the facility to analyze clusters and/or significant increases in the rate of infection.

(2) Decides what procedures (such as isolation) should be applied to an individual resident, including, but not limited to, written, current infection control program policies and procedures for an isolation/precautions system to prevent the spread of infection that isolates the infectious agent and includes full implementation of universal precautions.

(3) Maintains a record of incidents and corrective actions related to infections.

(4) Provides orientation and in-service education on infection prevention and control, including universal precautions.

(5) Provides a resident health program, including, but not limited to, appropriate personal hygiene and immunization.

(6) Provides an employee health program, including appropriate handling of an infected employee as well as employee exposure.
(7) Reports communicable disease to public health authorities.
(c) A diagnostic chest x-ray completed no more than six (6) months prior to admission shall be required.
(d) Prior to admission, each resident shall be required to have a health assessment, including history of significant past or present infectious diseases and a statement that the resident shows no evidence of tuberculosis in an infectious stage as verified upon admission and yearly thereafter.
(e) In addition, a tuberculin skin test shall be completed within three (3) months prior to admission or upon admission and read at forty-eight (48) to seventy-two (72) hours. The result shall be recorded in millimeters of induration with the date given, date read, and by whom administered and read.
(f) The baseline tuberculin skin testing should employ the two-step method. For residents who have not had a documented negative tuberculin skin test result during the preceding twelve (12) months, the baseline tuberculin skin testing should employ the two-step method. If the first step is negative, a second test should be performed within one (1) to three (3) weeks after the first test. The frequency of repeat testing will depend on the risk of infection with tuberculosis.
(g) All residents who have a positive reaction to the tuberculin skin test shall be required to have a chest x-ray and other physical and laboratory examinations in order to complete a diagnosis.
(h) All skin testing for tuberculosis shall be done using the Mantoux method (5 TU PPD) administered by persons having documentation of training from a department-approved course of instruction in intradermal tuberculin skin testing, reading, and recording.
(i) Persons with a documented history of a positive tuberculin skin test, adequate treatment for disease, or preventive therapy for infection, shall be exempt from further skin testing. In lieu of a tuberculin skin test, these persons should have an annual risk assessment for the development of symptoms suggestive of tuberculosis, including, but not limited to, cough, fever, night sweats, and weight loss. If symptoms are present, the individual shall be evaluated immediately with a chest x-ray.
(j) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident only to the degree needed to isolate the infecting organism.
(k) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food if direct contact will transmit the disease. An employee with signs and symptoms of a communicable disease, including, but not limited to, an infected or draining skin lesion shall be handled according to a facility's policy regarding direct contact with residents, their food, or resident care items until the condition is resolved. Persons with suspected or proven active tuberculosis will not be permitted to work until determined to be noninfectious and documentation is provided for the employee record.
(l) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.
(m) For purposes of IC 16-28-5-1, a breach of:
(1) subsection (a) is an offense;

(2) subsection (b)(1), (b)(2), (j), (k), or (l) is a deficiency; and
(3) subsection (b)(3), (c), (d), (e), (f), (g), (h), or (i) is a noncompliance.

410 IAC 16.2-5-12 Infection Control Program [Rule 5 – Residential Care Facilities]

Sec. 12
(a) The facility must establish and maintain an infection control practice designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of diseases and infection.
(b) The facility must establish an infection control program that includes the following:
(1) A system that enables the facility to analyze patterns of known infectious symptoms.
(2) Provides orientation and in-service education on infection prevention and control, including universal precautions.
(3) Offering health information to residents, including, but not limited to, infection transmission and immunizations.
(4) Reporting communicable disease to public health authorities.
(c) Each resident shall have a diagnostic chest x-ray completed no more than six (6) months prior to admission.
(d) Prior to admission, each resident shall be required to have a health assessment, including history of significant past or present infectious diseases and a statement that the resident shows no evidence of tuberculosis in an infectious stage as verified upon admission and yearly thereafter.
(d) Prior to admission, each resident shall be required to have a health assessment, including history of significant past or present infectious diseases and a statement that the resident shows no evidence of tuberculosis in an infectious stage as verified upon admission and yearly thereafter.
(h) All skin testing for tuberculosis shall be done using the Mantoux method (5TU, PPD) administered by persons having documentation of training from a department approved course of instruction in intradermal tuberculin skin testing, reading, and recording.
(i) Persons with a documented history of a positive tuberculin skin test, adequate treatment for disease, or preventive therapy for infection shall be exempt from further skin testing. In lieu of a tuberculin skin test, these persons should have an annual risk assessment for the development of symptoms suggestive of tuberculosis, including, but not limited to, cough, fever, night sweats, and weight loss. If symptoms are present, the individual shall be evaluated immediately with a chest xray.
(j) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident only to the degree needed to isolate the infecting organism.
(k) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.

410 IAC 16.2-6-2 Medical and dental services (Rule 6 – Health Care Facilities for Children)

Sec. 2. (a) A complete physical, including an acceptable skin test for tuberculosis, a dental examination, and an evaluation of the child's medical and physical capabilities, shall be completed on the day of admission or not earlier than thirty (30) days prior to admission.
(b) Upon admission, written evidence shall indicate completion of an immunization series for diphtheria, tetanus, rubella, whooping cough, measles, and polio. The age of the child or the written order by the attending physician, contraindicating a new immunization, may alter the series. A planned program for booster immunization shall be maintained for each resident.
(c) For purposes of IC 16-28-5-1, a breach of subsection (a) or (b) is a noncompliance.

⌘ Employee Health Monitoring

IC 20-27-8-1 School bus driver or school bus monitor; requirements

Sec. 1. (a) An individual may not drive a school bus for the transportation of students or be employed as a school bus monitor unless the individual satisfies the following requirements:

(1) Is of good moral character.
(2) Does not use intoxicating liquor during school hours.
(3) Does not use intoxicating liquor to excess at any time.
(4) Is not addicted to any narcotic drug.
(5) Is at least:
(A) twenty-one (21) years of age for driving a school bus; or
(B) eighteen (18) years of age for employment as a school bus monitor.
(6) In the case of a school bus driver, holds a valid public passenger chauffeur's license or commercial driver's license issued by the state or any other state.
(7) Possesses the following required physical characteristics:
(A) Sufficient physical ability to be a school bus driver, as determined by the committee.
(B) The full normal use of both hands, both arms, both feet, both legs, both eyes, and both ears.
(C) Freedom from any communicable disease that:
(i) may be transmitted through airborne or droplet means; or
(ii) requires isolation of the infected person under 410 IAC 1-2.3.
(D) Freedom from any mental, nervous, organic, or functional disease that might impair the person's ability to properly operate a school bus.
(E) Visual acuity, with or without glasses, of at least 20/40 in each eye and a field of vision with one hundred fifty (150) degree minimum and with depth perception of at least eighty percent (80%).

(b) This subsection applies to a school bus monitor. Notwithstanding subsection (a)(5)(B), a school corporation or school bus driver may not employ an individual who is less than twenty-one (21) years of age as a school bus monitor unless the school

corporation or school bus driver does not receive a sufficient number of qualified applicants for employment as a school bus monitor who are at least twenty-one (21) years of age. A school corporation or school bus driver shall maintain a record of applicants, their ages, and their qualifications to show compliance with this subsection.

410 IAC 17-12-1 Home health agency administration and management
Note: this is an excerpt from Sec. 1. Starting with (i)

(i) The home health agency shall ensure that all employees, staff members, persons providing care on behalf of the agency, and contractors having direct patient contact are evaluated for tuberculosis and documentation as follows:
(1) Any person with a negative history of tuberculosis or a negative test result must have a baseline two-step tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual has documentation that a tuberculin skin test has been applied at any time during the previous twelve (12) months and the result was negative.
(2) The second step of a two-step tuberculin skin test using the Mantoux method must be administered one (1) to three (3) weeks after the first tuberculin skin test was administered.
(3) Any person with:
(A) a documented:
(i) history of tuberculosis;
(ii) previously positive test result for tuberculosis; or
(iii) completion of treatment for tuberculosis; or
(B) newly positive results to the tuberculin skin test; must have one (1) chest radiograph to exclude a diagnosis of tuberculosis.
(4) After baseline testing, tuberculosis screening must:
(A) be completed annually; and
(B) include, at a minimum, a tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual was subject to subdivision (3).
(5) Any person having a positive finding on a tuberculosis evaluation may not:
(A) work in the home health agency; or
(B) provide direct patient contact; unless approved by a physician to work.
(6) The home health agency must maintain documentation of tuberculosis evaluations showing that any person:
(A) working for the home health agency; or
(B) having direct patient contact;
has had a negative finding on a tuberculosis examination within the previous twelve (12) months.
(j) The information obtained from the:
(1) physical examinations required by subsection (h); and
(2) tuberculosis evaluations and clinical follow-ups required by subsection (i);
must be maintained in separate medical files and treated as confidential medical records, except as provided in subsection (k).
(k) The following records shall be made available, on request, to the department for review:

(1) Personnel records and policies that document the home health agency's compliance with subsection (f).
(2) Records of physical examinations that document the agency's compliance with subsection (h).
(3) Records of the following:
(A) Tuberculosis evaluations.
(B) Appropriate clinical follow-up for positive findings.
(C) Any other records that document the home health agency's compliance with subsection (i).
(l) The department shall:
(1) treat the information described in subsection (k) as confidential medical records; and
(2) use it only for the purposes for which it was obtained.
(m) Policies and procedures shall be written and implemented for the control of communicable disease in compliance with
applicable federal and state laws.

410 IAC 26-8-2 *[Abortion Clinics]*

Sec. 2. The clinic shall do the following:
(1) Develop, implement, and maintain a written policy for the control of communicable disease in compliance with applicable federal and state laws.
(2) Monitor employee health in accordance with the clinic's infection control program.
(3) Ensure that all employees, staff members, and contractors having direct patient contact are evaluated at least annually for tuberculosis as follows:
(A) Any person with a negative history of tuberculosis or a negative test result must have a baseline two-step tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual has documentation that a tuberculinskin test has been applied at any time during the previous twelve (12) months and the result was negative.
(B) The second step of a two-step tuberculin skin tests using the Mantoux method must be administered one (1) to three
(3) weeks after the first tuberculin skin test was administered.
(C) Any person with a documented history of tuberculosis, documented previously positive test result for tuberculosis, documented completion of treatment for tuberculosis, or newly positive results to the tuberculin skin test must have one
(1) chest radiograph to exclude a diagnosis of tuberculosis.
(D) After baseline testing, tuberculosis screening must be completed annually and must include at a minimum a tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual was subject to subdivision "C" of this subsection *[clause (C)]*.
(E) Any person having a positive finding on a tuberculosis evaluation may not work in the abortion clinic or provide direct patient contact unless approved by a physician to work.
(F) The abortion clinic must maintain documentation of tuberculosis evaluations showing that any person working for the abortion clinic or having direct patient contact has had a negative finding on a tuberculosis examination within the previous twelve (12) months.

410 IAC 27-8-2 ***[Birthing Centers]***

Sec. 2. The center shall ensure that all employees, staff members, persons providing care on behalf of the center, and contractors having direct patient contact are evaluated for tuberculosis and documentation as follows:
(1) Any person with a negative history of tuberculosis or a negative test result must have a baseline two (2) step tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual has documentation that a tuberculin skin test has been applied at any time during the previous twelve (12) months and the result was negative.
(2) The second step of a two-step tuberculin skin test using the Mantoux method must be administered one (1) to three (3) weeks after the first tuberculin skin test was administered.
(3) Any person with a documented history of tuberculosis, documented previously positive test result for tuberculosis, documented completion of treatment for tuberculosis, or newly positive results to the tuberculin skin test must have one (1) chest radiograph to exclude a diagnosis of tuberculosis.
(4) After baseline testing, tuberculosis screening must be completed annually and must include at a minimum a tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual was subject to subdivision (3) of this subsection *[subdivision (3)]*.
(5) Any person having a positive finding on a tuberculosis evaluation may not work in the center or provide direct patient contact unless approved by a physician to work.
(6) The center must maintain documentation of tuberculosis evaluations showing that any person working for the birthing center or having direct patient contact has had a negative finding on a tuberculosis examination within the previous twelve (12) months.

431 IAC 1.1-3-3 Facility staffing ***[Community Residential Facilities for Persons with Developmental Disabilities]***

Sec. 3. (a) The residential facility shall meet all conditions specified in 42 CFR 483.430 (10-1-95).
(b) Orientation to the facility shall be as follows:
(1) Each residential facility shall have a written orientation plan for all residential staff. The orientation plan shall include, but not be limited to, the following:
(A) A review of the policy and procedure manual.
(B) Emergency procedures and appropriate telephone numbers.
(C) On-the-job observation and training.
(D) Any other suitable training required by the facility policy.
(2) Each residential staff person shall receive orientation and training in tasks required to be performed in the facility prior to independently assuming the position, including life safety training. Records of such training shall be documented by the provider.
(c) The provider shall have a written plan for inservice training or require all residential staff to attend other staff development programs. Each provider shall provide or require at least twenty-four (24) hours of training per residential staff person per year.
Records of such training, including that provided to relief or part-time staff, shall be documented and retained according to the provider's written policy.

(d) The provider shall demonstrate that its employment practices assure that the health of residential staff shall not be detrimental to the health or welfare of the residents.
(e) Prior to assuming residential job duties and annually thereafter, each residential staff person shall submit written evidence that a Mantoux (5TU, PPD) tuberculosis skin test or chest x-ray was completed. The result of the Mantoux shall be recorded in millimeter of induration with the date given, date read, and by whom administered. If the skin test result is significant (ten (10) millimeters or more), then a chest film shall be done with other physical and laboratory examinations as necessary to complete a diagnosis. Prophylactic treatment shall be provided as per diagnosis for the length of time prescribed by the physician.

⌘ Child Services

465 IAC 2-9-75 Health requirements for children *[Department of Child Services, Rule 9 – Children's Homes and Child Caring Institutions]*

Sec. 75. (a) The child caring institution shall obtain from the placing agency or placing parent a statement indicating whether or not the child has, to the best of the applicant's knowledge, been exposed to a communicable disease within three (3) weeks prior to the date of admission.
(b) Each child shall receive a health examination by a licensed physician within three (3) months prior to admission, or not later than two (2) weeks after admission. The examination shall include the following:
(1) Health history.
(2) Physical examination.
(3) Vision and hearing screening.
(4) A Mantoux intradermal skin test for tuberculosis if the last such test is known to be negative or if there is no record of a test. If the Mantoux test is positive the child shall have a diagnostic chest x-ray and other indicated laboratory test to determine whether or not the disease is in an infectious state.
(5) A written statement from the licensed physician that in the physician's opinion there is no health condition that would be hazardous either to the child or to other children in the child caring institution.
(6) A statement of the medical findings, including physical defects and need for dental care, state of development, and ability of the child to take part in group activities, or a schedule of permitted activities if activities need to be limited.
(7) A health examination, including a Mantoux tuberculin test annually and whenever there is reason to suspect that the child may have a condition hazardous or potentially hazardous to others or whenever the child's general condition indicates the need for an examination.
(c) Each child shall receive a dental examination from a licensed dentist as follows:
(1) Within thirty (30) days of admission unless the child caring institution has documentation of a dental examination within the six (6) months prior to admission.
(2) Annually.
(3) Whenever an interim condition indicates the need for examination or treatment.

(d) Any treatment or corrective measures required by the licensed physician or dentist shall be arranged by the child caring institution, as approved by a parent, legal guardian, or placing agency.
(e) The child caring institution, after attempting to determine the child's immunization history, shall ensure that each child has received all immunizations and booster shots which are required by the SBH.
(f) All children shall be immunized against routine childhood diseases unless exempted by a licensed physician's statement.
(g) A child may be exempted from immunizations against routine childhood diseases upon the good faith religious belief statement of the parent or guardian.
(h) The adequate immunizing doses and the child's age for administering each vaccine shall be those recommended by the American Academy of Pediatrics or by the United States Public Health Service Immunization Practices Advisory Committee.
(i) Adequate documentation of an immunization history shall consist of one (1) of the following:
(1) A licensed physician's certificate including the number and dates of doses administered.
(2) Immunization records forwarded from a school corporation including the number and dates of doses administered.
(3) A record maintained by the parent or guardian showing the month, day, and year during which each dose of vaccine was administered.
(j) If a licensed physician certifies in writing that a particular immunization required under this section is detrimental, or may be detrimental, to the child's health, the requirements for that particular immunization are not applicable for that child until the immunization is found no longer to be detrimental to the child's health.
(k) The child caring institution shall maintain a health record for each child. The record shall include the following:
(1) Admission and periodic health and dental examination information.
(2) A licensed physician's written instructions with regard to special dietary or health care required.
(3) Record of all medications and treatments.
(4) Record of observations and incidents, including accidents, injuries, or any other condition which may be associated with
a health condition or possible abuse or neglect.

465 IAC 2-11-75 Health requirements for children *[Department of Child Services, Rule 11 – Private Secure Facilities]*

Sec. 75. (a) The child caring institution shall obtain from the placing agency or placing parent a statement indicating whether or not the child has, to the best of the applicant's knowledge, been exposed to a communicable disease within three (3) weeks prior to the date of admission.
(b) Each child shall receive a health examination by a licensed physician within three (3) months prior to admission, or not later than two (2) weeks after admission. The examination shall include the following:
(1) Health history.

(2) Physical examination.
(3) Vision and hearing screening.
(4) A Mantoux intradermal skin test for tuberculosis if the last such test is known to be negative or if there is no record of a test. If the Mantoux test is positive the child shall have a diagnostic chest x-ray and other indicated laboratory test to determine whether or not the disease is in an infectious state.
(5) A written statement from the licensed physician that in the physician's opinion there is no health condition that would be hazardous either to the child or to other children in the child caring institution.
(6) A statement of the medical findings, including physical defects and need for dental care, state of development, and ability of the child to take part in group activities, or a schedule of permitted activities if activities need to be limited.
(7) A health examination, including a Mantoux tuberculin test annually and whenever there is reason to suspect that the child may have a condition hazardous or potentially hazardous to others or whenever the child's general condition indicates the need for an examination.
(c) Each child shall receive a dental examination from a licensed dentist as follows:
(1) Within thirty (30) days of admission unless the child caring institution has documentation of a dental examination within the six (6) months prior to admission.
(2) Annually.
(3) Whenever an interim condition indicates the need for examination or treatment.
(d) Any treatment or corrective measures required by the licensed physician or dentist shall be arranged by the child caring institution, as approved by a parent, legal guardian, or placing agency.
(e) The child caring institution, after attempting to determine the child's immunization history, shall ensure that each child has received all immunizations and booster shots which are required by the SBH.
(f) All children shall be immunized against routine childhood diseases unless exempted by a licensed physician's statement.
(g) A child may be exempted from immunizations against routine childhood diseases upon the good faith religious belief statement of the parent or guardian.
(h) The adequate immunizing doses and the child's age for administering each vaccine shall be those recommended by the American Academy of Pediatrics or by the United States Public Health Service Immunization Practices Advisory Committee.
(i) Adequate documentation of an immunization history shall consist of one (1) of the following:
(1) A licensed physician's certificate including the number and dates of doses administered.
(2) Immunization records forwarded from a school corporation including the number and dates of doses administered.
(3) A record maintained by the parent or guardian showing the month, day, and year during which each dose of vaccine was administered.
(j) If a licensed physician certifies in writing that a particular immunization required under this section is detrimental, or may be detrimental, to the child's health, the requirements for that particular immunization are not applicable for that child until the immunization is found no longer to be detrimental to the child's health.

(k) The child caring institution shall maintain a health record for each child. The record shall include the following:
(1) Admission and periodic health and dental examination information.
(2) A licensed physician's written instructions with regard to special dietary or health care required.
(3) Record of all medications and treatments.
(4) Record of observations and incidents, including accidents, injuries, or any other condition which may be associated with a health condition or possible abuse or neglect.

465 IAC 2-12-73 Health requirements for children ***[Department of Child Services, Rule 1 - Children's Homes and Child Caring Institutions Defined as Group Homes]***

Sec. 73. (a) The child caring institution shall obtain from the placing agency or placing parent a statement indicating whether or not the child has, to the best of the applicant's knowledge, been exposed to a communicable disease within three (3) weeks prior to the date of admission.
(b) Each child shall receive a health examination by a licensed physician within three (3) months prior to admission, or not later than two (2) weeks after admission. The examination shall include the following:
(1) Health history.
(2) Physical examination.
(3) Vision and hearing screening.
(4) A Mantoux intradermal skin test for tuberculosis if the last such test is known to be negative or if there is no record of a test. If the Mantoux test is positive the child shall have a diagnostic chest x-ray and other indicated laboratory test to determine whether or not the disease is in an infectious state.
(5) A written statement from the licensed physician that in the physician's opinion there is no health condition that would be hazardous either to the child or to other children in the child caring institution.
(6) A statement of the medical findings, including physical defects and need for dental care, state of development, and ability
of the child to take part in group activities, or a schedule of permitted activities if activities need to be limited.
(7) Each child shall receive a health examination, including a Mantoux tuberculin test annually and whenever there is reason to suspect that the child may have a condition hazardous or potentially hazardous to others or whenever the child's general condition indicates the need for an examination.
(c) Each child shall receive a dental examination from a licensed dentist as follows:
(1) Within thirty (30) days of admission unless the child caring institution has documentation of a dental examination within the six (6) months prior to admission.
(2) Annually.
(3) Whenever an interim condition indicates the need for examination or treatment.
(d) Any treatment or corrective measures required by the licensed physician or dentist shall be arranged by the child caring institution, as approved by a parent, legal guardian, or placing agency.

(e) The child caring institution, after attempting to determine the child's immunization history, shall ensure that each child has received all immunizations and booster shots which are required by the SBH.
(f) All children shall be immunized against routine childhood diseases unless exempted by a licensed physician's statement.
(g) A child may be exempted from immunizations against routine childhood diseases upon the good faith religious belief statement of the parent or guardian.
(h) The adequate immunizing doses and the child's age for administering each vaccine shall be those recommended by the American Academy of Pediatrics or by the United States Public Health Service Immunization Practices Advisory Committee.
(i) Adequate documentation of an immunization history shall consist of one (1) of the following:
(1) A licensed physician's certificate including the number and dates of doses administered.
(2) Immunization records forwarded from a school corporation including the number and dates of doses administered.
(3) A record maintained by the parent or guardian showing the month, day, and year during which each dose of vaccine was administered.
(j) If a licensed physician certifies in writing that a particular immunization required in this section is, or may be, detrimental to the child's health, the requirements for that particular immunization are not applicable for that child until the immunization is found no longer detrimental to the child's health.
(k) The child caring institution shall maintain a health record for each child. The record shall include the following:
(1) Admission and periodic health and dental examination information.
(2) A licensed physician's written instructions with regard to special dietary or health care required.
(3) Record of all medications and treatments.
(4) Record of observations and incidents, including accidents, injuries, or any other condition which may be associated with a health condition or possible abuse or neglect.

IC 12-17.2-3.5-6 [Chapter 3.5. Eligibility of Child Care Provider to Receive Reimbursement Through Voucher Program]

Sec. 6. (a) A provider who is an individual shall have an intradermal tuberculosis test before the provider is eligible for a voucher payment.

(b) A provider shall assure that an individual who is at least eighteen (18) years of age and:

(1) who, if the provider operates a child care program in the provider's home, resides with the provider; or

(2) who:

(A) is employed; or

(B) volunteers;

as a caregiver at the facility where the provider operates a child care program; has an intradermal tuberculosis test before the individual resides with the provider or is employed or allowed to volunteer as a caregiver.

(c) A provider shall maintain documentation of an annual health assessment by a physician reflecting the results of symptom screening for tuberculosis for:

(1) the provider, if the provider is an individual; and

(2) an individual described in subsection (b);

who has a history of latent or active tuberculosis.

(d) A provider shall provide the results of the tests and screening required under this section to the division upon request.

Indiana State and National Objectives

The goal of the ISDH TB Control Program is to decrease the incidence of TB and progress towards its elimination in Indiana by:

- Collecting and evaluating surveillance data
- Developing TB control policies
- Providing consultation and technical assistance to local health departments and other providers
- Providing case management oversight of active TB cases to ensure appropriate treatment, completion of therapy, and thorough contact investigations
- Increasing the public's awareness of TB

State and National Program Objectives

Below are the Centers for Disease Control and Prevention (CDC) national TB program objectives and the state of Indiana TB program objectives targeted for 2015 (unless otherwise indicated).

Table 1: PROGRAM OBJECTIVES AND PERFORMANCE TARGETS BY 2015

Indicator		National and State Tuberculosis Program Objectives and Performance Targets
1	Completion of Treatment	National Objective: For patients with newly diagnosed TB for whom 12 months or less of treatment is indicated, increase the proportion of patients who complete treatment within 12 months to 93%. Indiana Objective: For patients with newly diagnosed TB for whom 12 months or less of treatment is indicated, increase the proportion of patients who complete treatment within 12 months to 92%.

Indicator		National and State Tuberculosis Program Objectives and Performance Targets
2	TB case rates	National Objective: Decrease the TB case rate in U.S.-born persons to less than 0.7 cases per 100,000. Indiana Objective: Decrease the TB case rate in U.S.-born persons to less than 0.5 cases per 100,000. National Objective: Decrease the TB case rate for foreign-born persons to less than 14.0 cases by 100,000. Indiana Objective: Decrease the TB case rate for foreign-born persons to less than 16.5 cases by 100,000. National Objective: Decrease the TB case rate in U.S.-born non-Hispanic blacks to less than 1.3 cases per 100,000. Indiana Objective: Decrease the TB case rate in U.S.-born non-Hispanic blacks to less than 3.3 cases per 100,000. National Objective: Decrease the TB case rate for children younger than 5 years of age to less than 0.4 cases per 100,000. Indiana Objective: Decrease the TB case rate for children younger than 5 years of age to less than 0.8 cases per 100,000.

Indicator		National and State Tuberculosis Program Objectives and Performance Targets
3	Contact Investigation	National Objective: Increase the proportion of TB patients with positive acid-fast bacillus (AFB) sputum-smear results who have contacts elicited to 100.0%. Indiana Objective: Increase the proportion of TB patients with positive acid-fast bacillus (AFB) sputum-smear results who have contacts elicited to 99.0%. National Objective: Increase the proportion of contacts to sputum AFB smear-positive TB patients who are evaluated for infection and disease to 93.0%. Indiana Objective: Increase the proportion of contacts to sputum AFB smear-positive TB patients who are evaluated for infection and disease to 90.0%. National Objective: Increase the proportion of contacts to sputum AFB smear-positive TB patients with newly diagnosed latent TB infection (LTBI) who start treatment to 88.0%. Indiana Objective: Increase the proportion of contacts to sputum AFB smear-positive TB patients with newly diagnosed latent TB infection (LTBI) who start treatment to 80.0%. National Objective: For contacts to sputum AFB smear-positive TB patients who have started treatment for the newly diagnosed LTBI, increase the proportion who complete treatment to 79.0%. Indiana Objective: For contacts to sputum AFB smear-positive TB patients who have started treatment for the newly diagnosed LTBI, increase the proportion who complete treatment to 75.0%.

Indicator		National and State Tuberculosis Program Objectives and Performance Targets
4	Timely laboratory reporting	National Objective: Increase the proportion of culture-positive or nucleic acid amplification (NAA) test-positive TB cases with a pleural or respiratory site of disease that have the identification of *M. tuberculosis* complex reported by laboratory within N days from the date the initial diagnostic pleural or respiratory specimen was collected to n%. Indiana Objective: Increase the proportion of culture-positive or nucleic acid amplification (NAA) test-positive TB cases with a pleural or respiratory site of disease that have the identification of *M. tuberculosis* complex reported by laboratory within 48 hours from the date the initial diagnostic pleural or respiratory specimen was collected to 50% by 2010. National Objective: Increase the percentage of TB patients with initial positive cultures who also are tested for and receive drug susceptibility results to 100%. Indiana Objective: Increase the percentage of TB patients with initial positive cultures who also are tested for and receive drug susceptibility results to 20% by 2010.
5	Treatment Initiation	National Objective: Increase the proportion of TB patients with positive AFB sputum-smear results who initiate treatment within 7 days of specimen collection to n%. Indiana Objective: Increase the proportion of TB patients with positive AFB sputum-smear results who initiate treatment within 7 days of specimen collection to n+5%.
6	Sputum Culture Conversion	National Objective: Increase the proportion of TB patients with positive sputum culture results who have documented conversion to sputum culture-negative within 60 days of treatment initiation to 61.5%. Indiana Objective: Increase the proportion of TB patients with positive sputum culture results who have documented conversion to sputum culture-negative within 60 days of treatment initiation to 56.0%.

Indicator		National and State Tuberculosis Program Objectives and Performance Targets
7	Data Reporting	National Objective: Increase the completeness of each core Report of Verified Case of Tuberculosis (RVCT) data item to CDC, as described in the TB Cooperative Agreement announcement, to 99.2%. Indiana Objective: Increase the completeness of each core Report of Verified Case of Tuberculosis (RVCT) data item to CDC, as described in the TB Cooperative Agreement announcement, to 99.2%. National Objective: Increase the completeness of each core Aggregated Reports of Program Evaluation (ARPEs) data items reported to CDC, as described in the TB Cooperative Agreement announcement, to 100.0%. Indiana Objective: Increase the completeness of each core Aggregated Reports of Program Evaluation (ARPEs) data items reported to CDC, as described in the TB Cooperative Agreement announcement, to 100.0%. National Objective: Increase the completeness of each core Electronic Disease Notification (EDN) system data item reported to CDC, as described in the TB Cooperative Agreement announcement, to n%. Indiana Objective: Increase the completeness of each core Electronic Disease Notification (EDN) system data item reported to CDC, as described in the TB Cooperative Agreement announcement, to n%.
8	Recommended Initial Therapy	National Objective: Increase the proportion of patients who are started on the recommended initial 4-drug regimen when suspected of having TB disease to 93.4%. Indiana Objective: Increase the proportion of patients who are started on the recommended initial 4-drug regimen when suspected of having TB disease to 91.0%.
9	Universal Genotyping	National Objective: Increase the proportion of culture-confirmed TB cases with genotyping result reported to 94.0%. Indiana Objective: Increase the proportion of culture-confirmed TB cases with genotyping result reported to 94.0%.
10	Known HIV Status	National Objective: Increase the proportion of TB cases with positive or negative HIV test results reported to 88.7%. Indiana Objective: Increase the proportion of TB cases with positive or negative HIV test results reported to 75.0%.

Indicator		National and State Tuberculosis Program Objectives and Performance Targets
11	Evaluation of Immigrants and Refugees	National Objective: For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who initiate medical evaluation within 30 days of arrival to n% by. Indiana Objective: For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who initiate medical evaluation within 30 days of arrival to n+8%. National Objective: For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who complete medical evaluation within 90 days of arrival to n%. Indiana Objective: For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who complete medical evaluation within 90 days of arrival to 50.0%. National Objective: For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S., increase the proportion who start treatment to n%. Indiana Objective: For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S., increase the proportion who start treatment to n+8%. National Objective: For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S., and started on treatment, increase the proportion who complete LTBI treatment to n%. Indiana Objective: For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S., and started on treatment, increase the proportion who complete LTBI treatment to n+4%.
12	Sputum-Culture Reported	National Objective: Increase the proportion of TB cases with a pleural or respiratory site of disease in patients ages 12 years or older that have a sputum-culture result reported to 95.7%. Indiana Objective: Increase the proportion of TB cases with a pleural or respiratory site of disease in patients ages 12 years or older that have a sputum-culture result reported to 94.0%.

Indicator		National and State Tuberculosis Program Objectives and Performance Targets
13	Program Evaluation	National Objective: Increase program evaluation activities by monitoring program progress and tracking evaluation status of cooperative agreement recipients Indiana Objective: The goal of the ISDH TB evaluation plan is to determine the effectiveness of state and LHD program activities in meeting two of the national TB elimination objectives, these are: known HIV status and evaluation of contacts. National Objective: Increase the percent of cooperative agreement recipients that have an evaluation focal point. Indiana Objective: The outcome goals of the ISDH TB evaluation plan is utilize the cohort review process to increase the known HIV status of counted TB cases and increase the number of contacts who are properly evaluated.
14	Human Resource Development Plan	National Objective: Increase the percent of cooperative agreement recipients who submit a program-specific human resource development plan (HRD), as outlined in the TB Cooperative Agreement announcement, to 100.0%. Indiana Objective: ISDH has developed a human resource development plan that includes 5 specific objectives that are to be met by 2015. National Objective: Increase the percent of cooperative agreement recipients who submit a yearly update of progress-to-date on HRD activities to 100.0%. Indiana Objective: ISDH will submit a yearly update of progress-to-date on HRD activities
15	Training Focal Point	National Objective: Increase the percent of cooperative agreement recipients that have a TB training focal point. Indiana Objective: Barbara Weber-White, TB Regional Nurse Consultant, is the designated TB training focal point for ISDH.

NOTES:

Performance targets will not be established for Laboratory Turnaround Time and Treatment Initiation objectives until data become available from the implementation of revised RVCT in 2009.

Performance targets will not be established for EDN Data Reporting and Evaluation of Immigrants and Refugees objectives until the data collection in EDN has been enhanced.

The average change in the case rates for U.S. born and foreign-born populations will be monitored at the national level only.

CDC Fact Sheet, National TB Program Objectives and Performance Targets for 2015, January 2009

National Standards and Recommendations for Medical Treatment and Control of TB

The standards of care for the medical treatment and control of TB are published jointly by the American Thoracic Society (ATS), the Infectious Diseases Society of America (IDSA), and the CDC. These standards should be available for reference by each TB staff member. The standards are included in the following guidelines:

- **TREATMENT OF TB DISEASE** - ATS, CDC, IDSA. "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .

> NOTE: Errata for this MMWR (available at the site listed above). Two errors as follows:
>
> In Table 3 (pages 4-5), the subheading of the second column under "Doses" should read, "1 x/wk".
>
> On page 25, column 2, in section 3.2.1 Cycloserine, the adult dosage should read, "Serum concentration measurements aiming for a peak concentration of 20-35 mg/l are often useful in determining the optimum dose for a given patient."

- **CONTACT INVESTIGATION** - CDC, NTCA. "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC "Guidelines for Using the QuantiFERON TB-Gold Test for Detecting *Mycobacterium tuberculosis* Infection". Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf .

> NOTE: Errata for this MMWR (available at the site listed above). One error as follows:
>
> Page 55, Reference No. 18, last sentence should read: MMWR 2005;54(No. **RR-15**):1–47.

- **INFECTION CONTROL** - CDC. "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005" (*MMWR* 2005;54[No. RR-17]). Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

> NOTE: Original List of Major Errata *(18 pages in length)* can be found at:
>
> http://198.246.98.21/tb/publications/reportsarticles/mmwr/Errata09-25-06.pdf .

- **LTBI / TARGETED TESTING** - CDC. “Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection” (*MMWR* 2000;49[No. RR-6]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf .

- **LTBI** - CDC. “Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection—United States” *(MMWR 2003;52(31)*. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5231a4.htm

- **TB CONTROL** - ATS, CDC, IDSA. “Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America” (*MMWR* 2005;54[No. RR-12]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5412.pdf .

For additional guidelines, see the Division of Tuberculosis Elimination’s “TB Guidelines” Web page (Division of Tuberculosis Elimination Web site; accessed November 25, 2006). Available at: http://www.cdc.gov/tb/pubs/mmwr/Maj_guide/default.htm .

Roles, Responsibilities, and Contact Information

State Tuberculosis Control Program Staff

The ISDH is responsible for oversight of TB control activities in the state of Indiana, technical assistance to LHDs and physicians, evaluation of local TB control programs and policy development related to TB control. ISDH works in consultation with members of the ISDH Tuberculosis Medical Advisory Board on issues related to medical management and policy development. ISDH is further responsible for securing advice on the management of difficult cases from the ISDH TB Medical Advisory Board and when necessary, consultation with the experts at the **New Jersey Medical School Global Tuberculosis Institute** (designated by the CDC as Indiana's Regional Training and Medical Consultation Center [RTMCC]). (Reference: ISDH, TB Case Management, 1999)

Table 2: STATE TUBERCULOSIS CONTROL PROGRAM STAFF ROLES, RESPONSIBILITIES, AND CONTACT INFORMATION

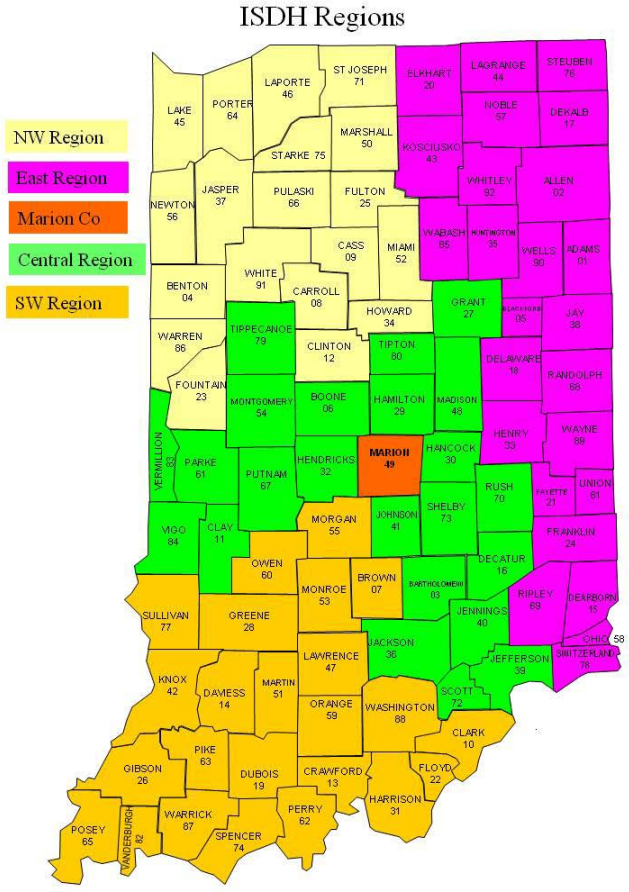
Roles and Responsibilities	**Contact Information**
Director: Oversees cases reported by all county health departments except Marion County. Represents TB/Refugee Health Division, is a liaison with local health departments, CDC and other organizations, contract managements, supports regional TB nurse consultants, and has overall responsibility for the division.	**Sarah Burkholder, BSN, RN, MPH** 317-233-7545 sburkholder@isdh.in.gov
CDC Public Health Advisor: Provides oversight to grants and in conjunction with the director develops policy and protocols and evaluates program effectiveness. Oversees cases reported by Marion County and assists with education/training.	**Shanica Alexander, MPH** 317-234-2885 shalexander@isdh.in.gov

TB Epidemiologist: Supports contact investigation and follow-up, coordinates analysis of genotyping, provides overall surveillance, oversees case counting, and assists with any outbreak investigation.	**Tina Feaster, BS** 317-233-7548 Cfeaster@isdh.in.gov
Program Assistant: Answers phones, maintains all files and patient charts, oversees data entry into the Tuberculosis Information Management System (TIMS) and SWIMSS assists with budgets, grants, etc.	**Lori Mathews** 317-233-7434 lmathews@isdh.in.gov
Refugee Health Coordinator: Oversees refugee and immigrant B1/B2 health screening processes and the Immigrant TB and All Refugee Application Database (ITARA). Coordinates LTBI and TB case medication orders.	**Helen Townsend, BSN, MPH** 317-233-1321 htownsend@isdh.in.gov

Tuberculosis Consultants

Table 3: REGIONAL TB NURSE CONSULTANTS' ROLES, RESPONSIBILITIES, AND CONTACT INFORMATION

Roles and Responsibilities	Contact Information
Regional TB Nurse Consultants: Provide direct guidance to county health departments for reporting of suspects and follow up of confirmed TB cases, makes onsite field visits, identifies and provides educational opportunities for county health staff. The Regional TB Nurse Consultants are the first level of state support and communication.	Northwest Region: **Linda Ramirez** 219-746-1337 Eastern Region: **Joy Hardacre** 765-208-5723 Central Region: **Donna Ewing** 765-208-5162 Southwest Region: **Barbara Weber-White** 812-278-2075



Local Public Health Agencies

Public Health departments must assure that medical management is performed according to American Thoracic Society and CDC standards. In addition, the LHD carries the responsibility to assure that the health of the community is fully protected. This responsibility means that LHDs must assure complete and adequate treatment of all TB patients, isolation of infectious individuals, and identification and treatment of recently infected individuals through complete and timely contact investigation. To this end, every TB patient and suspect should be assigned to a specific LHD employee who will serve as the TB Case Manager.
(Reference: ISDH, TB Case Management, 1999)

TABLE 4: LHDs' roles, Responsibilities and Contact information

Roles and Responsibilities	Contact Information
Local Health Officer: Responsible for TB control and oversight of all TB control activities in the jurisdiction. Assists the TB Case Manager with diagnosis and case management, communication with private physicians, education of physicians in the jurisdiction about TB control issues, and management of difficult cases. Nurse Case Manager: Acts as an agent of the local health officer Coordinates all aspects of TB control – medical – social – public health Social Worker: Access to medical and social services Evaluation for financial assistance Referral to drug / alcohol treatment HIV Counselor or case manager: HIV testing HIV Case Management Out Reach Worker: Direct patient assessment Directly Observed Therapy Other duties as assigned	For a list of all LDHs and their contact information refer to: http://www.in.gov/isdh/23926.htm NOTE: in smaller health departments, the TB Case Manager may have to assume the role of the social worker, HIV Case manager and outreach worker.

Private Medical Providers

Table 5: ROLES AND RESPONSIBILITIES OF PRIVATE MEDICAL PROVIDERS FOR TUBERCULOSIS DIAGNOSIS AND TREATMENT

Roles and Responsibilities

In Indiana, the patient's primary care physician performs the medical management of TB according to current American Thoracic Society and CDC standards. Diagnostic work-up, prescribing of medication, and monitoring for side effects and clinical response are among the responsibilities of the physician. (Reference: ISDH, TB Case Management, 1999)

Pre-treatment Screening procedures:

- Obtain a PA & Lateral chest x-ray
- Place and read a tuberculin skin test using the Mantoux (intradermal) technique or an IGRA
- Obtain 3 consecutive sputum specimens 8-24 hours apart for AFB smear, culture, and drug susceptibility testing
- Test visual acuity and red-green color discrimination
- Lab Work: Liver function tests, CBC w/platelets, serum uric acid, BUN and creatinine
- HIV testing should be performed for all patients
- Perform serologic testing for hepatitis B and C if risk factors are present
- A history of BCG vaccination IS NOT a contraindication for tuberculin skin testing (may wish to use an IGRA)

Treatment and Management:

- Begin treatment with 4 drugs: INH, RIF, PZA, and EMB. Doses should not be divided. Use EMB with caution in children whose vision cannot be monitored (< 5 years of age)
- Directly observed therapy (DOT) is the international standard of care and should be used for all patients.
- For pulmonary TB patients, perform bacteriological monitoring at least monthly until at least 2 consecutive sputum cultures become negative
- Discontinue EMB when susceptibility to INH and RIF is demonstrated
- Discontinue PZA after the 8-week initial phase unless there is resistance to either INH or RIF
- Extend the continuation phase from 4 to 7 months for patients with cavities on the chest x-ray and who are still culture-positive at the end of the 2-month initial phase
- ISDH recommends extending the continuation phase to 7 months for ALL patients with cavitary disease and ANYONE who is still sputum culture-positive at the end of the initial treatment phase
- Evaluate monthly for clinical improvement and medication side effects
- Perform follow-up laboratory tests if necessary
- Continue RIF, PZA and EMB if resistance to INH is demonstrated
- Multi-drug resistant disease (resistant to INH and RIF) requires individualized regimens and prolonged treatment. Seek expert consultation.
- RIF should not be used in HIV-infected patients who are receiving most PIs and NNRTIs. RFB should be used in most instances. Please consult with an expert.
- RFB dosage may need to be adjusted for concurrent administration of some PIs and NNRTIs
- RPT and INH may be used once weekly during the continuation phase for patients who are HIV-negative, have non-cavitary disease, and are sputum smear-negative after 2 months of treatment. This regimen must be used with DOT.
- Never add a single drug to a failing regimen (Reference: ISDH, Treatment and Management of TB Disease, pocket card)

Resources and References

Resources

- CDC. “Framework for Program Evaluation in Public Health” (*MMWR* 1999;48[No. RR-11]). Available at: ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4811.pdf .
- Division of Tuberculosis Elimination. *A Guide to Developing a TB Program Evaluation Plan* (Division of Tuberculosis Elimination Web site; accessed November 1, 2006). Available at: http://www.cdc.gov/tb/Program_Evaluation/default.htm .
- Division of Tuberculosis Elimination. *Understanding the TB Cohort Review Process: Instruction Guide* (Division of Tuberculosis Elimination Web site; accessed November 1, 2006). Available at: http://www.cdc.gov/tb/pubs/cohort/default.htm .
- New Jersey Medical School National Tuberculosis Center. *Planning & Implementing the TB Case Management Conference: A Unique Opportunity for Networking, Peer Support and Ongoing Training* (Newark, NJ; 2004). Available at: http://www.umdnj.edu/globaltb/products/planning&implementing.htm .

References

[1] CDC. Progressing toward tuberculosis elimination in low-incidence areas of the United States: recommendations of the Advisory Council for the Elimination of Tuberculosis. *MMWR* 2005;51(No. RR-5):1.

[2] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):14.

[3] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):15.

Surveillance

CONTENTS

Introduction

Purpose

Use this section to do the following:

- Understand the importance of surveillance in tuberculosis (TB) control and prevention.
- Report suspected and confirmed TB cases.
- Ensure you are using the required data collection forms.
- Understand how the computerized TB registry works.
- Understand how genotyping can assist TB control efforts.

Surveillance—the ongoing systematic collection, analysis, interpretation, and dissemination of data about a health-related event—is a critical component of successful TB control, providing essential information needed to do the following:

1. Determine TB patterns and trends of the disease.
2. Identify sentinel events, such as potential outbreaks, recent transmission, multidrug resistance, and deaths.
3. Identify high-risk populations and settings.
4. Establish priorities for control and prevention activities.
5. Strategically plan use of limited resources.[1]

Surveillance data are also essential for quality-assurance purposes, program evaluation, and measurement of progress toward TB elimination.

State and local TB control programs should have the capability to monitor trends in TB disease and latent TB infection (LTBI) in populations at high risk, in order to detect new patterns of disease and possible outbreaks. Populations at high risk should be identified and targeted for active surveillance and prevention, including targeted testing and treatment of LTBI. The following populations have been demonstrated to be at risk for TB exposure, progression from exposure to disease, or both: children, foreign-born persons, human immunodeficiency virus (HIV)-infected persons, homeless persons, and detainees and prisoners. Surveillance and surveys from throughout the United States indicate that certain epidemiologic patterns of TB are consistently observed among these populations, suggesting that the recommended control measures are generalizable. State and local surveillance data should be analyzed to determine additional high-risk population groups.

In addition to providing the epidemiologic profile of TB in a given jurisdiction, state and local surveillance are essential to national TB surveillance.[2] Data for the national TB surveillance system are reported by state health departments in accordance with standard TB case definition and case report formats. The ***Report of Verified Case of Tuberculosis (RVCT)*** forms are designed to collect information on cases of TB. The CDC's national TB surveillance system publishes epidemiologic analyses of reported TB cases in the United States.[3]

Reporting of new cases is essential for surveillance purposes.[4]

Surveillance in TB Control Activities

Case detection: Case reporting to the jurisdictional public health agency is done for surveillance purposes and for facilitating a treatment plan and case management services.[5]

For more information on case reporting, see the "Reporting Tuberculosis" topic in this section.

Outbreak detection: Surveillance data should be routinely reviewed to determine if there is an increase in the expected number of TB cases, one of the criteria for determining if an outbreak is occurring. For an increase in the expected number of TB cases to be identified, the local epidemiology of TB should be understood. Detection of a TB outbreak in an area in which prevalence is low might depend on a combination of factors, including recognition of sentinel events, routine genotype cluster analysis of surveillance data, and analysis of *Mycobacterium tuberculosis* drug resistance and genotyping patterns.[6] Genotyping data should routinely be reviewed because genotype clusters also may indicate an outbreak. Prompt identification of potential outbreaks and rapid responses are necessary to limit further TB transmission. When an outbreak is identified, short-term investigation activities should follow the same principles as those for the epidemiologic part of the contact investigation (i.e., identifying the infectious period, settings, risk groups, and mode of transmission and conducting contact identification and follow-up). However, long-term activities require continued active surveillance.

For more information see the "Outbreak Investigation" topic in Section 10 - Contact Investigation.

Contact investigation: Collecting, analyzing, interpreting, and disseminating data on contacts and contact investigations are necessary for prioritizing the highest-risk contacts to focus the use of resources, in accordance with national guidelines. Although surveillance of individual contacts to TB cases is not conducted in the United States, the CDC collects aggregate data from state and local TB programs through the *Aggregate Report for Program Evaluation (ARPE).* Routine collection and review of this data can provide the basis for evaluation of contact investigations for TB control programs.[7]

For more information see Section 10 - Contact Investigation.

Targeted testing: Review and interpretation of surveillance data inform targeted testing policies and strategies. 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, in order to prevent subsequent progression to TB disease. Targeted testing and treatment of LTBI are 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.[8]

For more information see Section 3 - Targeted Testing section.

Treatment of LTBI: Surveillance of persons with LTBI does not routinely occur in the United States. However, the CDC is developing a national surveillance system to record adverse events leading to the hospitalization or death of a person under treatment for LTBI. Healthcare providers are encouraged to report such events to the CDC's Division of Tuberculosis Elimination by calling 1-404-639-8401. Surveillance of these events will provide data to evaluate the safety of treatment regimens recommended in current guidelines.[9]

For more information see Section 8 – Treatment of LTBI.

Tuberculosis Classification System

The system for classifying tuberculosis (TB) is based on how the infection and disease develop in the body. Use this classification system to help track the status of TB in your patients and to allow comparison with other reporting areas.

Table 1: TUBERCULOSIS CLASSIFICATION SYSTEM[10]

Class	Type	Description
0	▪ No tuberculosis (TB) exposure ▪ Not infected	▪ No history of exposure ▪ Negative reaction to the tuberculin skin test (TST) or interferon gamma release assay (IGRA)
1	▪ TB exposure ▪ No evidence of infection	▪ History of exposure ▪ Negative reaction to the TST or IGRA
2	▪ TB infection ▪ No disease	▪ Positive reaction to the TST or IGRA ▪ Negative bacteriologic studies (if done) ▪ No clinical, bacteriologic, or radiographic evidence of TB disease
3	▪ TB disease ▪ Clinically active	▪ *Mycobacterium tuberculosis* complex cultured (if this has been done) ▪ Clinical, bacteriologic, or radiographic evidence of current disease
4	▪ TB disease ▪ Not clinically active	▪ History of episode(s) of TB Or ▪ Abnormal but stable radiographic findings ▪ Positive reaction to the TST or IGRA ▪ Negative bacteriologic studies (if done) And ▪ No clinical or radiographic evidence of current disease
5	▪ TB suspect	▪ Diagnosis pending

Source: Adapted from: CDC. Classification system. In: Chapter 2: transmission and pathogenesis. *Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]. Updated November 2001. Available at: http://www.cdc.gov/tb/pubs/corecurr/default.htm . Accessed July 3, 2006.

Reporting Tuberculosis

Detecting and reporting suspected cases of tuberculosis (TB) is the key step in stopping transmission of *Mycobacterium tuberculosis* because it leads to prompt initiation of effective multiple-drug treatment, which rapidly reduces infectiousness. The CDC reports that delays in reporting cases of pulmonary TB are one of the major challenges to successful control of TB.[11] As one of the strategies to achieve the goal of reduction of TB morbidity and mortality, the CDC recommends immediate reporting of a suspected or confirmed case of TB to the jurisdictional health agency.[12]

INDIANA

Indiana State laws and communicable disease reporting rules requires that all confirmed and suspected cases of TB disease must be reported to the LHD by physicians, hospital administers, and laboratories. LHDs are required to forward all reporting information to the ISDH. Information is to include:

- State reporting forms
- Copies of laboratory and radiographic reports
- Copies of appropriate medical evaluation reports, e.g., progress reports, history and physical reports, and hospital discharge summaries
- Autopsy reports and death certificates, if applicable

REFERENCE: TB Case Management, ISDH, 1999

When reporting TB, keep the following definitions in mind:

- **Case:** An episode of TB disease in a person meeting the laboratory or clinical criteria for TB, as defined in the document "Case Definitions for Infectious Conditions Under Public Health Surveillance."[13] These criteria are listed below in Table 2.[14]
- **Suspect:** A person for whom there is a high index of suspicion for active TB (e.g., a known contact to an active TB case or a person with signs or symptoms consistent with TB) who is currently under evaluation for TB disease.[15]
- **Confirmed:** A case that meets the clinical case definition or is laboratory confirmed, as described below in Table 2.[16]

Table 2: CASE DEFINITIONS[17]

Clinical Case Definition	Laboratory Criteria for Diagnosis
A clinical case meets all of the following criteria: ▪ A positive tuberculin skin test ▪ Other signs and symptoms compatible with tuberculosis (e.g., an abnormal, unstable [i.e., worsening or improving] chest radiograph, or clinical evidence of current disease) ▪ Treatment with 2 or more antituberculosis medications ▪ Completed diagnostic evaluation	A case is laboratory confirmed when it meets one of the following criteria: ▪ Isolation of *Mycobacterium tuberculosis from* a clinical specimen* ▪ Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification (NAA) test† ▪ Demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained

* Use of rapid identification techniques for *M. tuberculosis* (e.g., deoxyribonucleic acid [DNA] probes and mycolic acids high-pressure liquid chromatography performed on a culture from a clinical specimen) is acceptable under this criterion.

† NAA tests must be accompanied by culture for mycobacteria species. However, for surveillance purposes, the CDC will accept results obtained from NAA tests approved by the Food and Drug Administration and used according to the approved product labeling on the package insert.

Source: Adapted from: CDC. Case definitions for infectious conditions under public health surveillance. *MMWR* 1997;46(No. RR-10):40–41.

Suspect pulmonary TB and initiate a diagnostic investigation when the historic features, signs, symptoms, and radiographic findings of TB are evident among adults. TB should be suspected in any patient who has a persistent cough for over two to three weeks, or other indicative signs and symptoms.[18]

For more information on suspected pulmonary TB, see Section 5 - Diagnosis of TB Disease.

Mandatory and timely case reporting from community sources (e.g., providers, laboratories, and hospitals) should be enforced and evaluated regularly. Reporting enables the TB control program to take action at local, state, and national levels and to understand the magnitude and distribution of the TB problem.[19]

Prompt reporting (prior to culture confirmation) allows ISDH and the LHD to do the following quickly:

- Verify diagnosis.
- Assign a case manager and coordinate treatment.
- Determine if an outbreak is occurring.
- Control the spread of TB.[20]

Failure to report cases threatens public health because it may result in the adverse outcome of a patient's treatment or delayed contact investigation of an infectious case.[21]

Reporting gives physicians access to resources provided by the LHD. Private physicians are encouraged to work collaboratively with their LHD in the management of their TB cases and contacts. All providers who undertake evaluation and treatment of patients with TB must recognize that, not only are they delivering care to an individual, they are assuming an important public health function that entails a high level of responsibility to the community, as well as to the individual patient. The following services may be available, through the LHD, to assist physicians with managing their TB cases:
(refer to page 2.8 for link to LHD contact information)

- Epidemiologic investigation, including identification and examination of contacts
- Antituberculosis medications
- LHD laboratory services for sputum specimens
- Consultation (with the ISDH TB Medical Consultant, and when necessary, with the New Jersey Medical School Global Tuberculosis Institute [designated by the CDC as Indiana's RTMCC]).

Reporting Suspected or Confirmed Cases of Tuberculosis in Indiana to the LHD

Data collection and reporting on TB should be done in accordance with Indiana laws and regulations. Reporting and recordkeeping requirements are covered in this section.

Refer to Indiana laws and rules on TB located in Section 1 – Introduction.

For roles and responsibilities, refer to the "Roles, Responsibilities, and Contact Information" topic in Section 1 - Introduction.

For more information on confidentiality and the Health Insurance Portability and Accountability Act (HIPAA), see Section 13 – Confidentiality.

Healthcare providers and laboratories should report suspected or confirmed cases of TB using the information in Table 3 (next page).

Prior approval from a patient is not required before releasing medical or epidemiological information to the LHD or ISDH. All information obtained under this rule, whether from patient records or other sources, is confidential as specified in the *Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories*, 12-12-2008.

Table 3: WHO, WHAT, WHEN HOW TO REPORT TUBERCULOSIS

What Condition/ Test Result	Who Reports	When to Report	How to Report
Confirmed (Class 3) or suspected cases (Class 5) of TB disease Confirmation by laboratory tests is not required. This includes pulmonary and extrapulmonary cases.	▪ Physicians ▪ Hospitals ▪ Anyone providing treatment to the confirmed or suspected case Note: The attending physician or other healthcare provider must report even if the laboratory is also reporting the test results.	Report within 72 hours of first knowledge or suspicion of the diagnosis.	Report to the local health officer at the LHD by: telephone, electronic data transfer, or other confidential means of communication. The official "Report of Tuberculosis" form and instructions for completion are available online at http://www.in.gov/isdh/19682.htm See also page 2.10 For a list of LHDs and their contact information refer to: http://www.in.gov/isdh/23926.htm
Sputum smears positive for acid-fast bacilli (AFB) Cultures growing AFB or cultures that are demonstrated positive for *Mycobacterium tuberculosis* complex* Nucleic acid amplification tests/DNA probes positive for *M. tuberculosis* complex	All laboratories that perform TB testing In-state laboratories that send specimens for out-of-state testing Note: Laboratories must report even if the attending physician or other healthcare provider is also reporting.	Report at least weekly In addition: Laboratories shall submit all isolates of M. tb to the ISDH microbiology laboratory for further evaluation within five (5) business days of isolation. Note: Laboratories submitting a specimen, portion of a specimen, or culture to the ISDH microbiology lab for confirmation, genotyping, or other approved service, are not excluded from reporting requirements.	Report to ISDH by: telephone, electronic data transfer, or other confidential means of communication. Instead of electronic data transfer or reporting by telephone, a laboratory may submit a legible copy of the laboratory report, provided that the information specified contains the necessary information required in the *Communicable Disease Reporting Rule for Physicians, Hospitals and Laboratories* http://www.in.gov/isdh/files/comm_dis_rule(1).pdf See also page 2.10 Laboratories may also report to the Local Health Officer at the LHD, but any such local report shall be in addition to reporting to ISDH. HIV serologic results of tests performed anonymously in conjunction with the operation of a counseling and testing site registered with ISDH shall not be identified by the name of the patient, but by a numeric identifier code.

* Note: This includes both the preliminary report of cultures growing AFB without confirmation of *M. tuberculosis* complex and the final report of

What Condition/ Test Result	Who Reports	When to Report	How to Report
cultures that are demonstrated to be positive for *M. tuberculosis* complex.			

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The ***Report of Tuberculosis*** shall be made to the Local Health Officer in whose jurisdiction the patient normally resides or, in the absence of such information, in whose jurisdiction the patient was examined at the time of the diagnosis was made or suspected.

If the patient is a resident of a different jurisdiction, the LHD receiving the report shall forward the report to the LHD where the patient resides.

If the patient is not a resident of Indiana, the report shall be forwarded to ISDH.

Healthcare Providers should report on confirmed or suspected cases of TB on the ***Report of Tuberculosis.*** For required topics on the on the ***Report of Tuberculosis*** see next page. For ***Report of Tuberculosis*** and instructions for completing the ***Report*** (see page 2.13).

Required topics on the Indiana *Report of Tuberculosis* (see ***Report*** for full details)

1. Patient name
2. Address
3. Date of birth
4. At time of report (alive/dead)
5. Age
6. Sex
7. Occupation (within past 12 months
8. Race
9. Ethnic origin
10. Born in the U.S.?
11. Primary reason evaluated for TB disease
12. Reported by (agency, telephone, attending physician, telephone)
13. Skin test/IGRA and TB disease history
14. Alcohol and drug use
15. Additional Risk factors
16. Has the patient been homeless within the past year?
17. Resident of LTC facility at the time of diagnosis?
18. Resident of correctional facility at time of diagnosis?
19. Any history of incarceration?
20. Clinical symptoms (check list)
21. Radiology (Chest x-ray, Chest CT)
22. Laboratory Specimens (sputum, culture, other specimens)
23. Disease site(s)
24. Initial drug regimen (drugs, dose, patient weight)
25. Date therapy started (if requesting drugs through ISDH submit prescription and drug request form (see ***Request for TB Drugs***, page 2.13)
26. Infectious Period (beginning 3 months prior to start of symptoms).

Laboratories

Laboratories should report, at a minimum, the following information on test results. For detailed information see the ***Communicable Disease Reporting Rule for Physicians, Hospitals and Laboratories*** in Section 1 – Information.

Reporting Laboratory

- Name
- Address
- Telephone number
- CLIA ID number

of the Reporting Laboratory

- Name
- Address
- Telephone number

of the attending physician; hospital; clinic; or other specimen submitter

- Date of report
- Name, date and results of test performed
- The lab's normal limits for the test
- The lab's interpretation of the test results
- The lab's accession number or other numeric identifier
- The name, address, and date of birth (or age if date of birth is not available) of the person from whom the specimen was obtained

Required TB Reporting Forms for Indiana

LHDs complete and submit the reports 1 through 5 listed below to the ISDH TB/Refugee Health Division.

The following forms are available online. Click on form name to go directly to form OR view all TB Reporting Forms at http://www.in.gov/isdh/19682.htm

1) Report of Treatment for Latent TB Infection :

Submit only for persons being treated for LTBI who are requesting drugs through ISDH.

Submit with prescriptions and chest x-ray report to the LHD.

DO NOT use to report verified or suspected case of TB Disease

2) Report of Tuberculosis :

Submit for every suspected and verified case of TB disease.

Must be reported to the Local Health Officer within 72 hours (from probable diagnosis).

DO NOT use this form for reporting person with LTBI ("reactors").

Further instructions on completing the form are included with the online form.

3) TB Contact Investigation Report :

The ***TB Contact Investigation "Summary"*** Report is due in 3 stages:

1) 3 weeks after the index case has been reported / after the first round of TST or IGRA.
2) 12 weeks after the index case has been reported / after the second round of TST or IGRA.
3) 12 months after the index case has been reported.

Further instructions on completing the form are included with the online form.

4) Request for TB Drugs :

NOTE: this form is for LHD use only for Isoniazid, Rifampin, Pyrazinamide, Ethambutol, Pyridoxine (Vitamin B6), Rifabutin, Levofloxacin, and other second line drugs require prior approval).

Submit this form with the appropriate report form and copy of prescriptions.

Further instructions on completing the form and the appropriate report (Report of TB or Report of Treatment of LTBI) to be filed are included on the online form.

5) Monthly TB Follow Up Report

The monthly ***TB Follow Up Report*** should be completed, signed by the Case Manager, and faxed to ISDH after each 30 days of treatment.

Further instructions on completing the form, including the fax number, are included with the online form.

Hospital Reimbursement

TB Hospital Reimbursement Claim (for patients with no source of payment).

If a patient being evaluated and treated for TB has no source of payment for services rendered, the hospital may apply for reimbursement from ISDH under the Hospital Tuberculosis Fund.

Claims shall be submitted no later than three (3) months after patient discharge from the applying hospital. If there are insufficient funds to pay the claim, all paperwork will be returned to the submitter with an explanation to that effect.

Submit page 1 and 2 – INCLUDE all supporting documents. Claims cannot be processed without the attending physician's original signature.

Click on form name above to go directly to form OR view all TB Reporting Forms at http://www.in.gov/isdh/19682.htm. Further instructions on the criteria for submitting a claim and completing the form are included with the online form.

Admissions of Patients with Confirmed or Suspected TB to LTC

This specific waiver program will allow the admission of patients with confirmed or suspected TB or patients under treatment for TB to licensed long-term facilities which meet the specific criteria detailed in the **Guidelines for Preventing Transmission of *Mycobacterium tuberculosis* in Health Care settings**, **2005** – refer to Section 1 – Introduction for web address and list of errata. No waiver will be considered by the ISDH Division of Long Term Care unless there is prior written assurance by the Attending Physician, Administrator and Medical Director of the Long Term Care facility that these guidelines have been met. These assurances should be provided to the ISDH Division of Long Term Care and will be kept on file, prior to the admission of any patient under the waiver program.

Each waiver will be specific for only one person, only for facilities which have proper assurance on file with the ISDH Division of Long Term Care, for a period not to exceed one (1) year.

Section 1 of the ***Tuberculosis Waiver Request*** form is to be completed by requestor and submitted to the ISDH Division of Long Term Care to the attention of the Program Director-Provider Services. The initial request for a waiver may be verbal, and permission to admit may be given verbally by the Director or his/her designee. Written confirmation must be expeditiously initiated by the facility administrator on the ***Tuberculosis Waiver Request*** form. This form must be signed by the administrator, medical director and attending physician.

Section 2 of the ***Tuberculosis Waiver Request*** form is to be completed by Division of Long Term Care.

A copy of the form will be returned to the facility and the original will be retained by the Division of Long Term Care in a confidential file.

The Tuberculosis Waiver Request form is available online. Click on form name to go directly to form OR view all TB Reporting Forms at http://www.in.gov/isdh/19682.htm.

Reference: http://www.in.gov/isdh/files/patients-tb.pdf see also Indiana Laws and Rules - 410 IAC 16.2-3.1-18 in Section 1 – Introduction.

Report of Verified Case of Tuberculosis (RVCT)

Refer to your ***RVCT Form Completion Instructions*** for details on completing the form.

The Report of Verified Case of Tuberculosis (RVCT) is the national TB surveillance form. Data are collected by state and local TB programs and submitted electronically to the Centers for Disease Control and Prevention (CDC), Division of Tuberculosis Elimination (DTBE). These data are used to monitor national TB trends, identify priority needs, and create the DTBE Annual Surveillance Report.

Data obtained from RVCT forms are entered into the Statewide Information Management and Surveillance System (SWIMSS) and then transferred electronically to the CDC. Completed RVCT forms should never be sent to the CDC. Forms should be stored in a secure (locked) location designated by each state or LDH. (*RVCT Form Completion Instructions January 2003)*

Note: A verified case of TB for public health surveillance may be laboratory confirmed or, in the absence of laboratory confirmation, meet the clinical case definition as defined in the CDC document "Case Definitions for Infectious Conditions Under Public Health Surveillance." The criteria for determining a laboratory confirmed case are

1. isolation of M. tuberculosis complex from a clinical specimen;
2. demonstration of M. tuberculosis from a clinical specimen by nucleic acid amplification test; or
3. demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained.

A clinically verified case of TB meets all of the following criteria:

1. a positive tuberculin skin test;
2. signs and symptoms compatible with current TB disease, such as an abnormal, unstable (worsening or improving) chest x-ray, or clinical evidence of current disease;
3. current treatment with two or more antituberculosis medications; and
4. a completed diagnostic evaluation.

Reference: CDC Fact Sheet, The Revised Report of Verified Case of Tuberculosis, May 2008, http://www.cdc.gov/tb/publications/factsheets/statistics/rvct.htm

Data Collection

Computerized Tuberculosis Registry

To carry out mandatory community public health responsibilities, the ISDH TB Program uses a computerized record system (case registry) called SWIMSS (State Wide Investigating Monitoring Surveillance System) to maintain up-to-date information on all current clinically active and suspected TB cases in the community.[22] TB SWIMSS will serve as a real time web based data entry application used by ISDH and LHDs for surveillance, contact investigations and case management of all TB cases.

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The State TB Registry is maintained for four key reasons:

1. As required by law, the ISDH tabulates all case reports of TB and determines the incidence and distribution of disease in Indiana; the department is responsible for developing policies and other measures for controlling the disease based on disease incidence.

2. A centralized repository of information is maintained so aggregate and cumulative information can be reported to the CDC. This information is used, in part, to determine needs for federal funding and assistance.

3. Case management oversight. Information in the TB Case Registry is used to indentify case-specific problems so that they can be corrected in a timely fashion.

4. Program evaluation. Using a set of case management quality indicators, the quality of TB control efforts in the state of Indiana can be evaluated on an ongoing basis. Evaluation is used to identify areas where training and education should be offered to LHDs.

Reference: Tuberculosis Case management, Quality Assurance Protocol, 1999, ISDH.

The TB case registry should ensure that laboratory data, including all initial diagnostic tests, are promptly reported, if applicable, to the healthcare provider and LHD. Follow-up tests, including data on sputum culture conversion and drug susceptibility testing of clinical isolates, should also be promptly reported so any needed modifications in management can be made. Aggregate program data should be analyzed, interpreted, and made available to the healthcare community and to community groups and organizations with specific interests in public health.

Genotyping

Genotyping is a useful tool for studying the pathogenesis, epidemiology, and transmission of *Mycobacterium tuberculosis. M. tuberculosis* genotyping refers to laboratory procedures developed to identify *M. tuberculosis* isolates that are identical in specific parts of the genome (of similar strain types).

Genotyping is based on an analysis of deoxyribonucleic acid (DNA). Mycobacteria reproduce by binary fission, which means that in almost all cases each new bacillus has identical DNA, just as human identical twins are genetically identical to each other. However, changes in the DNA occur spontaneously at low frequency. Over time, these changes, known as DNA mutations, have accumulated to produce the diversity of *M. tuberculosis* strains currently circulating in the world.

The diversity of strain provides a means to identify instances of recent transmission of tuberculosis (TB) as well as the chains of transmission that occur among persons with TB. This diversity also helps to elucidate the patterns and dynamics of TB transmission. When a person with TB improves but then becomes ill again, this diversity can differentiate reactivation with the same strain of *M. tuberculosis* from reinfection with a different strain. Genotyping can also be used to identify false-positive cultures. Advances in DNA analytic methods have made it possible for TB programs to obtain rapid and reliable genotyping results.

The addition of genotype information to the pool of information generated by surveillance data and data collected through epidemiologic investigation allow confirmation of suspected transmission. A potential outbreak should be suspected whenever there is more than one case of TB whose isolate has the same genotype (genotype cluster). Further investigation that includes review of surveillance data, chart review, and reinterview of TB cases may refute or confirm the epidemiologic connection between more than one TB case. In some instances, a genotype cluster reflects a false-positive culture that may be a result of laboratory cross-contamination. Routine review of genotyping data, along with epidemiologic, clinical, and laboratory data, may identify patients who are wrongly classified as TB patients and should be further investigated.

The ISDH TB Program reviews genotyping data to check for any matches. Upon identification of a match, the ISDH TB Epidemiologist contacts the LHD managing the case to discuss what further steps should be taken.

For more information on Genotyping refer to the CDC “TB Genotyping Fact Sheet”, “Laboratory Information” and “Guide to the Application of Genotyping to TB Prevention and Control” available at http://www.cdc.gov/tb/programs/genotyping/default.htm

All positive *M. tb* cultures are to be sent to the ISDH microbiology laboratory for referral to the assigned national genotyping laboratory. For information on how to request genotyping tests, see Section 11 - Laboratory Services.

Dissemination and Evaluation

Dissemination

Tuberculosis (TB) surveillance data should be disseminated periodically to healthcare providers, health agencies, and the public through multiple channels including health alerts, reports, summaries, and presentations.

To view Indiana State Department of Health's annual TB reports, go to http://www.in.gov/isdh/19668.htm

Evaluation

The purpose of evaluating public health surveillance systems is to ensure that problems of public health importance are being monitored efficiently and effectively. TB surveillance systems should be evaluated periodically, and the evaluation should include recommendations for improving quality, efficiency, and usefulness. Evaluation of a public health surveillance system focuses on how well the system operates to meet its purpose and objectives.

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Targeted Testing for Latent Tuberculosis Infection

CONTENTS

Introduction

Purpose

In the 2005 guideline "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, Centers for Disease Control and Prevention" (CDC and IDSA), one of the recommended strategies to achieve the goal of reduction of tuberculosis (TB) morbidity and mortality is to identify persons with LTBI who are at risk for progression to TB disease and to treat them with an effective drug regimen.[1]

For information on treatment, refer to Section 6 - Treatment of Tuberculosis Disease and Section 8 - Treatment of LTBI.

Reducing LTBI in high-risk populations is an important strategy to control TB. Targeted testing for LTBI is a strategic component of TB control that identifies persons who are at high risk for developing TB and who would benefit by treatment of LTBI, if detected. Persons with increased risk for developing TB include those who have had recent infection with *M. tb* and those who have clinical conditions that are associated with an increased risk for progression of LTBI to active TB.[2]

Policy

- Persons who show or report signs and symptoms of TB should be evaluated for TB disease (see Section 5 - Diagnosis of TB Disease) and reported as suspected cases of TB (see Section 2 – Surveillance, "Reporting Tuberculosis").
- Contacts should be evaluated (see Section 10 - Contact Investigation).
- Targeted testing for LTBI should be conducted only among persons in groups with identified risk factors for LTBI and/or progression to TB disease.
- For the list of High-Risk Groups" see Section 7 - Diagnosis of LTBI.

For roles and responsibilities, refer to the "Roles, Responsibilities, and Contact Information" topic in Section 1 - Introduction.

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There are laws that require testing of individuals in special circumstances (e.g. school bus drivers, foreign born students residing on college campuses, daycare workers, etc.) refer to Section 1 – Introduction for state laws that mandate TB testing of certain groups.

For guidelines on TB skin testing of high risk groups see next page.

When to Conduct Targeted Testing

INDIANA: GUIDELINES FOR TB SCREENING of High Risk Groups

NOTE: Screening can include a TST or an IGRA when applicable.

Why screen for tuberculosis?

The goal of screening programs is to identify persons with latent TB infection (LTBI) who are at high risk for progressing to active disease and would benefit from treatment, or to find persons who have clinical TB disease and need treatment.

Who should be screened for TB?

The following groups should be screened with the tuberculin skin test (or the IGRA when applicable):

- Close contacts of persons known or suspected to have TB, i.e. those sharing the same household or other enclosed environments
- Persons infected with HIV
- Persons who have certain clinical conditions known to increase the risk for disease if infection occurs
- Persons with a history of inadequately treated TB
- Persons who inject illicit drugs
- Residents and employees of high-risk congregate settings (i.e. nursing homes, correctional facilities, mental institutions, other long-term care facilities, and homeless shelters)
- Health-care workers who serve high-risk clients
- Persons born outside the U.S. and Canada, including children. Prior vaccination with BCG is not a contraindication for testing, nor does it affect the treatment protocol.
- Some medically underserved, low-income populations, including high-risk racial and ethnic groups
- Infants, children, and adolescents exposed to adults in high-risk categories
- Locally defined high prevalence groups (substance abusers, migrant workers, the homeless)

Who should not be routinely screened with the tuberculin skin test?

The following are examples of groups who do not need to be screened routinely for TB unless one or more of the above risk factors are present:

- School children and day care attendees
- Foreign-born persons living in the U.S. for more than 5 years who have been screened previously
- Pregnant women

- Food handlers (TB is not a food-borne illness, and is not transmitted by cooking or eating utensils, dishes, or other inanimate objects)

Why limit tuberculin screening to just high-risk individuals?

- Targeted screening allows resources to be directed at the two top priorities of TB control: treatment of active TB cases and conducting thorough contact investigations.
- The tuberculin skin test is an important detection method but is not 100% specific, for this reason it is a better test when its use is restricted to high-risk individuals. There are fewer false positives, which means less money is spent on unnecessary diagnostic evaluation and treatment.
- School-based screening for TB among children was started in the 1950's when infection and disease rates were higher than at the present time.
- Broad-based school testing involves screening large numbers of low-risk children and the majority of children who have TB are preschool age.
- Generalized screening of school children as a public health measure is not a cost-effective method of detecting or preventing cases of childhood TB and should be discontinued.

In summary, efficient screening programs are limited to high-risk persons who would benefit from treatment for LTBI.

This statement was approved by the ISDH TB Medical Advisory Board

Reference: ISDH **Guidelines for TB Skin Test Screening and Treatment of LTBI** at http://www.in.gov/isdh/19692.htm

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Review the **Guidelines and Recommendations on the Use of QuantiFERON® – TB Gold for the Diagnosis of Active and Latent Tuberculosis Infection,** approved by the ISDH Tuberculosis Medical Advisory Board on 7-2007 at http://www.in.gov/isdh/files/QuantiFeronGoldGuidelines.pdf

Refer also to: **CDC, Updated Guidelines for Using Interferon Gamma Release Assays to detect *Mycobacterium tuberculosis* Infection, 2010** at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_e

Approaches to Increasing Targeted Testing and Treatment of Latent Tuberculosis Infection

The Centers for Disease Control and Prevention (CDC) describes two approaches to increasing targeted testing and treatment of LTBI. To plan and implement programs for targeted testing and treatment of LTBI, follow the recommended approaches outlined below.[3]

One approach is to promote clinic-based testing of persons who are under a clinician's care for a medical condition (e.g., human immunodeficiency virus [HIV] infection, diabetes mellitus, treatment with tumor necrosis factor blocker medications, etc.) that also confers a risk for acquiring TB. This approach depends on a person's risk profile for TB.[4]

The other approach is to establish specific programs that target a subpopulation of persons who have a high prevalence of LTBI or who are at high risk for acquiring TB disease if they have LTBI, or both. This approach requires identifying the subpopulations or areas with high TB risk through epidemiologic analysis and profiling.[5]

For information on the system for prioritizing persons for targeted testing, refer to "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America" (*MMWR* 2005;54[No. RR-12]:40–42) at http://www.cdc.gov/mmwr/PDF/rr/rr5412.pdf .

For assistance in planning targeted testing, contact your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.

Screening for Latent Tuberculosis Infection in Facilities

Screening for LTBI should be conducted based upon each facility's risk for transmission of *Mycobacterium tuberculosis* (i.e., low risk, medium risk, or potential for ongoing transmission),[6] as determined in its TB risk assessment (both the initial baseline assessment and periodic reassessments).

Risk assessment protocols and elements are outlined in the CDC's "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings, 2005" (*MMWR* 2005;54[No. RR-17]) at http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf . (for Errata refer to Section 1 – Introduction page 1.57). See also Section 15 – Infection Control

Screening determines if a person should be evaluated for LTBI or TB disease by asking questions to gather information about whether the person has signs or symptoms of TB

disease, belongs to a group at high risk for LTBI or (if infected) for progression to TB disease, or has a prior positive tuberculin skin test (TST).

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B Notifications

CONTENTS

Introduction

Purpose

Use this section to do the following:

- Follow up on B1, B2, and B3 notifications.
- Evaluate and treat immigrants, refugees and derivative asylees with B1, B2, and B3 notifications (See Table 1 for definitions).

B1/B2/B3 notifications are sent by the Centers for Disease Control and Prevention (CDC) to the Indiana Tuberculosis (TB) Control Program as follow-up to overseas screening mandated by United States immigration law. The CDC and the Advisory Council for the Elimination of Tuberculosis (ACET) recommend screening high-risk populations for TB, including recent arrivals from areas of the world with a high prevalence of TB. Therefore, screening of foreign-born persons is a public health priority.[1]

On the basis of its very high success rate of detecting TB cases, follow-up evaluation of immigrants, refugees and derivative asylees with Class B notification status should be given highest priority by all TB control programs.[2] Immigrants, refugees, and derivative asylees with Class B notification status are also a high-priority subpopulation for screening for LTBI. [2]

The purpose of mandated screening is to deny entry to persons who have either communicable diseases of public health import or physical or mental disorders associated with harmful behavior, abuse drugs or are addicted to drugs, or are likely to become wards of the state.[1]

Pre-Arrival Medical Screening for Tuberculosis

Not all foreign-born persons who enter the United States go through the same official channels or through the screening process.[2] Persons entering in the nonimmigrant category do not require pre-entry screening, but as a condition of entry, persons migrating as immigrants, refugees, and derivative asylees are required to be screened outside the United States for diseases of public health significance, including TB.[3,4] Applicants for immigration who plan to relocate permanently to the United States are required to have a medical evaluation prior to entering the country. **NOTE: Children from other countries who are being adopted by US citizens are applying for US entry as immigrants – therefore, must undergo the required immigrant TB examination according to the CDC Technical Instructions.**

For a summary of which groups of foreign-born persons are screened, refer to Table 1: **Numbers of Foreign-Born Persons Who Entered the United States, by Immigration Category, 2002**.

Table 1: NUMBERS OF FOREIGN-BORN PERSONS WHO ENTERED THE UNITED STATES, BY IMMIGRATION CATEGORY, 2002[5,6]

Category	Number	Percentage of Total	Screening Required?
Immigrants are defined by the Office of Immigration Statistics (OIS) as persons legally admitted to the United States as permanent residents.	384,000	1.38%	Yes
Refugees and asylees, as defined by OIS, are persons admitted to the United States because they are unable or unwilling to return to their country of nationality due to persecution or a well-founded fear of persecution. Refugees apply for admission at an overseas facility and enter the United States only after their application is granted; asylees apply for admission when already in the United States or at a point of entry. Asylees are not medically screened before entry into the United States. However, derivative asylees are screened before they enter into the United States.	132,000	0.46%	Yes
Nonimmigrants are aliens granted temporary entry to the United States for a specific purpose (the most common visa classifications for nonimmigrants are visitors for pleasure, visitors for business, temporary workers, and students).	27,907,000	98.18%	No
The foreign-born population, as defined by the Census Bureau, refers to all residents of the United States who were not US citizens at birth, regardless of their current legal or citizenship status.	28,423,000	100%	See above
Unauthorized immigrants (also referred to as illegal or undocumented immigrants) are foreign citizens illegally residing in the United States. They include both those who entered without inspection and those who violated the terms of a temporary admission without having gained either permanent resident status or temporary protection from removal.[7]			

Sources: Congress of the United States, Congressional Budget Office. *A Description of the Immigrant Population*. Washington, DC: Congressional Budget Office; November 2004; and ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):46.

1991 verses 2007 Technical Instructions

The TB Notification System continues follow-up of persons with A and B classifications after their arrival in the US. Immigrants with a Class A or Class B status are identified at ports of entry to the US by the US Citizenship and Immigration Services (USCIS) and reported to CDC's Division of Global Migration and Quarantine (DGMQ). (NOTE: the A "Waiver" classification is described in Table 3, but as very few persons with A Waivers enter the US, the Class A designation is not covered in detail in this document).

The DGMQ notifies the ISDH TB Control Program of refugees, immigrants and derivative asylees with TB classifications who are moving to their jurisdiction and need follow-up evaluations.

At the present time, there are two (2) CDC versions of technical instructions for panel physicians that are being followed:

- ***2007 Technical Instructions for Tuberculosis Screening and Treatment for Panel Physicians***
  http://www.cdc.gov/ncidod/dq/panel_2007.htm
  referred to in the remainder of this section as the *2007 Technical Instructions*

- ***1991 Technical Instructions for Panel Physicians***
  http://www.cdc.gov/ncidod/dq/panel_1991.htm
  referred to in the remainder of this section as the *1991 Technical Instructions*

Why are there different sets of Technical Instructions? The original *1991 Technical Instructions* were based on the best screening tests and treatment at that time. The *2007 Technical Instructions* were updated to reduce the chance of bringing TB into the US and improve the health of immigrants and refugees.

What improvements were added to the *2007 Technical Instructions*? The 2007 instructions revise the definitions of B1/B2 classifications, add a B3 classification for contacts, and strengthen TB screening components. Other significant changes include:

- TSTs for applicants < 15 years of age in countries with a WHO estimated TB incidence rate > 20 per 100,000.
- CXR for all applicants < 15 years of age with TST $\geq$ 5 mm. Mycobacterial cultures for applicants with CXRs suggestive of TB disease.
- Treatment under a DOT program.
- Completion of treatment prior to immigrating the US, according to ATS / CDC / IDSA guidelines.

- New TB classifications for all applicants with suspected LTBI and for contacts for cases of TB disease.

The guideline for diagnosis of LTBI is still a TST of ≥ 10 mm of induration. However, the trigger for a CXR for persons being evaluated under the ***2007 Technical Instructions*** is 5 mm of induration.

How are the *2007 Technical Instructions* being implemented? The CDC is working to apply the *2007 Technical Instructions* to all countries. The guidelines are being implemented in a few countries each year. The order of implementation is based on a country's: number of immigrants coming to US, number of refugees resettling to US, health care resources, TB rates, AND the rate of TB in immigrant groups in the US.

How do you know which set of Technical Instructions is being used? Immigrants coming from several countries with high rates of TB are being screened according to the CDC *2007 Technical Instructions* (see Table 2). All other applicants for US immigration are being screened according to the *1991 Technical Instructions*.

For a comparison of the Classification Systems in the *1991 and 2007 Technical Instructions* see Table 3.

Table 2: Applicants for US Immigration being screened with *2007 Technical Instructions**

Country	Population	Start date
Botswana	All applicants	March 3, 2008
China	All applicants	July 1, 2009
Dominican Republic	All applicants	February 2, 2009
Ethiopia	Refugees (Eritreans)	March 10, 2009
	All applicants	April 1, 2009
Hong Kong SAR	All applicants	November 3, 2008
Japan	All applicants	June 1, 2009
Jordan	All applicants	April 5, 2009
Kenya	Refugees (includes Ethiopians, Somalis, and Sudanese)	January 1, 2008
	All applicants	April 10, 2009
Lesotho	All applicants	March 3, 2008
Macau SAR	All applicants	November 3, 2008
Malaysia	Refugees (Burmese)	January 1, 2009
Mexico	All applicants	October 1, 2007
Mozambique	All applicants	March 3, 2008
Namibia	All applicants	March 3, 2008
Nepal	Refugees (Bhutanese)	December 13, 2007
Philippines	All applicants	October 1, 2007
South Africa	All applicants	March 3, 2008
Swaziland	All applicants	March 3, 2008
Taiwan	All applicants	April 1, 2009
Tanzania	Refugees (Burundian)	January 1, 2008
	All applicants	June 5, 2008
Thailand	Refugees (includes Burmese and Hmong refugees)	April 9, 2007
Turkey	All applicants	February 4, 2008
Uganda	All applicants	March 2, 2009
Vietnam	All applicants	February 1, 2008

*NOTE: This table changes frequently. For most current version, go to http://www.cdc.gov/ncidod/dq/panel_2007.htm

Table 3: Classification Systems for Immigrants & Refugees: TB Notification Program

Classification Systems: ***1991 Technical Instructions*** compared to **2007 Technical Instructions** *(applicants can be assigned 1 or more classifications)*		
Category	**1991**	**2007**
No TB classification	Applicants with normal TB screening examinations	Applicants with normal TB screening examinations
Class A	"TB, infectious" Abnormal CXR and 1 or more positive sputum smears. May not enter the U.S. unless started on anti-TB therapy with sputum smears converted to negative **AND** apply for an A Waiver signed by the local health jurisdiction at their intended U.S. destination OR complete TB therapy overseas.	Applicants who have TB disease diagnosed (sputum smear positive or culture positive) and require treatment overseas but who have been granted a waiver to travel prior to the completion of therapy. (*Petitions for an A Waiver are reviewed by the Department of Homeland Security on an individual basis & considered in situations with extenuating medical circumstances. Regardless of their TB classification, applicants who have HIV infection will have to obtain an A Waiver for their HIV condition).*
Class B1 – Pulmonary	"TB clinically active, not infectious" Abnormal CXR and sputum smears negative. *Instructed to voluntarily report to the local health jurisdiction in the U.S. for further medical evaluation within 30 days of arrival	No Treatment: Applicants who have medical history, physical exam, HIV, or CXR findings suggestive of pulmonary TB but have negative AFB sputum smears and cultures and are not diagnosed with TB or can wait to have TB treatment started after immigration. Completed treatment: Applicants who were diagnosed with pulmonary TB and successfully completed directly observed therapy (DOT) prior to immigration.
Class B1 – Extrapulmonary	"Extrapulmonary TB" Radiographic or other evidence of extrapulmonary TB, clinically active. *Same as above	Applicants with evidence of extrapulmonary TB. *(site of infection to be documented)*
Class B2	TB, not clinically active Abnormal CXR suggestive of TB, not clinically active. No sputum smears required	LTBI Evaluation: Applicants who have a TST $\geq$ 10 mm but who otherwise have a negative evaluation for TB. (*size of TST reaction & medication(s) to be documented.*
Class B 3	"Consistent with TB, old or healed" Abnormal CXR; only abnormality is calcified hilar lymph node, primary complex, or granuloma. No sputum smears required	Contact Evaluation: Applicants who are a contact of a know TB case. *(size of TST reaction, source case, name, alien #, relationship to contact, and type of TB to be documented)*
Detailed comparison 1991/2007 Tech. Instructions http://www.cdc.gov/ncidod/dq/pdf/comparison_1991_2007_tb_ti.pdf		

Follow-up of Class B TB Arrivals

Newly arrived refugees, immigrants and derivative asylees with Class B1/B2/B3 TB will receive thorough and timely TB evaluations and appropriate treatment to ensure prompt detection of TB disease and prevention of future cases.[8]

Persons with a Class A waiver are required to report to the LHD for evaluation or risk deportation. For persons with Class B1/B2/B3 status, however, the stipulated evaluation visits to the LHD are voluntary.

Division of Global Migration and Quarantine Forms

DS forms are Department of State forms used to collect the medical screening results from the overseas examinations. The panel physicians complete these forms overseas, and the immigrant carries copies to the US. After processing the documents of the immigrant at the Port of Entry, the CDC Quarantine Station sends the DS forms to the CDC Headquarters. Then CDC Headquarters send DS forms to state or local health department at the immigrant's destination.

DS forms include:

- DS-2053 (Medical Examination for Immigrant or Refugee Applicant)

and associated worksheets:

- DS-3024 (Chest X-Ray and Classification Worksheet)
- DS-3025 (Vaccination Documentation Worksheet)
- DS-3026 (Medical History and Physical Examination Worksheet)

The DGMQ sends the notifications to the ISDH TB/Refugee Health Division using an electronic system called EDN (electronic data notification). DGMQ scans overseas medical documents and enters immigrant information into the system. The system then automatically sends an email notification of the immigrant's arrival to the ISDH TB/Refugee Health Division.

The DGMQ also sends a letter to any immigrant or refugee with a tuberculosis (TB) condition, indicating that a follow-up is needed in the US.[9]

The ISDH TB/Refugee Health Division notifies LHDs of arrivals by forwarding the B notifications to the county designated as the intended residence of the immigrant, refugee or derivative asylee. The ISDH TB/Refugee Health Division calls the LHD before forwarding the appropriate paperwork by mail.

LHD Patient Follow-up

The immigration paperwork may make it appear that a patient has had a complete evaluation for TB disease. However,

The *1991 Technical Instructions* overseas evaluation is designed only to detect abnormal CXRs and determine infectiousness at the time of travel. The evaluation does not rule out disease.

Under the *2007 Technical Instructions* a more thorough evaluation is done overseas, however, individuals may enter the US with "non-infectious" TB disease such as extrapulmonary TB.

All B1 and B2 arrivals under the *1991 Technical Instructions* need a new diagnostic evaluation for active disease, including a TST (or IGRA Test) and new CXR and sputum cultures if symptomatic or CXR is indicative of TB. Even if active TB disease is ruled out, most B1 and B2 arrivals are priority candidates for treatment of LTBI.

Under the *2007 Technical Instructions*, B1 arrival evaluation is the same (except AFB cultures as well as smears are obtained). B2 arrivals need to be evaluated for LTBI as do B3 arrivals who are contacts to cases in their country of origin.

Follow-up on each B1, B2 and B3 arrival is described below (the term "immigrant" used in the rest of this document includes all 3 categories: immigrants, refugees & derivative asylees).

1. Determine if the immigrant has already visited the LHD or a private provider.
2. If not, make a telephone call to the home of the immigrant's sponsor or relative within five business days after receiving the notification. Arrange for the immigrant to come in during clinic hours at the LHD and/or arrange for the patient to see a private provider. Communications should be made in the immigrant's first language. Whenever possible, a trained interpreter should be used.
3. If the immigrant does not visit the LHD or a private provider within 10 business days (two weeks) of the telephone call, send a letter to the home of the immigrant's sponsor or relative. Communications should be made in the immigrant's first language.
4. If the immigrant does not visit the LHD or a private provider within 10 business days (two weeks) of the letter, make a visit to the home of the immigrant's sponsor or relative. If indicated, bring a representative with you who speaks the immigrant's first language.

5. Every effort should be made to locate B1, B2 and B3 arrivals as these immigrants are considered high risk for TB disease. Call the ISDH TB/Refugee Health Division for consultation when an immigrant is not located.
6. Complete Class B follow-up within one month.
7. Complete and return the TB Follow-up Worksheet to the ISDH TB/Refugee Health Division.[10] This form is essential for the ISDH TB/Refugee Health Division to conduct statewide surveillance, follow up on all B1, B2, and B3 arrivals, and report results to the CDC.

NOTIFICATION PROCESS:

1. DGMQ:
   - Sends email to ISDH TB/Refugee Health Division using EDN
   - Sends a letter to immigrant (with TB condition) indicating follow-up needed in US

2. ISDH TB/Refugee Health Division:
   - Telephones LHD and forwards appropriate paperwork by mail (this paperwork includes the TB Follow-up Worksheet)

3. Designated Healthcare Provider (e.g., LHD Clinic or Private Provider):
   - Completes the TB Follow-up Worksheet and submits to LDH

4. LHD:
   - Reviews the TB Follow-up Worksheet for accuracy and forwards to ISDH TB/Refugee Health Division - within 30 days if possible

5. ISDH TB/Refugee Health Division:
   - Enters the TB Follow-up Worksheet information into the EDN system and forwards to CDC

Healthcare Providers Patient Follow-up

INDIANA:

The ISDH TB/Refugee Health Division includes a copy of the TB Follow-up Worksheet when sending the B notifications in the mail. Complete the TB Follow-up Worksheet (information on this form is confidential). Written instructions and a PowerPoint presentation on completing the form are available at the ISDH TB/Refugee Health Division website: http://www.in.gov/isdh/24668.htm

The completed form is to be forwarded to ISDH TB/Refugee Health Division by fax or mail, preferably within thirty (30) days.

For questions or more information call the ISDH TB/Refugee Health Division at 317.233.1321

Evaluation of Class B TB Arrivals

Evaluation Activities

Upon receipt of immigration paperwork, the LHD needs to look at what country the immigrant comes from to determine whether they have been screened according to the *1991 or 2007 Technical Instructions* (refer to country list page 4.5). If unsure whether the country of origin is under the newer Technical Instructions refer to http://www.cdc.gov/ncidod/dq/panel_2007.htm for the most current list.

- Refer to Table 4 to determine which evaluation tasks should be done for B1 and B2 arrivals under the *1991 Technical Instructions*.
- Refer to Table 5 to determine which evaluation tasks should be done for B1/B2/B3 arrivals under the *2007 Technical Instructions*.

LHDs need to share which Technical Instructions apply with the designated private provider.

Table 4: EVALUATION ACTIVITIES FOR B1/B2 ARRIVALS *1991 TECHNICAL INSTRUCTIONS*

Evaluation Activities	B1 Active TB	B2 Inactive TB
Determine TST status. If documentation is not available, administer a TST. A reaction of ≥5 mm is considered significant for persons with an abnormal CXR. • Screening may also be done using an IGRA Test.	Yes	Yes
Review the CXR. Even if patients have their overseas chest radiographs available for comparison, a new chest radiograph should be taken.	Yes	Yes
Review TB treatment history with the patient. Treatment history may be on the visa medical examination report, form DS-2053: *Medical Examination for Immigrant or Refugee Application.* In some cases, patients have received treatment not documented on the DS-2053. • Regardless of CXR result, collect sputum specimens if patient is symptomatic.	Yes	Yes
Collect sputum for testing based on the evaluation. Sputum specimens should be collected 8 to 24 hours apart, with at least one being an early morning specimen. A CXR does not rule out TB disease with certainty. • Regardless of CXR result, collect sputum specimens if patient is symptomatic.	Yes	If symptoms present

Sources: Francis J. Curry National Tuberculosis Center. Recommended TB clinic procedures for Class B1 TB arrivals and recommended TB clinic procedures for Class B2 TB arrivals. In: Text: step-by-step guide. *B Notification Assessment and Follow-up Toolbox* [Francis J. Curry National Tuberculosis Center Web site]. San Francisco, CA; January 2004. Available at: http://www.nationaltbcenter.edu/products/product_details.cfm?productID=WPT-06%20A . Accessed November 1, 2006.

Table 5: EVALUATION ACTIVITIES FOR B1/B2/ B3 ARRIVALS *2007 TECHNICAL INSTRUCTIONS*

Evaluation Activities	B1 Active / Inactive TB	B2 LTBI	B3 Contacts
Determine TST status. If documentation is not available, administer a TST. A reaction of ≥ 5 mm is considered significant for persons with an abnormal CXR. • Screening may also be done using an IGRA Test.	YES	YES	YES
Review the CXR. Even if patients have their overseas CXRs available, a new CXR must be taken.	YES	YES, if TST positive	YES, if TST positive
Review TB treatment history with the patient. Treatment history may be on the visa medical examination report, form DS-2053: *Medical Examination for Immigrant or Refugee Application*. In some cases, patients have received treatment not documented on the DS-2053.	YES	YES	YES
Collect sputum for testing. Sputum specimens should be collected 8 to 24 hours apart, with at least one being an early morning specimen.	YES	If symptoms present	If symptoms present

Sources: Francis J. Curry National Tuberculosis Center. Recommended TB clinic procedures for Class B1 TB arrivals and recommended TB clinic procedures for Class B2 TB arrivals. In: Text: step-by-step guide. *B Notification Assessment and Follow-up Toolbox* [Francis J. Curry National Tuberculosis Center Web site]. San Francisco, CA; January 2004. Available at: http://www.nationaltbcenter.edu/products/product_details.cfm?productID=WPT-06%20A . Modified 1/11/2008

Treatment

Prescribe medications as appropriate. *Do not start patients on single-drug therapy for LTBI until TB disease is ruled out.* B1/B2 immigrants with positive tuberculin skin tests and for whom active TB has been ruled out are priority candidates for treatment of LTBI because of the increased probability of recent infection and subsequent progression to active TB disease. Patients with fibrotic lesions on a CXR suggestive of old, healed TB are candidates for treatment of LTBI, regardless of age.

The overseas diagnosis of clinically active TB disease is based on the abnormal CXR. Reevaluation in the US may show the patient actually to have old, healed TB. According to current CDC/ATS recommendations, old, healed TB can be treated with four months of isoniazid and rifampin using a combined pill, Rifamate (if available), or with nine months of isoniazid.[11]

For more information on treatment refer to Section 8 – Treatment of LTBI and Section 6 - Treatment of TB Disease.

Resources and References

Resources

- California Department of Health Services (CDHS)/California Tuberculosis Controllers Association (CTCA). “Guidelines for the Follow-up and Assessment of Persons with Class B1/B2 Tuberculosis” *(CDHS/CTCA Joint Guidelines;* September 1999). Available at: http://www.ctca.org/guidelines/IIA7bnotification.pdf .
- Centers for Disease Control and Prevention (CDC) Division of Global Migration and Quarantine (DGMQ). “Medical Examinations of Aliens (Refugees and Immigrants)” (CDC Web site; accessed September 25, 2006). Available at: http://www.cdc.gov/ncidod/dq/health.htm .
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[9] Tuberculosis Control Program. *B1/B2 Notification and Monitoring Procedures.* New York State Department of Health. April 1996 in Text: step-by-step guide. *Notification Assessment and Follow-up Toolbox.* Francis J. Curry National Tuberculosis Center [Francis J. Curry National Tuberculosis Center Web site]. January 2004. Available at: http://www.nationaltbcenter.edu/products/product_details.cfm?productID=WPT-06%20A .

[10] Francis J. Curry National Tuberculosis Center. Class A and B immigrant TB follow-up protocol. In: Text: step-by-step guide. *B Notification Assessment and Follow-up Toolbox* [Francis J. Curry National Tuberculosis Center Web site]. San Francisco, CA; January 2004. Available at: http://www.nationaltbcenter.ucsf.edu/products/product_details.cfm?productID=WPT-06%20A .Accessed November 1, 2006.

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Diagnosis of Tuberculosis Disease

CONTENTS

Quick Start Check List: Diagnosis of TB Disease

This check list is designed to assist public health nurses when evaluating a patient for TB Disease. The tasks below should be performed by licensed nursing, medical and laboratory staff. This check list requires understanding the instructions in this manual and familiarity with local protocols.

Tasks for Diagnosis of Tuberculosis Disease
Start the initial assessment of the patient within ≤1 business day of receipt of case report for all TB suspects or cases.
Take infection control precautions: ☐ Isolate the patient, if necessary (if the patient has positive acid-fast bacilli [AFB] sputum smear results and/or cavitary disease with symptoms consistent with TB disease) ☐ Advise staff to take personal respiratory precautions, if necessary
Evaluate the patient: ☐ Initiate immediate medical evaluation of patient, if not already done ☐ Assure that a medical evaluation of the patient is completed within 1 week of referral ☐ Gather medical history ☐ Screen for human immunodeficiency virus (HIV) ☐ Assure that physical examination is performed ☐ Administer, measure, and interpret a Mantoux tuberculin skin test or interferon gamma release assay blood test (IGRA) ☐ Order chest radiography (CXR) ☐ Collect and submit 3 sputum specimens for AFB smear and culture. Obtain specimens 8 to 24 hours apart with at least one being an early morning specimen ☐ Receive, review and document results of AFB sputum smear tests ☐ Assure that a nucleic acid amplification (NAA) test is ordered to quickly identify MTB Complex for a patient highly suspicious to have pulmonary tuberculosis. PHL NAA technique is Gen-Probe Amplified Mycobacterium Tuberculosis Direct Test (AMTD) ☐ Reassess information about the patient weekly until drug susceptibility results are available and then at least monthly thereafter
Monitor laboratory test results for culture and drug susceptibility: ☐ Receive, review and document AFB smear results for response to treatment ☐ Receive, review and document culture results ☐ Receive, review and document drug susceptibility results as soon as available, usually about four weeks after the patient's initial specimen collection date

Tasks for Follow up of Patients Diagnosed with Tuberculosis Disease
Communicate to ISDH TB/Refugee Health Division staff: ☐ LDH submits Report of Tuberculosis form within 72 hours (See Section 2 – Surveillance details and hyperlink) of receiving notification of the suspect OR case
Start the patient on treatment for TB disease ☐ Fax the Request for TB Drugs form and prescriptions to ISDH TB/Refugee Health Division. (See Section 2 – Surveillance details and hyperlink)
Manage the case
Conduct the contact investigation ☐ Submit the Summary of TB Contact Investigation Report to ISDH TB/Refugee Health Division (Note: the form is submitted in 3 stages. See Section 2 – Surveillance details and hyperlink)

Introduction

Purpose

Use this section to understand and follow national and Indiana guidelines to do the following:

- Classify patients with tuberculosis (TB) disease and latent TB infection (LTBI).
- Detect suspected cases of TB.
- Know when to report suspected or confirmed cases of TB.
- Diagnose TB disease.

It is important to understand when a person should be evaluated further for TB disease. Not recognizing TB symptoms promptly leads to delays in treating a TB case—and to more infection, TB disease, and contacts to evaluate.

In the 2005 guideline, "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, Centers for Disease Control and Prevention, and the Infectious Diseases Society of America," one of the recommended strategies to achieve the goal of reduction of TB morbidity and mortality is early and accurate detection, diagnosis, and reporting of TB cases, leading to initiation and completion of treatment.[1]

Contacts are mentioned within this section, but their evaluation and follow-up and contact investigation are covered in more depth in the Contact Investigation section. For information on treatment, refer to the Treatment of Tuberculosis Disease section.

Improvement in the detection of TB cases is essential to progress toward elimination of TB in the United States.[2] Case detection includes the processes that lead to the presentation, evaluation, diagnosis, and reporting of persons with active TB.[3] Detecting and reporting suspected cases of TB are key steps in stopping transmission of *Mycobacterium tuberculosis* because it leads to prompt initiation of effective multiple-drug treatment, which rapidly reduces infectiousness.[4]

TB is commonly diagnosed when a person seeks medical attention for symptoms caused by the disease or a concomitant medical condition. Thus, healthcare providers, particularly those providing primary healthcare to populations at high risk, are key contributors to TB case detection.[5] However, the majority of pulmonary TB cases continue to be diagnosed at an advanced stage. Earlier diagnosis would result in less individual morbidity and morbidity, greater success in treatment, less transmission to contacts, and fewer outbreaks of TB.[6]

A diagnosis of TB disease is usually based on positive cultures for *M. tuberculosis.* However, TB may also be diagnosed on the basis of clinical signs and symptoms in the absence of a positive culture.

Policy

- Persons who show or report signs and symptoms of TB should be evaluated for TB disease as described in the "Diagnosis of Tuberculosis Disease" topic in this section and reported as suspected cases of TB as described in the "Reporting Tuberculosis" topic in the Surveillance section.
- Contacts should be evaluated as described in the Contact Investigation section.

For roles and responsibilities, refer to the "Roles, Responsibilities, and Contact Information" topic in Section 1 - Introduction.

State Laws and Regulations

Refer to Section 1 – Introduction for Indiana state laws that mandate screening and diagnosis policy and procedures.

Case Finding

Identifying Suspected Pulmonary Tuberculosis Cases

The majority of tuberculosis (TB) cases are detected during the medical evaluation of symptomatic individuals. Persons experiencing symptoms ultimately attributable to TB usually seek care not at a public health TB clinic but rather from other medical practitioners in other healthcare settings.[7] Professionals in the primary healthcare sector, including hospital and emergency department clinicians, should be trained to recognize patients with symptoms consistent with TB.[8]

Be alert for cases of TB among persons who have not sought medical care during evaluation of contacts to patients with pulmonary TB and to other persons with newly diagnosed infection with *Mycobacterium tuberculosis.* Perform screening for TB during evaluation of immigrants and refugees with Class B1 or Class B2 TB notification status, during evaluations of persons involved in TB outbreaks, and occasionally in working with populations with a known high incidence of TB. Also, screen for TB disease when the risk for TB in the population is high and when the consequences of an undiagnosed case of TB are severe, such as in jails, nursing homes and other institutional settings.[9]

Factors that identify persons at high risk of LTBI infection and/or of progression to TB disease are listed in the “High-Risk Groups” topic in Section 7 - Diagnosis of LTBI.

Suspect pulmonary TB and initiate a diagnostic investigation when the historic features, signs, symptoms, and radiographic findings listed in Table 1 occur among adults. The clinical presentation of TB varies considerably as a result of the extent of the disease and the patient’s response. **TB should be suspected in any patient who has a persistent cough for more than two to three weeks, or other compatible signs and symptoms**.[10]

NOTE: These symptoms should suggest a diagnosis of TB but are not required. TB should still be considered a diagnosis in asymptomatic patients who have risk factors for TB and chest radiographs compatible with TB.

All persons who have a chronic cough for more than two to three weeks[11] should be evaluated and be asked to use a mask or tissue to cover their mouth. Hemoptysis, or coughing up blood, is a serious symptom, and patients who cough up blood should be evaluated as soon as possible. Be sure to have these patients use a surgical mask and tissues.

Table 1: WHEN TO SUSPECT PULMONARY TUBERCULOSIS IN ADULTS[12]

Historic Features	▪ Exposure to a person with infectious tuberculosis (TB) ▪ Positive TST or IGRA (results may be negative in immunosuppressed individuals) ▪ Presence of risk factors, such as immigration from a high-prevalence area, human immunodeficiency virus (HIV) infection, homelessness, or previous incarceration* ▪ Diagnosis of community-acquired pneumonia that has not improved after 7 days of treatment †,[13]
Signs and Symptoms Typical of TB	▪ Prolonged coughing (≥2–3 weeks) with or without production of sputum that might be bloody (hemoptysis)§,[14] ▪ Chest pain[15] ▪ Chills[16] ▪ Fever ▪ Night sweats ▪ Loss of appetite[17] ▪ Weight loss ▪ Weakness or easy fatigability[18] ▪ Malaise (a feeling of general discomfort or illness)[19]
Chest Radiograph: Immunocompetent patients	▪ Classic findings of TB are upper-lobe opacities, frequently with evidence of contraction fibrosis and/or cavitation¶
Chest Radiograph: Patients with advanced HIV infection	▪ Lower-lobe and multilobar opacities, hilar adenopathy, or interstitial opacities might indicate TB

* See Table 1: Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease in the section on Diagnosis of Latent Tuberculosis Infection.

† Patients treated with levofloxacin or moxifloxacin may have a clinical response when TB is the cause of the pneumonia.

§ Do **not** wait until sputum is bloody to consider a productive cough a symptom of TB. Sputum produced by coughing does **not** need to be bloody to be a sign of TB.

¶ These features are not specific for TB, and, for every person in whom pulmonary TB is diagnosed, an estimated 10–100 persons are suspected on the basis of clinical criteria and must be evaluated.

Source: Adapted from: ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):33.

Identifying Extrapulmonary Tuberculosis Cases

Extrapulmonary TB is usually more of a diagnostic problem than pulmonary TB, in part because it is less common and therefore less familiar to clinicians. In addition, extrapulmonary TB involves relatively inaccessible sites - because of the nature of the sites involved fewer bacilli can cause greater damage. The combination of small numbers of bacilli and inaccessible sites causes bacteriologic confirmation of a diagnosis to be more difficult. Recovery of MTB from a specimen is still the hallmark of confirming the diagnosis, but it is more frequently necessary to obtain tissue for the diagnosis of extrapulmonary TB. Since most forms of extrapulmonary disease represent reactivation TB, skin tests are often positive in patients with extrapulmonary disease, although anergy is still a problem for those with underlying disease or poor nutritional states.

Symptoms of Pulmonary/Extrapulmonary Tuberculosis

COMMON SYSTEMIC SYMPTOMS:

- Fever
- Night sweats
- Fatigue
- Loss of appetite/weight loss

SITE-SPECIFIC SYMPTOMS:

Pulmonary

- Cough, initially sporadic and non-productive, but becomes persistent and productive
- Shortness of breath
- Hemoptysis (minimal to extensive; usually a sign of advanced disease)
- Chest pain (usually due to pleuritic involvement)
- Chest radiograph shows predominately upper lobe involvement; cavitation is common in adults
- Radiographic features associated with TB disease in HIV-infected patients include diffuse infiltrates, normal-appearing parenchyma, and lymphadenoapathy

Pleural

- Non-productive cough
- Pleuritic chest pain
- Shortness of breath
- Effusions are usually unilateral
- Pleural fluid is usually gradually discharged with lymphocytosis
- AFB smears of pleural fluid are frequently negative; 50% of cultures are positive
- Pleural biopsy is more sensitive, with cultures positive 75-90% of the time

Pericardial

- Dyspnea
- Chest pain
- Tachycardia
- Pleural dullness
- Increased jugular venous pressure
- Hepatomegaly
- Ascites
- Peripheral edema

Lymphatic

- Most common site of extrapulmonary disease (approximately 1/3 of the extrapulmonary in the U.S.)
- Usually presents as a painless swelling, most commonly in the neck
- Any node can be involved
- Bilateral disease is uncommon, although multiple nodes may be involved at one site
- Diagnosed by microscopic examination and culture of aspirated material or the excised node

Central Nervous System

- May present as meningitis or parenchymal brain or spinal cord lesions (tuberculomas)
- Tuberculomas are visible as round or ovoid lesions on CT scan and MRI
- Headache, altered mental status, nausea and vomiting are common
- Cerebrospinal fluid is usually AFB smear-negative; cultures are negative in as many as 50% of cases

Bone and Joint

- Most commonly effects the spine and the weight-bearing joints (hips and knees)
- Insidious onset of joint pain and swelling
- X-rays show destruction of bone and cartilage

Genitourinary - kidneys are a frequent site given the large blood supply to these organs

- Flank pain
- Hematuria
- Recurrent urinary tract infections
- Pyuria
- Urine culture is gold standard for diagnosis – 3 to 6 first morning midstream specimens to maximize likelihood of a positive result (bacilli are shed into urine intermittently so only 30-40% of single specimens are positive in patients with active disease)
- AFB smears are not performed on urine since other mycobacterial species can be found as saprophytes (an organism, especially a fungus or bacterium, which obtains food from dead or decaying organic matter).

Abdominal

- Abdominal pain and swelling
- Abdominal tenderness
- “Doughy” abdomen (rare)
- Ascites

Miliary TB

The term miliary TB is now used to denote all forms of progressive, widely disseminated hematogenous TB, even if the classical pathological or radiologic findings are absent (i.e. the term "miliary" is derived from the visual similarity of some disseminated lesions to millet seeds. Grossly, these lesions are 1- to 2-mm yellowish nodules that, histologically, are granulomas. When these small nodules occur in the lung, the resulting radiographic pattern is also termed "miliary").

Disseminated TB occurs because of the inadequacy of host defenses in containing tuberculous infection. This failure of containment may occur in either latent or recently acquired tuberculous infection. Because of HIV or other causes of immunosuppression, the organism proliferates and disseminates throughout the body. Multiorgan involvement is probably much more common than is recognized because, generally, once MTB is identified in any specimen, other sites are not evaluated.

Presenting symptoms are generally nonspecific and dominated by systemic effects because of multisystem involvement:

- Fever and/or night sweats
- Anorexia
- Weight loss
- Weakness
- GI (abdominal pain, nausea, vomiting, diarrhea)
- Headache or mental status changes

Physical findings are variable:

- Pulmonary findings (common because most patients also have pulmonary involvement)
- Hepatomegaly
- Splenomegaly
- Choroidal tubercle (granuloma in the choroid of the retina) - is strongly suggestive of disseminated tuberculosis
- Chest film - at the time of diagnosis approximately 85% have the characteristic radiographic findings of miliary tuberculosis. Other radiographic abnormalities may be present as well: upper lobe infiltrates with or without cavitation, pleural effusion, and pericardial effusion. With HIV infection the pattern is usually one of diffuse infiltration rather than discrete nodules.

Follow-up on Suspected Cases of Tuberculosis

When a suspected case of TB is identified, the following should be done:

When a suspected case of pulmonary TB is identified, refer to Table 2: **Guidelines for the Evaluation of Pulmonary Tuberculosis in Adults in Five Clinical Scenarios** in the "Diagnosis of Tuberculosis Disease" topic in this section. This table presents guidelines for the initial steps of TB case detection in five clinical scenarios encountered by providers of primary health care, including those serving in medical emergency departments.[20]

For a summary of the TB classification numbers, refer to the "Tuberculosis Classification System" topic in Section 2 – Surveillance.

To formally report a suspected case of TB, see the "Reporting Tuberculosis" topic in Section 2 – Surveillance.

The patient should be masked and immediately excluded from the workplace or placed in airborne infection isolation (AII) until confirmed noninfectious. For more information, see the "Isolation" topic in Section 15 - Infection Control.

Laboratories should report positive smears or positive cultures, and primary healthcare providers should report suspected or confirmed cases of TB to the LHD, as specified in the "Reporting Tuberculosis" topic in Section 2 - Surveillance. Prompt reporting allows the health department to organize treatment and case management services and to initiate a contact investigation as quickly as possible.[21]

Within 48 hours of suspect identification, administer a tuberculin skin test (TST) or perform an interferon gamma release assay (IGRA) and/or provide a chest radiograph. Evaluate the patient for TB disease as specified in the "Diagnosis of Tuberculosis Disease" topic in this section.

Diagnosis of Tuberculosis Disease

Consideration of tuberculosis (TB) disease as a possible diagnosis is the first step that must be taken before further evaluation, diagnosis, and management can occur. The diagnosis of TB disease is often overlooked because of the failure to consider it among possible diagnoses. While a definitive diagnosis may involve the addition of laboratory and radiographic findings, a high degree of suspicion can be based on epidemiology, medical history, and physical examination. In considering TB disease, it is also important to consider factors that may affect the typical presentation of TB, such as the patient's age, nutritional status, and coexisting diseases.

An individual who is suspected of having TB disease requires a complete medical evaluation, including the following:

- Medical history, including exposure, symptoms, previous treatment for TB, and risk factors
- Human immunodeficiency virus (HIV) screening
- Physical examination
- Tuberculin skin test (TST) or interferon gamma release assay (IGRA)
- Chest radiography
- Bacteriologic examination

When a suspected case of pulmonary TB is identified, refer to Table 2 for guidelines on the initial steps of TB case detection in five clinical scenarios encountered by providers of primary healthcare, including those serving in medical emergency departments.[22]

Table 2: GUIDELINES FOR THE EVALUATION OF PULMONARY TUBERCULOSIS IN ADULTS IN FIVE CLINICAL SCENARIOS[23]

Patient and Setting	Recommended Evaluation
Any patient with a cough of ≥2–3 weeks' duration	Chest radiograph: If suggestive of tuberculosis (TB)*, collect 3 sputum specimens for acid-fast bacilli (AFB) smear microscopy, culture, and nucleic acid amplification (NAA), if available[24]
Any patient at high risk for TB with an unexplained illness, including respiratory symptoms of ≥2–3 weeks' duration†	Chest radiograph: If suggestive of TB, collect 3 sputum specimens for AFB smear microscopy, culture, and NAA, if available
Any patient with human immunodeficiency virus (HIV) infection and unexplained cough or fever	Chest radiograph, and collect 3 sputum specimens for AFB smear microscopy, culture, and NAA, if available
Any patient at high risk for TB with a diagnosis of community-acquired pneumonia who has not improved after 7 days of treatment†	Chest radiograph, and collect 3 sputum specimens for AFB smear microscopy, culture, and NAA, if available
Any patient at high risk for TB with incidental findings on chest radiograph suggestive of TB even if symptoms are minimal or absent†§	Review of previous chest radiographs, if available, 3 sputum specimens for AFB smear microscopy, culture, and NAA, if available

* Opacities with or without cavitation in the upper lobes or the superior segments of the lower lobes.[25]

† See Table 1: Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease in the section on Diagnosis of Latent Tuberculosis Infection.

§ Chest radiograph performed for any reason, including targeted testing for latent TB infection and screening for TB disease.

Source: Adapted from: ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):33.

Medical History

The clinician should interview patients to document their medical histories. A written record of a patient's medical history should include the following:

- Exposure to infectious TB
- Symptoms of TB disease (as listed in Table 1: **When to Suspect Pulmonary Tuberculosis in Adults,** Table 2: **Guidelines for the Evaluation of Pulmonary Tuberculosis in Adults in Five Clinical Scenarios,** and Table 3: **Symptoms of Tuberculosis Disease**)
- Previous TB infection or disease
- Risk factors (as listed in Table 1: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease** in the section on Diagnosis of Latent Tuberculosis Infection)
- Recent medical encounters (e.g., going to the emergency department for pneumonia)
- Previous antibiotic therapy

1. Exposure to Infectious TB:
Ask patients if they have spent time with someone with infectious TB.

Question patients about whether they know of any contact in the recent or distant past with persons diagnosed with TB. It is important to note that patients often refer to latent TB infection (LTBI) as TB disease. Be aware that most persons become infected with *Mycobacterium tuberculosis* without knowing they were exposed. Clinicians should also consider demographic factors that may increase a patient's risk for exposure to TB disease and drug-resistant TB, such as country of origin, age, ethnic or racial group, occupation, and residence in congregate settings (such as a jail, homeless shelter, or refugee camp).

2. Symptoms of TB Disease:
Ask patients about their symptoms.

Although TB disease does not always produce symptoms, most patients with TB disease have one or more symptoms that led them to seek medical care. When symptoms are present, they usually have developed gradually and been present for weeks or even months. Occasionally, however, TB is discovered during a medical examination for an unrelated condition (e.g., through a chest radiograph given to patients before surgery).

The symptoms in Table 3 below may be caused by other diseases, but they should prompt the clinician to suspect TB disease. For historic features and chest radiograph results that should raise suspicion of pulmonary TB disease, refer to Table 1: When to Suspect Pulmonary Tuberculosis in Adults**.**

3. Previous Latent TB Infection or TB Disease:
Ask patients whether they have ever been diagnosed with or treated for TB infection or disease.

- **Patients who have had TB disease before** should be asked when they had the disease and how the disease was treated. Ask how many pills were taken per day (to determine what treatment regimen was used and whether they received injections). If the regimen prescribed was inadequate or if the patient did not follow the recommended treatment, TB may reoccur, and it may be resistant to one or more of the drugs used.
- **Patients known to have a positive skin test reaction** probably have TB infection. If they were infected within the past two years, they are at high risk for TB disease if certain immunosuppressive conditions exist or if immunosuppressive therapies are being taken. (See Table 1: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease** in the section on Diagnosis of Latent Tuberculosis Infection.)[26] For persons previously skin tested, an increase in induration of 10 mm within a two-year period is classified as a conversion to positive.

4. Risk Factors for Developing TB Disease:
Determine whether patients have any conditions or behaviors that are risk factors for developing TB disease.

For a list of behaviors and conditions that appear to increase the risk that TB infection will progress to disease, see Table 1: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease** in the section on Diagnosis of Latent Tuberculosis Infection.

Human Immunodeficiency Virus Screening

Voluntary counseling and testing for human immunodeficiency virus (HIV) is recommended for all patients with TB. HIV counseling and testing has also been recommended for contacts of persons with TB.[27]

The Centers for Disease Control and Prevention (CDC) recommends the following:

- Routine HIV screening for all patients ages 13–64 seeking health care for any reason, without regard to any patient's known risks for HIV infection
- Annual HIV screening of patients known to be at high risk[28]

Physical Examination

A physical examination is an essential part of the evaluation of any patient. It cannot be used to confirm or rule out TB, but it can provide valuable information about the patient's overall condition; other factors, such as human immunodeficiency virus (HIV) infection, which may affect how TB is manifested; and the presence of extrapulmonary TB.[29]

Tuberculin Skin Test and Interferon Gamma Release Assays

For information on interferon gamma release assays (IGRAs), refer to the "Interferon Gamma Release Assays" topic in Section – 7 Diagnosis of LTBI.

Use the Mantoux tuberculin skin test (TST) or an interferon gamma release assay (IGRA) to test for *M. tuberculosis* infection. Note that for patients with a previous documented positive TST reaction, a TST is not necessary. Additional tests, such as chest radiography and bacteriologic examination, are required to confirm TB disease.

For both the TST and IGRA, additional tests, such as chest radiography and bacteriologic examination, are required to confirm TB disease.[30]

Persons with a positive TST or IGRA result, regardless of signs or symptoms, should be evaluated for TB disease before LTBI is diagnosed. At minimum, a chest radiograph should be examined for abnormalities consistent with TB disease.[31]

A negative TST does not rule out TB disease[32], as many as 20% of patients with TB disease have a negative TST reaction.[33] A negative TST or IGRA result should not be used alone to exclude *M. tuberculosis* infection in persons with symptoms or signs suggestive of TB disease. Medical evaluation of such persons should include a history and physical examination, chest radiograph, bacteriologic studies, serology for human immunodeficiency virus (HIV), and, when indicated, other tests or studies.[34]

Chest Radiography

A posterior-anterior and lateral radiograph of the chest is the standard view used for the detection and description of chest abnormalities in adults. In some instances, other views (e.g., lateral, lordotic) or additional studies (e.g., computed tomography [CT] scans) may be necessary.

Children younger than five years of age should receive posterior-anterior and lateral radiographs.[35]

Certain abnormalities on CXR are suggestive, but are not diagnostic, of TB. In pulmonary TB, radiographic abnormalities are often seen in the apical and posterior segments of the upper lobe or in the superior segments of the lower lobe. However, lesions may appear anywhere in the lungs and may differ in size, shape, density, and presence or absence of cavitation, especially in HIV-infected and other immunosuppressed persons.

In HIV-infected persons, pulmonary TB may present atypically on the CXR. For example, TB may cause opacities without cavities in any lung zone, or it may cause mediastinal or hilar lymphadenopathy with or without accompanying opacities and/or cavities. In HIV-infected persons, almost any abnormality on a chest radiograph may indicate TB. In fact, the radiograph of an HIV-infected person with TB disease may even appear entirely normal.[36]

For more information on CXR, see the Francis J. Curry National Tuberculosis Center's *Radiographic Manifestations of Tuberculosis: A Primer for Clinicians* Second Edition, June 2006 at this hyperlink (to order or view online):

http://www.nationaltbcenter.edu/products/product_details.cfm?productID=EDP-04

CXRs should always be obtained whenever a specific medical indication exists (e.g., relevant history, symptoms and/or significant TST reaction) however, screening or repeated CXRs solely because of administrative mandate or protocol have not been shown to be of sufficient clinical value. For ISDH policy on CXRs for employment, LTC, routine follow-up, etc. refer to **Repeat Chest X-Rays** at http://www.in.gov/isdh/19684.htm.

Bacteriologic Examination

Refer to Table 4 below to determine the types of specimens needed to assist in the diagnosis of TB.

Table 3: SPECIMENS FOR DIAGNOSING TUBERCULOSIS DISEASE

Suspected Diagnosis	Specimen Needed
Pulmonary or laryngeal tuberculosis (TB)	Sputum (phlegm from deep in the lungs) samples for smear and culture examination. If a diagnosis of pulmonary TB cannot be established from sputum smear, other procedures may be necessary, including nucleic acid amplification (NAA), bronchoscopy, and gastric aspiration in children (must be neutralized).
Extrapulmonary TB	Depending on the anatomical site, other clinical specimens are necessary, such as: ▪ Urine ▪ Cerebrospinal fluid ▪ Pleural fluid ▪ Pus or other aspirated fluid ▪ Biopsy specimens

Refer to Table 5 below for information on the bacteriologic tests used to diagnose TB.

Table 4: BACTERIOLOGIC TESTS USED IN DIAGNOSING TUBERCULOSIS DISEASE[37]

Test	Description	Laboratory Turnaround Times
Acid-Fast Bacilli (AFB) Smear	▪ Provides the physician with a preliminary confirmation of the diagnosis. It usually is the first bacteriologic evidence of the presence of mycobacteria in a clinical specimen. ▪ If positive, gives a semiquantitative estimate of the number of bacilli being excreted (which is of vital clinical and epidemiologic importance in assessing the patient's infectiousness).	▪ On-site test: within 24 hours from specimen collection ▪ Off-site test: within 24 hours from laboratory receipt of specimen (time from specimen collection to laboratory receipt should be 24 hours or less)[38]
Nucleic Acid Amplification (NAA) Assay[39]	▪ A test done on sputum specimens for the direct and rapid identification of the *Mycobacterium tuberculosis* complex. ▪ Allows for the amplification of specific target sequences of nucleic acids that will be detected by a nucleic acid probe. ▪ Does not replace the need for routine AFB smear and culture.[40]	▪ Within 48 hours from specimen collection[41,42]
Culture	▪ Usually necessary for species identification of all clinical specimens suspected of containing mycobacteria. ▪ Required for drug susceptibility testing and genotyping.	▪ Mycobacterial growth detection: within 14 days from specimen collection ▪ Identification of mycobacteria: within 21 days from specimen collection [43,44]
Drug Susceptibility Testing	▪ For first-line drugs: performed on initial isolates of all patients to identify an effective antituberculosis regimen. ▪ For both first-line and second-line drugs: repeated on interim isolates when a patient remains culture-positive after 3 months of treatment.[45,46]	▪ First-line drugs: within 30 days from specimen collection ▪ Second-line drugs: within 4 weeks from date of request

Sources: ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):19; and Tenover, R., et al. The resurgence of tuberculosis: is your laboratory ready? *Journal of Clinical Microbiology* 1993:767–770.

Laboratories should immediately report positive smears or positive cultures, and primary healthcare providers should report suspected or confirmed cases of TB to the LHD, as specified in the “Reporting Tuberculosis” topic in Section 2 – Surveillance. Prompt reporting allows the health department to organize treatment and case management services and to initiate a contact investigation as quickly as possible.[47]

For information on reporting, see the “Reporting Tuberculosis” topic in Section 2 – Surveillance.

For a list of all of the laboratory services available and information on specimen collection and shipment, see Section 11 - Laboratory Services.

Resources and References

Resources

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Treatment of Tuberculosis Disease

Quick Start Check List: Treatment of TB Disease

This check list is designed to assist public health nurses when treating a patient for TB Disease. The tasks below should be performed by licensed nursing, medical and laboratory staff. This check list requires understanding the instructions in this manual and familiarity with local protocols.

Tasks for Diagnosis of TB Disease
Perform the initial assessment of the patient
Evaluate the patient
Tasks for Treatment of TB Disease
Follow basic principles for tuberculosis (TB) disease
Plan and initiate treatment for TB disease: ☐ Initiate medical treatment as soon as possible after positive acid-fast bacilli (AFB) sputum smear results ☐ Obtain baseline biochemistry tests for toxicity monitoring (choose tests based on regimen and for special situations such as HIV infection, history of liver disease, alcoholism, and pregnancy): Complete blood count Platelets Liver function tests ☐ Perform baseline visual acuity and color discrimination tests for toxicity monitoring if the patient is prescribed ethambutol ☐ Assure that an appropriate treatment regimen, dosages, and duration are selected. The preferred regimen for treating TB disease consists of an initial 2-month phase of 4 drugs: isoniazid, rifampin, pyrazinamide, and ethambutol followed by a 4-month continuation phase of isoniazid and rifampin[1] ☐ Assure that the following special situations are considered: Drug-resistant TB HIV infection Alcoholism Liver disease Renal insufficiency and end-stage renal disease TB associated with tumor necrosis factor-alpha antagonists Culture-negative pulmonary TB Extrapulmonary TB Pregnancy and breastfeeding TB in children ☐ Assure that a written treatment plan is developed ☐ Assure that the patient and provider are aware of and educated about the treatment plan ☐ Begin implementing the treatment plan

Tasks for Treatment of Tuberculosis Disease

Monitor the patient regularly:

☐ DOT is the standard of care in Indiana
☐ Assess adherence and drug toxicity at each directly observed therapy (DOT)/Videophone (VDOT)
☐ Conduct ongoing assessment and monitoring at least monthly for clinical response, drug toxicity, and adherence
☐ Reassess treatment and, if concerned about response or drug toxicity, consult with the treating physician. If a change is decided upon, obtain new physician's orders and order drugs
☐ Receive and review drug susceptibility results 1 to 2 months after the patient's initial sputum collection date
☐ Consult with ISDH TB Regional Consultant if drug susceptibility results show drug resistance to first-line drugs.

Monitor the patient for drug toxicity:

☐ Assess drug toxicity at each DOT visit
☐ Repeat liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and serum bilirubin) when the patient is taking isoniazid, a rifamycin, or pyrazinamide if
- Baseline results are abnormal
- The patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions
- The patient has symptoms of adverse reactions

☐ If the patient is taking ethambutol, question the patient monthly regarding possible visual disturbances, including blurred vision or scotomata
☐ Test visual acuity and color discrimination monthly when the patient is taking ethambutol

Assess the patient's response to treatment:

☐ If the patient initially had positive AFB sputum smear results quantified as greater than or equal to 1 per field then every two weeks collect 3 consecutive sputum specimens and submit them for testing until AFB sputum smear results are less than one per field. Once the AFB sputum smear results are quantified as less than 1 per field, every week collect 3 consecutive sputum specimens until AFB sputum smear results are negative.
☐ When the patient has negative AFB sputum smear results, then each month collect sputum specimens and submit them for testing until 2 consecutive negative culture results are reported -
- For multidrug-resistant TB (MDR-TB) patients, monthly sputum specimens are required
- For non-MDR-TB patients who can produce sputum, monthly specimens are recommended

☐ If sputum smear results are positive after 2 months of treatment discuss with Medical Care Provider or LHD.
☐ Take the following actions if cultures or smears remain positive and symptoms continue after 3 months of treatment:
- Evaluate the patient for drug-resistant TB
- Provide DOT if the patient is self-administering medication
- Seek expert consultation

Confirm the completion of treatment:

☐ Verify completion of treatment 6 to 9 months after treatment was started depending upon
- Regimen
- Adherence
- Response to treatment
- Number of weeks on DOT
- Number of doses taken

Introduction

Purpose

The overall goals for treatment of tuberculosis (TB) are to cure the patient and to minimize the transmission of *Mycobacterium tuberculosis* to others. In the 2005 "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, Centers for Disease Control and Prevention, and the Infectious Diseases Society of America," one of the recommended strategies to achieve the goal of reduction of TB morbidity and mortality is the early and accurate detection, diagnosis, and reporting of TB cases, leading to initiation and completion of treatment.[1] Successful treatment of TB has benefits both for the individual patient and for the community in which the patient resides.

Use this section to understand and follow national and Indiana guidelines to do the following:

- Follow basic treatment principles for TB disease.
- Select appropriate treatment regimens, dosages, and duration.
- Monitor patients for side effects and adverse reactions.
- Assess patients' response to treatment.
- Determine completion of therapy.
- Determine the need for post-treatment evaluation.
- Provide treatment in special situations, such as when a patient has drug-resistant TB or TB–human immunodeficiency virus (HIV) coinfection.
- Hospitalize and coordinate hospital discharges of patients with infectious TB.

Policy

Patients with TB disease in Indiana or who moved to Indiana with reported TB disease should receive and complete treatment in accordance with the national guidelines and in accordance with the following Indiana state laws and guidelines.

State Laws and Regulations

Refer to Section 1 – Introduction for Indiana state laws that mandate TB Disease treatment policy and/or procedures.

For roles and responsibilities, refer to the "Roles, Responsibilities, and Contact Information" topic in Section 1 - Introduction.

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Reporting: TB is a reportable disease in the state of Indiana. A **Report of Tuberculosis** form must be submitted by a licensed physician or hospital administrator (or assignee) to the LHD. For additional details on reporting requirements refer to Section 2 – Surveillance.

Medications: ISDH TB/Refugee Health Division provides drugs to TB patients and suspects through a state-funded program for patients who reside in Indiana, with the exception of counties that have their own drug program.

A **Report of Tuberculosis** form must be submitted by the LHD Public Health Nurse if the patient will receive TB medication through the state. The **Request for TB Drug Form** and a copy of the appropriate medication prescriptions must be submitted with this report.

The **TB Medication Policy** and the required forms can be found at:

TB Medication Policy: http://www.in.gov/isdh/19685.htm

Request for TB Drugs Form: http://www.in.gov/icpr/webfile/formsdiv/48085.pdf

Basic Treatment Principles

Follow the basic treatment principles for TB disease, as outlined below in Table 1.

Table 1: BASIC TREATMENT PRINCIPLES FOR TUBERCULOSIS DISEASE

Phase	Principles
At Start of Treatment	**Directly observed therapy (DOT) and Patient centered care.** An adherence plan should tailor treatment and supervision to each patient by emphasizing **DOT as the standard of care** and considering his or her clinical and social circumstances (patient-centered care).
	Cultural competence. It is imperative to become culturally competent and guide other healthcare providers toward culturally competent healthcare. A culturally competent system acknowledges cultural differences regarding healthcare and incorporates them into all levels of the healthcare delivery system, from policy to provider to patient.
	HIV testing. HIV testing should be performed to all patients with TB disease.
	Medical supervision. Patients with confirmed or suspected tuberculosis (TB) disease must be under the medical supervision of a primary care physician, pulmonologist or infectious disease physician
	Prompt start. Start patients with confirmed or suspected TB disease promptly on appropriate treatment. It is not necessary to wait for laboratory confirmation.
Regimen During Treatment	**Multiple drugs.** Treatment regimens must contain multiple drugs to which the organism is susceptible. **The administration of a single drug or the addition of a single drug to a failing regimen can lead to the development of resistance.**
	Single doses. TB medications should be administered together as a single dose rather than in divided doses. A single dose leads to higher, and potentially more effective, peak serum concentrations, and facilitates DOT. Although ingesting the medications with food will delay or moderately decrease the absorption of the medications, the effects are of little clinical significance.
	Pyridoxine to prevent neuropathy. Pyridoxine (Vitamin B-6, 25 mg) is recommended for some individuals receiving INH as part of their treatment regimen to prevent peripheral neuropathy. It should be used in persons at risk for neuropathy (women who are pregnant or breastfeeding or persons with nutritional deficiency, diabetes, HIV infection, renal failure, or alcoholism).
Persistent Positive Cultures	**Evaluation when positive cultures persist.** Monitor for culture conversion and promptly evaluate patients with persistently positive cultures after 3 months of therapy to identify the cause. Treatment failure is defined as continued or recurrent positive cultures after 4 months of treatment.
At Completion of Treatment	**Completion in terms of the number of doses.** The criteria for treatment completion are based upon the total number of doses taken and not solely on the duration of therapy.

Treatment Regimens and Dosages

ISDH TB Medical Advisory Board Statement: Treatment of Active TB

1. Recommended Treatment Regimens

Unless there are contraindications, patients with active tuberculosis should be treated initially with four drugs: isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB). Four drugs are recommended because (1) EMB helps to prevent the emergence of RIF-resistant organisms when primary resistance to INH may be present; (2) INH resistance continues to occur in our state, (3) foreign-borne persons from countries with high rates of drug resistance make up a growing number of TB cases in Indiana, and (4) six-month treatment regimens are not possible without the use of PZA.

2. Drug Administration

The preferred regimen in our state is the 'Denver Regimen.' In this regimen, the patient is treated with daily medication for the first two weeks, followed by twice-weekly dosing until a total of 62 doses (26 weeks) of therapy are completed. This regimen must be given using directly observed therapy (DOT), meaning that a public health worker delivers medication to the patient and observes the patient ingest the medication. Completion of treatment is defined by the total number of doses ingested as well as the duration of treatment. **Note:** twice-weekly therapy is contraindicated for HIV-infected patients with CD4+ lymphocyte counts < 100 cells/µl. An overview of the 'Denver Regimen' is provided in Table 4 as Option 2. Doses for anti-tuberculosis medications are as follows:

Daily dosing for 5 rather than 7 days per week is an option for the daily portion of treatment options 1 and 2, but should only be used if dosing 7 days per week is not feasible. DOT must be used with this option.

INH, RIF and PZA should be continued for the entire first two months. EMB may be discontinued after the drug susceptibility test shows that the patient's organism is susceptible to both INH and RIF.

3. Major Adverse Effects

All patients should be counseled to watch for symptoms of hepatotoxicity such as; nausea, vomiting, abdominal pain, loss of appetite, diarrhea, feeling tired or weak, jaundice (yellowing of the skin and eyes), and/or hepatomegaly (liver enlargement). If hepatotoxicity develops (ALT or AST greater than five times the upper limit of normal, elevated bilirubin, or symptoms of hepatotoxicity), all drugs should be discontinued, and ISDH should be consulted immediately. The ISDH TB Medical Advisory Board has

published guidelines on the management of hepatotoxicity. Other significant adverse reactions are listed in the table below:

Table 2. Adverse affects of first line drugs for tuberculosis

Drug	Major Adverse Effects
Isoniazid	Hepatitis, peripheral neuropathy
Rifampin	Drug interactions, hepatitis
Pyrazinamide	Hepatitis, GI upset, hyperuricemia
Ethambutol	Optic neuritis

4. Drug Dosages and Toxicity

The ISDH TB Medical Advisory Board does not recommend prescribing anything other than standard therapeutic doses (Table 5). Prior to treatment, measure CBC with platelets, liver enzymes, uric acid, visual acuity, and perform color vision screening. Then, clinically assess monthly for side effects and order laboratory tests as indicated.

5. Use of Drugs Other Than INH, RIF, PZA, or EMB

There are no substitutes for any of the first-line agents. Before RIF was available, TB patients had to take medication for 18-24 months. The combination of INH and RIF allowed completion of therapy within 9 months. Routine addition of PZA during the first two months has shortened duration of therapy to 6 months for most cases. EMB is known as a 'companion drug,' and has bacteriostatic activity. Its primary purpose is to suppress the further development of resistance in situations where INH resistance is already present at diagnosis. EMB can be discontinued as soon as the organism is known to be susceptible to both INH and RIF.

The drugs are not interchangeable. Second-line agents must be used when patients cannot take first-line drugs because of resistance, intolerance or adverse reactions. These second-line agents are substantially less active and not without risks of toxicity. Patients taking second-line drugs in lieu of both INH and RIF require treatment durations of up to 2 years with frequent monitoring for side effects.-

6. Drug Resistance

Contact ISDH immediately when drug resistance strain is identified. The preferred regimen for INH-resistant tuberculosis is RIF, PZA and EMB for at least six months. Intermittent therapy should not be used. For treatment of multi-drug resistant cases, or cases resistant only to RIF, ISDH can arrange for expert consultation.-

7. Avoid Divided Medication Doses

Patients are sometimes given split-dose medications for the first few days as a last resort to improve their tolerance if they are experiencing adverse effects. Otherwise, there is no rationale for treatment with divided doses. Therapeutic levels of these drugs are based on single doses. The use of divided doses can markedly reduce adherence to the medication regimen because this practice is not compatible with directly observed therapy.

8. Culture-negative Pulmonary TB

If the patient has a clinical picture consistent with tuberculosis and has responded to therapy, the patient may have smear-negative, culture-negative tuberculosis. Tuberculosis documented with at least three negative smears and cultures may be treated for four months (17 weeks), provided that the patient does not have HIV infection. Contact the Regional TB Nurse Consultant, local health department, or a TB Medical Advisory Board member for details.

9. Complete Diagnostic Evaluation

It is important to try to make a culture-confirmed diagnosis whenever TB is suspected. The local health department can collect three sputum specimens on pulmonary TB suspects and the ISDH laboratory will perform AFB smears, cultures, and drug susceptibility tests at no charge.

10. Length of Treatment

Patients with pulmonary TB, no radiographic evidence of cavitation or cavitary lesions, and who are HIV-negative, can generally be treated successfully in 6 months (26 weeks). Revised treatment guidelines issued by the American Thoracic society recommend extending the continuation phase from 4 to 7 months for (1) patients with cavitary disease and whose sputum specimens collected at the end of the 8-week initial phase are still culture-positive; (2) patients with non-cavitary disease, who are HIV-positive, but whose sputum specimens collected at the end of the 8-week initial phase are still culture-positive, and (3) patients who did not receive PZA during the initial phase.

To further reduce the risk of relapse, ISDH recommends that the continuation phase be extended to 7 months (39 weeks minimum total treatment) for patients with cavitary disease **and** who are culture-positive after the initial treatment phase.

Most forms of extrapulmonary TB can be treated in 6-9 months as long as the regimen contained both INH and RIF. Meningeal TB should be treated for 9-12 months. Many experts recommend 12 months of treatment for bone and joint TB.

11. HIV Infection

Since co-infection with TB and HIV is becoming increasingly more common, all patients diagnosed with TB should be evaluated for HIV infection as well, preferably with serologic studies. RIF is a potent inducer of cytochrome P450 isoenzymes (CYP450) and can cause serious reductions in the therapeutic levels of most non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs). Some NNRTIs and PIs inhibit CYP450, resulting in serum levels of RIF that are too high. For these reasons it is often necessary to use rifabutin in place of rifampin. In addition, HIV-infected TB patients whose CD4+ lymphocyte counts are < 100 cells/µl should not receive their TB drugs with intermittent therapy. Management of AIDS patients with TB is complicated and should be done by physicians who are experts in this field.

> See the "Treatment in Special Situations" topic in this section for information on treatment when there is drug-resistant TB, human immunodeficiency virus (HIV) infection, liver disease, or renal disease; when the patient is taking tumor necrosis factor-alpha (TNF-α) antagonists; where there is culture-negative TB or extrapulmonary TB; when the patient is pregnant or breastfeeding; or when the patient is considered to be of pediatric age.

Regimens

Identify the appropriate regimen for the patient. There are four basic regimens recommended for treating adults with TB caused by organisms that are known or presumed to be susceptible to isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB). Children, depending on the circumstances, may not receive EMB in the initial phase of a six-month regimen, but the regimens are otherwise identical. The preferred regimen for treating TB disease consists of an initial two-month phase of four drugs: INH, RIF, PZA, and EMB followed by a four-month continuation phase of INH and RIF. **In Indiana, the preferred regimen is the Denver Regimen** – refer to ISDH TB Medical Advisory Board Statements on the Treatment of Active TB, page 6.6 and Treatment of TB in Children page 6.11.

Each regimen has an initial phase of two months, followed by a choice of several options for a continuation phase of either four or seven months. In Table 3: **Drug Regimens for Culture-Positive Pulmonary Tuberculosis Caused by Drug-Susceptible Organisms**, the initial phase is denoted by a number (1, 2, 3, or 4), and the options for the continuation phase are denoted by the respective number and a letter designation (a, b, or c).

Directly observed therapy (DOT) is the preferred initial management strategy for all regimens and should be used whenever feasible. All patients being given drugs less than seven days per week (five, three, or two days per week) must receive DOT.

The recommended regimens, and the number of doses specified by each regimen, are described on page 6.13 in Table 4. First-line antituberculosis medications should be administered together; split dosing should be avoided.

Table 3. Suggested Pyrazinamide and Ethambutol Doses, Using Whole Tablets,For Adults Weighing 40-90 Kg

Pyrazinamide Doses	**Weight (Kg)** †		
	40-55	**56-75**	**76-90**
Daily	1000 mg	1500 mg	2000 mg‡
(mg/kg)	(18.2-25.0)	(20.0-26.8)	(22.2-26.3)
Thrice Weekly	1500 mg	2500 mg	3000‡
(mg/kg)	(27.3-37.5)	(33.3-44.6)	(33.3-39.5)
Twice Weekly	2000 mg	3000 mg	4000‡
(mg/kg)	(36.4-50.0)	(40.0-53.6)	(44.4-52.6)
Ethambutol Doses	**Weight (Kg)** †		
	40-55	**56-75**	**76-90**
Daily	800 mg	1200 mg	1600 mg‡
(mg/kg)	(14.5-20.0)	(16.0-21.4)	(17.8-21.1)
Thrice Weekly	1200 mg	2000 mg	2400‡
(mg/kg)	(21.8-30.0)	(26.7-35.7)	(26.7-31.6)
Twice Weekly	2000 mg	2800 mg	4000‡
(mg/kg)	(36.4-50.0)	(37.3-50.0)	(44.4-52.6)

† Based on estimated lean body weight. ‡ Maximum dose regardless of weight.

For questions regarding the treatment of TB or second-line drugs, contact your Regional TB Consultant, contact information in Section 1 – Introduction.

A **Tuberculosis Drug Information Guide** on first and second line TB drugs including information on use in pregnancy/breast feeding, renal disease, hepatic disease, seizure medication, etc. is available from Francis J. Curry National TB Center at http://www.nationaltbcenter.ucsf.edu/tbdruginfo/.

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To request ISDH TB Treatment Pocket Guides call 317.233.7434.

ANY INTERMITTENT REGIMEN SHOULD BE GIVEN AS DOT (Directly Observed Therapy) and ANY REGIMEN FOR CHILDREN SHOULD BE GIVEN AS DOT.

Review ISDH Consensus Statement of the Tuberculosis Medical Advisory Board on **Directly Observed Therapy,** adopted 1-1999, at http://www.in.gov/isdh/files/TB_DOT_MAB_revised.pdf

Table 4: DRUG REGIMENS FOR CULTURE-POSITIVE PULMONARY TB CAUSED BY DRUG-SUSCEPTIBLE ORGANISMS[2]

INITIAL PHASE					CONTINUATION PHASE						
R	Drugs	Interval & doses (minimal duration)	Rating (evidence) HIV-	Rating (evidence) HIV+	R	Drugs	Interval & doses (minimal duration)	Range of total doses	(minimal duration)	Rating (evidence) HIV-	Rating (evidence) HIV+
1	INH RIF EMB PZA	7 d / wk - 56 doses (8wk) **OR** 5 d / wk - 40 doses (8wk) **DOT**	A (I) A (III)	A (II) A (III)	1a	INH RIF	7 days per week - 126 doses (18wk) **OR** 5 days per week - 90 doses (18wk) **DOT**	182-130	(26 wk)	A (I) A (III)	A (II) A (III)
					1b	INH RIF	2 **x's** wkly - 36 doses (18 wk)	92-76	(26 wk)	A (I)	A (II)
					1c	INH RPT	1 **x** wkly - 18 doses (18 wk)	74-58	(26 wk)	**B (I)**	E (I)
2	INH RIF EMB PZA	7 d / wk - 14 doses (2 wk), **then** 2 **x's** wkly - 12 doses (6 wk) **OR** 5 d / wkly - 10 doses (2 wk), **then** 2 **x's** wkly – 12 doses (6 wk) **DOT**	A (II) A (III)	B (II) A (III)	2a	INH RIF	2 **x's** wkly - 36 doses (18 wk)	62-58	(26 wk)	A (II)	B (II)
					2b	INH RPT	1 **x** wkly - 18 doses (18 wk)	44-40	(26 wk)	**B (I)**	E (I)
3	INH RIF EMB PZA	3 **x's** wkly - 24 doses (8 wk)	B (I)	B (II)	3a	INH RIF	3 **x's** wkly - 54 doses (18 wk)	78	(26 wk)	B (I)	B (II)
4	INH RIF EMB	7 d / wk - 56 doses (8 wk) **OR** 5 d / wk - 40 doses (8 wk) **DOT**	C (I) A (III)	C (II) A (III)	4a	INH RIF	7 d / wk - 217 doses (31 wk) **OR** 5 d / wk - 155 doses (31 wk) **DOT**	273-195	(39 wk)	C (I) A (III)	C (II) A (III)
					4b	INH RIF	2 **x's** wkly – 62 doses (31 wk)	118-102	(39 wk)	C (1)	C (II)

5 day a week administration is ALWAYS given by **DOT** (there are no studies that compare 5 with 7 daily doses, extensive experience indicates this would be an effective practice)

Patients with cavitation on initial CXR & + cultures at completion of 2 months of therapy should receive a 7-month continuation phase of 31 weeks - 217 doses [daily] **OR** 62 doses [twice wkly]

Options 1 c & 2b should be used only in HIV neg patients with neg sputum smears at the completion of 2 months of therapy and without cavitation on initial CXR. For patients started on this regimen with a positive culture from the 2 month specimen, treatment should be extended an extra 3 months

Not for pts with CD4+ cell counts of < 100 cells µl

EVIDENCE RATINGS DEFINITIONS: A = preferred; B = acceptable alternative; C = offer when A & B cannot be given; D = should generally not be offered; E = should never be given
I = randomized clinical trial; II = data from clinical trials that were not randomized or were conducted in other populations; III = expert opinion

Source: ATS, CDC, IDSA. Treatment of tuberculosis, MMWR 52(RR11); 6-20-2003

Table 5: DOSES*OF FIRST-LINE ANTITUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN[† 3]

Drug	Preparation	Adults/children	Doses			
			Daily	1x/wk	2x/wk	3x/wk
INH	Tablets (50 mg, 100 mg, 300 mg); elixir (50 mg/5 ml); aqueous solution (100 mg/ml) for intramuscular injection[¶]	Adults (max.)	5 mg/kg (300 mg)	15 mg/kg (900 mg)	15 mg/kg (900 mg)	15 mg/kg (900 mg)
		Children (max.)	10–15 mg/kg (300 mg)	—	20–30 mg/kg (900 mg)	—
RIF	Capsule (150 mg, 300 mg); powder may be suspended for oral administration; aqueous solution for intravenous injection	Adults[‡] (max.)	10 mg/kg (600 mg)	—	10 mg/kg (600 mg)	10 mg/kg (600 mg)
		Children (max.)	10–20 mg/kg (600 mg)	—	10–20 mg/kg (600 mg)	—
RFB	Capsule (150 mg)	Adults[‡] (max.)	5 mg/kg (300 mg)	—	5 mg/kg (300 mg)	5 mg/kg (300 mg)
		Children	Appropriate dosing for children is unknown	Appropriate dosing for children is unknown	Appropriate dosing for children is unknown	Appropriate dosing for children is unknown
RPT	Tablet (150 mg, film coated)	Adults	—	10 mg/kg (continuation phase) (600 mg)	—	—
		Children	This drug is not approved for use in children	This drug is not approved for use in children	This drug is not approved for use in children	This drug is not approved for use in children
PZA	Tablet (500 mg, scored)	Adults	See Table 5	—	See Table 5	See Table 5
		Children (max.)	15–30 mg/kg (2.0 g)	—	50 mg/kg (2.0 g)	—
EMB	Tablet (100 mg, 400 mg)	Adults	See Table 6	—	See Table 6	See Table 6
		Children[§] (max.)	15–20 mg/kg daily (1.0 g)	—	50 mg/kg (2.5 g)	—

Definitions of abbreviations: EMB = ethambutol; FDA = Food and Drug Administration; INH = isoniazid; PZA = pyrazinamide; RFB = rifabutin; RIF = rifampin; RPT = rifapentine.

* Dose per weight is based on ideal body weight. Children weighing more than 40 kg should be dosed as adults.

† For the purposes of this document, adult dosing begins at the age of 15 years.

¶ INH is used, but not FDA-approved, for intravenous administration. For IV use of INH, please consult with the ISDH Regional TB Nurse Consultant (contact info Section 1 – Introduction).

‡ Dose may need to be adjusted when there is concomitant use of protease inhibitors or nonnucleoside reverse transcriptase inhibitors.

§ The drug can likely be used safely in older children but should be used with caution in children less than 5 years of age, in whom visual acuity cannot be monitored. In younger children, EMB at the dose of 15 mg/kg per day can be used if there is suspected or proven resistance to INH or RIF.

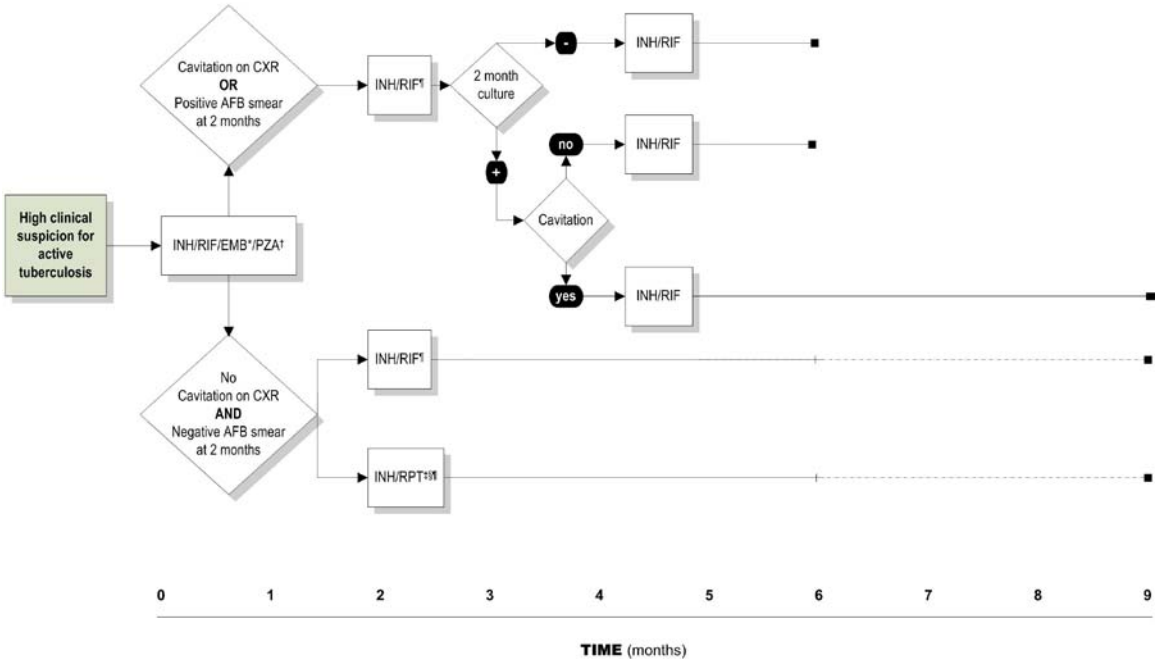
Source: ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):4.

Duration of Treatment

Use the **Treatment Algorithm for Tuberculosis** algorithm (Figure 1) to determine the duration of treatment. The 4 recommended regimens for treating drug-susceptible TB have a duration of 6 to 9 months. Each regimen has an initial phase of 2 months and a continuation phase of either 4 or 7 months. Figure 1 gives directions for treating pulmonary and extrapulmonary TB. The standard duration of treatment for pulmonary TB should be 6 months unless **both** cavitation is present **and** the patient is still culture positive after 2 months, in which case 9 months is recommended. Note that there are 3 exceptions to the standard 6-month duration of treatment.

1. For TB meningitis, the optimal length of therapy has not been established, although some experts recommend 9 to 12 months.[4]
2. Treatment (containing RIF) for bone or joint TB may need to extend to 9 months[5]
3. In HIV-negative, culture-negative patients, treatment for 4 months may be adequate if there is clinical or radiographic improvement and no other etiology identified.[6] However, HIV-infected patients with culture-negative pulmonary TB should be treated for a minimum of 6 months.[7]

Figure 1. TREATMENT ALGORITHM FOR TUBERCULOSIS[8]



Abbreviations: AFB = acid-fast bacilli; CXR = chest radiograph; EMB = ethambutol; HIV = human immunodeficiency virus; INH = isoniazid; PZA = pyrazinamide; RIF = rifampin; RPT = rifapentine.

* EMB may be discontinued when results of drug susceptibility testing indicate no drug resistance.

† PZA may be discontinued after it has been taken for 2 months (56 doses).

‡ RPT should not be used in HIV-infected patients with TB or in patients with extrapulmonary TB.

§ Therapy should be extended to 9 months if the 2-month culture is positive.

¶ At 2 months, review drug susceptibility and culture results, if applicable, and review these results regularly throughout treatment if the patient is drug resistant. Source: ATS, CDC, IDSA. Treatment of TB. *MMWR* 2003;52(No. RR-11):6.

Side Effects and Adverse Reactions

The patient should be monitored by a registered nurse and/or clinician or case manager at least monthly for signs and symptoms of adverse reactions until treatment is completed. If a patient is symptomatic, the provider should be consulted and the patient monitored more frequently. Chemistries and complete blood count (CBC), aspartate aminotransferase (AST)/alanine aminotransferase (ALT), or other tests based on specific drugs should be done periodically, as indicated. See Table 8**: Monitoring and Interventions for Side Effects and Adverse Reactions** in this section.

As is true with all medications, combination chemotherapy for tuberculosis is associated with a predictable incidence of adverse effects, some mild, some serious.[9]

Adverse effects are fairly common and often manageable. Although it is important to be attuned to the potential for adverse effects, it is at least equally important that first-line drugs not be stopped without adequate justification.[10] However, adverse reactions can be severe, and thus, it is important to recognize adverse reactions that indicate when a drug should not be used. Mild adverse effects can generally be managed with symptomatic therapy; whereas with more severe effects, the offending drug or drugs must be discontinued.[11] In addition, proper management of more serious adverse reactions often requires expert consultation.[12]

Monitor patients for side effects and adverse reactions following the basic monitoring steps listed below.

Basic Monitoring Steps

1. All healthcare workers providing treatment for TB disease should be familiar with the American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC) guidelines.
   a. All jurisdictions should follow the national monitoring guidelines identified in the current guidelines for treatment of TB, “Treatment of Tuberculosis” (*MMWR* 2003;52[No. RR-11]) at http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .
   b. It is also important to check for guideline updates posted on the CDC’s Division of Tuberculosis Elimination home page at http://www.cdc.gov/tb/ and the list of guidelines by date at http://www.cdc.gov/tb/pubs/mmwr/Maj_guide/List_date.htm.
2. While on treatment, all patients should be evaluated in person at baseline (before starting treatment) and then at least monthly for side effects and adverse reactions.

3. The common side effects of and adverse reactions to drugs used to treat for TB disease are listed below in Table 7: **Reporting Reactions to Antituberculosis Medications**. Educate patients to stop the medicine and promptly report any of the symptoms or signs listed in Table 7 or any unexplained illness to the prescribing physician or the nurse case manager immediately.
   a. If a patient reports a potentially serious adverse reaction, hold the medications and call the patient's provider immediately and alert the LHD.
   b. If a patient reports a potentially less severe side effect, call the patient's provider immediately and monitor the patient.
4. If you suspect that an antituberculosis drug may be causing a particular side effect or adverse reaction:
   a. Refer to Table 8: **Monitoring and Interventions for Side Effects and Adverse Reactions**.
   b. Consult with the state TB program by calling your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.
5. If you suspect that an antituberculosis drug may be interacting with other medications that the patient is taking, refer to pages 45–47 in the "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]) at http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .
6. Document the following patient information:
   a. Review of symptoms, test results, side effects, and adverse reactions
   b. Education given
   c. DOT provided
   d. Description of any problems encountered and action taken for that visit
   e. Next DOT visit

Reporting Reactions

The table below is intended for use by a healthcare worker who performs case management services. The healthcare worker should instruct the patient to report to the provider the side effects and adverse reactions listed below in Table 7.

If a patient reports to a healthcare worker a potentially serious adverse reaction, the healthcare worker should call the patient's medical provider immediately and alert the patient's nurse case manager.

If a patient reports to a healthcare worker a potentially less severe side effect, the healthcare worker should call the patient's medical provider immediately and monitor the patient.

Table 7: REPORTING REACTIONS TO ANTITUBERCULOSIS MEDICATIONS[13]

Potentially Serious Adverse Reactions*	Less Severe Signs and Symptoms*
Immediately report the following signs and symptoms or other abnormalities or unexpected events to the patient's provider. These signs and symptoms suggest side effects, including hepatotoxicity: ▪ Jaundice ▪ Dark urine ▪ Vomiting ▪ Abdominal pain ▪ Fever ▪ Visual changes ▪ Marked clinical rash In consultation with the provider, instruct the patient to stop TB medications until evaluated by the provider.	Report the following signs and symptoms to the patient's provider within 24 hours: ▪ Anorexia ▪ Nausea ▪ Malaise ▪ Peripheral neuropathy: tingling or burning sensation in hands or feet ▪ Rashes
* These lists are not all-inclusive. Second-line drugs are not included. For a complete list, refer to the current guidelines for treatment of TB, "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]), at http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .	

Source: California Department of Health Services (CDHS)/California Tuberculosis Controllers Association (CTCA). TB case management—core components. *CDHS/CTCA Joint Guidelines* [CTCA Web site]. May 11, 1998:9. Available at: http://www.ctca.org/guidelines/index.html . Accessed July 11, 2006.

Monitoring for Side Effects and Adverse Reactions by Antituberculosis Drug

Refer to Table 8**: Monitoring and Interventions for Side Effects and Adverse Reactions** to do the following:

- Identify the side effects and adverse reactions associated with particular antituberculosis drugs
- Determine how to monitor for side effects and adverse reactions

Table 8: MONITORING AND INTERVENTIONS FOR SIDE EFFECTS AND ADVERSE REACTIONS[14,15,16]

Anti-tuberculosis Drug	Side Effects/ Adverse Reactions	Monitoring	Comments
Isoniazid (INH)	▪ Rash ▪ Hepatic enzyme elevation ▪ Hepatitis ▪ Peripheral neuropathy ▪ Mild central nervous system effects	Clinical monitoring monthly Liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and serum bilirubin) at baseline in selected cases ((human immunodeficiency virus [HIV] infection, history of liver disease, alcoholism, and pregnancy) Repeat measurements if ▪ Baseline results are abnormal ▪ Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions ▪ Patient has symptoms of adverse reactions	Hepatitis risk increases with age and alcohol consumption. Pyridoxine (vitamin B6, 10–25 mg/d) might prevent peripheral neuropathy and central nervous system effects. Serum concentrations of phenytoin, disulfiram (Antabuse), and carbamazepine may be increased in persons taking INH. Measure serum concentrations of phenytoin and carbamazepine in patients receiving INH (with or without rifampin), and adjust the dose if necessary.

Anti-tuberculosis Drug	Side Effects/ Adverse Reactions	Monitoring	Comments
Rifampin (RIF)	▪ Rash ▪ Gastrointestinal upset ▪ Hepatitis ▪ Fever ▪ Bleeding problems ▪ Thrombocytopenia ▪ Renal failure ▪ Flu-like symptoms ▪ Orange-colored body fluids (secretions, urine, tears)	Complete blood count, platelets, and liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and serum bilirubin) at baseline in selected cases (human immunodeficiency virus [HIV] infection, history of liver disease, alcoholism, and pregnancy) Repeat measurements if ▪ Baseline results are abnormal ▪ Patient has symptoms of adverse reactions	There are a number of drug interactions with potentially serious consequences. Significant interactions with methadone, birth control hormones, and many other drugs. Contraindicated or should be used with caution when administered with protease inhibitors (PIs) and nonnucleoside reverse transcriptase inhibitors (NNRTIs). Reduces levels of many drugs (e.g., PIs, NNRTIs, methadone, dapsone, ketoconazole, coumadin derivatives, hormonal contraceptive, digitalis, sulfonylureas, diazepam, ß-blockers, anticonvulsants, and theophylline). For more information, refer to “Section 7: Drug Interactions” on page 45 in “Treatment of Tuberculosis” at http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf . Because information regarding rifamycin drug interactions is evolving rapidly, consult the CDC’s Division of Tuberculosis “News and Updates” Web page at http://www.cdc.gov/tb/ to obtain the most up-to-date information. Colors body fluids orange. May permanently discolor soft contact lenses.

Anti-tuberculosis Drug	Side Effects/ Adverse Reactions	Monitoring	Comments
Rifabutin (RFB)	▪ Rash ▪ Hepatitis ▪ Fever ▪ Thrombocytopenia ▪ Orange-colored body fluids (secretions, urine, tears) With increased levels of RFB: ▪ Severe arthralgias ▪ Uveitis ▪ Leukopenia	Complete blood count, platelets, and liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and serum bilirubin) at baseline in selected cases (human immunodeficiency virus [HIV] infection, history of liver disease, alcoholism, and pregnancy) Repeat measurements if ▪ Baseline results are abnormal ▪ Patient has symptoms of adverse reactions Use adjusted daily dose of RFB and monitor for decreased antiretroviral activity and for RFB toxicity if RFB taken concurrently with protease inhibitors (PIs) or nonnucleoside reverse transcriptase inhibitors (NNRTIs)	Although drug interactions are less problematic with RFB, they still occur and close monitoring is required. Contraindicated for HIV-infected patients taking hard-gel saquinavir or delavirdine; caution is also advised if RFB is administered with soft-gel saquinavir. Similar to rifampin but less potent of an inducer, rifabutin reduces levels of many drugs (e.g., PIs, NNRTIs, methadone, dapsone, ketoconazole, coumadin derivatives, hormonal contraceptive, digitalis, sulfonylureas, diazepam, ß-blockers, anticonvulsants, and theophylline). When used with efavirenz, the daily dose of RFB should be increased from 300 mg to 450 mg or 600 mg. May permanently discolor soft contact lenses.

Anti-tuberculosis Drug	Side Effects/ Adverse Reactions	Monitoring	Comments
Rifapentine (RPT)	Similar to those associated with rifampin	Similar to that for rifampin	Drug interactions involving RPT are being investigated and are likely to be similar to those of rifampin. RPT is an inducer of multiple hepatic enzymes and therefore may increase metabolism of coadministered drugs that are metabolized by these enzymes. For more information, refer to “Section 7: Drug Interactions” on page 45 in “Treatment of Tuberculosis” at http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .

Anti-tuberculosis Drug	Side Effects/ Adverse Reactions	Monitoring	Comments
Pyrazinamide (PZA)	▪ Gastrointestinal upset ▪ Hepatitis ▪ Rash ▪ Photosensitive dermatitis ▪ Hyperuricemia ▪ Joint aches ▪ Gout (rare)	Clinical monitoring at weeks 2, 4, and 8 If the drug is used in patients with underlying liver disease, laboratory and clinical monitoring should be increased Baseline measurements of uric acid Liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and serum bilirubin) at baseline in selected cases (human immunodeficiency virus [HIV] infection, history of liver disease, alcoholism, or pregnancy) Repeat measurements if ▪ Baseline results are abnormal ▪ Patient has symptoms of adverse reactions	Treat hyperuricemia only if patient has symptoms. Might make glucose control more difficult in persons with diabetes. Serum uric acid measurements are not recommended as a routine but may serve as a surrogate marker for compliance.

Anti-tuberculosis Drug	Side Effects/ Adverse Reactions	Monitoring	Comments
Ethambutol (EMB)	▪ Optic neuritis ▪ Rash	Baseline tests of visual acuity (Snellen chart) and color discrimination (Ishihara tests) At each monthly visit, patients should be questioned regarding possible visual disturbances, including blurred vision or scotomata Monthly testing of visual acuity and color discrimination is recommended for ▪ Patients taking doses >15–25 mg/kg ▪ Patients receiving EMB for >2 months ▪ Patients with renal insufficiency	Optic neuritis may be unilateral; check each eye separately. Patients should be instructed to contact their physician or public health clinic immediately if they experience a change in vision. EMB should be discontinued immediately and permanently if there are any signs of visual toxicity.
Rifamate® (INH and RIF) Rifater® (INH, RIF, PZA)	See comments under individual drugs above		

Definitions of abbreviations: ALT = alanine aminotransferase; AST = aspartate aminotransferase; EMB = ethambutol; HIV = human immunodeficiency virus; INH = isoniazid; NNRTIs = nonnucleoside reverse transcriptase inhibitors; PZA = pyrazinamide; PIs = protease inhibitors; RFB = rifabutin; RIF = rifampin; RPT = rifapentine.

Sources: CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49 (No. RR-6):26–29, 38–39; ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):19–25; CDC. Update: Adverse event data and revised American Thoracic Society/CDC recommendations against the use of rifampin and pyrazinamide for treatment of latent tuberculosis infection—United States. *MMWR* 2003;52(No. 31):735–736; CDC. Table 5: first-line anti-TB medications. In: Chapter 7: treatment of TB disease. *Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]. Updated November 2001. November 2001. Available at: http://www.cdc.gov/tb/pubs/corecurr/index.htm . Accessed July 3, 2006.

Response to Treatment

Refer to ISDH algorithm **Tuberculosis Sputum Collection**, Section 11 – Laboratory Services.

For patients whose sputum cultures are positive before treatment, the best way to measure the effectiveness of therapy is to obtain specimens for culture at least monthly until the cultures convert to negative (refer to the Sputum Collection Algorithm in Section 11). Patients with multidrug-resistant tuberculosis (MDR-TB) should have cultures performed monthly for the entire course of treatment.

In some cases, a patient may not be able to produce a sputum specimen at two months of treatment. If the patient has improved clinically and has shown chest radiograph improvement, treatment may be continued as if the patient had a negative sputum specimen at two months.

Radiographic evaluations during treatment are of less importance than sputum evaluation. However, a chest radiograph at completion of treatment provides a baseline for comparison with future films.

Patients whose cultures have not become negative or whose symptoms do not resolve despite three months of therapy should be reevaluated for potential drug-resistant disease, as well as for potential failure to adhere to the regimen. If the patient is receiving self-administered therapy, the remainder of treatment should be directly observed.

If drug susceptibility results show resistance to any of the first-line drugs or if the patient remains symptomatic or smear- or culture-positive after three months, a TB medical expert should be consulted. **Contact the ISDH TB/Refugee Health Division at 317.233.7434 immediately.**

In patients with negative sputum cultures before treatment, the major indicators of response to therapy are the chest radiograph and clinical evaluation. The intervals at which chest radiography should be repeated depend on the clinical circumstances and the differential diagnosis that is being considered but usually should be no more than every three months. If the radiograph does not improve after the patient has received three months of treatment, the abnormality may be the result of either previous (not current) TB or another process.[17]

For questions regarding a patient's response to treatment, contact your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.

Completion of Therapy

A full course of therapy (completion of treatment) is determined more accurately if the **total number of doses ingested** is taken into account, as well as the duration of therapy. If there are no interruptions in drug administration, six months is usually the minimum duration of treatment and accurately indicates the amount of time in which drugs are given. However, in human immunodeficiency virus (HIV)-negative, culture-negative patients, treatment for four months may be adequate if there is clinical or radiographic improvement and no other etiology identified.[18]

For questions regarding the treatment of tuberculosis (TB) in a patient with negative cultures, contact your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.

In some cases, either because of drug toxicity or nonadherence to the treatment regimen, the specified number of doses cannot be administered within the targeted period. In such cases, the goal is to deliver the specified number of doses within a recommended maximum time. For example, for a six-month daily regimen, the total doses should be administered within nine months of beginning treatment. If treatment is not completed within this period, the patient should be assessed to determine the appropriate action to take, such as continuing treatment for a longer duration or restarting treatment from the beginning.

Treating a patient for a defined duration, without accounting for the number of doses taken, can result in undertreatment.

Interruptions in treatment may have a significant effect on the duration of therapy. Reinstitution of treatment must take into account the extensiveness of the disease (e.g., cavitary versus noncavitary disease on chest radiograph, smears and cultures, immunologic status), the point in time when the interruption occurred, and the duration of the interruption. In general, the earlier in treatment and the longer the duration of the interruption, the more serious the effect and the greater the need to restart therapy from the beginning.[19]

For questions regarding completion of therapy or considerations for retreatment, contact your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.

Post-Treatment Evaluation

Routine follow-up after completion of therapy is not necessary for patients with a satisfactory and prompt bacteriologic response to a six- or nine-month regimen that included both isoniazid and rifampin.

The table below describes the clinician's responsibilities at completion of therapy for cases in which the organisms are drug-susceptible and drug-resistant.

Table 9: CLINICIAN'S RESPONSIBILITIES AT COMPLETION OF THERAPY

Drug Susceptibility	Clinician's Actions
Drug-susceptible organisms	Instruct the patient to promptly report the development of any symptoms, particularly prolonged cough, fever, or weight loss.
Organisms resistant to isoniazid, rifampin, or both	Individualize follow-up evaluation.[20]

For questions regarding post-treatment evaluation, contact your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.

Treatment in Special Situations

Treatment of tuberculosis (TB) in the following situations requires a high level of expertise or close consultation with an expert to provide appropriate management:

- Drug-resistant TB
- Human immunodeficiency virus (HIV) infection
- Alcoholism
- Liver disease
- Renal insufficiency and end-stage renal disease
- TB associated with tumor necrosis factor-alpha (TNF-α) antagonists
- Culture-negative pulmonary TB
- Extrapulmonary TB
- Pregnancy and breastfeeding
- TB in children

For questions regarding treatment in the special situations, contact your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.

Drug-Resistant Tuberculosis

Treatment of TB caused by drug-resistant organisms should be provided by, or in close consultation with, an expert in the management of these difficult situations. Second-line regimens often represent the patient's last hope for being cured, and inappropriate management can have life-threatening consequences.[21]

Drug resistance is proven only by drug-susceptibility testing performed in a competent laboratory. A patient with a strain of *Mycobacterium tuberculosis* resistant to both isoniazid (INH) and rifampin (RIF) has multidrug-resistant TB (MDR-TB). Refer MDR-TB patients immediately to a specialist or seek consultation with a specialized treatment center.[22]

Extensively drug-resistant tuberculosis (XDR TB) is a relatively rare type of multidrug-resistant tuberculosis (MDR TB). It is resistant to almost all drugs used to treat TB, including the two best first-line drugs: isoniazid and rifampin. XDR TB is also resistant to the best second-line medications: fluoroquinolones and at least one of three injectable drugs (i.e., amikacin, kanamycin, or capreomycin).

Acquired drug resistance usually develops when an inadequate drug regimen is prescribed (e.g., inappropriate drugs or insufficient dosage) or when there is a combined failure of both the patient and the provider to ensure that an adequate regimen is taken. A patient with acquired drug resistance may transmit his or her strain to others, who may then develop primary drug-resistant TB.[23]

Resources

- ATS, CDC, IDSA. "Treatment of Tuberculosis" *(MMWR* 2003;52[No. RR-11]:11-12, 68–70). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf
- CDC. "Multidrug-Resistant Tuberculosis (MDR TB)" (*TB Elimination Fact Sheet;* accessed June 30, 2008). Available at: http://www.cdc.gov/tb/publications/factsheets/drtb/mdrtb.htm
- CDC. "Extensively Drug-Resistant Tuberculosis (XDR TB)" (*TB Elimination Fact Sheet;* accessed June 30, 2008). Available at: http://www.cdc.gov/tb/publications/factsheets/drtb/xdrtb.htm

Human Immunodeficiency Virus Infection

Management of HIV-related TB is complex and requires expertise in the management of both HIV disease and TB. Because HIV-infected patients often take numerous medications, some of which interact with antituberculosis medications, clinicians are strongly encouraged to consult with experts who treat HIV-related TB.

It is especially important to use directly observed therapy (DOT) and other adherence-promoting strategies with patients with HIV-related TB.

The following are contraindicated in HIV-infected patients:

- Isoniazid-rifapentine (INH-RPT) once weekly
- Twice-weekly rifampin (RIF)- or rifabutin (RFB)-based regimens in patients with CD4+ cell counts of less than 100 per microliter [24]

Patients with HIV-related TB may experience a temporary exacerbation of symptoms, signs, or radiographic manifestations (paradoxical reactions) of TB while receiving antituberculosis treatment.[25]

Resources

- ATS, CDC, IDSA. "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]:9, 50–55). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .
- ATS, CDC. "Notice to Readers: Updated Guidelines for the Use of Rifamycins for the Treatment of Tuberculosis among HIV-infected Patients Taking Protease Inhibitors or Nonnucleoside Reverse Transcriptase Inhibitors" (*MMWR* 2004;53[No. 2]:37). Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5302a6.htm .

- CDC. *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/Default.htm .
- CDC. "Treatment of Drug-Susceptible TB in HIV-Infected Persons" (*TB Elimination Fact Sheet*; March 2003). Available at: http://www.cdc.gov/tb/pubs/tbfactsheets/treatmentHIVpositive.htm .
- CDC. "Treating Opportunistic Infections Among HIV-exposed and Infected Children" (*MMWR* 2004;53[No. RR-14]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5314.pdf .

Alcoholism

Alcohol-Related Treatment Complications

Risk of drug-induced liver injury and nonadherence complicate health interventions for patients who are diagnosed with TB disease or latent tuberculosis infection (LTBI) and who also are known or suspected to have an alcohol use disorder, who drink heavily, or who regularly consume alcohol.

In several important ways related to tuberculosis and its treatment, alcohol consumption increases health risks and can complicate the treatment of patients.

- **Immunosuppression:** Persons who use alcohol may be at increased risk for acquiring or developing TB, but given the many other potential risk factors that commonly occur among such persons, alcohol use has been difficult to identify as a separate risk factor for TB.[26] However, studies have shown that "alcohol consumption is a major risk factor for infection with opportunistic bacterial, viral, fungal, and parasitic pathogens."[27]
- **Liver injury and death**: Drug-induced liver injury "may occur with all currently recommended regimens for the treatment of …LTBI".[28] In the treatment of TB disease, "the crucial efficacy of isoniazid, and particularly rifampin, warrants their use and retention, if at all possible, even in the face of preexisting liver disease."[29] However, it is not fully understood yet how antituberculosis medications cause drug-induced liver injury.[30] For persons taking isoniazid, an association of hepatitis was found with alcohol consumption, with rates being fourfold higher among persons consuming alcohol daily than among those who did not drink alcohol.[31] When a patient has hepatic disease, the risk of drug accumulation and drug-induced hepatitis is increased. However, with more frequent laboratory and clinical monitoring, isoniazid may be used in patients with stable hepatic disease. Transient asymptomatic hyperbilirubinemia may occur in patients taking rifampin or rifapentine, and more severe clinical hepatitis may also occur. Hepatitis is more common when rifampin is given with isoniazid than when rifampin is given alone or with drugs other than isoniazid.[32,33] Pyrazinamide has slightly lower rates of hepatotoxicity than isoniazid or rifampin, but pyrazinamide can cause liver injury that may be severe and prolonged.[34]

To prevent and manage drug-induced liver injury, the American Thoracic Society recommends the following systematic steps: consideration of benefits and risks in selecting patients and regimens, careful and thorough staff and patient education, ready access to care, good communication between providers, and clinical and biochemical monitoring.[35]

- **Nonadherence to treatment:** Patients who do not complete LTBI treatment risk progression to TB disease, and those who do not complete treatment for TB disease risk relapse, development of drug-resistant TB, serious illness, and possible death. Barriers to adherence may be patient related, such as conflicting health beliefs, alcohol or drug dependence, or mental illness, or they may be system related, such as lack of transportation, inconvenient clinic hours, and lack of interpreters.[36] It is more difficult for patients who have an alcohol use disorder to adhere to therapy. In a prospective study of 224 patients, "noncompliance was significantly associated with homelessness and alcoholism."[37] In a study of 237 patients in the Russian Federation undergoing DOTS treatment for TB disease, "substance abuse was identified as the only factor that was strongly associated with non-adherence…These results suggest that DOTS programmes [sic] might be more likely to achieve TB control targets if they include interventions aimed at improving adherence by diagnosing and treating substance abuse concurrently with standard TB therapy."[38] DOTS programs that have explicitly offered substance abuse treatment have reported better outcomes that those that have not.[39] In South Carolina, joint treatment programs to treat patients with TB who have alcohol and substance abuse problems were used in conjunction with incentives, enablers, and a process of increasing restrictions (health department warnings, then court-ordered directly observed therapy, then involuntary confinement) as needed to address noncompliance. This combination of strategies was associated with an increase in overall completion of antituberculosis therapy and a decrease in new cases between 1986-1991.[40]

Liver Disease

Management of TB in patients with unstable or advanced liver disease is difficult. The likelihood of drug-induced hepatitis may be greater in these patients. The implications of drug-induced hepatitis for patients with marginal hepatic reserve are potentially serious, even life-threatening. Also, fluctuations in the biochemical indicators of liver function (with/without symptoms) related to the preexisting liver disease confound monitoring for drug-induced hepatitis.[41]

For all patients with preexisting liver disease, frequent clinical and laboratory monitoring should be performed to detect drug-induced hepatic injury.[42]

For more information on the Management of the Active TB Patient at Risk of Hepatotoxicity see Heartland National TB Center's algorithm at:

http://www.heartlandntbc.org/products/management_of_the_active_tb_patient_at_risk_of_hepatotoxicity.pdf.

Resources

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Renal Insufficiency and End-Stage Renal Disease

Treatment Complications

Renal insufficiency complicates the management of TB because some antituberculosis medications are cleared by the kidneys. Management may be further complicated by the removal of some antituberculosis agents via hemodialysis. Thus, some alteration in dosing antituberculosis medications is commonly necessary in patients with renal insufficiency and end-stage renal disease (ESRD) receiving hemodialysis.

Creatinine Clearance

Dosing recommendations are based on patients' creatinine clearance.

Administration of drugs that are cleared by the kidneys is managed in the same manner, with an increase in dosing interval for patients having a creatinine clearance of less than 30 ml/minute or for patients receiving hemodialysis.

In patients having a reduced creatinine clearance (but not less than 30 ml/minute), standard doses should be used, but measurement of serum concentrations should be considered to avoid toxicity. [43]

Dosing Recommendations

For patients having a creatinine clearance of less than 30 ml/minute or for patients receiving hemodialysis, the following adjustments to conventional dosing are recommended. Refer to Table 10.

Table 10: DOSING RECOMMENDATIONS FOR ADULT PATIENTS WITH REDUCED RENAL FUNCTION AND FOR ADULT PATIENTS RECEIVING HEMODIALYSIS[44]

Drug	Change in Frequency?	Recommended dose and frequency for patients with creatinine clearance <30 ml/min or for patients receiving hemodialysis
Isoniazid	No change	300 mg once daily, or 900 mg 3 times per week
Rifampin	No change	600 mg once daily, or 600 mg 3 times per week
Pyrazinamide	Yes	25–35 mg/kg per dose 3 times per week (not daily)
Ethambutol	Yes	15–25 mg/kg per dose 3 times per week (not daily)
Moxifloxacin	No	400 mg/dose daily†
Levofloxacin	Yes	750–1,000 mg per dose 3 times per week (not daily)
Cycloserine	Yes	250 mg once daily, or 500 mg/dose 3 times per week*
Ethionamide	No change	250-500 mg/dose daily
p-Aminosalicylic acid	No change	4 g/dose, twice daily
Streptomycin	Yes	12–15 mg/kg per dose 2 or 3 times per week (not daily)
Capreomycin	Yes	12–15 mg/kg per dose 2 or 3 times per week (not daily)
Kanamycin	Yes	12–15 mg/kg per dose 2 or 3 times per week (not daily)
Amikacin	Yes	12–15 mg/kg per dose 2 or 3 times per week (not daily)

* The appropriateness of 250-mg daily doses has not been established. There should be careful monitoring for evidence of neurotoxicity. (See Section 3 of the "Treatment of Tuberculosis" guidelines.)

† No adjustment in dose is needed for those with low creatinine clearance or those on hemodialysis. No adjustment in dosing frequency is needed, but it may be given three times per week to facilitate administration.

Standard doses are given unless there is intolerance. The medications should be given after hemodialysis on the day of hemodialysis. Monitoring of serum drug concentrations should be considered to ensure adequate drug absorption, without excessive accumulation, and to assist in avoiding toxicity.

Data currently are not available for patients receiving peritoneal dialysis. Until data become available, begin with doses recommended for patients receiving hemodialysis and verify adequacy of dosing, using serum

Drug	Change in Frequency?	Recommended dose and frequency for patients with creatinine clearance <30 ml/min or for patients receiving hemodialysis
concentration monitoring.		

Source: ATS, CDC, IDSA. Treatment of Tuberculosis. *MMWR* 2003;52(No. RR-11): 64; with information on Moxifloxacin added by Dr. Charles Daley.

- **Rifampin** and **isoniazid** are metabolized by the liver, so conventional dosing may be used in the setting of renal insufficiency.
- Supplemental dosing is not necessary for **isoniazid, rifampin,** or **ethambutol**. Supplemental dosing is necessary for **pyrazinamide** if it is given before hemodialysis.
- A longer interval between doses with three times a week administration is recommended for **pyrazinamide** and **ethambutol**.
- Doses of **streptomycin, kanamycin, amikacin,** and **capreomycin** must be adjusted in patients with renal failure, and the dosing interval should be increased. In general, the dose should not be reduced because the drugs exhibit concentration dependent bactericidal action, and smaller doses may reduce drug efficacy.
- **Ethionamide** requires no dose adjustment.
- Twice daily dosing (4 g) of **p-Aminosalicylic acid (PAS)** should be adequate if the granule formulation is used. Its metabolite, acetyl-PAS, is substantially removed by hemodialysis.
- **Cycloserine** requires an increase in the dosing interval to avoid accumulation between hemodialysis sessions, and the drug should be given after hemodialysis to avoid underdosing.
- The **fluoroquinolones** undergo some degree of renal clearance that varies from drug to drug. For example, levofloxacin undergoes greater renal clearance than moxifloxacin. It should be noted that the fluoroquinolone dosing recommendations for end-stage renal disease provided by the manufacturers were developed for treating pyogenic bacterial infections. These recommendations may not be applicable to the treatment of tuberculosis in patients with end-stage renal disease.

Administration of Drugs Immediately After Hemodialysis

Administration of all antituberculosis drugs immediately after hemodialysis will facilitate DOT (three times per week) and avoid premature removal of the drugs.

Monitoring of Serum Drug Concentrations

It is important to monitor serum drug concentrations in persons with renal insufficiency who are taking cycloserine, ethambutol, or any of the injectable agents to minimize dose-related toxicity, while providing effective doses.

Clinicians also should be aware that patients with end-stage renal disease may have additional clinical conditions, such as diabetes mellitus with gastroparesis, that may affect the absorption of the antituberculosis drugs, or they may be taking concurrent medications that interact with these drugs. Under these circumstances a careful clinical and pharmacologic assessment is necessary, and, in selected cases, serum drug concentration measurements may be used to assist in determining the optimum dose of the antituberculosis drugs.

Finally, data currently do not exist for patients receiving peritoneal dialysis. Because the drug removal mechanisms differ between hemodialysis and peritoneal dialysis, it cannot be assumed that all of the recommendations in Table 1 will apply to peritoneal dialysis. Such patients may require close monitoring, including measurements of the serum concentrations of the antituberculosis drugs.[45]

Tuberculosis Associated with Tumor Necrosis Factor-Alpha Antagonists

TB is a potential consequence of treatment with tumor necrosis factor-alpha (TNF-α) antagonists such as the following:

- Infliximab (Remicade®)
- Etanercept (Enbrel®)
- Adalimumab (Humira®)

These drugs work by blocking TNF-α, an inflammatory cytokine, and are approved for treating rheumatoid arthritis and other selected autoimmune diseases. Blocking TNF-α can allow TB disease to emerge from latent TB infection (LTBI). Healthcare providers should take steps to prevent TB in immunocompromised patients and remain vigilant for TB as a cause of unexplained febrile illness.[46]

Patients should be screened for risk factors for *M. tuberculosis* infection and tested for infection before initiating immunosuppressive therapies, including TNF-α antagonists.[47]

Resources

- CDC. “Tuberculosis Associated with Blocking Agents against Tumor Necrosis Factor-Alpha—California, 2002–2003” (*MMWR* 2004;53[No. 30]:83–686). Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5330a4.htm .

Culture-Negative Pulmonary Tuberculosis

A diagnosis of TB should not be ruled out if *M. tuberculosis* cannot be isolated from persons suspected of having pulmonary TB on the basis of clinical features and chest radiographic examination. Alternative diagnoses should be carefully considered and further appropriate diagnostic studies undertaken in persons with apparent culture-negative TB.[48]

A diagnosis of culture-negative pulmonary TB can be made if all the following conditions are met:

- Initial acid-fast bacilli (AFB) smears and cultures are negative.
- Clinical or radiographic response occurs within two months of initiation of therapy.
- No other diagnosis has been established.[49]

After the initial phase (first two months), continue treatment with an additional two months of isoniazid and rifampin during the continuation phase to complete a total of four months of treatment.[50] However, HIV-infected patients with culture-negative pulmonary TB should be treated for a minimum of six months.[51]

Resources

- ATS, CDC, IDSA. "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]:10, 61). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf **.**

Extrapulmonary Tuberculosis

The basic principles for treating pulmonary TB also apply to extrapulmonary forms of the disease. The addition of corticosteroids is recommended for patients with TB pericarditis and TB meningitis. Recommendations concerning duration of therapy are as follows:

- Use a six-month course of therapy for TB involving any site.[52] **Exceptions:** For bone or joint TB, use a six- to nine-month regimen.[53] For the meninges, use a nine- to twelve-month regimen.[54]
- Consider prolonging therapy for patients with TB in any site that is slow to respond.[55]

Note: Affected lymph nodes may enlarge while patients are receiving appropriate therapy or after treatment has ended without any evidence of bacteriologic relapse. On occasion, new nodes can appear during or after treatment as well.[56]

Resources

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- CDC. *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 1999). Available at: http://www.cdc.gov/tb/education/ssmodules/default.htm.

Pregnancy and Breastfeeding

Because of the risk of TB to the fetus, treatment in pregnant women should be initiated whenever the probability of maternal disease is moderate to high. The initial treatment regimen should consist of isoniazid (INH), rifampin (RIF), and ethambutol (EMB). As pyrazinamide (PZA) generally is not included in the initial treatment regimen, the minimum duration of therapy is nine months. Although these drugs cross the placenta, they do not appear to have teratogenic effects.

Breastfeeding should not be discouraged in women being treated with first-line antituberculosis agents because the small concentrations of drugs in breast milk do not produce toxicity in the nursing newborn. Conversely, drugs in breast milk should not be considered an effective treatment for TB in a nursing infant.[57]

Pyridoxine supplementation (25 mg/day) is recommended for all women taking INH who are either pregnant or breastfeeding.[58]

Tuberculosis in Children

ISDH TB Medical Advisory Board Statement: Treatment of TB in Children

Until susceptibility results are available, three or four-drug therapy is recommended, with INH, rifampin, pyrazinamide, and ethambutol as the fourth drug. The ethambutol may be dropped as soon as the tuberculosis isolate (from the child or adult source case) is known to be susceptible. For cases in which drug susceptibilities are not available because an isolate cannot be obtained, ISDH or the local health department can assist the practitioner in the choice of drug regimen, based on local susceptibility patterns and the case history. More detailed treatment recommendations are available from the American Academy of Pediatrics Red Book, or the ISDH TB Medical Advisory Board.

The recommended treatment regimens are as follows:

Initial Phase			**Continuation Phase**	
Drugs	**Interval and Duration (total doses)**		**Drugs**	**Interval and Duration (total doses)**
Option I (preferred)	Daily for 2 weeks, and then . . .	Twice weekly for six weeks under	INH RIF	Twice weekly for 16 weeks under direct

INH RIF PZA EMB	(14 doses)	direct observation (12 doses)		observation (36 doses)
Option II INH RIF PZA EMB	Daily for two months (60 doses)		INH RIF	Daily for four months (120 doses)

Doses for anti-tuberculosis medications are as follows:

Drugs	***Daily Dose* of Anti-tuberculosis Medications** **mg / kg** **(Maximum Dose)**		***Twice Weekly* Dose of Anti-tuberculosis Medications** **mg / kg** **(Maximum Dose)**	
	Adults	**Children**	**Adults**	**Children**
INH	5 (300 mg)	10-20 (300 mg)	15 (900 mg)	20-40 (900 mg)
RIF	10 (600 mg)	10-20 (600 mg)	10 (600 mg)	10-20 (600 mg)
PZA	15-30 (2 gm)	15-30 (2 g)	50-70 (4 gm)	50-70 (4 g)
EMB	15-25	15-25	50	50

Because of the high risk of disseminated TB in infants and children younger than five years of age, treatment should be started as soon as the diagnosis of TB is suspected.[59]

The following recommendations have been developed for children:

- Regimens recommended for infants, children, and adolescents with TB are generally the same as those for adults.
  Exception: Ethambutol (EMB) is not used routinely in children.[60]

- Duration of treatment in children is six months.
  Exception: For disseminated disease and TB meningitis, use a nine- to twelve-month regimen.[61] For other exceptions, refer to “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in this section.
- Directly observed therapy (DOT) always should be used in treating children.[62]

Due to the difficulty of isolating *M. tuberculosis* in a child with pulmonary TB, the choice of drugs for the child is frequently guided by the drug susceptibility test results of the presumed source case. If drug-resistant TB is suspected or the source case isolate is not available, specimens for microbiological evaluation should be obtained via early morning gastric aspiration, bronchoalveolar lavage, or biopsy.[63]

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- Refer to the most current edition of the American Academy of Pediatrics Committee on Infectious Diseases **Red Book®** ; Editor: Larry K. Pickering, MD, FAAP; Associate Editors: Carol J. Baker, MD, FAAP; David W. Kimberlin, MD, FAAP; Sarah S. Long, MD, FAA. **Red Book®** Online Web site) at: http://aapredbook.aappublications.org/.

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Diagnosis of Latent Tuberculosis Infection

CONTENTS

Introduction

Purpose

Use this section to understand and follow national and Indiana guidelines to do the following:

- Classify patients with latent TB infection (LTBI).
- Diagnose LTBI.

In the 2005 guideline "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, Centers for Disease Control and Prevention, and the Infectious Diseases Society of America," one of the recommended strategies to achieve the goal of reduction of TB morbidity and mortality is the identification of persons with LTBI at risk for progression to TB disease, and treatment of those persons with an effective drug regimen.[1]

- Contacts are mentioned within this section, but their evaluation and follow-up are covered in more depth in Section 10 - Contact Investigation.
- For information on treatment, refer to Section 8 - Treatment of Latent Tuberculosis Infection.

Policy

- Targeted testing for LTBI should be conducted only among persons in groups with identified risk factors for LTBI and/or progression to TB disease.
- Contacts should be evaluated as described in Section 10 - Contact Investigation.

For roles and responsibilities, refer to "Roles, Responsibilities, and Contact Information" in Section 1 - Introduction.

State Laws and Regulations

Refer to Section 1 – Introduction for Indiana state laws that mandate TB screening for designated populations.

High-Risk Groups

Certain factors identify persons at high risk for TB infection and/or for progression to TB disease. Persons in the high-risk groups listed in Table 1 below are candidates for TB skin testing in Indiana. Persons with risk factors from both columns may be at much higher risk than those with risk factors in only one column (e.g., an individual born in a high-TB-prevalence country with HIV infection is at much higher risk of having active TB than a US-born individual with HIV infection).

TABLE 1: Persons at high risk for TB Infection and Progression to TB Disease[2]

For TB Infection	For Progression to TB Disease[3]
▪ High-priority contacts such as housemates or coworkers or contacts of persons who have smear-positive pulmonary or laryngeal TB ▪ Infants, children, and adolescents exposed to adults in high-risk categories ▪ Recent immigrants (<5 years) from countries with high incidence of TB (Asian, African, Latin American, and Eastern European countries have TB rates 5–30 times higher than US rates, and an increasing percentage of TB cases here are occurring among immigrants from those countries.) ▪ Recent immigrants from Mexico ▪ Migrant workers ▪ Persons who have recently spent over 3 months in high-incidence countries (such as missionaries from the Church of Jesus Christ of Latter-Day Saints) ▪ Native Americans ▪ Persons with high rates of TB transmission: • Homeless persons • Injection drug users • Persons with human immunodeficiency virus (HIV) infection • Persons living or working in institutions with individuals at risk for TB such as: ▪ Hospitals, especially staff in nursing, emergency departments, and laboratories ▪ Long-term care facilities ▪ Homeless shelters ▪ Residences for acquired immunodeficiency syndrome (AIDS) patients ▪ Correctional facilities	▪ Persons with HIV infection ▪ Infants and children aged <5 years ▪ Persons infected with *Mycobacterium tuberculosis* within the previous 2 years ▪ Persons with a history of untreated or inadequately treated TB disease ▪ Persons with radiographic findings consistent with previous TB disease ▪ Persons who use alcohol or illegal drugs (such as injection drugs or crack cocaine) ▪ Persons with any of the following clinical conditions or other immunocompromising conditions: • Silicosis • Diabetes mellitus • End-state renal disease (ESRD)/chronic renal failure, hemodialysis • Some hematologic disorders (e.g., leukemias and lymphomas) • Other malignancies (e.g., carcinoma of head, neck, or lung) • Body weight ≥10% below ideal body weight • Prolonged corticosteroid use • Use of other immunosuppressive treatments (e.g., prednisone or tumor necrosis factor-alpha [TNF- α] antagonists) • Organ transplantation • Gastrectomy • Chronic malabsorption syndromes • Jejunoileal bypass

Source: Adapted from: CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR* 2005;54(No. RR-17):4–5; CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49(No. RR-6):7–9.

Diagnosis of Latent Tuberculosis Infection

The diagnosis of latent tuberculosis infection (LTBI) has traditionally been based upon results of tuberculin skin testing. However, blood assays for *M. tb* (BAMT) have recently been developed and are now other options for detecting TB.

Use the Mantoux tuberculin skin test (TST) or an IGRA to test for *M. tb* infection. Interferon gamma release assay blood test (IGRA) can be used in all circumstances in which the TST is used, and IGRA usually can be used in place of (and not in addition to) the TST.[4]

For a summary of the TB classification numbers, refer to the "Tuberculosis Classification System" topic in Section 2 – Surveillance.

Interferon Gamma Release Assays

Blood assay for *M. tuberculosis* (BAMT) is a general term referring to recently developed in vitro diagnostic tests that assess for the presence of infection with *M. tuberculosis.* This term includes, but is not limited to, interferon gamma release assays (IGRAs). Currently, there are two IGRAs approved by the FDA and available on the market. QuantiFERON®-TB Gold in-tube (QFT-GIT™) test was FDA approved in 2007 and T-Spot TB test was FDA approved in 2008. IGRAs can be used in all circumstances in which the TST is used, and usually can be used in place of the TST.[5]

The advantages of IGRA, compared with the TST, are that results can be obtained after a single patient visit, and that, because it is a blood test performed in a qualified laboratory, the variability associated with skin test reading can be eliminated.[6] In addition, IGRA tests appear to be less affected by past BCG vaccination than the TST and may eliminate the unnecessary treatment of patients with BCG-related false-positive results.[7] However, IGRA tests have practical limitations that include the need to draw blood and to ensure its receipt in a qualified laboratory in time for testing. For the QFT-G test, the blood must arrive at the laboratory less than 12 hours after collection to be incubated with the test antigens, while the lymphocytes are viable.[8] The T-Spot®-TB blood test must arrive at the laboratory within 24 hours after collection. For a QFT-GIT™ test, the blood specimens are collected directly into the three blood collection tubes, shaken vigorously, and then incubated at the collection site. After incubation, blood collection tubes should be stored no longer than three days prior to centrifugation and laboratory manipulation. The T-Spot®-TB blood test require that the blood specimens are collected into a single heparin lithium tube and shipped overnight by Fed-ex for laboratory manipulation.

REFERENCE: FDA, New Device Approval, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm074013.htm

INDIANA

Review the **Guidelines and Recommendations on the Use of QuantiFERON® – TB Gold for the Diagnosis of Active and Latent Tuberculosis Infection,** approved by the ISDH Tuberculosis Medical Advisory Board on 7-2007 at http://www.in.gov/isdh/files/QuantiFeronGoldGuidelines.pdf

Refer also to: **CDC, Updated Guidelines for Using Interferon Gamma Release Assays to detect Mycobacterium tuberculosis Infection, 2010** at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_e

Mantoux Tuberculin Skin Testing

The Mantoux method of tuberculin skin testing is also used to detect infection with *M.tuberculosis.*

In general, it takes 2 to 10 weeks after infection for a person to develop a delayed-type immune response to tuberculin measurable with the Mantoux tuberculin skin test (TST).[9] During the test, tuberculin is injected into the skin. The immune system of most persons with tuberculosis (TB) infection will recognize the tuberculin, causing a reaction in the skin. Repeated TSTs do not produce hypersensitivity.

The size of the measured induration (a hard, dense, raised formation) and the patient's individual risk factors should determine whether TB infection is diagnosed.[10] Based on the sensitivity and specificity of the purified protein derivative (PPD) TST and the prevalence of TB in different groups, three cut-points have been recommended for defining a positive tuberculin reaction:

- Greater than or equal to 5 mm of induration
- Greater than or equal to 10 mm of induration
- Greater than or equal to 15 mm of induration[11]

For more information on cut-points for the TST, see the “Interpretation of the Tuberculin Skin Test” topic in this section.

Candidates for Mantoux Tuberculin Skin Testing

The Mantoux TST can be administered to all persons, including pregnant women,[12] persons who have previously been vaccinated with bacille Calmette-Guérin (BCG),[13]

and human immunodeficiency virus (HIV)-infected persons. However, persons with a documented prior positive TST do not need another TST, and the Mantoux TST should not be administered until four weeks after vaccination with live-virus vaccines (e.g. varicella vaccination)

If the person being tested is a contact, follow the procedures outlined in Section 10 - Contact Investigation.

Pregnancy

Tuberculin skin testing is entirely safe and reliable for pregnant women, and pregnant women at high risk for TB infection or disease should be tested. Screen pregnant women for TB infection if they have any of the following conditions:

- Symptoms suggestive of TB disease
- HIV infection
- Behavioral risk factors for HIV
- Medical conditions other than HIV infection that increase the risk for TB disease
- Close contact with a person who has pulmonary or laryngeal TB disease
- Immigration from an area of the world where incidence of TB is high

Bacille Calmette-Guérin Vaccine

BCG vaccines are live vaccines derived from a strain of *Mycobacterium bovis.* Because their effectiveness in preventing infectious forms of TB has never been demonstrated in the United States, they are not recommended as a TB control strategy in the United States, except under rare circumstances. They are, however, used commonly in other countries. A history of BCG vaccination is not a contraindication for tuberculin skin testing nor does it influence the indications for a TST. Administer and measure TSTs in BCG-vaccinated persons in the same manner as in those with no previous BCG vaccination.

The TST should be interpreted using the same criteria as for those not BCG vaccinated.

Anergy Testing

Anergy testing is not routinely recommended in conjunction with TST for HIV-infected persons in the United States.[14]

Anergy testing is a diagnostic procedure used to obtain information about the competence of the cellular immune system. Conditions that cause an impaired cellular immune system include HIV infection, severe or febrile illness, measles or other viral

infections, Hodgkin's disease, sarcoidosis, live-virus vaccination, and corticosteroid or immunosuppressive therapy. Persons with conditions such as these may have suppressed reactions to a TST even if infected with TB. However, there are no simple skin testing protocols that can reliably identify persons as either anergic or nonanergic and that have been proven to be feasible for application in public health TB screening programs.

Factors limiting the usefulness of anergy skin testing include the following:

- Problems with standardization and reproducibility
- Low risk for TB associated with a diagnosis of anergy
- Lack of apparent benefit of treatment for LTBI in groups of anergic HIV-infected persons

Documented Prior Positive Tuberculin Skin Test

Persons who have tested positive in the past and can provide **documentation** of their status should not have another TST. Instead, they should have a TB symptom assessment questionnaire administered to identify any symptoms of TB disease.[15 A]

A symptom review for positive TST reactors should include: name, date of birth, date of positive TST (with supporting documentation), date of last CXR and results, medication history relating to anti-TB drug therapy for TB infection or disease (including length of treatment and date completed), and symptom review (i.e., cough greater than 2 weeks duration, hemoptysis, night sweats, loss of appetite, unexplained weight loss, fatigue, fever, chills, chest pain). Persons who are symptomatic should receive a medical evaluation and if indicated, CXR.

If persons who have tested positive in the past cannot provide documentation of their status, then another TST or IGRA (preferable) should be administered.

Live-Virus Vaccines

The Mantoux TST can be administered in conjunction with all vaccines. However, live-virus vaccinations (e.g., influenza vaccine [nasal spray], measles, mumps, rubella [MMR], Rotavirus, varicella [chickenpox], vaccinia [smallpox], yellow fever, and Zoster [shingles vaccine]) may transiently suppress the response to PPD.[16] Therefore, if a vaccine containing live virus has already been given, the TST should be deferred until (or repeated) at least 4 weeks after the vaccine was administered.

When giving the TST and a live-virus vaccine, one of the following three sequences should be used:

- Apply the TST at same visit as the live-virus vaccine.
- Delay the TST at least four weeks if the live-virus vaccine is given first.
- Apply the TST first and then give the live-virus vaccine when the TST is measured.[17]

Refer to the most current edition of the American Academy of Pediatrics Committee on Infectious Diseases **Red Book®** ; Editor: Larry K. Pickering, MD, FAAP; Associate Editors: Carol J. Baker, MD, FAAP; David W. Kimberlin, MD, FAAP; Sarah S. Long, MD, FAA. **Red Book®** Online Web site). at: http://aapredbook.aappublications.org/

Multiple Puncture Tests

Multiple puncture tests (MPTs), such as the Tine test, should not be used. The MPTs are not reliable because the amount of tuberculin injected intradermally cannot be precisely controlled and there is no standard for interpretation.

Administration of the Tuberculin Skin Test

The TST should be placed by a healthcare worker who has received appropriate training and is following written protocols and Infection Control procedures. Obtain the patient's written consent if required by the provider's agency/institution.

Table 2: HOW TO ADMINISTER A TUBERCULIN SKIN TEST

How to Administer a Tuberculin Skin Test
REFERENCE: CDC. *Mantoux Tuberculin Skin Test Facilitator Guide*: http://www.cdc.gov/tb/pubs/Mantoux/guide.htm (note: the facilitator guide is part of the CDC. Mantoux Tuberculin Skin Test – DVD Kit available at http://wwwn.cdc.gov/pubs/tb.aspx)

PREPARATION STEPS: When preparing to administer the Mantoux tuberculin skin test, make sure that the area for administering the test has a firm, well-lit surface, and that equipment and supplies are ready.

Supplies should include:

- vial of tuberculin
- single-dose disposable tuberculin syringe
- ruler with millimeter (mm) measurements
- 2x2 gauze pads or cotton balls
- alcohol swabs
- puncture-resistant sharps disposal container
- record-keeping forms for the patient and provider
- pen(s)

Tubersol® and Aplisol® are the two commercially available tuberculin products. The multidose vials contain tuberculin for either 10 or 50 tests. The tuberculin is administered using a single-dose disposable tuberculin syringe that has a one-quarter to one-half inch, 27-gauge needle with a short bevel. In the United States, the Mantoux tuberculin skin test consists of an intradermal injection of exactly one tenth of a milliliter (ml), which contains 5 tuberculin units.

Syringe and needle technologies continue to evolve to help prevent needlestick injuries. Institutional policy should determine which skin test device has been evaluated and approved for use by your facility.

- Look at the vial label to make sure the vial contains the tuberculin that you want to use, including the tuberculin unit strength. The label should indicate the expiration date. **If it's been open more than 30 days or the expiration date has passed, the vial should be thrown away and a new vial used.**
- When you open a new vial, write the date and your initials on the label to indicate when the vial was opened and who opened it.
- To avoid reducing the potency of the tuberculin, store it inside a refrigerator so that it remains between 35 and 46 degrees Fahrenheit or between 2 and 8 degrees Centigrade.
- Store and transport the tuberculin in the dark as much as possible and avoid exposure to light.

In certain settings, such as when you're in the field, you may need to use another type of cooling container to control the temperature and protect from light.

After collecting supplies, the next step is patient education. You should sit so that you are both comfortable and facing each other.

Discuss why the skin test is given, what is involved in the procedure, and when the patient should return for the test to be read. Explain that 48 to 72 hours after the test is administered, the patient must return to have the induration measured and evaluated. Make an appointment for the patient to return. **If a patient can't return within the 48- to 72-hour time period, do not administer the test.** Instead, schedule another time that allows the patient to come for both the test and the return appointment.

It's also important to encourage the patient to ask questions and talk about any anxieties he or she may have about the test. That way you can answer any questions and ease any fears the patient may have. Consult local practice to find out how best to document informed consent in your setting.

After providing patient education, you should wash your hands, using an appropriate hand-washing technique, before administering the test or any other procedure involving patient contact. In certain field settings it may be necessary to use other hand-hygiene techniques.

INJECTION STEPS: Always follow your institution's standard precautions for infection control (*i.e., use gloves if that is the policy in your facility*).

1. On a firm, well-lit surface, expose the patient's arm and slightly flex it at the elbow. **The injection should be placed on the palm-side-up surface of the forearm, about 2 to 4 inches below the elbow.** Your local institutional policy may specify the right or the left forearm for the skin test.

   The area selected should be free of any barriers to placing and reading the skin test such as muscle margins, heavy hair, veins, sores, or scars. If the patient has any of these at the site, then you should use the other arm or the standard alternative site selected by your institution (the shoulder is an alternative site, as it is often selected in patients who have less skin turgor).

2. After choosing the injection site, clean the area with an alcohol swab by circling from the center of the site outward. Allow the site to dry completely before the injection.

   Because some of the tuberculin solution can adhere to the inside of the plastic syringe, the skin test should be given as soon as possible after the syringe is filled.

3. Wipe the top of the vial with a new alcohol swab before drawing up the tuberculin solution.

4. Pick up the syringe and be sure to fasten the needle tightly on the syringe by holding the cap and twisting it onto the tip of the syringe. Next, remove the needle cap.

   The needle bevel should be perpendicular to the flange of the syringe. If necessary, turn and tighten the needle to line up the bevel correctly with the flange.

5. Place the vial on a flat surface, hold the vial between the thumb and fingers, and insert the needle through the neoprene stopper.

6. Invert the vial while keeping a firm hold on the syringe and plunger. The tip of the needle should be below the fluid level in the vial. Pull back on the plunger and draw out slightly more than the one tenth of a milliliter needed for the test.

7. Remove the needle from the vial. Hold the syringe in an upright position, then draw back slightly on the plunger. Tap the syringe lightly to break up air bubbles, then push forward.

8. Expel all air and excess fluid from the syringe and needle, leaving exactly one tenth of a milliliter of tuberculin solution in the syringe.

The second step in administering the Mantoux tuberculin skin test is injection. You'll inject the tuberculin, discard the needle and syringe, check that the skin test was administered properly, and repeat the test if needed.

9. Stretch taut the selected area of skin between the thumb and forefinger. This provides a surface that is easier for the needle to penetrate.

10. With the needle bevel facing up and the syringe flange parallel to the forearm, hold the syringe between your thumb and forefinger. There are several techniques for pulling the skin taut for placement (e.g., pulling from under the arm, inserting with one hand from the side, pulling toward the wrist with one finger).

11. The Mantoux tuberculin skin test is an intradermal injection. With the needle bevel against the patient's skin, insert it slowly at a 5- to 15-degree angle. The 5- to 15-degree angle is very important because this layer of skin is very thin.

    For an intradermal injection, the needle bevel is advanced through the epidermis, the superficial layer of skin, approximately 3 mm so that the entire bevel is covered and lies just under the skin.

    The injection will produce inadequate results if the needle angle is too deep or too shallow. When the needle is inserted at the correct angle you can see the bevel of the needle just below the skin surface. Next, release the stretched skin and hold the syringe in place on the forearm.

12. Grip the flange of the syringe between your first and middle fingers. Use your thumb to press on the plunger.

13. Now, slowly inject the tuberculin solution. You should feel fairly firm resistance as the tuberculin enters the skin. A tense, pale wheal that's 6 to 10 mm in diameter appears over the needle bevel.

14. Remove the needle without pressing or massaging the area. Next, discard the used syringe immediately in the designated puncture-resistant container (if you're using a safety needle, engage the safety-needle mechanism before discarding). To prevent needlestick injuries, used needles should not be recapped, purposely bent or broken, removed from disposable syringes, or otherwise manipulated by hand.

    It's not unusual for a drop of blood to appear at the injection site, even when the needle is inserted properly.

    Should this happen, lightly blot the blood away with a 2x2 gauze pad or cotton ball. **Do not cover the site with an adhesive bandage because the adhesive could cause irritation and interfere with the test.** Properly dispose of the contaminated gauze pad. To determine if the skin test was administered properly, use the millimeter ruler to immediately measure the wheal at its maximum size.

The wheal should be at least 6 mm in diameter. **If the wheal is less than 6 mm in diameter, then the test should be administered again.** The needle bevel may have been inserted too deeply or an inadequate dose administered. If leakage occurs at the insertion site, the needle bevel may not have been inserted far enough for the bevel to be covered by the skin.

If the tuberculin test must be repeated, use another site at least 2 inches, or 50 mm, from the original site. Or use the standard alternate placement site. You will need to indicate this alternate site when you fill out the record keeping forms.

FINAL STEPS: The final step in administering the Mantoux tuberculin skin test includes:

- washing your hands
- recording information
- reminding the patient about the return visit
- providing patient education
- returning the vial to the refrigerator

In this step, immediately and thoroughly wash your hands. This step also includes recording information on the patient's chart and other record-keeping forms.

Document:

- date and the time the test was administered
- name and manufacturer of the injected solution
- lot number
- tuberculin dose administered
- expiration date
- forearm or alternative site in which the injection was given
- site location if you repeat the test
- name of the person who administered the test
- reason for giving the skin test

Since it's important for the patient to return within 48 to 72 hours to have the test result read, always remind the patient to return.

Giving the patient a card with information on care of the site and the date for the return appointment may help serve as a reminder. Explain that mild itching, swelling, or irritation may occur and that these are normal reactions that do not require any treatment.

These types of reactions usually go away within a week. Explain how to care for the injection site after the test. Tell the patient to avoid scratching the site, keep the site clean and dry, and avoid putting creams, lotions, or adhesive bandages on it. Also mention that getting the site wet with water is not harmful, but the site should not be wiped or scrubbed.

Finally, return the tuberculin vial to the refrigerator, or other cooling container if you are in the field.

Read the PPD labels carefully before administering a TST. The packaging of tetanus toxoid-containing vaccines (TTCVs) is similar to Tubersol® and Aplisol®, and all are refrigerated. See the CDC's "Errors Involving Mix-up of Tuberculin Purified Protein Derivative and Vaccine Products" (*TB Notes Newsletter*. 2005;No. 1) at this hyperlink: http://www.tbchicago.org/tbguidecdc/newsletters/notes/TBN_1_05/Errors_mix_up.htm .

Measurement of the Tuberculin Skin Test

A trained healthcare worker should read the TST 48 to 72 hours after the intradermal injection. **Patients should never be allowed to read their own TSTs.**[18]

- A positive reaction can be measured anytime after 48 hours.
- If the results appear negative and more than 72 hours have passed, the test should be repeated. It can be repeated immediately, or after one week, if two-step testing is required.

See the topic titled “Two-Step Tuberculin Skin Testing” in Section 16 - Infection Control.

Table 3: HOW TO MEASURE A TUBERCULIN SKIN TEST

How to Measure a Tuberculin Skin Test
REFERENCE: CDC. *Mantoux Tuberculin Skin Test Facilitator Guide*: http://www.cdc.gov/tb/pubs/Mantoux/guide.htm (note: the facilitator guide is part of the CDC. Mantoux Tuberculin Skin Test – DVD Kit available at http://wwwn.cdc.gov/pubs/tb.aspx)
A great deal of practice is required to achieve consistently reliable measurements. The skin test should be read between 48 and 72 hours after the skin test has been administered. A patient who doesn’t return within 72 hours will probably need to be rescheduled for another skin test. **PREPARATION STEPS:** To begin, collect the following supplies: a small, plastic, flexible ruler marked in millimeters to measure the test, a pen to mark the edges of the induration, and an alcohol pad to clean off the pen marks. You’ll need the patient’s record or other appropriate forms for documenting the measurement results. Also have culturally appropriate patient education materials available for the patient to reinforce information that is explained to the patient, help answer questions, and provide information on follow-up evaluation. **PALPATION METHOD:** To locate the skin-test site, inspect the arm in good light and on a firm surface. When the site is on the forearm, turn the arm palm up, support it, and slightly flex it at the elbow. The basis of reading the skin test is the presence or absence of induration, which is a hard, dense, raised formation. This is the area that is measured. Sometimes the site has erythema, a reddening of the skin that can also have swelling. The erythema should NOT be measured. Whatever induration is present at 48 to 72 hours should be measured and recorded. Only the part of the reaction that can be felt, which is the induration, is measured, even if there is soft swelling or redness at the site. Keep in mind there might not be an induration. Reactions to the tuberculin test at the injection site can range from no induration to a large, well-defined induration. In order to feel the induration properly, keep your fingernails short enough so that they don’t protrude beyond the finger.

The induration is not always visible, so you must rely on palpation with your fingertips to discover if there's induration at the site. With your fingers together, touch the area lightly with the pads of your fingertips. Using a light, gentle motion, sweep the fingertips over the surface of the forearm in a 2-inch diameter in all four directions to locate the margins or edges of induration.

If induration is present, use a zigzag, feather-like touch over the area of induration to outline the margins of induration. Determining margins all around the induration helps to find the edges, which will be measured later.

When palpating for margins, be careful not to confuse a margin of induration with a margin of muscle on the forearm. To check this, raise the patient's arm to a 45-degree angle and palpate again. You should still be able to palpate the margins of induration.

The diameter of the induration is measured across the forearm, from the thumb side of the arm to the little finger side of the arm or vice versa.

To mark the edges of the induration, hold your palm over the injection site with your fingertips at the outer edge of the patient's forearm. Without lifting, move the fingertips from the outer edge of the forearm towards the induration. Rest one fingertip firmly against the induration margin border on one side before marking the margin. The fingertip should remain in contact with the skin at all times. Mark lightly with a fine dot at the widest edge of the induration, using the fingertip as a guide.
Repeat the procedure from the other side of the patient's forearm and place the second mark on the margin of induration. Palpate again to double check that the induration was marked correctly.
If the margin is not equally clear all the way around the induration, it's still necessary to mark the margins on each side of the induration. Palpate around the induration from the easily felt margin to the not-so-easily-felt margin.

If the margins of induration are irregular, mark and measure the longest diameter across the forearm.

To measure the diameter of the induration, use the millimeter ruler. Place the zero ruler line inside the left dot edge and read the ruler line inside the right dot edge. If the measurement falls between two divisions on the millimeter scale, record the lower mark.

Reactions to the skin test will vary. Make sure to record blistering, even if no induration is present. . Measure only the induration.

Immediately after the test is measured, write the exact measurement in millimeters of induration on the patient's record. Do not simply record the interpretation of the results as "negative" or "positive," and do not record the results in centimeters. For example, an induration that measures 3 mm should be recorded as "3 mm" and not as "negative."

Additional information should include the date and time the test was read, the name and signature of the person who read the skin test, and the presence or absence of adverse effects.

State or local policies may require additional documentation of adverse effects.

Accurately reading and recording skin test measurement results is important and gives the health care provider useful information for evaluation. Results are often used as a baseline or as a comparison with past or future test results.

Report adverse reactions to a TST (e.g., blistering, ulcerations, necrosis) to the FDA's MedWatch Program at 1-800-FDA-1088, or via the Internet at this hyperlink: http://www.fda.gov/medwatch/ .

Interpretation of the Tuberculin Skin Test

TSTs should be interpreted by a trained healthcare worker. Use Tables 4 and 5 below to interpret TSTs. If you have a difficult TST to read, get a second opinion or when in doubt REPEAT THE TEST.

Call ISDH TB/Refugee Health Division at 317.233.7434 regarding TST reactions when interpretation and medical follow-up are unclear.

Table 4: HOW TO INTERPRET A TUBERCULIN SKIN TEST

How to Interpret a Tuberculin Skin Test
REFERENCE: CDC. *Mantoux Tuberculin Skin Test Facilitator Guide*: http://www.cdc.gov/tb/pubs/Mantoux/guide.htm (note: the facilitator guide is part of the CDC. Mantoux Tuberculin Skin Test – DVD Kit available at http://wwwn.cdc.gov/pubs/tb.aspx)
INTERPRETATION: Interpretation should be performed by a trained health care provider in accordance with institutional policies based on CDC guidelines. Check your institution's policy for evaluation and referral procedures. Reliable reading of the tuberculin skin test requires a great deal of practice and adherence to appropriate steps for quality control. The steps in this method include standardization of procedures, training, supervision, and practice. This may include periodic standardized reliability testing.

Use Table 5, next page to determine when a reaction is positive (reminder: TSTs in BCG-vaccinated persons are interpreted using the same criteria as those not BCG vaccinated).

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Table 5: POSITIVE TUBERCULIN SKIN TEST REACTIONS

Induration Size	Considered Positive For:
5 mm or more	▪ Persons with human immunodeficiency virus (HIV) infection/acquired immunodeficiency syndrome (AIDS) ▪ Recent contacts to an infectious case of tuberculosis (TB) disease ▪ Persons with fibrotic lesions on chest radiograph consistent with healed TB ▪ Persons with organ transplants or other immunosuppressed persons (such as those receiving the equivalent of >15 mg/day of prednisone for >1 month) ▪ Persons receiving treatment with tumor necrosis factor-alpha (TNF-α) antagonist
10 mm or more	▪ Foreign-born persons recently arrived (within 5 years) from countries with a high TB incidence or prevalence (e.g., most countries in Africa, Asia, Latin America, Eastern Europe, the former USSR, or from refugee camps) ▪ Persons who inject drugs or use other high-risk substances, such as crack cocaine ▪ Alcoholics ▪ Residents and employees in high-risk, congregate settings (e.g., correctional institutions; long-term residential care facilities, such as nursing homes, mental institutions, etc.; hospitals and other healthcare facilities; homeless shelters; and refugee camps) ▪ Mycobacteriology laboratory personnel ▪ Persons with other medical conditions that increase the risk of TB disease ▪ Children younger than 5 years of age, or children and adolescents exposed to adults in high-risk categories
15 mm or more	▪ Persons with no known risk factors for TB

The TST is a valuable tool but it is not perfect. Several factors can lead to false-positive or false-negative TST reactions. When interpreting TST results be aware of the following:

Skin test conversions: For persons previously skin tested, an increase in induration of 10 mm or more within a two-year period is classified as a conversion to positive.

False-negative reactions may be due to the following:

- Incorrect administration (too little antigen, subcutaneous injection)
- Incorrect interpretation (inexperience TST reader, difficult reaction to interpret)
- Anergy (may be caused by conditions that cause an impaired cellular immune system such as HIV infection, severe or febrile illness, measles or other viral infections, Hodgkin's disease, sarcoidosis, live-virus vaccination, and corticosteroid or immunosuppressive therapy).

- Booster phenomenon (as we get older, immune responsiveness decreases but reacts to a second TST)
- Recent TB infection (within the past 10 weeks)
- Very young age (less than six months of age, because the immune system is not fully developed)
- Overwhelming TB disease
- Vaccination with live viruses (e.g., influenza vaccine [nasal spray], measles, mumps, rubella [MMR], Rotavirus, varicella [chickenpox], vaccinia [smallpox], yellow fever, and Zoster [shingles vaccine]).

TB skin testing should be done either on the same day as vaccination with live virus or at least four weeks after vaccination.

See “Live-Virus Vaccines” under “Candidates for Mantoux Tuberculin Skin Testing” in this section.

- Some viral infections (measles, mumps, chickenpox, or HIV)
- Recent live bacterial vaccination (e.g., BCG and oral typhoid)
- Corticosteroids or other immunosuppressive agents given for two or more weeks

False-positive reactions may be due to the following:[19]

- Incorrect administration (wrong solution)
- Incorrect interpretation (inexperience TST reader, difficult reaction to interpret)
- Nontuberculous mycobacteria (NTM) or mycobacterium other than tuberculosis (MOTT)
- BCG vaccination

Human Immunodeficiency Virus Screening

The Centers for Disease Control and Prevention (CDC) recommends the following:

- Routine HIV screening for all patients ages 13–64 seeking health care for any reason, without regard to patient’s known risks for HIV infection
- Annual HIV screening of patients known to be at high risk[20]

Follow-Up Activities

Treatment for LTBI should not begin until active TB disease has been excluded by history, physical examination, CXR and bacteriologic studies (when indicated).

After testing, complete the following tasks:

If the person has signs or symptoms of TB, evaluate for TB disease as described in the "Diagnosis of Tuberculosis Disease" topic in Section 5 - Diagnosis of TB Disease.

If the person is a contact, follow the procedures for testing and evaluation in Section 10 - Contact Investigation.

If the person is a participant in two-step screening, see the topic titled "Two-Step Tuberculin Skin Testing" in Section 16 - Infection Control.

If the TST result is positive, a CXR should be obtained for the patient, as specified in the "Chest Radiography" topic in this section.

Chest Radiography

INDIANA - Standards for CXR evaluations indicated in the workup of patients with suspected LTBI

- A chest radiograph is indicated for all persons being considered for treatment of LTBI to exclude active pulmonary TB. Children younger than 5 years of age should have both posterior–anterior and lateral radiographs. All other persons should receive at least posterior–anterior radiographs.
- Patients with questionable findings on initial radiographs should be evaluated with alternative x-ray views (lateral, apical lordotic, obliques).
- If these views do not resolve visualization of any questionable areas on initial radiographs, a CT scan can be considered. (*Normally, there is little to no indication for the use of CT scans of the chest. CT scans often are indicated for other purposes, but that would not be considered part of the LTBI workup.*)
- For persons with LTBI who have had active disease ruled out and for asymptomatic tuberculosis patients who have completed treatment, repeat chest x-ray examinations have been shown to be of insufficient clinical value or productivity to justify their continued use and are not recommended unless specific medical conditions exist.

References: ISDH, **Guidelines for TB Skin Test Screening and Treatment of LTBI**, at http://www.in.gov/isdh/19692.htm. For ISDH policy on CXRs for employment, LTC, routine follow-up, etc. refer also to **Repeat Chest X-Rays** at http://www.in.gov/isdh/19684.htm.

All individuals being considered for LTBI treatment should undergo a (CXR) to rule out pulmonary TB disease. For information on how to classify TB, see the "Tuberculosis Classification System" topic at the beginning of this section. Refer to Table 4 below to determine when to obtain a CXR and what follow-up is required for CXR results.

Children younger than five years of age should receive posterior-anterior and lateral radiographs.[21]

For more information on CXR, refer to the Francis J. Curry National Tuberculosis Center's *Radiographic Manifestations of Tuberculosis: A Primer for Clinicians* (FJC National TB Center Web site; 2006) at: http://www.nationaltbcenter.ucsf.edu/products/product_details.cfm?productID=EDP-04 .

For persons recently exposed to TB, follow the procedures for testing and evaluation in Section 10 - Contact Investigation.

Table 4: TARGETED TESTING FOR LATENT TUBERCULOSIS INFECTION: WHEN CHEST RADIOGRAPHS ARE REQUIRED AND HOW TO FOLLOW UP ON RADIOGRAPHY RESULTS

Signs or Symptoms of TB Disease?	TST or IGRA Result?	Recent Exposure to Infectious TB?	Chest Radiograph: Required and Results?	Follow-up Action
Yes	Positive or negative	Yes or No	CXR Required: Yes Results: normal or abnormal	▪ Classify as TB Suspect ▪ Evaluate for TB disease. Refer to Section 5 - Diagnosis of TB Disease.
No	Negative	No	CXR not recommended unless the patient has HIV infection or other forms of immunosuppression are present	▪ Classify as No TB Exposure/ No Infection.
No	Positive	No	CXR Required: Yes Results: normal	▪ Classify as TB Infection/No Disease. ▪ Consider treatment for LTBI. Refer to Section 8 - Treatment of LTBI.
			CXR Required: Yes Results: abnormal noncalcified fibrotic lesions suggestive of old, healed TB; comparison film available and stable	▪ Classify as TB Not Clinically Active or TB Suspect. ▪ Consider evaluating for TB disease. Refer to Section 5 - Diagnosis of TB Disease.
			CXR Required: Yes Results: abnormal consistent with TB disease; no comparison film	▪ Classify as TB Clinically Active/TB Suspect. ▪ Evaluate for TB disease. Refer to Section 5 - Diagnosis of TB Disease.

Definitions of abbreviations: CXR = chest radiograph; HIV = human immunodeficiency virus; IGRA = interferon gamma release assay; LTBI = latent tuberculosis infection; TB = tuberculosis; TST = tuberculin skin test.

Resources and References

Resources

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Treatment of Latent Tuberculosis Infection

CONTENTS

Introduction

Purpose

Use this section to understand and follow national and Indiana guidelines to do the following:

- Determine whom to treat for latent tuberculosis infection (LTBI).
- Select appropriate treatment regimens and dosages.
- Monitor patients for adverse reactions.
- Monitor patients' adherence to treatment.
- Determine whether and when therapy is completed.
- Provide treatment in special situations, such as when a patient is pregnant or has tuberculosis (TB)-human immunodeficiency virus (HIV) coinfection.

Prevention of TB has major public health implications, so it is essential to identify and treat all those with risk factors for TB disease.[1] LTBI is the presence of *Mycobacterium tuberculosis* organisms (tubercle bacilli), with no symptoms and no radiographic or bacteriologic evidence of TB disease.[2] A person with LTBI is noninfectious but can develop active TB disease. Persons with increased risk for developing TB include those who have had recent infection with *M. tuberculosis* and those who have clinical conditions associated with an increased risk for the progression of LTBI to TB disease.

To control and prevent TB, our healthcare resources and efforts should be directed to meet the priorities outlined in the 2005 "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, Centers for Disease Control and Prevention, and the Infectious Diseases Society of America." One of the recommended strategies to achieve the goal of reduction of TB morbidity and mortality is the identification and treatment of persons with LTBI at risk for progression to TB.[3]

Healthcare providers must communicate the risks and benefits of treatment to their patients and encourage adherence and treatment completion. LTBI treatment substantially reduces the risk that TB infection will progress to disease: depending upon adherence and length of treatment, completing treatment for LTBI can reduce the risk of TB disease by 65–90%.[4,5]

Policy

Treatment for LTBI should not begin until active TB disease has been excluded by:

- Physical examination
- CXR
- Bacteriologic studies (when indicated)

A history should also be conducted that includes: 1) an assessment of preexisting medical conditions that are contraindications to treatment or are associated with an increased risk of adverse effects of treatment (e.g. hepatotoxicity) and 2) current and previous drug therapy including any previous adverse reactions to LTBI drugs or drugs with known interactions with LTBI drugs.

Isoniazid (INH) is normally used alone for treatment of LTBI. When INH is given alone to persons with active TB disease, resistance to INH is more likely to develop. FOR THIS REASON, persons suspected of having TB disease should receive the recommended multidrug regimen for treatment of disease until the diagnosis is confirmed or ruled out.

Treatment should be considered for all persons who are determined to be candidates for the treatment of LTBI.

For ISDH roles and responsibilities, refer to the "Roles, Responsibilities, and Contact Information" in Section 1 - Introduction.

INDIANA

LTBI is not a reportable disease in the state of Indiana, however, a **Report of Treatment of LTBI** form must be submitted by the LHD Public Health Nurse if the patient will receive LTBI medication through the state. The **Request for TB Drug Form** and a copy of the appropriate medication prescriptions and chest x-ray report must be submitted with this report.

The **TB Medication Policy** and the required forms can be found at:

TB Medication Policy http://www.in.gov/isdh/19685.htm

Report of Treatment of LTBI http://www.in.gov/icpr/webfile/formsdiv/49894.pdf

Request for TB Drugs Form http://www.in.gov/icpr/webfile/formsdiv/48085.pdf

Whom to Treat

Determine whom to treat for latent tuberculosis infection (LTBI). Persons with LTBI should be treated unless there are specific contraindications to treatment. Certain groups are at high risk of developing tuberculosis (TB) disease once infected, so make every effort to begin appropriate treatment and to ensure those persons complete the entire course of treatment for LTBI.[6]

For a list of high-risk groups by tuberculin skin test (TST) results, see the Tuberculin Skin Test Results listings below. For more information on targeted testing, see Section 3 -Targeted Testing for LTBI.

High-risk contacts (under five years of age or immunocompromised) should be started promptly on treatment for LTBI. For more information on time frames, see “Time Frames for Contact Investigation” in Section 10 - Contact Investigation.

For questions regarding the treatment of LTBI, contact your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.

Susceptible and Vulnerable Contacts

A contact is someone who has been exposed to *M. tuberculosis* infection by sharing air space with a person with infectious TB.[7] Susceptible contacts are those who are more likely to become ill with TB disease if they are infected, and vulnerable contacts are those who could suffer severe morbidity if they progress to TB disease.[8] Persons who are susceptible and/or vulnerable to TB disease are candidates for window period treatment, which is administering treatment for presumptive TB infection during the interval between infection and detectable skin test reactivity or positive blood testing (IGRA). The National Tuberculosis Controllers Association (NTCA) and the CDC recommend that the window period be estimated at 8 to 10 weeks.[9]

The following contacts with initially negative TST or IGRA results should receive treatment for LTBI after TB disease has been ruled out by clinical examination and chest radiograph:

1. Contacts younger than 5 years of age (with highest priority given to those under 3 years)
2. Contacts with human immunodeficiency virus (HIV) infection or who are otherwise immunocompromised

If the second skin test or IGRA result is negative, and the contact is immunocompetent (including immunocompetent young children) and no longer exposed to infectious TB, treatment for LTBI may be discontinued, and further follow-up is unnecessary. If the second test is negative, but the contact is immunocompromised (e.g., with human immunodeficiency virus [HIV] infection), a course of therapy for LTBI should be completed.

If the second test result is negative, but the person remains in close contact with an infectious patient, treatment for LTBI should be continued if the contact is:

1. Younger than 5 years old;
2. Aged 5 to 15 years, at the clinician's discretion;
3. HIV-seropositive or otherwise immunocompromised[10]

Persons known to be (or suspected of being) immunocompromised, such as HIV-infected persons, should be given treatment for LTBI regardless of the TST or IGRA reaction.[11]

Tuberculin Skin Test Results of 5 mm or More

Persons in the following high-risk groups are candidates for treatment of LTBI if their skin test result is 5 mm or more:

- Persons with HIV infection
- Recent contacts of persons with newly diagnosed infectious TB
- Persons with fibrotic changes on their chest radiographs that are consistent with old TB and a history of inadequately treated TB or no prior history of treatment for TB.
- Persons on prolonged corticosteroid therapy (prednisone equivalent to 15 mg or more/day for 1 month or more).[12]
- Persons on immunosuppressive therapy (as with organ transplant).

- Persons on tumor necrosis factor blocker medications (e.g., Remicade®, Embrel®, Humira®, Cimzia® – used to treat arthritis, Crohn's disease in adults and children, ulcerative colitis, and ankylosing spondylitis).

Tuberculin Skin Test Results of 10 mm or More

Persons in the following high-risk groups are candidates for treatment of LTBI if their skin test result is greater than or equal to 10 mm:

- Foreign-born persons who have recently arrived (within five years) from countries with a high TB incidence or prevalence, or persons who have recently traveled to these countries (most countries in Africa, Asia, Latin America, Eastern Europe, and the former USSR)
- Persons who are alcoholics, who inject drugs, or who use other high-risk substances, such as crack cocaine
- Residents and employees of high-risk congregate settings, such as correctional institutions, homeless shelters, long-term residential care facilities (e.g., nursing homes, mental institutions), hospitals, and other healthcare facilities
- Mycobacteriology laboratory personnel
- Persons with medical conditions or undergoing treatments that increase the risk of TB disease (diabetes mellitus, silicosis, recent infection with *M. tuberculosis* within the past two years, bone marrow and organ transplant recipients, prolonged high-dose corticosteroid therapy and other immunosuppressive therapy, chronic renal failure, hemodialysis, some hematological disorders [e.g., leukemias and Hodgkin's disease], other specific malignancies [e.g., carcinoma of the head, neck, or lung], chronic malabsorption syndromes, weight of 10% or more below ideal body weight, and intestinal bypass or gastrectomy)
- Children less than five years of age and adolescents exposed to adults at high risk for developing TB disease[13]

TST Results of 15 mm or More[14]

Persons in the following groups may be considered for treatment of LTBI if their skin test result is greater than or equal to 15 mm. These groups should be given a lower priority for prevention efforts than the groups already listed above.

- Persons with no known risk factors for TB disease
- Healthcare workers who are otherwise at low risk for TB disease and who received baseline testing at the beginning of employment as part of a TB screening program[15]

Treatment Regimens and Dosages

Select appropriate treatment durations, regimens, and dosages. There are several treatment regimens available for the treatment of LTBI, and providers should discuss options with patients. Persons who are at especially high risk for TB, and either are suspected of nonadherence or are on an intermittent dosing regimen, should be treated using directly observed therapy (DOT). This method of treatment is especially appropriate when a household member is on DOT for TB disease or in institutions and facilities where a staff member can observe treatment.

Regimens

The recommended treatment regimens are, in large part, based on evidence from clinical trials and are rated on the basis of a system developed by the Infectious Diseases Society of America (IDSA) and the United States Public Health Service (USPHS). Identify an appropriate regimen using the national guidelines. A summary of the guidelines is provided in Table 1 (page 8.9).

Isoniazid (INH) for 9 months, regardless of age or HIV status is the preferred regimen. Active hepatitis and end-stage liver disease are relative contraindications to the use of INH. Peripheral Neuropathy, associated with Isoniazid use is not common at doses of 5 mg/kg, however, vitamin B_6 (Pyridoxine 10 – 25 mg/day) is recommended for pregnant women and for persons with alcoholism, diabetes mellitus, HIV, malnutrition, seizure disorders, and uremia.

Baseline lab testing is not routinely indicated for all patients. Clinical monitoring and patient education is **very important**. Baseline hepatic measurements of **serum aminotransferase and bilirubin** are indicated for patients whose initial evaluation suggests a liver disorder. Baseline testing is also indicated for patients with HIV infection, women who are pregnant or in the immediate postpartum period, persons with a history of liver disease, persons who use alcohol regularly and others who are at risk of chronic liver disease.

Baseline laboratory testing is not routinely indicated in older persons. However, testing may be considered on an individual basis, particularly for patients who are taking other medications for chronic medical conditions.

For more detailed information on treatment regimens for LTBI, refer to the CDC publication "Targeted Tuberculin Testing and Treatment of LTBI" at http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf

A **Tuberculosis Drug Information Guide** on first and second line TB drugs including information on use in pregnancy/breast feeding, renal disease, hepatic disease, seizure medication, etc. is available from Francis J. Curry National TB Center at http://www.nationaltbcenter.ucsf.edu/tbdruginfo/

NOTE: The 2-month regimen of rifampin (RIF) and pyrazinamide (PZA) is no longer recommended for treatment of LTBI because of its association with severe liver injury. For more information, see the CDC's "Update: Adverse Event Data and Revised ATS/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of LTBI" (*MMWR* 2003;52[No. 31]:735) at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5231a4.htm

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To request ISDH TB Treatment Pocket Guides call 317.233.7434.

Dosages

Once the appropriate regimen has been identified, refer to Table 2 for instructions on dosages for each drug. The information in Table 2 is taken from ATS, CDC, and Infectious Diseases Society of America (IDSA) guidelines.

Table 1: RECOMMENDATIONS FOR TREATMENT FOR LTBI (Regimens 1 – 3)

R	Drugs	Interval	Duration	Comments	Evidence Rating	
					HIV-	HIV+
1	INH	7 days per week (270 doses) **or** 2 **x's** wkly **DOT** (76 doses)	9 months *completed within 12 months*	Recommended for persons < 18 years of age Recommended for Pregnant women HIV + :INH may be given with NRTIs, protease inhibitors, or NNRTIs ★ NOT indicated for persons with active hepatitis and end-stage liver disease	A (II) B (II)	A (II) B (II)
2	INH	7 days per week (180 doses) **or** 2 **x's** wkly **DOT** (52 doses)	6 months *completed within 9 months*	Recommended for Pregnant women NOT indicated for HIV infected persons NOT indicated for those with fibrotic lesions on CXR NOT indicated for CHILDREN NOT indicated for persons with active hepatitis and end-stage liver disease	B (I) B (II)	C (I) C (I)
3	RIF	7 days per week (120 doses) 2 **x's** wkly **NOT RECOMMENDED**	4 months *completed within 6 months*	Used for persons who are contacts of patients with INH resistant, rifampin-susceptible TB **The optimal length of RIF therapy in children with LTBI is not known; however, the American Academy of Pediatrics recommends 6 months of treatment.** HIV + : most protease inhibitors or delavirdine should NOT be given with RIF Rifabutin (with appropriate dose adjustments) can be used with protease inhibitors (saquinavir should be augmented with ritonavir) and NNRTIs (except delavirdine) ✪ Substitution of rifapentine NOT recommended – safety not established for LTBI	B (II)	B (III)

2 day a week administration is ALWAYS given by **DOT**

★ NRTIs = nucleoside reverse transcriptase inhibitor
NNRTIs = non-nucleoside reverse transcriptase inhibitors

✪ Consult web-based updates for latest recommendations and drug interactions:
http://www.aidsinfo.nih.gov/guidelines

DEFINITIONS OF EVIDENCE RATINGS: A = preferred; B = acceptable alternative; C = offer when A & B cannot be given. I = randomized clinical trial; II = data from clinical trials that were not randomized or were conducted in other populations; III = expert opinion.

Sources: CDC MMWR 52(31):2003 and Interactive Core Curriculum on TB: What the Clinician Should Know, October 2004

The use of INH elixir is discouraged, as it commonly causes diarrhea and cramping in children. If children have difficulty taking medications, open capsules and crush tablets, and then hide the drugs in soft foods or liquids. Possible foods include maple syrup, hot fudge, Nutella, apple sauce, jams and jellies, spinach baby food, and chocolate whipped cream, etc. Layer the food and drug on a spoon, and teach the child to take the contents of the spoon without chewing.[16]

ISDH provides drugs to TB patients and suspects through a state-funded program for patients who reside in Indiana, with the exception of Marion and Allen Counties, which have their own drug program. View the ISDH TB Medication Policy at http://www.in.gov/isdh/19685.htm

For information regarding the treatment of LTBI in persons who have been in contact with a case who is resistant to drugs in the recommended regimens, contact the ISDH TB/Refugee Division at 317.233.7434.

Side Effects and Adverse Reactions

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Standards for the evaluation and monitoring of treatment for LTBI

- Baseline laboratory testing is not routinely indicated for all patients at the start of treatment for LTBI.
- Recent data indicate that baseline testing is no longer routinely indicated in persons older than 35 years of age.
- Once patients have been identified as requiring treatment for LTBI, they should receive an initial clinical evaluation. This evaluation should include a detailed history for risk factors that increase the likelihood of hepatotoxicity and a brief physical assessment checking for signs of hepatitis.
- Patients whose initial evaluation suggests these risk factors should have baseline hepatic measurements of serum AST (SGOT) or ALT (SGPT) and bilirubin.
- **Patients should be educated about the side effects associated with treatment of LTBI and advised to promptly seek medical evaluation when they occur.**
- Patients being treated for LTBI should also receive follow-up evaluations at least monthly. This evaluation should consist of questioning about side effects and a brief physical assessment checking for signs of hepatitis.

Standards for CXR evaluations

- For persons with LTBI who have had active disease ruled out and for asymptomatic tuberculosis patients who have completed treatment, repeat chest x-ray examinations have been shown to be of insufficient clinical value or productivity to justify their continued use and are not recommended unless specific medical conditions exist.

Reference: ISDH, **Guidelines for TB Skin Test Screening and Treatment of LTBI**, at http://www.in.gov/isdh/19692.htm

For ISDH policy on CXRs for employment, LTC, routine follow-up, etc. refer also to **Repeat Chest X-Rays** at http://www.in.gov/isdh/19684.htm.

The patient should be monitored by a registered nurse and/or clinician or case manager at least **monthly** for adherence to the prescribed regimen, signs and symptoms of active disease, signs and symptoms of adverse reactions (e.g., hepatitis: emesis, dark urine, yellowing of the eyes/skin, abdominal pain) until treatment is completed. If a patient is symptomatic, the provider should be consulted and the patient monitored more frequently. Chemistries and complete blood count (CBC), aspartate aminotransferase (AST)/alanine aminotransferase (ALT), or other tests based on specific drugs should be done periodically. Routine monitoring is indicated only for those whose baseline tests suggest a liver disorder and for other persons with a risk of hepatic disease or for patients with symptoms compatible with hepatotoxicity to allow for the evaluation of possible adverse reactions that might occur during treatment. See Table 4**: Monitoring and Interventions for Side Effects and Adverse Reactions** in this section.

As is true with all medications, combination chemotherapy for tuberculosis (TB) is associated with a predictable incidence of adverse effects, some mild, some serious.[17]

Adverse effects are fairly common and often manageable. Although it is important to be attuned to the potential for adverse effects, it is at least equally important that the drugs with the highest evidence rating not be stopped without adequate justification.[18] However, adverse reactions can be severe, and, thus, it is important to recognize adverse reactions that indicate when a drug should not be used. Mild adverse effects can generally be managed with symptomatic therapy; whereas, with more severe effects, the offending drug or drugs must be discontinued.[19] In addition, proper management of more serious adverse reactions often requires expert consultation.[20]

Monitor patients for side effects and adverse reactions following the basic monitoring steps listed below.

Basic Monitoring Steps

1. All healthcare workers providing treatment for LTBI should be familiar with the American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC) guidelines.
    a. All jurisdictions should follow the national monitoring guidelines identified in the current treatment guidelines for treatment of LTBI, “Targeting Tuberculin Testing and Treatment of Latent Tuberculosis Infection,” pages 26–29 at this hyperlink: http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf .
    b. It is also important to check for guideline updates posted on the CDC’s Division of Tuberculosis Elimination home page at this hyperlink: http://www.cdc.gov/tb/default.htm and the list of guidelines by date at this hyperlink: http://www.cdc.gov/tb/pubs/mmwr/Maj_guide/List_date.htm .
2. While on treatment, all patients should be evaluated in person, at baseline (before starting treatment), and then at least monthly, for side effects and adverse reactions.

3. The common side effects of and adverse reactions to drugs used to treat for LTBI are listed in Table 3: **Reporting Reactions to Antituberculosis Medications**. Educate patients to stop the medicine and promptly report any of the symptoms or signs listed in Table 3 or any unexplained illness to the prescribing physician or nurse case manager immediately.

If a patient reports to a healthcare worker a potentially serious adverse reaction, the healthcare worker should inform the patient's provider immediately and alert the LHD.

   a. If a patient reports a potentially less severe side effect, inform the patient's provider immediately and monitor the patient.

4. If you suspect that an antituberculosis drug may be causing a particular side effect or adverse reaction:

   a. Refer to Table 4: **Monitoring and Interventions for Side Effects and Adverse Reactions** below.

   b. Consult with the patient's medical provider and contact the ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.

5. If you suspect that an antituberculosis drug may be interacting with other medications that the patient is taking, refer to pages 45–47 in the "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]) at this hyperlink: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .

6. Document the following patient information:

   a. Review of symptoms, test results, side effects, and adverse reactions

   b. Education given

   c. Refill provided

   d. Description of any problems encountered and action taken for that visit

   e. Next appointment

For more information on Assessing and Managing the Risk of Liver Disease in treating LTBI see Heartland National TB Center's algorithm at:

http://www.heartlandntbc.org/products/assessing_and_managing_the_risk_of_liver_disease_in_the_treatment_of_ltbi.pdf

Reporting Reactions

The table below is intended for use by a healthcare worker who performs case management services. The healthcare worker should instruct the patient to report to the provider the side effects and adverse reactions listed in Table 3.

a. If a patient reports to a healthcare worker a potentially serious adverse reaction, the healthcare worker should inform the patient's provider immediately, take action according to the provider's instructions, and alert the LHD.

If a patient reports to a healthcare worker a potentially less severe side effect, the healthcare worker should inform the patient's provider immediately and monitor the patient.

Table 3: REPORTING REACTIONS TO ANTITUBERCULOSIS MEDICATIONS[21]

Potentially Serious Adverse Reactions*	Less Severe Signs and Symptoms*
Immediately report the following signs and symptoms or other abnormalities or unexpected events to the patient's provider. These signs and symptoms suggest side effects, including hepatotoxicity: ▪ Jaundice ▪ Dark urine ▪ Vomiting ▪ Abdominal pain ▪ Fever ▪ Visual changes ▪ Marked clinical rash In consultation with the provider, instruct the patient to stop TB medications until evaluated by the provider.	Report the following signs and symptoms to the patient's provider within 24 hours: ▪ Anorexia ▪ Nausea ▪ Malaise ▪ Peripheral neuropathy (tingling or burning sensation in hands or feet) ▪ Rashes
* These lists are not all-inclusive. For a complete list, refer to the current guidelines for treatment of TB, "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]) at this hyperlink: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .	

Source: California Department of Health Services(CDHS)/California Tuberculosis Controllers Association(CTCA). TB case management—core components. *CDHS/CTCA Joint Guidelines* [CTCA Web site]. 1998:9. Available at: http://www.ctca.org/guidelines/index.html . Accessed July 11, 2006.

The two-month regimen of rifampin and pyrazinamide is no longer recommended due to serious and fatal hepatitis associated with this regimen.[22]

At present, the CDC Division of Tuberculosis Elimination (DTBE) urges health departments, hospices, hospitals, jails, prisons, and private medical offices to report all severe adverse events (e.g., liver injury, pancreatitis, metabolic acidosis, anaphylaxis, seizure, severe dermatitis) leading to hospitalization or death of a person receiving treatment for LTBI that occurred after January 1, 2004, to DTBE by calling 404-639-8401. Also, if not done previously, please call the ISDH TB/Refugee Division at 317.233.7434 to report severe adverse events.

Table 4: MONITORING AND INTERVENTIONS FOR SIDE EFFECTS AND ADVERSE REACTIONS[23,24,25]

Anti-TB Drug	Side Effects/ Adverse Reactions	Monitoring	Comments
Isoniazid (INH)	▪ Rash ▪ Hepatic enzyme elevation ▪ Hepatitis ▪ Peripheral neuropathy ▪ Mild central nervous system effects	Clinical monitoring monthly Liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and serum bilirubin) at baseline in selected cases ((human immunodeficiency virus [HIV] infection, history of liver disease, alcoholism, and pregnancy) Repeat measurements if ▪ Baseline results are abnormal ▪ Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions ▪ Patient has symptoms of adverse reactions	Hepatitis risk increases with age and alcohol consumption. Pyridoxine (vitamin B6, 10–25 mg/d) might prevent peripheral neuropathy and central nervous system effects. Serum concentrations of phenytoin, disulfiram (Antabuse), and carbamazepine may be increased in persons taking INH. Measure serum concentrations of phenytoin and carbamazepine in patients receiving INH (with or without rifampin), and adjust the dose if necessary. More information available in the Official ATS Statement: Hepatotoxicy of Antituberculosis Therapy at http://ajrccm.atsjournals.org/cgi/reprint/174/8/935.pdf.

Anti-TB Drug	Side Effects/ Adverse Reactions	Monitoring	Comments
Rifampin (RIF)	▪ Rash ▪ Gastrointestinal upset ▪ Hepatitis ▪ Fever ▪ Bleeding problems ▪ Thrombocytopenia ▪ Renal failure ▪ Flu-like symptoms ▪ Orange-colored body fluids (secretions, urine, tears)	Complete blood count, platelets, and liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and serum bilirubin) at baseline in selected cases (human immunodeficiency virus [HIV] infection, history of liver disease, alcoholism, and pregnancy) Repeat measurements if ▪ Baseline results are abnormal ▪ Patient has symptoms of adverse reactions	There are a number of drug interactions with potentially serious consequences. Significant interactions with methadone, birth control hormones, and many other drugs. Contraindicated or should be used with caution when administered with protease inhibitors (PIs) and nonnucleoside reverse transcriptase inhibitors (NNRTIs). Reduces levels of many drugs (e.g., PIs, NNRTIs, methadone, dapsone, ketoconazole, coumadin derivatives, hormonal contraceptive, digitalis, sulfonylureas, diazepam, ß-blockers, anticonvulsants, and theophylline). For more information, refer to “Section 7: Drug Interactions” on page 45 in “Treatment of Tuberculosis” at http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf . Because information regarding rifamycin drug interactions is evolving rapidly, consult the CDC’s Division of Tuberculosis “News and Updates” Web page at http://www.cdc.gov/tb/default.htm to obtain the most up-to-date information. Colors body fluids orange. May permanently discolor soft contact lenses.

Adherence

Monitor patients for adherence to self-administered latent tuberculosis infection (LTBI) treatment regimens at least monthly throughout treatment.[26] It is difficult to identify who will and who will not be adherent.[27] If patients do not take medicine as directed, the effectiveness of the regimen decreases, and the patient will be at greater risk of progressing to disease in the future and of infecting others.

Monthly Assessment of Adherence

At each visit, the case manager should assess adherence by doing the following:

1. Ask patients how many doses they have missed since their last refill. If patients are asked, “Did you take all your pills last month?” the natural inclination is to agree and say “yes” even if they did not.
2. Have patients bring their bottle of medicine to the refill appointment, and count how many pills are left.
3. If adherence problems are identified, include patients in the problem-solving process.
   a. Ask patients why they think that doses are missed and what could be done better: change the time of day, the location where they keep or take their pills, etc.
   b. Find out if there are barriers to obtaining refills in a timely manner that could be corrected.
   c. Review with patients what they believe is their risk of developing tuberculosis (TB) if medicine is not taken. Provide education again, as needed.
   d. Mutually agree upon a plan to improve adherence.
   e. Praise patients for cooperation.
4. If adherence seems to be good, praise patients.

For information on what to include in a patient education session, see Section 12 - Patient Education.

Directly Observed Therapy

INDIANA

Review ISDH Consensus Statement of the Tuberculosis Medical Advisory Board on **Directly Observed Therapy,** adopted 1-1999, at http://www.in.gov/isdh/files/TB_DOT_MAB_revised.pdf

Patients in the following high-risk groups are strongly recommended for directly observed therapy (DOT).

- DOT is mandatory for any intermittent regimen.
- DOT is strongly encouraged for those with the greatest risk for progression to tuberculosis (TB) disease:
  - Young children who are recent contacts to infectious cases.
  - Human immunodeficiency virus (HIV)-infected persons.

For more information, see the "Directly Observed Therapy" topic in Section 9 - Case Management.

For more information on adherence strategies for different developmental stages, see Appendix C in the New Jersey Medical School National Tuberculosis Center's *Management of Latent Tuberculosis Infection in Children and Adolescents: A Guide for the Primary Care Provider* at http://www.umdnj.edu/globaltb/downloads/products/PediatricGuidelines.pdf

Completion of Therapy

Determine whether and when therapy is completed based upon the total number of doses administered, not on the duration of therapy. When patients have had lapses in therapy but are still able to complete the recommended number of doses in the allotted time period, encourage them to complete therapy.

Assess patients who will not complete appropriate therapy within the time frame specified to determine whether or not to restart treatment. If the decision is made to retreat the patient, then restart the entire regimen and follow the recommended treatment plan of therapy. Specific factors to consider when determining whether to restart treatment include the following:

- Individual's risk for developing tuberculosis (TB) disease
- Total number of doses of latent tuberculosis infection (LTBI) treatment administered
- Time elapsed since the last dose of treatment for LTBI
- Patient adherence issues (previous attempts, willingness to continue, etc.)

Give nonadherent patients who are at very high risk of developing TB disease every opportunity to complete treatment for LTBI. Consider these patients for intermittent therapy with directly observed therapy (DOT) and evaluate the use of incentives and enablers.[28]

Treatment of LTBI in contacts is considered a priority in TB control activities. Make every effort to assure completion of treatment in contacts. All contacts who are being treated for infection should be seen face-to-face by nurse case manager at least every month or more often. Incentives and enablers are recommended as aids to adherence, and the nurse case manager should educate the patient about TB, its treatment, and the signs of adverse drug effects at each patient encounter.[29]

Table 1, "Recommendations for Treatment of LTBI", page 8.9 describes the duration of therapy and the number of doses that patients are required to take to complete therapy as well as the time frame within which the total number of doses must be administered for completion of therapy.

Make every effort to encourage patients to adhere to the LTBI treatment regimen. However, if a patient has failed three attempts to complete treatment, no further effort may be merited. The healthcare provider should contact patients who interrupt therapy and are at high risk of developing TB disease (for example, contacts of patients with infectious TB, human immunodeficiency virus (HIV)-infected patients, or TB Class 4 patients) for reevaluation.[30]

For consultation regarding completion of therapy and factors to consider when restarting treatment in noncompliant patients, contact the ISDH TB/Refugee Division at 317.233.7434.

Treatment in Special Situations

Treatment of latent tuberculosis infection (LTBI) in the following situations requires special consideration:

- Human immunodeficiency virus (HIV) infection
- Alcoholism
- Pregnancy and breastfeeding

Human Immunodeficiency Virus and Latent Tuberculosis Infection

Treatment of latent tuberculosis infection (LTBI) in a person with human immunodeficiency virus (HIV) infection can be extremely complicated. Before treatment is initiated, contact the LHD or ISDH Regional TB Nurse Consultant (contact information in Section 1 – Introduction) for consultation.

HIV infection is the strongest known risk factor for the progression of LTBI to tuberculosis (TB) disease. HIV-infected persons with LTBI are 100 times more likely to progress to TB disease than are those patients without HIV infection. Coinfected HIV and LTBI patients have a 7 to 10 percent yearly risk of developing TB disease. Patients with only LTBI have a 10 percent lifetime risk of developing TB disease.

High-risk contacts (less than 5 years of age or immunocompromised) should be started promptly on treatment for LTBI. For more information on time frames, see the “Time Frames for Contact Investigation” topic in Section 10 - Contact Investigation.

For more info on time frames see “Guidelines for the Investigation of Contacts of Persons with Infectious TB at http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf

Alcoholism

For information on treating patients for LTBI who also are known or suspected to have an alcohol use disorder, who drink heavily, or who regularly consume alcohol, see the “Alcoholism” topic under Special Considerations in Section 6 - Treatment of TB Disease.

Pregnancy and Breastfeeding

Pregnancy has minimal influence on the pathogenesis of TB or the likelihood of LTBI progressing to disease. Pregnant women should be targeted for testing only if they have a specific risk factor for LTBI or for progression of LTBI to disease. There is an increased risk of post partum women with LTBI to progress to active disease. Extensive use of isoniazid (INH) during pregnancy has shown that, although it readily crosses the placental barrier, the drug is not teratogenic, even when given during the first four months of gestation. Pregnant women taking INH should receive pyridoxine supplementation.

Breastfeeding is not contraindicated when the mother is being treated for LTBI. However, infants whose breastfeeding mothers are taking INH should receive supplemental pyridoxine. Note that the amount of INH provided by breast milk is inadequate for treatment of the infant.[31]

Refer to the most current edition of the American Academy of Pediatrics Committee on Infectious Diseases **Red Book®** ; Editor: Larry K. Pickering, MD, FAAP; Associate Editors: Carol J. Baker, MD, FAAP; David W. Kimberlin, MD, FAAP; Sarah S. Long, MD, FAA. **Red Book®** Online Web site). at: http://aapredbook.aappublications.org/

Resources and References

Resources

Whom to Treat

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- American Academy of Pediatrics Committee on Infectious Diseases **Red Book®** ; Editor: Larry K. Pickering, MD, FAAP; Associate Editors: Carol J. Baker, MD, FAAP; David W. Kimberlin, MD, FAAP; Sarah S. Long, MD, FAA. **Red Book®** Online Web site). at: http://aapredbook.aappublications.org/

HIV and Latent TB

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Treatment Regimens and Dosages

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Infection" (*MMWR* 2003;52[No. 31]). Available at: http://www.cdc.gov/tb/pubs/mmwr/mmwr_updates.htm .

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Side Effects and Adverse Reactions

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- CDC. Module 4: "Treatment of Tuberculosis and Tuberculosis Infection" (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web Site]; 1999:15–17, 30–32). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/Default.htm .

Adherence

- CDC. Module 9: "Patient Adherence to Tuberculosis Treatment" (*Self-Study Modules on Tuberculosis.* Division of Tuberculosis Elimination Web Site; 1999). Available at: http://www2a.cdc.gov/phtn/tbmodules/modules6-9/m9/9-toc.htm .
  This module is entirely devoted to assessing and promoting adherence. It covers the many areas that need to be addressed, such as:
  - Case management: assigning responsibility to the healthcare worker
  - Communication and problem-solving skills
  - Education of the patient
  - Using interpreters when needed
  - Using incentives and enablers
  - Using directly observed therapy (DOT)
- CDC. *Improving Patient Adherence to Tuberculosis Treatment.* (1994)

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Case Management

CONTENTS

Introduction

Purpose

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

Use this section to understand and follow national and Indiana guidelines to do the following:

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

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

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

These adverse outcomes are preventable by case-management strategies provided by TB control programs, including use of DOT.[5] It is strongly recommended that the initial treatment strategy utilize patient-centered case management with an adherence plan that emphasizes DOT.[6] It is essential to provide patient-centered case management in

which treatment is tailored and supervision is based on each patient's clinical and social circumstances.[7] Programs utilizing DOT as the central element in a comprehensive, patient-centered approach to case management (enhanced DOT) have higher rates of treatment completion than less intensive strategies.[8]

Policy

Although some patients may undergo most of their evaluation and treatment in settings other than a local public health agency, a local public health agency has the major responsibility for monitoring and ensuring the quality of all TB-related activities in the community as part of its duties to protect the public health.[9]

Effective TB case management requires administrative commitment and support. This includes education, staff training, and ensuring adequate funding to maintain program activities.[10] It is recognized that local public health agencies differ in their staffing and organization and that no set of guidelines can cover all the situations that may arise relating to case management.[11]

State Laws and Regulations

Refer to Section 1 – Introduction for Indiana state laws related to TB Case Management.

Acknowledgments

The authors want to acknowledge the extensive use of two non–CDC sources for the content in this section.

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

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

ISDH TB Case Management

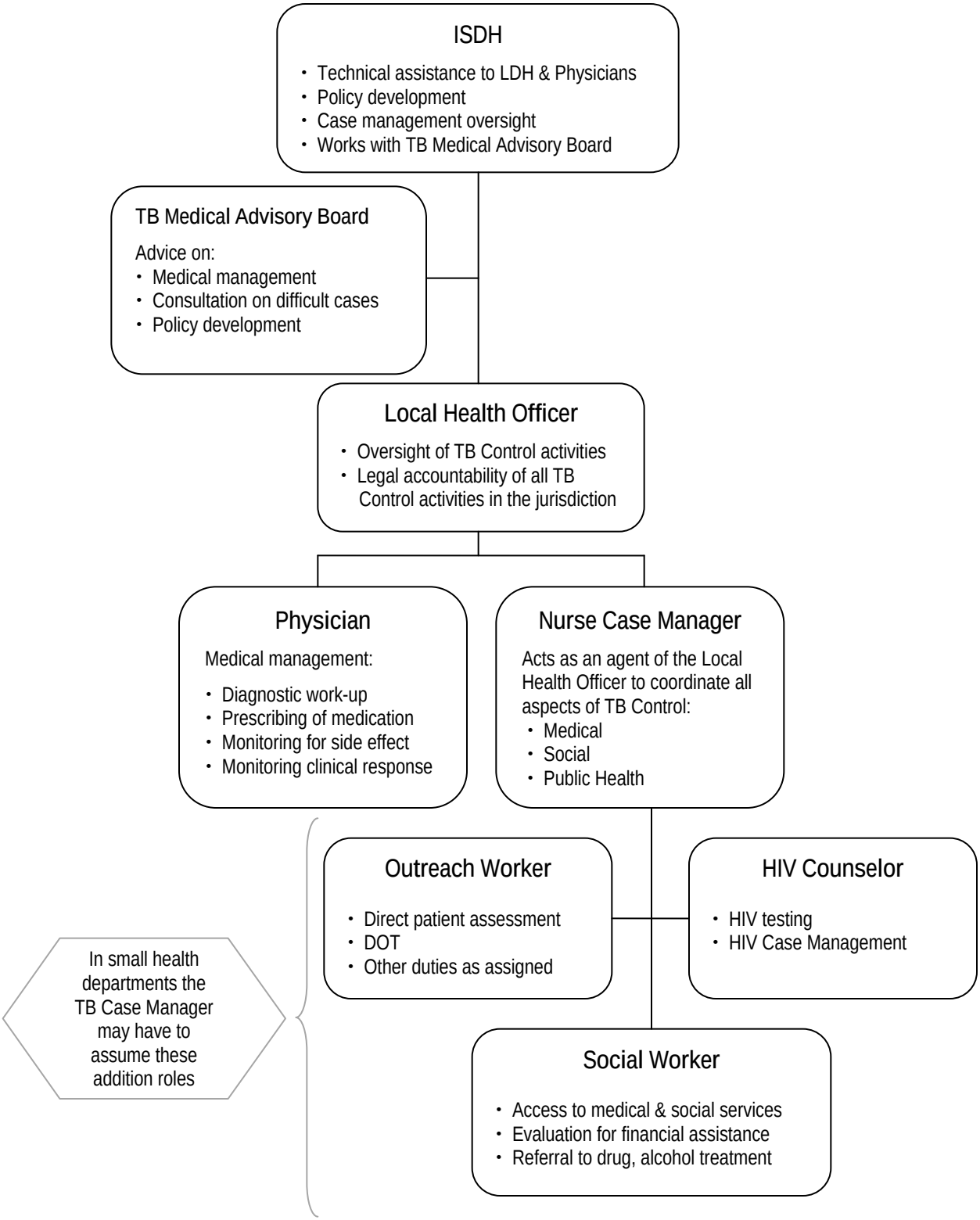
In Indiana, the patient's primary care physician performs the medical management of TB. Diagnostic work-up, prescribing of medication, and monitoring for side effects and clinical response are among the responsibilities of the physician. Public health departments must assure that medical management is performed according to ATS and CDC standards. In addition, the LHD carries the responsibility to assure that the health of the community is fully protected. This responsibility means that LHDs must assure complete and adequate treatment of all TB patients, isolation of infectious individuals, and identification and treatment of recently infected individuals through complete and timely contact investigation.

To this end, every TB patient and suspect should be assigned to a specific LHD employee who will serve as the TB Case Manager. The TB Case Manager works as an agent of the Local Health Officer. The Local Health Officer oversees all TB control activities in the jurisdiction. In particular, the Local Health Officer should assist the TB Case Manager with diagnosis and case management, communication with private physicians, education of physicians in the jurisdiction about TB control issues, and management of difficult cases. At the discretion of the Local Health Officer, the duties of the TB Case Manager may be assigned to other individuals so long as the overall goals of TB control are achieved in the jurisdiction.

ISDH TB/Refugee Health Division (ISDH) is responsible for oversight of TB Control activities in the state of Indiana, technical assistance to LHDs and physicians, evaluation of local TB control programs, and policy development related to TB Control. ISDH works in consultation with members of the ISDH TB Medical Advisory Board on issues related to medical management and policy development. ISDH is further responsible for securing consultation on management of difficult cases, when necessary. This may include consultation with experts at the New Jersey Medical School Global Tuberculosis Institute (designated by the CDC as Indiana's Regional Training and Medical Consultation Center (RTMCC), the CDC, or other appropriate experts.

A suggested organizational chart for TB Case Management follows. In smaller LHDs, the TB Case Manager may have to assume the role of HIV Case Manager, Outreach worker and Social Worker. In larger counties, where case burdens are larger, TB control requires a multidisciplinary team approach. Where multiple individuals are involved in the care of TB patients, regular staff meetings are encouraged to promote communication between all persons taking care of individual TB patients.

TB Case Management



Qualifications and Duties of the TB Case Manager

The TB Case Manager must be a licensed nurse with specific training in TB treatment, case management, patient interview techniques, and contact investigation that is provided by the Regional Nurse Consultants. A TB Case Manager not trained in TB Control at the time of employment should complete training within 3 months. If the TB Case Manager is off work or out of the office, a second trained employee must be assigned as back up.

The TB Case Manager has primary responsibility for case management of TB suspects and cases and therefore must:

- Assure that sufficient information is available to confirm the presence or absence of TB disease, and to determine whether the patient may be infectious.
- Verify that appropriate isolation measures have been implemented to protect the health of the community until such time the patient is noninfectious.
- Assure that each TB patient completes an appropriate course of antituberculosis therapy at the proper dose and for the appropriate amount of time.
- Assure that a complete contact investigation is performed in a timely manner
- Document that each TB patient converts his/her sputum culture to negative (ideally within 3 months of initiating therapy).
- Assure that each TB patient is thoroughly educated about TB and its treatment.
- Establish ongoing positive working relationships with physicians, infection control nurses, and healthcare facilities so that reporting and disease control efforts are fully coordinated in an efficient and effective manner.

Some specific responsibilities may be delegated to other trained persons, but the TB Case Manager still oversees the outcome.

TB Case Managers must be aware of the Indiana Reporting requirements, refer to Section 2 – Surveillance for details on reporting.

Initial Case Management

Upon notification of a TB suspect, the TB Case Manager must **immediately assess the degree of risk to the community**. If an abnormal CXR is present, and a laboratory diagnosis of TB has not yet been established the TB Case Manager should coordinate with the physician and immediately arrange for smears and cultures to be obtained and sent to the ISDH Laboratory. Even if the patient has undergone bronchoscopy, routine expectorated sputum for AFB should be collected, especially if the diagnosis is not yet confirmed. The **patient should be isolated** until it is determined that he/she is noninfectious. Refer to Section 16 – Infection Control for guidelines on Isolation (in hospitals and other settings) and determining noninfectiousness.

Upon notification of a TB suspect, the TB Case Manager must send the initial TB Report form to ISDH within 3 working days. Prior to submission, the TB Report Form must be reviewed for completeness, including the dose, route, frequency and mode of administration of prescribed medications, patient's weight, copy of CXR report, and copies of reports of any diagnostic studies (e.g., sputum smear and culture, HIV status, bronchoscopy report, CT scan, biopsy (pathology) report, cell count and chemistry from sterile body fluids such as CSF and pleural fluid, and culture and sensitivity for AFB, or alternate methods of TB diagnosis, e.g., HPLC). The physician/institution should be contacted immediately if information is missing from the initial

report. If an inappropriate treatment regimen has been identified, the TB Case Manager should call the physician and clarify the order.

With the assistance of the Local Health Officer, the TB Case Manager should review all clinical data and establish whether the patient is a case or a suspect. Diagnosis of TB should be established as completely as possible at the earliest feasible time. A confirmed case of TB is one that is laboratory confirmed or meets the clinical case definition.

The laboratory criteria for diagnosis are <u>one</u> of the following:

- Isolation of *M. tb* from a clinical specimen (e.g., DNA probes, HPLC)
- Demonstration of *M. tb* from a clinical specimen by a nucleic acid amplification (NAA) test, or
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not or cannot be obtained

In the absence of culture confirmation of TB, a clinical case diagnosis is made if <u>all</u> of the following criteria are present:

- A positive TST or IGRA
- Other signs and symptoms compatible with TB (e.g., an abnormal, unstable [i.e., worsening or improving] CXR, or clinical evidence of current disease
- Treatment with 2 or more antituberculosis medications
- Completed diagnostic evaluation that has not identified other causes for the findings

A case may also be diagnosed as a confirmed case of active TB on the basis of physician diagnosis. TB suspects are to be followed as closely as confirmed cases of TB. All suspects should be closed out as confirmed cases or as not having TB within 3 months of the initial report.

NOTE: The process of making a diagnosis of TB may be very difficult. ISDH TB/Refugee Health Division should be consulted in ALL cases where there is no culture confirmation of TB. In cases where laboratory contamination is suspected (e.g., a positive culture identified from a patient not thought to have TB) ISDH should be contacted immediately at 317.233.7434.

The TB Case Manager should contact the treating physician/institution by telephone or in person within 3 calendar days to:

- Confer whether isolation is needed and how it should be achieved.
- Offer information on treatment. The "Denver Regimen" is the preferred regimen in Indiana (refer to Section 6 – Treatment of TB Disease for details).
- Develop a written plan to implement DOT (Note: DOT is considered the medical standard of care in Indiana and a physician order is not required for implementation). If the patient is not on DOT the TB Case Manager should be able to explain/justify why.
- Explain the role and services of the LHDs TB Program, including provision or coordination of DOT, state-supplied medications, laboratory services and medical consultation.
- Explain the importance of coordinating the patient's care.
- Provide the name and telephone number of the TB Case Manager assigned to the case by the LHD.
- Plan for direct patient assessment and the Contact Investigation (refer to Section 10 – Contact Investigation for details).

The TB Case Manager should visit the patient within 3 working days (for smear positive cases) and within 7 days (for smear negative cases) of the receipt of the initial report to:

- Make an assessment of how to place the patient on DOT.
- Initiate a contact investigation (refer to Section 10 – Contact Investigation for details)
- Verify initial information and establish what information will be needed to complete the **TB Report Form**
- Provide patient and family education (e.g., basic information on TB disease and transmission, isolation requirements, procedures for contact investigation, medication side effects, what to expect during treatment, referral for social services or financial support while off work or under isolation). Refer to Section 12 – Patient Education for more details.

Case Management Follow-up

For hospitalized or institutionalized cases, the TB Case Manager should review the case at least monthly to monitor sputum status, assess drug sensitivities, sputum culture conversion, and completion of therapy. The TB Case Manager should visit the patient monthly to assess response to therapy.

For cases being actively followed by the LHD, the TB Case Manager or Outreach Worker should visit the patient for every dose of therapy.

To monitor clinical response:

Evaluate sputum smear and culture. Refer ISDH algorithm **Tuberculosis Sputum Collection** on page 9.26. The TB Case Manager should assure that a monthly specimen is obtained and sent to the ISDH Laboratory. It is preferred that a nurse or trained outreach worker observe and coach the patient in obtaining the sputum specimen. If sputum cannot be obtained after direct observation and coaching, the TB Case Manager should notify the physician and document this finding. The TB Case Manager should review smear and culture results; if bacterial load is not progressively falling or conversion to smear and culture negative does not occur within 3 months, ISDH TB Regional Nurse Consultant should be contacted immediately.

Review CXR results. Most physicians will order at least 1 repeat CXR to document a complete response. The TB Case Manager should obtain copies of all CXR reports and request a report for any indication of delayed or incomplete response to therapy.

Evaluate clinical status in the context of DOT. The patient should be queried about symptoms, observed for signs of improvement (including weight gain). If significant weight gain occurs, doses of medication may need to be adjusted. If significant improvement does not occur, full medical evaluation is indicated.

Communicate with the physician. The TB Case Manager should contact the physician on a monthly basis for the purpose of exchanging information on clinical status of the patient, to identify any problems with adherence or medication side effects, and to obtain copies of significant medical evaluations, progress notes, procedure notes, laboratory reports, discharge summaries, medication changes, etc.

If deficiencies are identified with the TB care provided by private providers, appropriate measures should be instituted, including provider education. Contact the Local Health Officer

for assistance. The goal of these efforts should be to improve the care of patients and to promote positive working relationships between LHDs and private providers.

Two month checkpoint

The patient's initial phase of therapy should be complete. The continuation should begin and treatment should be changed to Rifampin and Isoniazid.

Three month checkpoint

A crucial checkpoint occurs at 3 months. At this time, the major symptoms of TB should be resolved and the patient should be smear and culture negative. If symptoms persist and the smear/cultures remain positive, the TB Case Manager need to react immediately as follows:

1. Repeat drug sensitivities
2. Review serial smear and culture results
3. Assure that a full medical evaluation is conducted to assess response to therapy, including repeat CXR
4. Absolutely assure that DOT is being performed properly
5. Contact the Regional Nurse Consultant for technical assistance and consultation
6. Consult the physician to determine if the patient has an underlying medical illness contributing to his/her poor response.

Four Month Checkpoint

If the patient is still culture positive, then this will be considered treatment failure. The patient must restart therapy.

Case Closure

At the time of case closure, the TB Case Manager must establish that the Class 3 patient has been fully and adequately treated for TB according to CDC/ATS guidelines and that the patient has responded to therapy. In order to do this, the TB Case Manager should visit the patient one last time and obtain and review all of the following information:

1. The patient's clinical condition. Document that all symptoms of TB are resolved
2. Obtain a final sputum for smear and culture, if possible
3. Obtain CXR results, if done at close of therapy
4. Review the treatment history to confirm that the patient has received a complete course of medication
5. Educate the patient about symptoms of reactivation of TB.

Reference: Tuberculosis Case Management, Quality Assurance Protocol, 1999, ISDH

Initial Assessment

Conduct initial assessments of tuberculosis (TB) patients to gather data that will form the basis for TB treatment and care. It is essential to gather data to determine the clinical and social issues and circumstances of relevance to the patient and to assess each situation objectively to determine the appropriateness of the planned intervention. Many professionals involved in the patient's care contribute to the assessment data, and the case manager gathers assessment data from many sources, including community agencies, primary care providers, schools, and other healthcare facilities.[12]

When the patient with TB is a child, the case manager should involve both the child and family in the assessment process.[13]

Cultural Sensitivity and Language Issues

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

For more information on cultural sensitivity, refer to the *Participant's Workbook* for Session 4: "Working with Culturally Diverse Populations" in *DOT Essentials: The DOT Trainer's Curriculum* (Francis J. Curry National Tuberculosis Center Web site; 2003) at this hyperlink: http://www.nationaltbcenter.ucsf.edu/catalogue/epub/index.cfm?uniqueID=2&tableName=DOTE.

For assistance with language issues, see the National Health Law Program and The National Council on Interpreting Health Care's *Language Services Resource Guide for Health Care Providers* (National Health Law Program Web site; October 2006) at this hyperlink: http://www.healthlaw.org/library.cfm?fa=download&resourceID=89928&appView=folder&print . Please note that this download is very slow.

For more information on using interpreters, see the *Interpretation Services* lesson in Module 9: "Patient Adherence to Tuberculosis Treatment" of the CDC's *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 1999) at this hyperlink: http://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/m9/9-12.htm .

Patient's Medical Records

All medical records are needed in order to provide case management and recommend a treatment plan. Prior to the visit with the patient, the case manager should ensure that a

copy of all of the patient's medical records (from hospitals, clinics, and other healthcare providers) and chest radiographs are available to the treating physician. Without the medical records, the physician may not be able to make the correct judgements in medical management.[14]

Assessment Site

If the patient is hospitalized, conduct the initial assessment during the patient's hospitalization. If the patient is hospitalized outside of his/her county of residence, coordinate with the other county or hospital's infection control staff to conduct the assessment. If the patient is not hospitalized, conduct the initial assessment at the first clinic visit or during a home visit. **Indiana protocol is to start the initial assessment within 3 working days (for smear positive cases) and within 7 working days (for smear negative cases) of the receipt of the initial report.**

Discharge Planning

Patients who are diagnosed with TB during a hospitalization will require discharge planning. The case managers should ensure that appropriate discharge planning occurs for all patients with TB, to prevent transmission in the community and interruption in treatment.[15]

Initial Assessment Activities

To complete an initial assessment, perform the following activities:

- Visit the patient's home.
- Obtain or review demographic information.
- Ascertain the extent of TB illness.
- Obtain and review the patient's health history.
- Determine infectiousness or potential infectiousness.
- Evaluate the patient's knowledge and beliefs about TB.
- Initiate treatment, if not initiated during the hospital stay.
- Monitor the TB medication regimen.
- Identify any barriers or obstacles to adherence.
- Review psychosocial status.
- Identify and document a thorough history of the patient's social network.
- Gather information for a possible contact investigation.

Visit the patient's home. During the patient's TB treatment, at least one or more home visits are required. Home visits are useful for confirming the patient's address, particularly for patients at high risk for default from treatment. Information gathered at the patient's home is often more revealing than assessments performed in the clinical or health department settings and can lead to a more accurate understanding of the patient's lifestyle (for example, seeing a child's shoes or toys when a child was not named in the contact investigation).[16] Several home visits may be needed because usually not all of the necessary information is gathered from the patient and family at one time.

Obtain or review demographic information, including the name, address, telephone number(s), birth date, alternate contact person, alternate telephone numbers and identifying information.[17]

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

Diagnostic activities should be completed in a timely manner. The responsible physician and/or program medical consultant should be consulted immediately upon receipt of a suspect report. Upon suspicion of tuberculosis, a TST or IGRA should be completed and interpreted; and a CXR should be taken and interpreted. Also, a minimum of three consecutive sputum specimens of good quality should be collected eight to 24 hours apart (with at least one being an early morning specimen) and submitted to the laboratory.

In the case of pulmonary TB in children younger than 5 years of age, posterior-anterior and lateral CXRs are important in the initial diagnosis.[18] Adults who are suspected of TB or who are active cases usually need only an initial posterior-anterior CXR.

Obtain and review the patient's health history to determine concurrent medical problems, including HIV disease or risk factors, country of birth, sexual history, allergies, or medications that may interfere with TB drugs. The case manager should obtain the names, addresses, and telephone numbers of the patient's primary care provider and any specialists involved in his or her medical care, previous hospitalizations, allergies, and current medications. It is important to know the patient's history of treatment for TB infection and/or disease, especially for those who are treatment failures or have a relapse of TB disease, as they are at a higher risk for developing multidrug-resistant TB (MDR-TB). It is also important to determine what the patient perceives as his or her most important medical/health problem. The date of the last menstrual period and contraceptive use should be obtained from female patients.[19]

Some antituberculosis medications can reduce drug levels when a patient is taking birth control pills. Ensure that the patient receives education on other forms of contraception. Also check for other drug interactions. For more information, see the "Side Effects and Adverse Reactions" topic in Section 6 - Treatment of TB Disease.

Determine infectiousness or potential infectiousness. To determine the need for and scope of the contact investigation, the initial assessment should gather information to define the start and end dates of the period of infectiousness. This assessment should include the duration and frequency of symptoms, especially cough, and a review of the radiographic findings. If the patient is infectious or potentially infectious, the case manager should have an understanding of the period of infectiousness. The parameters of a contact investigation, including the need for repeating the tuberculin skin test for contacts that were initially negative, can then be determined.[20]

In the case of a child with TB who is younger than five years, the contact investigation should focus on determining the source case of TB. TB disease in children younger than 5 years typically indicates that the infection is recent. If the source case is identified, dates of exposure and most recent information concerning the infectiousness of the source should be documented.

For more information on the period of infectiousness and contact investigations, see the Section 10 - Contact Investigation.

Evaluate the patient's knowledge and beliefs about TB, including a history of TB in family and/or friends and the response to treatment. The case manager can assess TB knowledge by interviewing the patient regarding TB transmission, pathogenesis, and symptoms. Patient education should be based on current knowledge and ability to comprehend written, visual, and/or verbal information.[21]

It is important to interview both the child and parent or guardian in their own language when assessing TB knowledge; however, adolescents should be given the opportunity to speak to a healthcare provider alone. Keep in mind that parents who have misinformation or cultural bias about TB may affect their children's understanding of the disease.[22] Use age-appropriate educational materials and methods, especially when working with children. When working with a school-aged child, it is important to explain that TB is treatable, and with the adolescent, it may be necessary to constantly reaffirm confidentiality.[23]

Initiate treatment. Treatment with a four-drug regimen should be initiated promptly when a patient is seriously ill (history of cough, hemoptysis, night

sweats, fever, weight loss, chest pain, abnormal radiographs, sputum smear positive) with a disorder that is thought possibly to be tuberculosis. Initiation of treatment should not be delayed because of negative AFB smears for patients in whom TB is suspected and who have a life-threatening condition. Disseminated (miliary) TB, for example is often associated with negative sputum AFB smears. Likewise, for a patient with suspected TB and a high risk of transmitting *M. tb* if, in fact, she/he had the disease, 4-drug chemotherapy should be initiated in advance of microbiological confirmation of the diagnosis to minimize potential transmission.

Monitor the TB medication regimen. The case manager should ensure that medications and dosages are prescribed according to current ATS/IDSA/CDC guidelines. If the initial assessment occurs during the patient's hospitalization, the case manager should ensure that the ingestion of the TB medication is observed by a nurse. It is important to ensure that hospitals order and give the right doses and are observing patients taking medications. Since the outpatient phase of treatment will involve giving TB medications at one time, hospitals should be discouraged from splitting dosages for two reasons: (1) taking medications more than once a day creates an expectation for the patient that will have to change after discharge from the hospital, and (2) tolerance to the full dosage cannot be assessed while in the hospital. The patient's tolerance to TB medications should be noted, and interactions with other medications should be determined prior to the patient starting TB medications.[24] Upon discharge, the TB Case Manager should ensure that the LHD receives a copy of the prescriptions to order and administer treatment.

For more information on treatment regimens and dosages, see Section 6 - Treatment of TB Disease.

If the medications will be given to a child in a school or daycare setting, parental authorization must be obtained.

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

Review psychosocial status to identify unmet needs, the use of alcohol and/or illegal drugs, and any pre-existing psychiatric diagnoses.[25]

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

Gather information for a possible contact investigation.

For more information, see Section 10 - Contact Investigation.

Treatment Plan

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

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

Each patient's management plan should be individualized to incorporate measures that facilitate adherence to the drug regimen, such as social service support, treatment incentives and enablers, housing assistance, referral for treatment of substance abuse, and coordination of TB services with those of other providers.[26]

In the initial management strategy, regardless of the source of supervision, always include an adherence plan that emphasizes directly observed therapy (DOT), in which patients are observed as they ingest each dose of antituberculosis medications, to maximize the likelihood of completion of therapy.[27]

The case manager is responsible for the overall plan, including documentation, monitoring the patient response, interventions, intermediate and expected outcomes, and initiating changes in the plan to reflect changes in circumstances.[28] The treatment plan should be reviewed and updated at least monthly during reviews of clinical progress.[29]

Treatment Plan Components

The recommended components of a treatment plan include the following:

- Patient's verified address and contact information
- Assignment of responsibilities: case manager, clinical supervisor (nurse, physician, or physician assistant), DOT workers, other caregivers (outreach workers, nurses), and person managing the contact investigation
- Patient educator's name and dates of education sessions
- Method for prevention of transmission: no isolation, airborne infection isolation, home isolation, legal order for isolation
- Planned course of antituberculosis drug therapy

- Estimated date of completion of treatment
- Test results from initial medical evaluation
- Medical history
- Diagnosis
- Monitoring activities and schedule to assess response to therapy
- Baseline tests, monitoring activities, and schedule to detect potential side effects and adverse reactions
- Potential drug interactions
- Potential treatment adherence obstacles
- Personal service needs
- Referrals for social services
- Means of ensuring successful completion of treatment (DOT, incentives, enablers)
- Location(s) where DOT will be administered
- Approvals and signatures of the attending physician, local public health agency representative, and the patient
- Intermediate and expected outcomes[30]

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

Planning Activities

To complete planning, perform the following activities:

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

Establish the treatment plan, ensuring that all the components are included. The case manager should ensure that the treatment plan is useful and meaningful. It becomes the internal standard of care for the patient as well as the performance standard for the case manager. Good planning will allow the patient to experience TB care and treatment along the healthcare continuum and prevent duplication and fragmentation of services. The plan should be discussed and validated with all team members and the patient.[31] DOT is the medical standard of care for all TB cases and suspects in Indiana.

Establish time frames in the treatment plan to monitor the plan and patient response. Monitoring should be done at least monthly at the patient's home, ambulatory clinic, health department, or private physician's office. Each component of the plan should be reviewed to ensure that it is an accurate accounting of the patient's problems, required tests, and interventions. To track progress toward outcomes, document all treatment activities and their dates: medications taken, tests and results, patient visits, monitoring activities, side effects, adverse reactions, education sessions, social service referrals, incentives, enablers, isolation status changes, and patient problems.[32]

Negotiate and adjust the treatment plan as needed, to meet new realities. Since patient circumstances are usually fluid and personnel resources often change over time, it is essential that the plan be negotiated with the patient and changed to adjust to new situations. The adjusted plan should be discussed with the team members, as well as the patient.[33]

Implementation Activities

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

- Refer the patient to other healthcare providers, social service agencies, or community organizations as needed.
- Broker and locate needed services relating to TB treatment.
- Negotiate a plan for DOT.
- Coordinate strategies to improve adherence.

Refer the patient to other healthcare providers, social service agencies, or community organizations, as needed. The referral process requires the case manager to locate and coordinate accessible, available, and affordable resources for the patient. After the referral is made, the case manager should monitor the patient's adherence to the referral and obtain the consultation or follow-up report in writing. Immediate intervention may be necessary if the patient or the referring agency experiences difficulty.[34] All patients with suspected or proven TB should be offered counseling and voluntary testing for HIV, with referral for HIV treatment services when necessary. Referrals to medical specialists for conditions that would endanger the patient and/or affect the outcome of treatment should be made as soon as possible. The patient should be sent to an emergency department if the condition is serious when assessed by the case manager. The case manager should follow up a referral to obtain medical information and determine whether the necessary medical intervention has been completed.

Locate needed services relating to the TB treatment. This may include laboratory, auditory, or visual acuity testing; additional radiographs; or other tests required specifically for the patient such as HIV testing. It is important to schedule or assist the patient in scheduling appointments and to monitor the patient's adherence. An understanding of the patient's financial resources and health insurance coverage is important. Lack of financial resources or health insurance will affect the patient's

willingness to keep appointments, which may be critical to his or her health. The case manager may need to discuss essential services with insurance companies or other healthcare providers to obtain the most cost-effective, quality service.[35] Assistance should be provided to reinforce a patient's efforts to receive financial assistance and treatment for psychosocial, alcohol-related, and drug-related conditions.

Negotiate a plan for DOT. DOT is the medical standard of care for all patients. The case manager should ensure the plan is suitable for the patient's needs and achievable by the healthcare provider(s) and then have the patient sign a DOT agreement. Due to the length of TB treatment, the patient's circumstances may change. The case manager needs to verify that the time and place for DOT administration originally agreed upon is still agreeable to the patient and provider. It also may be necessary to coordinate the arrangements for DOT with outside organizations, such as school nurses or drug treatment center nurses.[36]

Refer to the "Directly Observed Therapy" topic in this section.

Coordinate strategies to improve adherence. The case manager must have knowledge of and proficiency in strategies to improve patient adherence, understand the importance of developing and maintaining a therapeutic relationship, and be familiar with the principles and practices of behavioral contracting and behavioral modification. Collaboration with team members is essential to obtain as much information as possible about strategies to improve adherence of individual patients and elicit opinions, attitudes, and feelings expressed by the patient. Incentives and enablers should be considered for use with all patients. Depending upon the obstacles to completion of therapy, the treatment plan also may include incentives and enablers, and, to be effective, incentives and enablers should be meaningful and specific for a particular patient.[37]

For more information on incentives and enablers, see the "Treatment of Tuberculosis" topic, Table 8, and the "Incentives and Enablers" topic in this section.

Ongoing Assessment and Monitoring

Conduct ongoing assessments and monitor patients at least monthly, either in an ambulatory clinic setting, local public health agency, or private physician's office. Schedule additional assessments throughout the month for patients experiencing problems in their tuberculosis (TB) treatment, or for those patients who are nonadherent to directly observed therapy (DOT) or follow-up appointments.[38]

There are countless stories from nurses and outreach workers reinforcing the fact that not all information is obtained from the patient or family at one time. Therefore, the case manager must ensure that the list of contacts is updated from time to time and determine the need for further testing. It is also important to review the status of the contact investigation to ensure that timelines and standards are followed. Also, checking for the accuracy of previously gathered information should occur throughout the patient's TB treatment.[39]

Ongoing Assessment Activities

To complete an ongoing assessment, perform the following activities:

- Monitor the clinical response to treatment.
- Determine HIV status and the risk factors for HIV disease, and refer the patient for treatment, if indicated.
- Review the treatment regimen.
- Ensure that medications are ordered and given at the correct time, and in the correct dosage.
- Monitor the side effects of and adverse reactions to medication.
- Assess adherence daily and monthly, and identify positive and negative motivational factors influencing adherence.
- Determine the unmet educational needs of the patient.
- Educate the patient about the TB disease process.
- Advocate for the patient with team members and other service providers.
- Review the status of the contact investigation, if one was started.

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

and CXR report to ensure accuracy. Also, conduct this review at culture conversion as evidence for the improving condition of the patient.[40]

Inconsistencies should trigger additional questions, such as the possibility of laboratory contamination. Bring these questions immediately to the attention of the physician and ISDH TB/Refugee Health Division at 317.233.7434.[41]

A child's clinical response to treatment may not be as significant as that of an adult. Therefore, it is important to reinforce what the expected response to treatment should be for the individual child during the course of treatment and to weigh the child monthly to assess clinical improvement and possible dosage changes. [42]

Determine HIV status and the risk factors for HIV disease, and refer the patient for treatment, if indicated. It is important for patients to understand the correlation between TB and HIV disease. The case manager should ensure that HIV counseling and testing are done at the beginning of TB treatment, if has been more than 12 months since the last test and the patient was negative at that time or the HIV status is not previously known. If the patient refuses HIV testing, an assessment of the risk factors for HIV should be completed.[43] If a patient refuses, voluntary HIV testing and counseling should continue to be offered periodically throughout treatment.

If the parents of a young child with TB refuse to permit the child to be HIV tested, the parents should be interviewed regarding the child's risk of HIV disease, including neonatal transmission.[44]

Review the treatment regimen to verify that the physician's orders are clear and concise. One of the case manager's primary responsibilities is to ensure that the patient completes treatment according to the physician's orders. It is also important to ensure that the plan is specific for the individual patient and follows the principles of TB treatment.[45]

Ensure that medications are ordered and given in the correct dosage.

Monitor the side effects of and adverse reactions to medication. Review laboratory findings and contact the treating physician if abnormal results are obtained.[46] The patient should be monitored by a registered nurse and/or clinician or case manager monthly for signs and symptoms of adverse reactions until treatment is completed. If a patient is symptomatic, the provider should be consulted and the patient monitored more frequently. Chemistries and complete blood count (CBC), aspartate aminotransferase (AST)/alanine aminotransferase (ALT), or other tests based on specific drugs should be done periodically per physician's order. See Table 8**: Monitoring and Interventions for Side Effects and Adverse Reactions** in Section 5 - Treatment of TB Disease.

If a child is taking TB medications at school, communicate at a minimum on a monthly basis with designated staff to determine whether the child is experiencing medication side effects or adverse reactions.[47]

Assess adherence daily and monthly, and identify positive and negative motivational factors influencing adherence. An assessment of adherence needs to occur at each patient encounter. Direct observation provides immediate information on poor adherence and adverse effects. The key to a successful DOT program is the timely use of this information in order to promptly identify and respond to potential barriers to adherence, missed doses, and potential adverse treatment effects. If the case manager is not involved in providing DOT, a notification system should alert him or her if the patient misses a DOT dose. A preventable interruption in treatment can be avoided if the case manager is notified immediately, rather than when the monthly DOT rate is calculated. If a DOT dose is missed, the patient should be contacted the same day or the next business day and the issue escalated to the case manager's supervisor. It is important not to send a mixed message to a patient by not promptly responding to missed DOT doses.

Policies and procedures must be in place to establish the expected monthly rate of DOT adherence. The case manager should review the monthly adherence rate to ensure that patients achieve the expected adherence rate. The case manager should ensure that the patient is informed about the consequences of nonadherence, including legal interventions. Changes in the patient's attitude toward the healthcare worker should be noted and verified with the patient.[48]

For more information, see the "Directly Observed Therapy" and "Legal Orders" topics in this section.

Determine the unmet educational needs of the patient regarding transmission, diagnosis, and treatment of TB. Identify the concerns and anxieties regarding diagnosis, and need for further education. The educational needs of the patient/family may vary throughout the course of treatment. Patient education also will vary depending on beliefs about TB treatment, acceptance of the diagnosis, coping mechanisms, cultural values, and the accuracy of the information they have already received. The case manager should explore the effect the diagnosis has on the patient's relationships with other family members, coworkers, and social contacts so that appropriate, culturally sensitive information can be provided.[49]

Educate the patient about the TB disease process during the course of TB treatment. Provide instruction relevant for the patient's level of education or ability to learn, and address healthcare beliefs that are in conflict with educational information. The case manager should ensure that education is provided in the patient's primary language and that it is culturally appropriate.[50] The case manager should provide patient and family

education monthly and until satisfactory recall is obtained.

For more information, see Section 12 - Patient Education.

Advocate for the patient with team members and other service providers when necessary. The case manager should demonstrate respect and understanding of the patient's cultural beliefs and values and should prevent team members from imposing their own values or belief systems on the patient. The case manager should be able to communicate the patient's fears/anxieties, likes/dislikes, and needs/wants to the team members in a nonjudgmental manner. The case manager must also have an understanding of the team members, and mediate, negotiate, and resolve differences of opinion regarding the patient and interventions.[51]

Review the status of the contact investigation, if one was initiated. It has been found that patients may not initially reveal the names of all close contacts. Over time, many more individuals are often identified.[52] The investigation should be repeated if for any reason the index patient becomes AFB sputum smear positive again during treatment and there has been sufficient exposure for the skin-test-negative persons to become infected.

Monitoring Side Effects and Adverse Reactions

Assess and document side effects and adverse reactions to antituberculosis medications and monitor toxicity. The patient should be monitored by a registered nurse and/or clinician or case manager at least monthly for signs and symptoms of adverse reactions until treatment is completed. If a patient is symptomatic, the provider should be consulted and the patient monitored more frequently. Chemistries and CBC, AST/ALT, or other tests based on specific drugs should be done periodically. See Table 8**: Monitoring and Interventions for Side Effects and Adverse Reactions** in Section 6 - Treatment of TB Disease.

As is true with all medications, combination chemotherapy for TB is associated with a predictable incidence of adverse effects, some mild, some serious.[53]

Adverse effects are fairly common and often manageable. Although it is important to be attuned to the potential for adverse effects, it is at least equally important that first-line drugs not be stopped without adequate justification.[54] However, adverse reactions can be severe, and, thus, it is important to recognize adverse reactions that indicate when a drug should not be used. Mild adverse effects can generally be managed with symptomatic therapy; whereas, with more severe effects, the offending drug or drugs must be discontinued. In addition, proper management of more serious adverse reactions often requires expert consultation. [55]

Instruct patients to report the side effects and adverse reactions listed in the "Side Effects and Adverse Reactions" topic in Section 6 - Treatment of TB Disease.

To record information from monitoring for side effects and adverse reactions, use the **Monthly Tuberculosis Follow-up Report** (see Section 2 – Surveillance).

Activities to Monitor for Side Effects and Adverse Reactions

To monitor for side effects and adverse reactions, perform the following activities:

- Educate the patient and family to report side effects and adverse reactions immediately
- Assess the patient for side effects and adverse reactions

Educate the patient and family to report side effects and adverse reactions. The case manager reinforces prior patient teaching and continues to educate the patient and family about TB medications, signs and symptoms of adverse effects, and the importance of continued treatment and uninterrupted drug therapy. Case managers should be familiar with all TB medications, their side effects, contraindications, and drug interactions.[56]

For more information, see Section 12 - Patient Education.

Assess the patient for adverse reactions and side effects. For patients on DOT, staff should assess patients for side effects and adverse reactions on each visit by performing a symptom review. If indicated, order liver function tests and monitor their results. The case manager should be aware of complications in patients on medications by maintaining close communication with outreach staff .[57]

Monitoring Bacteriologic Improvement

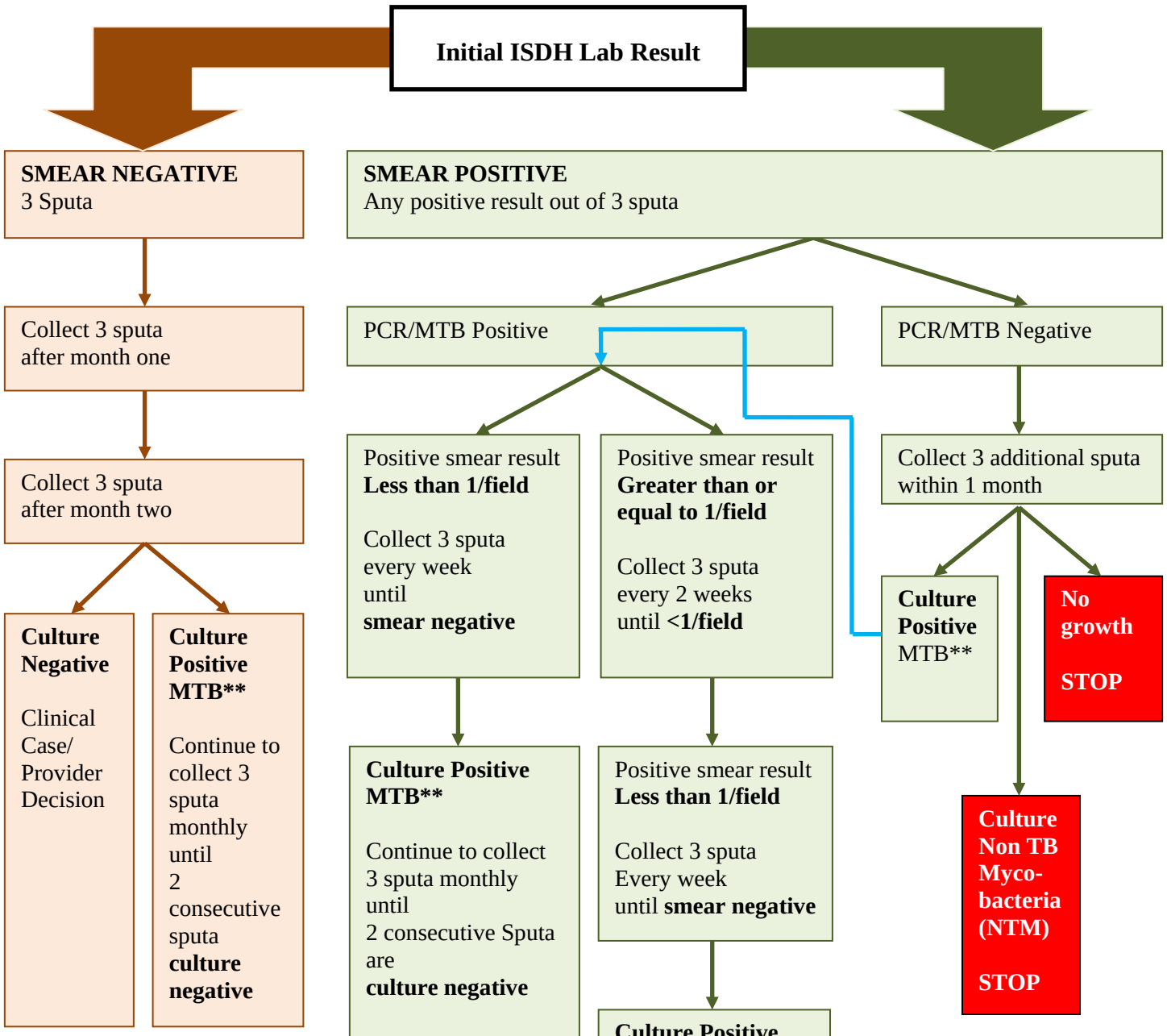
Assess and document response to treatment. The case manager should collect sputa for AFB sputum smear and culture until sputum smear conversion. Thereafter, sputa should be collected until there are two negative cultures. If a patient is on DOT, no further specimen collected is indicated unless the patient becomes symptomatic. [58]

Refer to ISDH Laboratory Services for algorithm on timing of sputa collection until conversion, next page.

To record information from monitoring for bacteriologic and clinical improvement, use **Monthly Tuberculosis Follow-up Report** (see Section 2 – Surveillance).

For information on discontinuing isolation, see Section 16 - Infection Control.

TUBERCULOSIS SPUTUM COLLECTION*



*If you need to submit specimens outside of these parameters, please contact the ISDH TB/Refugee Division at 317.233.7434 or your TB Regional Nurse Consultant (contact information in Section 1 – Introduction).
**TB sputum collection algorithm does not apply to Non Tuberculous Mycobacteria (NTM)

Effective Date 11/16/2009

Continued Positive Sputum Smears or Positive Cultures

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

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

1. Review and confirm the patient's medication compliance.
2. Place the patient on DOT, if not already on DOT.
    a. Reconfirm the appropriateness of the medication regimen, based on drug susceptibility results and other considerations. Consultation with a provider experienced in TB relapse and/or failing regimens is highly recommended.
3. If additional antituberculosis drugs are added to the treatment regimen, ensure that at least two new drugs that the patient has not been treated with previously are used. **Note: Never add a single drug to a failing regimen.**
4. Consider serum drug levels.
5. Repeat cultures and repeat drug susceptibility testing.[59]

Culture Negative or No Specimens

If a patient is culture negative or no specimens were collected:

1. Review other medications that the patient was on at the time TB medications were started, particularly other antibiotics.
2. If applicable, obtain follow-up CXR reports to determine status (i.e., improvement, stable, worsening).
3. Review the patient's symptoms for improvement, if applicable.
4. Review the patient's TST or IGRA information (retesting may be appropriate if initially negative or test if not initially done) and discuss this with the patient's provider.
5. Review information with the provider regarding his or her reasons for continuing TB medications.
6. Discuss the above findings with the ISDH Regional TB Nurse Consultant (see Section 1 – Introduction for contact information) to determine if the patient is to be reported as a case.

Verification of Isolate Drug Susceptibility Results

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

1. If a patient's TB organism is pan-susceptible: Follow the recommended treatment regimen (RIPE)
2. If a patient's TB organism is drug resistant:
   a. Notify the provider for adjustment of medications.
   b. Confirm the appropriateness of regimen.
   c. If the regimen is inappropriate, immediately notify the physician.
   d. Initiate DOT.
3. If isoniazid-resistant or multidrug-resistant TB (MDR-TB):
   a. Place contacts on appropriate LTBI treatment regimens. Treatment of LTBI caused by drug-resistant organisms should be provided by, or in close consultation with, an expert in the management of these difficult situations. For patients with MDR-TB, refer to the instructions on multidrug-resistant tuberculosis provided below.
   b. For patients with MDR-TB, refer to the instructions on multidrug-resistant tuberculosis provided below.

Multidrug-Resistant Tuberculosis

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

1. Notify his or her supervisor, the patient's provider and Regional TB Nurse Consultant the same day that MDR-TB findings are reported/known.
2. Confirm initiation of an appropriate regimen. If the provider is unwilling to institute an appropriate regimen, notify the local health officer and the Regional TB Nurse Consultant on the same day so they can intervene with the provider.
3. For consultation regarding the treatment of drug-resistant TB, contact the ISDH TB/Refugee Health Division at 317.233.7434.
4. Initiate transfer of patient care to a more appropriate provider, if necessary. The case manager, with TB clinician, should confer with the provider and arrange transfer of the case to a provider with experience/expertise in the management of MDR-TB. The case manager must document transfer of care and ongoing follow-up.
5. Obtain appropriate medications from suppliers.
6. Continue DOT and maintain accurate DOT records. If the patient is nonadherent with DOT, the case manager must document attempts to correct the situation and notify his or her supervisor and Regional TB Nurse Consultant.

7. Provide the following for patients with MDR-TB:
   a. Patient education, including information regarding second-line TB drugs
   b. DOT at the patient's convenience
   c. Incentives and enablers
   d. Legal orders

Clinical Response to Treatment

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

1. Lessening or resolution of TB symptoms
2. Weight gain
3. Progressive improvement in the CXR (if pulmonary TB disease is diagnosed and repeat radiographs are ordered)

Isolation

If a patient is isolated, ensure and document the patient's adherence to respiratory isolation. [60]

For more information on isolation and quarantine, refer to Section 16 - Infection Control.

Closing a Case

If the patient is not to be reported as a case, notify the provider that the patient is closed to TB control program services. The patient will be closed in the SWIMSS database.

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

Completion of Therapy

The case manager should verify completion of therapy. Completion of therapy is essential to ensure that the patient is cured. It is also a goal of Indiana and the CDC and an important measurement of the effectiveness of TB control efforts. Verification of completion of therapy and a completed contact investigation are the responsibility of the case manager.

To record verification and closure information, use the **Monthly Tuberculosis Follow-up Report** (see Section 2 – Surveillance).

Verifying Adequate Course of Treatment

Most cases of active TB can be successfully treated using the standard short course (6 months) of therapy. The case manager is responsible for considering the following conditions to ensure that the patient has received an adequate course of therapy.

- **Culture remains positive beyond two months of treatment:** Reasons for persistent positive cultures should be examined and treatment adjusted/prolonged.
- **For TB involving the bones or joints or tuberculous meningitis:** These are exceptions to the standard 6-month course. See “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in Section 6 - Treatment of TB Disease.
- **HIV-negative, culture-negative patients:** See “Duration of Treatment” in the “Treatment Regimens and Dosages” topic in Section 6 - Treatment of TB Disease.
- **Relapse of TB following treatment for TB with pan-susceptible organisms:** Treatment may be prolonged to 9 months or more. (Current drug susceptibility testing must be performed and the regimen adjusted if resistance has developed.)[61]

Calculating Completion of Therapy

So that doses missed due to nonadherence or other treatment interruptions are still given after treatment is resumed, base the completion of treatment on the number of doses of directly observed therapy (DOT) received rather than on the chronological passage of time (e.g., six months).[62]

For the total number of doses recommended for completion of regimens using first-line drugs, refer to the "Treatment Regimens and Dosages" topic in Section 6 - Treatment of TB Disease.

Closures Other than Completion of Therapy

- **Moved:** All attempts should be made by the case manager to obtain the new or forwarding address. If this new address is within the original jurisdiction, the case should be transferred, as per the local public health agency protocol. If the new address is in another jurisdiction, the Indiana TB Program and the new jurisdiction should be notified and procedures followed as described in the Transfer Notifications section. Cases should be closed as "moved" only if a new address is obtained.

For information on whom to alert when a case will move or has moved, refer to the Transfer Notifications section.

- **Not TB:** If the completed diagnostic evaluation determined that the diagnosis of TB is not substantiated and another diagnosis is established, the case is closed as "Not TB."
- **Lost:** If all attempts to locate the patient fail, the case should be closed as "Lost."
- **Died:** If the patient expired prior to completion of therapy, the case is closed as "Died."[63]

Ensure that the contact investigation on the case is also completed. For more information, see Section 10 - Contact Investigation.

Evaluation

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

Evaluation activities answer the following questions:

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

  Were the case manager and the team members satisfied with the plan and outcomes?

For evaluation activities, refer to CDC, Program Evaluation, http://www.cdc.gov/tb/programs/Evaluation/Default.htm

Evaluation Activities

To evaluate case management, perform the following activities:

- Monitor the multidisciplinary care plan at least twice per year.
- Identify strengths or weaknesses in the healthcare system.
- Conduct a cohort analysis at least every quarter.
- Monitor reports.

Monitor the treatment plan at least monthly or more frequently depending on the complexity of treatment and patient variables. Review the appropriateness of interventions, as well as dates when intermediate and/or expected outcomes were achieved. Pay attention to how rapidly the treatment plan was changed when the need was identified. If the treatment plan has remained unchanged, determine the reason why.[64]

Identify strengths or weaknesses in the healthcare system that negatively or positively affect the expected outcome. A good evaluation will lead to positive changes for the patient and others.

Conduct a cohort analysis at least every 3 months to identify variances or common elements among the group. Cohort review is a "systematic review of the management of TB patients with TB disease and their contacts."[65] With the information learned from the evaluation, the case manager can make changes to improve patient care outcomes.[66]

Monitor reports to ensure that the TB case reports are accurate and updated according to state standards and that the contact investigation is complete.[67]

Directly Observed Therapy

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

DOT is a component of case management that helps to ensure that patients receive effective treatment and adhere to it. The ATS, the CDC, and the state of Indiana recommend that every TB patient be considered for DOT.[68] DOT is implemented for the following reasons:

- DOT is the most effective strategy for making sure that patients take their medicines.
- DOT can lead to reductions in relapse and acquired drug resistance.[69]
- Directly observing each dose provides immediate information on poor adherence and adverse effects, information that cannot readily be obtained from patients treated with SAT.

Candidates for DOT

In Indiana and many other public health agencies, DOT *is* the standard of care. That is, it is the goal to place all patients on DOT regardless of the patient's circumstances because it has been shown to be such an important treatment tool.[70] Consider DOT for all patients with TB disease, and *ensure* that medications are delivered by DOT for the following patients:

- Patients on intermittent regimens (because of the potentially serious consequences of missed doses)
- Pediatric patients with TB disease
- Patients with MDR-TB
- Persons with HIV coinfection and on treatment for LTBI
- Immunocompromised persons on treatment for LTBI
- Pediatric contacts on treatment for LTBI
- Household contacts on treatment for LTBI
- Patients with relapse or previous nonadherence to therapy
- Patients with psychiatric illness or memory impairment

How to Deliver DOT

Who Can Deliver DOT?

- Usually TB clinic personnel, such as a nurse or other healthcare worker trained by the LHD
- Staff at other healthcare settings, such as outpatient treatment centers
- Other responsible persons, such as school personnel, employers, others trained by the LHD
- *Not* family members[71]

Principles of DOT

- The healthcare worker should watch the patient swallow each dose of medication.
- Use DOT with other measures to promote adherence.
- DOT can be given anywhere the patient and healthcare worker agree upon, provided the time and location are convenient and safe.[72,73]

DOT Tasks

1. Deliver medication.

2. Check for side effects and adverse reactions.

For more information, see the "Ongoing Assessment and Monitoring" topic in this section and the "Side Effects and Adverse Reactions" topic in Section 6 - Treatment of TB Disease.

3. Verify medication.

4. Watch the patient take pills.

Healthcare workers should watch for tricks or techniques some patients may use to avoid swallowing medication, such as hiding pills in the mouth and spitting them out later, hiding medicine in clothing, or vomiting the pills after leaving the clinic.

If it is necessary to make sure that the patient swallows the pills, the healthcare worker may have to check the patient's mouth, or ask the patient to wait for a half hour before leaving the clinic so the medication can dissolve in the patient's stomach.[74]

5. Document the visit.

A sample DOT Log, **TB Directly Observed Therapy Log**, is available from the Florida Department of Health at:

http://www.doh.state.fl.us/disease%5Fctrl/tb/TBForms/DOHpdfforms/TBFormslist.htm

6. As necessary and appropriate, do the following:
   - **a.** Provide patient education.
   - **b.** Help the patient keep appointments.
   - **c.** Connect the patient with social services and transportation.
   - **d.** Draw upon familiarity with the patient's home environment to identify household contacts.
   - **e.** Offer incentives and/or enablers to encourage adherence.[75]

For more information and sample DOT, refer to Section 12 - Patient Education and the "Incentives and Enablers" topic in this section.

For a hyperlink for a sample DOT agreement see page 12.4.

Adherence to DOT

Patient Education

The case manager should ensure that education is provided in the patient's primary language and is culturally appropriate.[76]

For more information, see Section 12 - Patient Education. For points to use to explain to the patient why DOT is important, refer to the CDC's *Questions and Answers About TB 2005. Active TB Disease: What is directly observed therapy?* (Division of Tuberculosis Elimination Web site; 2005) at this hyperlink: http://www.cdc.gov/tb/faqs/qa_TBDisease.htm .

Children with Tuberculosis

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

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

Agreements

It may be useful to develop a letter of agreement or acknowledgment (see Section 12 – Patient Education, page 9.34 for sample DOT agreement) between the patient and the DOT worker. Some jurisdictions have successfully used these as a method of ensuring adherence to therapy. The DOT worker and the patient negotiate dates, places, and times for DOT services to be provided, and both sign a document stating such agreements. Included in the agreement could be language specifying what consequences may result in the event that the client violates the terms of the contract.[77]

Incentives and Enablers

Incentives and enablers may be appropriate to help patients adhere to DOT. (See page 9.37).

Missed Directly Observed Therapy Dose

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

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

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

Incentives and Enablers

Use incentives and enablers to enhance adherence to therapy.[78] Incentives and enablers are used to improve patient attitudes and to foster good health behaviors.[79] They help patients stay with and complete treatment.[80]

Incentives are small rewards given to patients to encourage them to either take their own medicines or keep their clinic or field directly observed therapy (DOT) appointments. [81] **Enablers** are those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties.

Some examples of incentives and enablers are listed in Table 1.

INDIANA

The LDH should determine the most appropriate incentive and/or enabler on a case-by-case basis.

If financial assistance is required to supply an incentive and/or enabler consult your ISDH Regional TB Nurse Consultant – contact information in Section 1 – Introduction.

Table 1: INCENTIVES AND ENABLERS

Incentives	Enablers

▪ Food and beverages
▪ Food vouchers
▪ Clothing
▪ Clothing vouchers
▪ Automotive supplies
▪ Hobby/craft items
▪ Household items
▪ Laundry services
▪ Seasonal/holiday treats
▪ Movie passes
▪ Restaurant/fast food vouchers
▪ Toys
▪ Personal care items
▪ Pet food
	▪ Transportation
	  • Bus pass
	  • Bus route maps
	  • Cab fare
	  • Battery for patient's car
	  • Gas vouchers
	  • Fee for driver's license
	▪ Childcare
	▪ Obtaining and transporting specimens for the patient
	▪ Assisting the client to get medication refills
	▪ Rent assistance
	▪ Assisting the client to complete paperwork to get food/housing assistance
	▪ Assisting the client to get substance treatment

Legal Orders

Understand when and how to use legal orders, if necessary, for adherence to therapy. Nonadherent adults with pulmonary TB pose the greatest threat to the health of a community. It is the local public health agency's responsibility to ensure that compliance is maintained, treatment is completed, and the risk of transmission to others is eliminated. These responsibilities require that TB staff members be innovative and always "go the extra mile" to see that patients take their medicine as prescribed. The public health mandate and good judgment dictate that program staff should go to every extent possible to fulfill the job responsibilities outlined above before resorting to legal action.[82]

INDIANA

See Section 13 – Confidentiality and Legal Aspects of Patient Management for:

- General guidelines
- Documenting non-compliant or recalcitrant behavior,
- Local health agreement,
- Local health officer's order,
- Health directive
- Filing a petition for restrictions
- Imposition of restriction
- Emergency detention
- Examples of legal documents

Indiana laws and rules on TB, refer to Section 1 – Introduction.

Criteria for starting isolation and discontinuing isolation refer to Section 16 - Infection Control.

Progressive Interventions

Have an intervention plan that goes step-by-step from voluntary participation to involuntary confinement as a last resort. Refer to Figure 1: **Progressive Interventions for Nonadherent Patients**. Progressive intervention should begin with learning the possible reasons for nonadherence and addressing the identified problems using methods such as directly observed therapy (DOT), 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.[83] If indicated, an interpreter should be provided during this process.

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.[84]

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

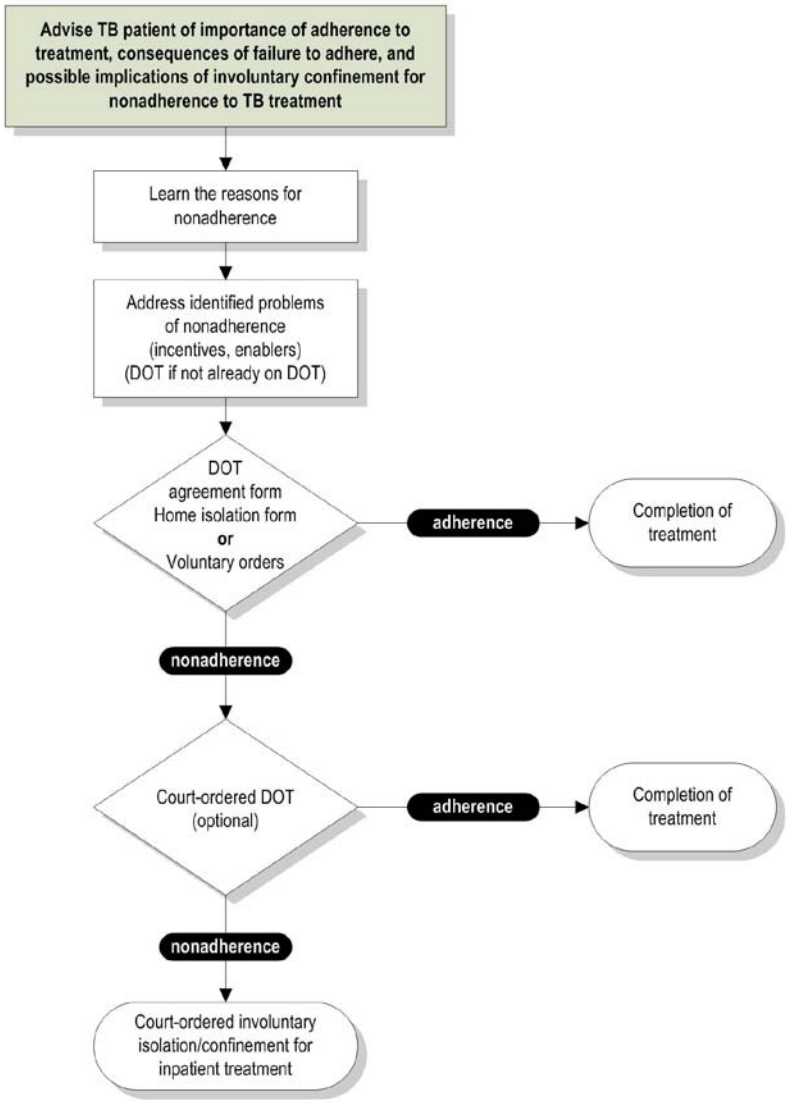
A sample DOT agreement can be viewed at New York City Department of Health and Mental Hygiene Tuberculosis Clinical Policies and Protocols, 4th Edition page 240, http://home2.nyc.gov/html/doh/downloads/pdf/tb/tb-protocol.pdf.

A sample Home Isolation Agreement can be viewed at New York City Department of Health and Mental Hygiene Tuberculosis Clinical Policies and Protocols, 4th Edition page 246, http://home2.nyc.gov/html/doh/downloads/pdf/tb/tb-protocol.pdf.

If the patient does not adhere to DOT voluntarily, the next step may be court-ordered DOT. An optional step toward other legal orders, court-ordered DOT can be successful in convincing a patient that his or her TB treatment is an important public health priority. Involuntary confinement or isolation for inpatient treatment should be viewed as the step of last resort, to be used only when all other options fail. However, when a patient with infectious TB refuses treatment and voluntary isolation, emergency detention to isolate the person is appropriate.[85] For more information see Section 13 – Confidentiality and Legal Aspects of Patient Management.

Under normal circumstances, patients with extrapulmonary TB do not transmit the disease to others, and, therefore, these persons usually cannot be legally ordered to take their medications. However, their personal health is endangered if they choose not to be treated. They should be educated regarding the possibility of their disease spreading to the lungs and becoming infectious to others.

Figure 1: PROGRESSIVE INTERVENTIONS FOR NONADHERENT PATIENTS[86]



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

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

Resources and References

General Case Management Resources

- CDC. Module 4: "Treatment of Tuberculosis Infection and Disease" (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules1-5/m4/4-toc.htm .
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- New Jersey Medical School National Tuberculosis Center. *Tuberculosis Case Management for Nurses: Self-Study Modules* (New Jersey Medical School Global Tuberculosis Institute Web site). Available at: http://www.umdnj.edu/globaltb/products/tbcasemgmtmodules.htm .

Directly Observed Therapy Resources

- CDC. Chapter 7: "Treatment of TB Disease" (*Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]; Updated November 2001). Available at: http://www.cdc.gov/tb/pubs/corecurr/Chapter7/Tableofcontents.htm .
- CDC. Module 9: "Patient Adherence to Tuberculosis Treatment" (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/m9/9-toc.htm .
- Francis J. Curry National Tuberculosis Center. *Directly Observed Therapy (DOT) Training Curriculum for TB Control Programs* (Francis J. Curry National Tuberculosis Center Web site; 2003). Available at: http://www.nationaltbcenter.ucsf.edu/catalogue/epub/index.cfm?uniqueID=1&tableName=DOTE .

Incentives and Enablers Resources

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- CDC. Module 9: "Patient Adherence to Tuberculosis Treatment" (*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/m9/9-toc.htm .

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- CDC. Module 9: "Patient Adherence to Tuberculosis Treatment "(*Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/m9/9-toc.htm .
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[2] CDC. Module 9: patient adherence to tuberculosis treatment. *Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]. 1999:3. Available at: http://www.cdc.gov/tb/pubs/ssmodules/default.htm . Accessed July 3, 2006.

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[6] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):1.

[7] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):1–2.

[8] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):1–2.

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Contact Investigation

CONTENTS

Introduction

Purpose

A contact investigation is the process of identifying, examining, evaluating, and treating all persons who are at risk for infection with *M. tb* due to recent exposure to a newly diagnosed or suspected case of pulmonary, laryngeal, or pleural TB.

The primary goal of a contact investigation is to do the following:

- Identify persons who were exposed to an infectious case of TB.
- Ensure that contacts receive these evaluation services:
  - Testing for *M. tb* infection
  - Screening for TB disease
  - Medical evaluation, if indicated
  - Prompt initiation of treatment for LTBI if at high risk for developing TB disease (younger than five years of age or immunocompromised)
  - A complete, standard course of treatment, unless medically contraindicated[1]

Secondary goals of a contact investigation:

- Stop transmission of *M. tb* by identifying persons with previously undetected infectious TB.
- Determine whether a TB outbreak has occurred (in which case, an expanded outbreak investigation should ensue).[2]

Use this section to understand and follow national and Indiana guidelines to address the following:

- Decide when to initiate a contact investigation.
- Understand the time frames for key contact investigation activities.
- Estimate the infectious period.
- Conduct index patient interviews.
- Assign priorities to contacts.
- Complete contact evaluation, treatment, and follow-up.
- Determine when to expand a contact investigation.
- Manage data and evaluate contact investigations.
- Conduct an outbreak investigation.

Except in rare cases, every case of TB begins as a contact to a person with active pulmonary, laryngeal, or pleural TB disease. For this reason, the CDC has identified

contact investigations (i.e., seeking and evaluating contacts) as a fundamental strategy for the prevention and control of TB. To control and prevent TB, our healthcare resources and efforts in Indiana should be directed to meeting the priorities outlined in the 2005 "Controlling Tuberculosis in the United States: Recommendations from ATS, CDC, and the IDSA. One of the recommended strategies for achieving the goal of reduction of TB morbidity and mortality is prompt identification of contacts to patients with infectious TB and timely treatment of those at risk with an effective drug regimen.[3] National recommendations for contact investigations are provided in the CDC's "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the NTCA and CDC, and Guidelines for Using the QFT®-TB Gold Test for Detecting *M. tb* Infection, U.S." (*MMWR* 2005;54[No. RR-15]:1–49).

One of the major challenges to successful control of TB is in protecting contacts of persons with infectious TB and in preventing and responding to TB outbreaks.[4] Reducing the risk of TB among contacts through the development of better methods of identification, evaluation, and management would lead to substantial personal and public health benefits and facilitate progress toward eliminating TB in the U.S.[5]

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 TB 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.[6] A study showed that improvements in contact investigations might have prevented 17 (10%) of 165 pediatric TB cases in California in 1994.[7]

Policy

A contact investigation is recommended for the following forms of suspected or confirmed TB because they are likely to be infectious:

- Pulmonary, laryngeal, or pleuropulmonary disease with either pulmonary cavities, or respiratory specimens that have acid-fast bacilli (AFB) on microscopy, or (especially) both.[8]
- Persons with AFB sputum smear negative results are less likely to be infectious but are still capable of infecting others.

Refer to the CDC, Guidelines for the Investigation of Contacts of Persons with Infectious TB Cases" (*MMWR* 2005;54[No. RR-15]: 31) at this hyperlink: http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf .

State Laws and Regulations

Refer to Section 1 – Introduction for Indiana state laws that mandate TB Disease Treatment policy and/or procedures.

INDIANA

The TB Case Manager is responsible for assuring that a contact investigation is conducted and that all contacts are appropriately evaluated and treated within recommended timeframes.

The TB Case Manager must interview the patient in person to identify contacts (**within 3 working days for smear positive cases or within 7 working days for smear negative cases**). The TB Case Manager must determine that the named persons meet the definition of a TB contact (a person who shares airspace with the index case). The TB Case Manager must have first hand information on the contacts.

The TB Case Manager should assign priorities to contacts (high, medium and low – according to CDC guidelines) and should facilitate the following:

- Screening of high-risk contacts, especially children and contacts know to be immunosuppressed, within **7 working days** after the initial interview with index case.
- Screening of lower risk contacts **within 21 working days** after the initial interview with the index case.
- Screening should include a TST or IGRA and a symptom review.
- Screening of medium and high-risk contacts under the age of 5 should include a physical exam and CXR (in addition to TST and symptom review).

To complete the investigation, the TB Case Manager must assure that all symptomatic contacts or contacts with a TST $\geq$ 5 mm or positive IGRA are evaluated with a CXR, medical history and physical exam. Contacts with abnormal CXRs should also be evaluated with 3 sputum smears and cultures for AFB (by direct observation and coaching). If sputum cannot be obtained, the TB Case Manager should document this finding. Information on any exams, CXRs, and additional follow-up completed by other providers should be reviewed by the TB Case Manager to assure that appropriate contact investigation has been completed. The time frame for full evaluation of contacts should depend on the circumstances, including: degree of exposure, presence of symptoms and degree of immunosuppression. Evaluation should be completed **within 2 weeks** of the initial screen.

Positive TST ($\geq$ 5mm) or IGRA contacts who have no evidence for TB disease after CXR and full medical evaluation should be offered preventive therapy (see Section 6 – Treatment of LTBI).

TST or IGRA negative high risk contacts younger than 5 years old or contacts known to be immunosuppressed should be offered INH prophylaxis until a second TST or IGRA is negative. The second test should be performed 10-12 weeks after the contact was last exposed to TB.

Contacts with a previously documented positive TST or IGRA must be screened for TB symptoms and a CXR performed: 1) if negative, INH preventive therapy should be recommended for immunocompromised individuals. 2) if normal, with no medical risk factors, assess the patient for INH. Consultation with the Local Health Officer may be helpful in determining whether to treat with INH. Household contacts receiving prophylactic therapy are easily placed on DOPT (directly observed preventive therapy) when the index case is receiving DOT. High priority contacts for DOPT include: household contacts $\leq$ 15 years of age, individuals $\geq$ 65 year of age, or persons known to be immunosuppressed.

Record information regarding the Contact Investigation on ISDH, Tuberculosis Contact Investigation Summary Report and Worksheet, at http://www.in.gov/isdh/files/50007(1).pdf .

Reference: Tuberculosis Case Management, Quality Assurance Protocol, 1999, ISDH

Structure of a Contact Investigation

Basic Steps of a Contact Investigation

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

1. Preinterview preparation
2. Index patient interviews
3. Field investigation
4. Risk assessment for *Mycobacterium tuberculosis* transmission
5. Decision about priority of contacts
6. Evaluation of contacts
7. Treatment and follow-up of contacts
8. Decision about whether to expand testing
9. Evaluation of contact investigation activities[9,10]

Although these steps are presented in sequence above, it is important to remember that contact investigations do not always follow a predetermined sequence of events.[11]

Contact Investigation Plan

The investigation plan starts with information gathered during interviews and site visits. It should include a registry of the contacts, their assigned priorities, and a written timeline. The timeline sets expectations for monitoring the progress of the investigation, and it informs public health officials whether additional resources are needed for finding, evaluating, and treating the high- and medium-priority contacts.

For more information on timelines, see Table 2: **Time Frames for Investigating the Index Patient and the Sites of Transmission** and Table 3: **Time Frames for Contact Evaluation and Treatment** in this section's topic "Time Frames for Contact Investigation."

The plan is a work in progress and should be revised if additional information indicates a need to expand a contact investigation. It is part of the permanent record of the overall investigation for later review and program evaluation.[12]

Decision to Initiate a Contact Investigation

Factors Predicting Transmission of Tuberculosis

Decide when to initiate a contact investigation using the criteria provided in this topic. Competing demands restrict the resources that can be allocated to contact investigations. Therefore, public health officials must decide which contact investigations are more significant and which contacts to evaluate first.

The index patient is the first patient that comes to the investigator's attention as an indicator of a potential public health problem. Whether or not to investigate an index patient depends upon factors predicting transmission. See Table 1: **Index Patient Factors Increasing Transmission Risk**. In addition, other information about the index patient, such as social habits or workplace environments, can influence the investigative strategy.[13]

Table 1. INDEX PATIENT FACTORS INCREASING TRANSMISSION RISK [14]

Characteristics of the Index Patient	Behaviors of the Index Patient
▪ Pulmonary, laryngeal, or pleuropulmonary tuberculosis (TB) ▪ Positive acid-fast bacilli sputum smear results ▪ Cavitation on chest radiograph ▪ Adolescent or adult patient ▪ Lack of treatment or ineffective treatment of TB disease	▪ Frequent coughing ▪ Sneezing ▪ Singing ▪ Close social network

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and Guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):4.

Anatomical Site of Disease

Ordinarily, patients with pulmonary or laryngeal tuberculosis (TB) are the only ones who can transmit their infection. For contact investigations, pleural disease is grouped with pulmonary disease because sputum cultures can yield *Mycobacterium tuberculosis* even when no lung abnormalities show on radiography. Rarely, extrapulmonary TB causes transmission during medical procedures, such as autopsy and embalming, that release aerosols.

Sputum Bacteriology

The relative infectiousness increases when the sputum culture results are positive and increases further when the acid-fast bacilli (AFB) sputum smear results are also

positive.[15] The significance of results from respiratory specimens other than expectorated sputum, such as bronchial washings or bronchoalveolar lavage fluid, is undetermined. Expert opinion recommends that these specimens be regarded as equivalent to sputum.

Radiographic Findings

Patients who have lung cavities observed on a chest radiograph are more infectious than patients with noncavitary disease. This is an independent predictor after bacteriologic findings are taken into account. The significance of small lung cavities that are detectable with computerized tomography (CT), but not with plain radiography, is undetermined.

Isolated instances of highly contagious endobroncheal TB in severely immunocompromised patients who temporarily had normal chest radiographs have contributed to outbreaks. The number and relative significance of such instances is unknown, but in one case series with human immunodeficiency virus (HIV)-infected TB patients, 3% who had positive AFB sputum smears had normal chest radiographs at the time of diagnosis.

Social Characteristics

Social issues can influence transmission. To assess the risk of transmission, it is important to consider the index patient's social factors, such as a close social network, residential setting or homelessness, employment, work setting, non-work-related activities, recent arrival from a foreign country, substance abuse, and intravenous drug use.

Age

Transmission from children younger than ten years of age is unusual, although it has been reported in association with those pulmonary forms of disease typically seen in adults. Contact investigations to evaluate transmission from pediatric cases should not be undertaken, except for those unusual cases. However, children younger than five years with TB, regardless of the site of disease, should have a contact investigation to identify the source case. A source-case investigation seeks the source of recent *M. tuberculosis* infection, perhaps newly diagnosed TB disease. TB disease in children younger than five years typically indicates that the infection is recent. Young children usually do not transmit TB to others, and their contacts are unlikely to be infected because of exposure to them.

Human Immunodeficiency Virus Status

Evaluation of HIV status needs to be done promptly since progression to active TB may occur within weeks of exposure among individuals with acquired immunodeficiency syndrome (AIDS). HIV-infected TB patients with low CD4 T-cell counts frequently have

chest radiographic findings that are not typical of pulmonary TB.[16] In particular, they are more likely to have mediastinal adenopathy and less likely to have upper-lobe infiltrates and cavities. The atypical radiographic findings increase the potential for delayed diagnosis, which increases transmission. However, HIV-infected patients who have pulmonary or laryngeal TB on average are only as contagious as similar patients who are not HIV infected. Contacts to HIV-infected index TB cases are also more likely to be HIV infected. Therefore, for all persons who were exposed to HIV-infected TB cases (or those with risk factors for HIV) and whose infection status is unknown, HIV counseling and testing is recommended.[17] Regardless of known HIV status, HIV counseling should always be recommended for all patients as a part of the screening process.[18]

After Starting Chemotherapy

TB patients rapidly become less contagious while under treatment. This has been corroborated by measuring the number of viable *M. tuberculosis* organisms in sputa and by observing infection rates in household contacts. However, the exact amount of time it takes for an individual patient to be non-infectious cannot be accurately predicted - it must be evaluated according to their sputum testing results and response to therapy.

Treatment After Exposure to Drug-Resistant Tuberculosis

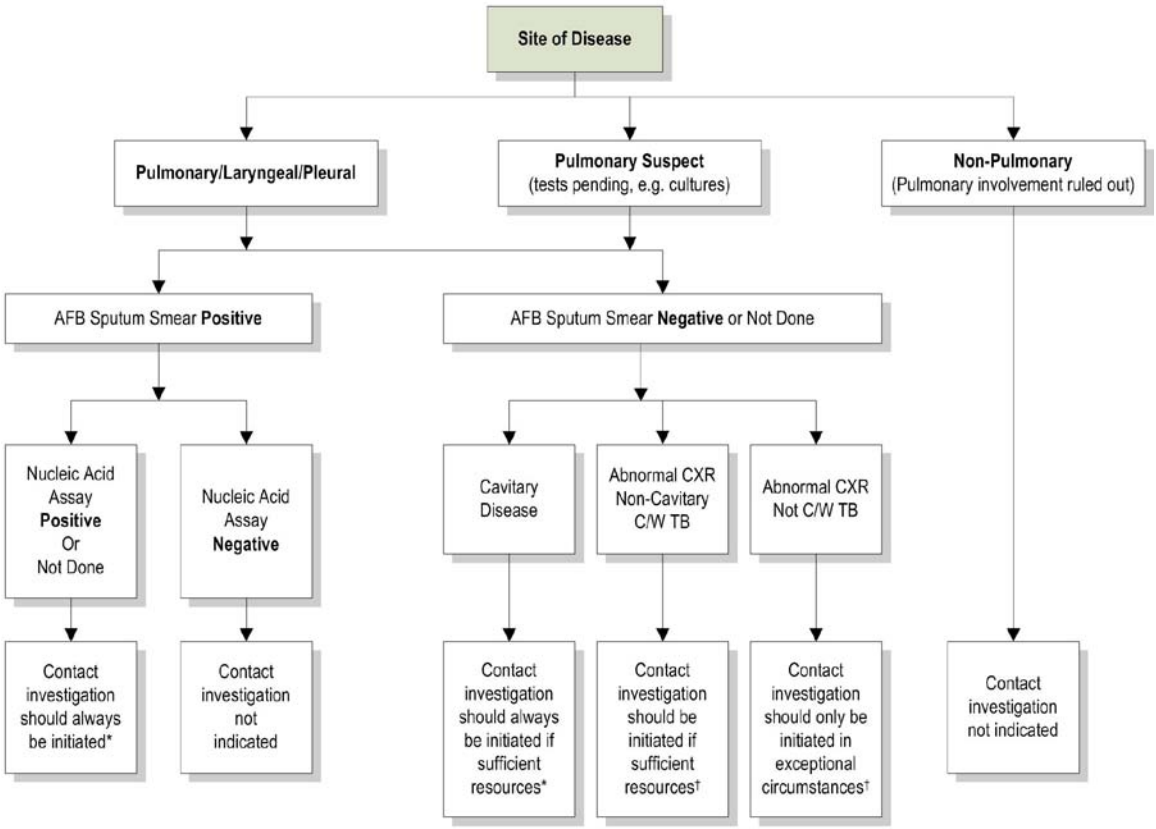
Drug susceptibility results for the *M. tuberculosis* isolate from the index patient (i.e., the presumed source of infection) are absolutely necessary for selecting the treatment regimen.

Resistance to only isoniazid (INH) leaves the option of four months of daily rifampin (RIF), but resistance to both INH and RIF constitutes multidrug-resistant TB (MDR-TB). If this is the case, all the potential regimens are poorly tolerated to some extent, while none of these regimens have been tested fully for efficacy. Therefore, a consultation with a physician having expertise in this area is strongly recommended for selecting a regimen and managing the care of contacts. Monitor contacts who are suspected to be infected with multidrug-resistant *M. tuberculosis* for two years after exposure.

Deciding to Initiate a Contact Investigation

Consider a contact investigation for any patient with confirmed or suspected pulmonary, laryngeal, or pleuropulmonary TB. Refer to Figure 1 to help determine whether to start a contact investigation.

Figure 1: DECISION TO INITIATE A CONTACT INVESTIGATION[19]



Definitions of abbreviations: AFB = acid-fast bacilli; C/W = consistent with; CXR = chest radiograph; TB = tuberculosis.
* Use time frames from the middle column of Table 2 in the "Time Frames for Contact Investigation" topic.
† Use time frames from the right-hand column of Table 2 in the "Time Frames for Contact Investigation" topic.
Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):5.

In general, a contact investigation should be promptly initiated for an AFB sputum smear-positive pulmonary TB suspect. However, many AFB sputum smear-positive suspects may turn out to have nontuberculous mycobacteria (NTM) instead of *M. tuberculosis*. An approved nucleic acid amplification (NAA) test for *M. tuberculosis* can be used to avoid unnecessary contact investigations for suspects with NTM, particularly in patients who are at low risk for TB.

If AFB are not detected by microscopy of three sputum smears, an investigation is still recommended if the chest radiograph shows cavities in the lung. Small parenchymal cavities that can be detected only by computerized imaging techniques (e.g., computed tomography [CT], computerized axial tomography [CAT] scan, or magnetic resonance imaging [MRI] of the chest) are not included in these guidelines.

When sputum samples have not been collected, either because of an oversight or the patient's inability to expectorate, results from other types of respiratory specimens (e.g., gastric aspirates or bronchoalveolar lavage) may be interpreted in the same way as in the above recommendations. However, whenever feasible, sputum samples for each case should be collected before or while initiating chemotherapy.

A contact investigation may still be considered for high-risk contacts of suspects with non-cavitary disease and negative AFB sputum smears. The decision depends on the amount of resources that can be allocated and on whether goals are being met for higher priority contact investigations.

Contact investigations generally should not be initiated around index patients who have suspected TB disease and minimal diagnostic findings in support of pulmonary TB**.** Possible exceptions can be found during outbreak investigations, especially when vulnerable or susceptible contacts are found, or during a source-case investigation. Outbreak investigations and source-case investigations are explained briefly below.

- **Outbreak Investigation:** Definitions for TB outbreaks are relative to the local context. Outbreak cases can be distinguished from other cases only when some association in time, location, patient characteristics, or *M. tuberculosis* attributes (e.g., drug resistance or genotype) becomes apparent. In low-incidence jurisdictions, any temporal cluster will cause suspicion regarding an outbreak. In places where cases are more common, clusters can be obscured by the baseline incidence rate until suspicion is triggered by a noticeable increase, a sentinel event (e.g., pediatric cases), or related *M. tuberculosis* isolates.
- **Source-Case Investigation:** A source-case investigation seeks the source of recent *M. tuberculosis* infection, perhaps newly diagnosed TB disease. A source case or patient is the original source of infection for secondary cases or contacts. The source case can be, but is not necessarily, the index patient.

For more information on source-case investigations, see the CDC's "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis Cases" (*MMWR* 2005;54[No. RR-15]: 31) at this hyperlink: http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf .

Time Frames for Contact Investigation

Use this topic to understand the time frames for key contact investigation activities. A suspected or confirmed case of tuberculosis (TB) becomes designated as an "index patient" when that person is the first patient to appear as an indicator of a potential public health problem. An investigation is launched because of an index patient, and the investigation often starts with an interview of the index patient.

Information about the Index Patient and Transmission Sites

Comprehensive information about an index patient is the foundation of a contact investigation. This information includes the disease characteristics, the onset date of the illness, names of contacts, exposure locations, and current medical factors, such as initiation of effective treatment and drug susceptibility results.

The infectiousness of the index patient determines the recommended time frames for pursuing the investigation. Indications of infectiousness include symptoms (such as cough, fever, weight loss, and night sweats), a positive acid-fast bacilli (AFB) sputum smear, a positive nucleic acid amplification (NAA) test, cavitary disease, or an abnormal chest radiograph consistent with TB.

Refer to Table 2: **Time Frames for Investigating the Index Patient and the Sites of Transmission** for the recommended time frames for index patient interviews and visits to the residence transmission sites.

Some readers confuse prioritizing an investigation with prioritizing follow-up of individual contacts within an investigation. The following explains the difference between the two:

- The time priority for investigating the index patient and transmission sites is determined by the infectiousness of the index patient. Indications of infectiousness include positive AFB sputum smear results as well as symptoms, positive NAA test results, and chest radiographs showing cavitary disease or abnormalities consistent with TB.
- Priority-ranking contacts for follow-up within an investigation is based on the characteristics of the index patient, the duration and circumstances of the exposure, and the vulnerability/susceptibility of the contacts to progression from *Mycobacterium tuberculosis* infection to the development of TB disease.

For information on how to determine which contacts are high, medium, and low priority, see the "Contact Priorities" topic in this section.

Table 2: TIME FRAMES FOR INVESTIGATING THE INDEX PATIENT AND THE SITES OF TRANSMISSION[20]

Activity	Suspects Expected to Be Cases of Tuberculosis	
	Suspects with Indications of Infectiousness	Suspects without Indications of Infectiousness
First Index Patient Interview Number of days following notification within which the index patient should be interviewed in person (i.e., not by telephone)	≤3 Business Day of Reporting	≤3 Business Days of Reporting
Residence Visit Number of days following the first index patient interview within which the place of residence of the index patient should be visited	≤3 Business Days After the First Interview	3 Business Days After the First Interview
Field Investigation Number of days following initiation of the contact investigation within which all potential settings for transmission should be visited	5 Business Days After the Start of the Investigation	5 Business Days After the Start of the Investigation
Index Patient Reinterviews Length of time after the first interview within which the index patient should be reinterviewed one or more times for clarification and additional information	1 or 2 Weeks After the First Interview	1 or 2 Weeks After the First Interview
Reassessment of the Index Patient Information about the index patient should be reassessed at least weekly until drug-susceptibility results are available for the *Mycobacterium tuberculosis* isolate or for 2 months following notification, whichever is longer.		

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):7–8.

Contact Evaluation and Treatment

In addition to the investigation of the index patient and transmission sites, a contact investigation also involves contact follow-up. Refer to Table 3: **Time Frames for Contact Evaluation and Treatment** to monitor the progress of the investigation and determine whether additional resources are needed for finding, evaluating, and treating the high- and medium-priority contacts.

Priority-ranking contacts for investigation is based on the likelihood of infection and the potential hazard to the individual contact if infected.[21] For information on how to determine which contacts are high-, medium-, or low-priority, see the “Contact Priorities” topic in this section.

The CDC recommends that IGRA testing may be used in all circumstances in which the TST is currently used, including contact investigation.

Table 3: TIME FRAMES FOR CONTACT EVALUATION AND TREATMENT[22]

Type of Contact	Business Days from Listing of a Contact to Initial Encounter*	Business Days from Initial Encounter to Completion of Medical Evaluation†	Business Days from Completion of Medical Evaluation to Start of Treatment
High-Priority Contact Index patient with positive acid-fast bacilli (AFB) sputum smear results or cavitary disease on chest radiograph	3 Business Days After Being Listed in the Investigation[23]	5 Business Days	10 Business Days
		5 Business Days  Children and high-risk contacts can develop complicated tuberculosis (TB) within a few weeks of infection.	
High-Priority Contact Index patient with negative AFB sputum smear results	3 Business Days After Being Listed in the Investigation[24]	10 Business Days	10 Business Days
Medium-Priority Contact Regardless of AFB sputum smear or culture result	3 Business Days After Being Listed in the Investigation[25]	10 Business Days	10 Business Days

* "Encounter" means a face-to-face meeting, which gives the public health worker a chance to determine whether the contact is generally healthy or ill. The initial encounter also provides opportunities to administer a tuberculin skin test (TST) and to schedule further evaluation.

† The medical evaluation is complete when the contact's status relative to *Mycobacterium tuberculosis* infection or TB disease has been determined. A normal exception to this schedule is the delay in waiting for final mycobacteriologic results, but this applies to relatively few contacts.

Source: Adapted from CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC. *MMWR* 2005;54(No. RR-15):9.

Ongoing Management Activities

Ongoing contact follow-up includes testing, medical evaluation, and treatment. Information from contact follow-up guides decisions about whether to expand a contact investigation. Refer to Table 4: **Overview of Ongoing Management Activities and Maximum Time Frames** to monitor the progress of ongoing contact follow-up and to determine when to decide whether to expand the investigation.

Table 4: OVERVIEW OF ONGOING MANAGEMENT ACTIVITIES AND MAXIMUM TIME FRAMES[26]

Activity	Purpose	Maximum Time Interval
Review all documentation	To ensure that contact list is complete	Ongoing
Review and assess completeness of each contact's medical follow-up and treatment plan	To ensure appropriate and complete medical follow-up	5 business days after each contact's medical evaluation is completed*
Review and assess the timeliness of initiating the treatment plan	To avoid delays in treatment initiation, particularly in high-risk contacts	10 business days after each contact's medical evaluation is completed*
Determine if transmission occurred	To decide whether to expand investigation	At completion of follow-up testing, or if secondary cases are identified
Obtain and review drug-susceptibility results	To determine if contacts are receiving appropriate treatment for latent tuberculosis infection (LTBI)	1 to 2 months after the index patient's initial sputum collection date
Repeat TST or IGRA if contact is initially TST or IGRA negative	To determine if contact has converted (TB Class I to TB Class II)	8 to 10 weeks after each contact's initial TST or last exposure to the index patient†
Reevaluate contacts who were initially TST or IGRA negative and started on LTBI treatment (Window Period Treatment for a TB Class I Contact)	To determine if treatment for LTBI should be continued	8 to 10 weeks after each contact's initial TST or last exposure to the index patient before the end of the infectious period†
Assess contacts' adherence with medical follow-up and TB medication	To remove barriers and ensure timely and complete evaluation and follow-up	Monthly, at the time of each visit

Activity	Purpose	Maximum Time Interval
Ensure contacts are monitored for adverse reactions and toxicity of LTBI treatment regimens	To prevent development of adverse effects and toxicity from drug regimens	At least monthly while on LTBI treatment
Evaluate problems and concerns that arise and may delay or hamper the contact investigation	To remove barriers and ensure timely and complete evaluation and follow-up	Whenever problems are identified
Collect and analyze data to evaluate the contact investigation and complete required forms	To provide epidemiologic analysis of investigations and to measure performance using indicators that reflect performance objectives[27] And report on investigation to the CDC	Ongoing

* The medical evaluation is complete when the contact's status relative to *Mycobacterium tuberculosis* infection or TB disease has been determined. A normal exception to this schedule is the delay in waiting for final mycobacteriologic results, but this applies to relatively few contacts.

† Third TST: In rare circumstances, an infectious index patient with advanced disease can stay infectious for several months. In these circumstances, the second TST for negative contacts should be performed in the usual time frame (8 to 10 weeks). This will identify any contacts who have already converted so they can be evaluated for treatment. However, any household members who remain TST negative and have continued exposure to the infectious index patient should have a third TST 8 to 10 weeks after the index patient becomes noninfectious. This is especially true for contacts who are infants in a household where a resident is culture positive after 3 months or has multidrug-resistant TB. For example, a household member with continued exposure to an infectious index patient had a negative second TST on 3/12/2007. The last date the index patient was infectious was 3/5/2007. The household member should have a third TST 8 to 10 weeks from 3/5/2007. For questions regarding the appropriateness of a third TST, call your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction.

Source: Adapted from: California Department of Health Services (CDHS)/California Tuberculosis Controllers Association (CTCA). Contact investigation guidelines. *CDHS/CTCA Joint Guidelines* [CTCA Web site]. November 12, 1998:18. Available at: http://www.ctca.org/guidelines/IID1contactinvestigation.pdf . Accessed July 6, 2006.

Infectious Period

Determine the infectious period to focus the investigation on those contacts most likely to be at risk for infection and to set the time frame for testing contacts.

The infectious period is the time frame in which potential exposure to others may have occurred while the patient was infectious or able to transmit tuberculosis (TB).[28] The exact start of the infectious period cannot be determined with any current methods, so a practical estimation is necessary. From expert opinion, an assigned start three months prior to TB diagnosis is recommended for the more infectious patients. Some circumstances may indicate an even earlier start, which should be used instead. The clearest example is when the patient or the patient's associates were aware of protracted illness, which can exceed one year in extreme examples.

Assemble information from the index patient interview and other sources to estimate the infectious period. Helpful details include the approximate dates that TB symptoms were noticed, bacteriologic results, and the extent of disease—especially the presence of large lung cavities, which imply prolonged illness as well as infectiousness.

Use Table 5: **Guide for Estimating the Beginning of the Period of Infectiousness** to determine the start of the infectious period.

Table 5: GUIDE FOR ESTIMATING THE BEGINNING OF THE PERIOD OF INFECTIOUSNESS[29]

Index Patient Characteristics						
Tuberculosis Symptoms		Positive Acid-Fast Bacilli Sputum Smear Results		Cavitary Chest Radiograph		Recommended Beginning of Likely Period of Infectiousness
Yes	No	Yes	No	Yes	No	
✓			✓		✓	3 months prior to symptom onset or first positive finding consistent with tuberculosis (TB) disease (whichever is longer)
✓		✓		✓		3 months prior to symptom onset or first positive finding consistent with TB disease (whichever is longer)
	✓		✓		✓	4 weeks prior to date of suspected diagnosis
	✓	✓		✓		3 months prior to first positive finding consistent with TB

Source: California Department of Health Services Tuberculosis Control Branch; California Tuberculosis Controllers Association. Contact investigation guidelines. Berkeley, CA: California Department of Health Services; 1998; in CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):7.

For the purposes of contact investigation, the end of potential exposure to the infectious case determines the end of the infectious period. The potential for transmission is reduced by the initiation and duration of treatment, the index patient's response to treatment, and/or the application of effective infection control measures.

In general, **for the purposes of contact investigation**, the infectious period is closed when exposure to contacts has ended **OR** when **all** three of the following criteria are met:

1. The index patient is receiving effective treatment (as demonstrated by Mycobacterium tuberculosis susceptibility results) for at least two weeks.
2. The index patient has diminished symptoms.
3. The index patient exhibits mycobacteriologic response (e.g., decrease in grade of sputum smear positivity detected on sputum-smear microscopy).[30,31]

Take careful note of the following exceptions:

- **Multidrug-resistant TB (MDR-TB):** MDR-TB can extend infectiousness if the treatment regimen is ineffective.
- **Signs of infectiousness:** Any index patient with signs of extended infectiousness should be continually reassessed for recent contacts.
- **Susceptible contacts:** Apply more stringent criteria for setting the end of the infectious period if particularly susceptible contacts are involved. A patient returning to a congregate living setting or to any setting in which susceptible persons might be exposed should have at least three consecutive negative AFB sputum smear results from sputum collected more than eight hours apart (with one specimen collected during the early morning) before being considered noninfectious.[32]

Index Patient Interviews

Conduct index patient interviews to set the direction for the contact investigation, identify contacts, provide opportunities for the patient to learn about tuberculosis (TB) and its control, and help the public health worker learn how to provide treatment and care specific to that patient.

In index patient interviews, gather information about the index patient's medical history, treatment needs, residence, transmission sites, dates and times at specific transmission sites, and contacts at specific sites. Use the information from these interviews to decide whether to start a contact investigation, establish its priority relative to other investigations, and determine the scope of the investigation.

There should be an initial interview and one or two reinterviews before discharge from the hospital, or within one to two weeks if the initial interview occurs in the home, to obtain further information and answer additional questions.[33]

TB Interviewing for Contact Investigation: A Practical Resource for the Healthcare Worker (New Jersey Medical School Global Tuberculosis Institute Web site; 2004) at this hyperlink: http://www.umdnj.edu/globaltb/products/tbinterviewing.htm offers specific suggestions on how to prepare for and conduct the interviews.[34]

Record information regarding the index patient and contacts on ISDH **Tuberculosis Contact Investigation Summary Report and Worksheet**, at http://www.in.gov/isdh/files/50007(1).pdf

Preinterview Preparation

Gather information on the patient and the circumstances of the illness to prepare for the first interview.

Consult these sources:

- Current medical record
- Physician
- Laboratory, clinic, or other reporting source
- Infection control nurse (if the patient is hospitalized)

The Privacy Rule in the Health Insurance Portability and Accountability Act (HIPAA) permits disclosure of medical record information to public health authorities.[35]

General Guidelines for Interviewing an Index Patient

1. Discuss confidentiality and privacy in frank terms to help the patient decide how to share information, and revisit these topics several times during the interview to stress their importance. Emphasize confidentiality, but inform the patient that relevant information may need to be shared with other health department staff or other persons who may assist in congregate settings to most efficiently determine which contacts need to be evaluated. Inform the patient that it will be necessary for visits to be made at sites such as the home, workplace/school, or leisure establishments to assess the shared air environment to accurately structure the contact investigation.[36]
2. Conduct the interviews in the patient's language, using a medical interpreter if the patient does not speak English.
3. Conduct the interviews in a culturally competent manner.

For more information on cultural sensitivity, refer to the *Participant's Workbook* for Session 4: "Working with Culturally Diverse Populations" in the *Directly Observed Therapy Training Curriculum for TB Control Programs* (Francis J. Curry National Tuberculosis Center Web site; 2003) at this hyperlink: http://www.nationaltbcenter.ucsf.edu/catalogue/epub/index.cfm?uniqueID=2&tableName=DOTE .

Field Investigation

A field investigation includes visiting the patient's home (or shelter), workplace, or school (if any), and the other places where the patient said he or she spent time while infectious. The field investigation is important and should be done even if the patient interview has already been conducted. The purpose of the field investigation is to identify contacts and evaluate the environmental characteristics of the places in which exposure occurred. The field investigation may provide additional information for use in the risk assessment and for identifying additional contacts.[37]

During field visits, the healthcare worker should do the following:

- **Observe environmental characteristics**, such as room size, crowding, and ventilation, to estimate the risk of tuberculosis (TB) transmission: air volume, exhaust rate, and circulation predict the likelihood of transmission in an enclosed space. In large indoor settings, the degree of proximity between contacts and the index patient can influence the likelihood of transmission. The most practical system for grading exposure settings is to categorize them by size (e.g., “1” being the size of a vehicle or car, “2” the size of a bedroom, “3” the size of a house, and “4” a size larger than a house). The volume of air shared between an infectious TB patient and contacts dilutes the infectious particles. Local circulation and overall room ventilation also dilute infectious particles, but both factors have to be considered because they can redirect exposure into spaces that were not visited by the index patient.[38]
- **Identify additional contacts** (especially children) and their locating information, such as phone numbers and addresses.
- **Look for evidence of other contacts** who may not be present at the time of the visit (for example, pictures of others who may live in or visit the house, shoes of others who may live in the house, or toys left by children).
- **Interview and skin test high- and medium-priority contacts** who are present and arrange for reading of the tuberculin skin test (TST) results.
- **Educate the contacts** about the purpose of a contact investigation, the basics of transmission, the risk of transmitting *Mycobacterium tuberculosis* to others, and the importance of testing, treatment, and follow-up for TB infection and disease.
- **Refer contacts who have TB symptoms** to the health department for a medical evaluation, including radiography and sputum collection.[39]

The New Jersey Medical School National Tuberculosis Center has published the Field Investigation Report form to be used on a monthly basis to report and summarize field investigation activity. The form can be tailored. For more information, see the Performance Guidelines: A Supervisor's Guide for the Development and Assessment of TB Field Investigation Skills at http://www.umdnj.edu/globaltb/products/performanceguide.htm

Healthcare workers should remember to follow infection control precautions while visiting a potentially infectious TB patient at home or in any other location. These precautions may include wearing a personal respirator.[40]

For more information on infection control, see Section 16 - Infection Control.

Another critical consideration during field investigations is safety. Healthcare workers should become familiar with policies and recommendations of local law enforcement agencies and health department administration regarding personal safety. Current information on local high-risk areas for crime can be very valuable in planning and conducting safe field visits.

General safety precautions that are recommended for the healthcare worker include the following:

- Wearing an identity badge with a current photo
- Working in pairs when visiting a potentially dangerous area
- Informing someone of your itinerary and expected time of return, especially if you anticipate problems[41]

Contact Priorities

Assign priorities to contacts, using the registry of contacts compiled from the index patient interviews, site visits, interviews with contacts, and information from other persons involved in the investigation. The Centers for Disease Control and Prevention (CDC) defines the three levels of contact priorities as follows:

- High-priority contacts
- Medium-priority contacts
- Low-priority contacts

Contact priorities are determined by the likelihood of infection and the potential hazards to the individual contact if infected.[42] Priority-ranking contacts for investigation is based upon the characteristics of the index patient, the duration and circumstances of the exposure, and the vulnerability/susceptibility of the contacts to disease from *Mycobacterium tuberculosis* infection.[43]

Use the assigned priorities to allocate resources to complete all investigative steps for the high- and medium-priority contacts.[44] Dividing contacts into these three levels provides a system for public health staff to reach high-priority contacts first, and then medium-priority contacts, and then low-priority contacts. The priority scheme directs resources to the following essential actions:

1. Find contacts who are secondary active tuberculosis (TB) cases.
2. Find contacts who have recent *M. tuberculosis* infection—the most likely to benefit from treatment.
3. Select contacts who are most likely to progress to TB disease if they are infected (i.e., susceptible contacts) or who could suffer severe morbidity if they had TB disease (i.e., vulnerable contacts).[45]

Timely initiation of treatment is especially important for susceptible and vulnerable contacts. Refer to Table 3: **Time Frames for Contact Evaluation and Treatment** in the “Time Frames for Contact Investigation” topic.

Use the tables on the following pages to assign priorities to contacts to the following:

- Table 6: **Prioritization of Contacts to Smear-Positive or Cavitary Cases**
- Table 7: **Prioritization of Contacts to Smear-Negative Cases**
- Table 8: **Prioritization of Contacts to Cases with Negative Bacteriologic Results and Abnormal Chest Radiographs not Consistent with Tuberculosis**

Index Patient with Positive Acid-Fast Bacilli Sputum Smear Results or Cavitary Tuberculosis

Use Table 6 to prioritize contacts to smear-positive or cavitary index patients.

Table 6: PRIORITIZATION OF CONTACTS TO SMEAR-POSITIVE OR CAVITARY CASES[46]

High-Priority Contacts	Medium-Priority Contacts	Low-Priority Contacts
▪ Household contacts ▪ Contacts <5 years old ▪ Contacts with human immunodeficiency virus (HIV) infection or other immunocompromising condition ▪ Contacts with exposure during a medical procedure such as bronchoscopy, sputum induction, or autopsy ▪ Contacts with exposure in a congregate setting ▪ Contacts whose exposure exceeds duration/environment limits (see below)	▪ Contacts not in high-priority groups ▪ Contacts 5–15 years old ▪ Contacts whose exposure exceeds duration/environment limits (see below)	▪ Contacts not in high-priority groups ▪ Contacts not in medium-priority groups
Exposure limits are to be set by LHDs. The CDC offers some examples, such as a grading system for exposure settings to categorize them by size: 1 = vehicle or car, 1 = size of a bedroom, 3 = size of a house, 4 = size larger than a house. They offer a cut off of 120 hours of exposure per month – for estimating risk after exposure to a person with pulmonary TB without lung cavities. And of course, environmental characteristics (e.g., crowding, ventilation, etc.) need to be considered.		

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC. *MMWR* 2005;54 (No. RR-15):12.

Index Patient with Negative Acid-Fast Bacilli Sputum Smear Results

Use Table 7 to prioritize contacts to smear-negative index patients.

Table 7: PRIORITIZATION OF CONTACTS TO SMEAR-NEGATIVE CASES[47]

High-Priority Contacts	Medium-Priority Contacts	Low-Priority Contacts
▪ Contacts <5 years old ▪ Contacts with human immunodeficiency virus (HIV) infection or other immunocompromising conditions ▪ Contacts exposed during a medical procedure such as bronchoscopy, sputum induction, or autopsy	▪ Contacts not in high-priority groups ▪ Household contacts ▪ Contacts exposed in a congregate setting ▪ Contacts whose exposure exceeds duration/environment limits per unit time established by the local TB control program for medium-priority contacts (see below)	▪ Contacts not in high-priority groups ▪ Contacts not in medium-priority groups
Exposure limits are to be set by LHDs. The CDC offers some examples, such as a grading system for exposure settings to categorize them by size: 1 = vehicle or car, 1 = size of a bedroom, 3 = size of a house, 4 = size larger than a house. They offer a cut off of 120 hours of exposure per month – for estimating risk after exposure to a person with pulmonary TB without lung cavities. And of course, environmental characteristics (e.g., crowding, ventilation, etc.) need to be considered.		

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC. *MMWR* 2005;54(No. RR-15):13.

Index Patient with Negative Bacteriologic Results and Abnormal Chest Radiographs not Consistent with Tuberculosis

Use Table 8 to prioritize contacts to a suspected case of pulmonary TB who is acid-fast bacilli (AFB) sputum smear negative, who is nucleic acid amplification (NAA) negative and culture negative, and who has abnormal chest radiographs not consistent with TB disease.

Table 8: PRIORITIZATION OF CONTACTS TO CASES WITH NEGATIVE BACTERIOLOGIC RESULTS AND ABNORMAL CHEST RADIOGRAPHS NOT CONSISTENT WITH TUBERCULOSIS[48]

High-Priority Contacts	Medium-Priority Contacts	Low-Priority Contacts
	▪ Household contacts ▪ Contacts <5 years old ▪ Contacts with human immunodeficiency virus (HIV) infection or other medical risk factor ▪ Contacts exposed during a medical procedure such as bronchoscopy, sputum induction, or autopsy	▪ Contacts not in medium-priority groups

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC. *MMWR* 2005;54(No. RR-15):14.

Contact Evaluation, Treatment, and Follow-up

Complete evaluation, treatment, and follow-up for high- and medium-priority contacts, as specified in your contact investigation plan. The Centers for Disease Control and Prevention (CDC) recommends the following:

- Provide each high- and medium-priority contact an initial assessment that includes a face-to-face encounter in which an impression of each contact's general health is formed and a tuberculin skin test (TST) is usually administered.
- Medically evaluate each high- and medium-priority contact to determine whether tuberculosis (TB) disease or latent tuberculosis infection (LTBI) is present or absent.
- Timely initiation of treatment is especially important for high-priority contacts and for contacts likely to progress to TB disease if they are infected (i.e., susceptible contacts) or contacts who could suffer severe morbidity if they had TB disease (i.e., vulnerable contacts). For recommended time frames, refer to Table 3: **Time Frames for Contact Evaluation and Treatment** in the "Time Frames for Contact Investigation" topic.
- Use the same diagnostic methods for all contacts, except when they have medical or constitutional conditions making TB more likely or more difficult to diagnose. A contact's country of origin and bacille Calmette-Guérin (BCG) vaccination are not included in algorithms for diagnosis or treatment. Interpret a positive TST in a foreign-born or BCG-vaccinated person as evidence of recent *Mycobacterium tuberculosis* infection in contacts of persons with infectious cases. Evaluate these contacts for TB disease and offer them a course of treatment for LTBI.[49]

NOTE: IGRA testing results are not affected by BCG vaccination.

Use the tables on the following pages to determine the evaluation activities for contacts in these different risk groups and priority rankings:

- Table 9: ***Evaluation*, Treatment, and Follow-Up of Immunocompromised Contacts and Children Under Five Years Old**
- Table 10: **Evaluation, Treatment, and Follow-Up of Immunocompetent Adults and Children Five and Older (High- and Medium-Priority Contacts)**
- Table 11: **Evaluation, Treatment, and Follow-Up of Contacts with Prior Positive Tuberculin Skin Tests**

During contact evaluation, treatment, and follow-up, use the ISDH **Tuberculosis Contact Investigation Summary Report and Worksheet** at http://www.in.gov/isdh/files/50007(1).pdf .

For time frames, see the "Time Frames for Contact Investigation" topic in this section. To arrange follow-up with public health officials in other jurisdictions for out-of-area contacts, see the Transfer Notifications section.[50]

Immunocompromised Contacts and Children under Five

Use Table 9 to select evaluation, treatment, and follow-up activities for contacts who are immunocompromised and/or under five years old.

Evaluate contacts who are immunocompromised or under five years of age with medical history, physical examination, chest radiograph, and tuberculin skin test (TST) or interferon gamma release assay (IGRA). Based on the results of these evaluations, take the actions in Table 9.

Timely initiation of treatment is especially important for these contacts. Refer to Table 3: **Time Frames for Contact Evaluation and Treatment** in the "Time Frames for Contact Investigation" topic.

Table 9: EVALUATION, TREATMENT, AND FOLLOW-UP OF IMMUNOCOMPROMISED CONTACTS AND CHILDREN UNDER FIVE YEARS OLD[51]

If evaluation or test results show that a contact has the following:		Then take this action or these actions:
Symptoms consistent with TB disease and/or Abnormal chest radiograph		Fully evaluate for TB disease
No symptoms consistent with TB disease and normal CXR	1st TST* ≥5 mm or positive IGRA	Complete a full course of treatment for LTBI
	1st TST <5 mm or negative IGRA and ≥8 weeks since last exposure	▪ If not HIV-infected, no further evaluation required ▪ If HIV-infected, no further evaluation required; consider a full course of treatment for LTBI
	1st TST <5 mm or negative IGRA and <8 weeks since last exposure	Begin treatment for LTBI and retest 8–10 weeks post exposure
	2nd TST ≥5 mm or positive IGRA	Complete a full course of treatment for LTBI
	2nd TST <5 mm or negative IGRA	▪ If not HIV-infected, no further evaluation required ▪ If HIV-infected, no further evaluation required; consider a full course of treatment for LTBI

Definitions of abbreviations: HIV = human immunodeficiency virus; IGRA = interferon gamma release assay; LTBI = latent tuberculosis infection; TB = tuberculosis; TST = tuberculin skin test.

* **Note:** An IGRA may be used in place of a TST.

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):15–16.

Immunocompetent Adults and Children Five and Older (High- and Medium-Priority Contacts)

Use Table 10 to select evaluation, treatment, and follow-up activities for high- and medium-priority contacts who are immunocompetent and/or five years of age or older.Evaluate high- and medium-priority contacts who are immunocompetent and/or five years of age or older, with medical history, exposure history, and TST or IGRA. Based on the results of these evaluations, take the actions in Table 10.

Table 10: EVALUATION, TREATMENT, AND FOLLOW-UP OF IMMUNOCOMPETENT ADULTS AND CHILDREN FIVE YEARS AND OLDER (HIGH- AND MEDIUM-PRIORITY CONTACTS)[52]

If evaluation or test results show that a contact has the following:		Then take this action or these actions:
Symptoms consistent with TB disease		Fully evaluate for TB disease
No symptoms consistent with TB disease	1st TST* ≥5 mm or Negative IGRA	Evaluate with a physical examination and CXR: ▪ If CXR abnormal, fully evaluate for TB disease ▪ If CXR normal, complete a full course of treatment for LTBI
No symptoms consistent with TB disease	1st TST <5 mm or Negative IGRA and 8–10 weeks since last exposure	No further evaluation or treatment required
No symptoms consistent with TB disease	1st TST <5 mm or Negative IGRA and <8 weeks since last exposure	Retest 8–10 weeks post exposure
No symptoms consistent with TB disease	2nd TST ≥5 mm or Positive IGRA	Evaluate with a physical examination and CXR: ▪ If CXR abnormal, fully evaluate for TB disease ▪ If CXR normal, complete a full course of treatment for LTBI
No symptoms consistent with TB disease	2nd TST <5 mm or Negative IGRA	No further evaluation or treatment required

Definitions of abbreviations: CXR = chest radiograph; IGRA = interferon gamma release assay; LTBI = latent tuberculosis infection; TB = tuberculosis; TST = tuberculin skin test.

* **Note:** An IGRA may be used in place of a TST.

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):17.

Contacts with Prior Positive Tuberculin Skin Tests

Use Table 11 to select evaluation, treatment, and follow-up activities for contacts who have prior positive TSTs or IGRAs.

For contacts with prior positive TSTs, evaluate them with medical and exposure history. Based on these histories, take the actions in Table 11.

Table 11: EVALUATION, TREATMENT, AND FOLLOW-UP OF CONTACTS WITH PRIOR POSITIVE TUBERCULIN SKIN TESTS[53]

If evaluation or test results show that a contact has the following:		Then take this action or these actions:
Symptoms consistent with TB disease		Fully evaluate for TB disease

No symptoms consistent with TB disease	Immunocompromised
	or
	<5 years old
		Evaluate with a physical examination and CXR:
		▪ If CXR or physical examination is indicative of TB disease, fully evaluate for TB disease
		▪ If results are not indicative of TB disease:
		  ▪ If contact previously completed treatment, consider retreatment
		  ▪ If treatment not completed previously, complete a full course of LTBI treatment

No symptoms consistent with TB disease	Immunocompetent and ≥5 years old	▪ If contact previously completed treatment for LTBI, no further evaluation or treatment required ▪ If contact has not completed treatment for LTBI, consider treatment for LTBI

Definitions of abbreviations: CXR = chest radiograph; LTBI = latent tuberculosis infection; TB = tuberculosis.

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):19.

When to Expand a Contact Investigation

Guidelines for Expanding an Investigation

Determine when to expand a contact investigation using the following guidelines:

1. Do not include lower-priority contacts unless objectives for high- and medium-priority contacts are being met.
2. Consider the extent of recent transmission.
3. Consider expanding the scope (e.g., number of contacts) of an investigation if any one or more of the following criteria are met:
   - **a.** Unexpectedly large rate of tuberculosis (TB) infection or disease in high-priority contacts: 10%, or at least twice the rate of a similar population without recent exposure, whichever is greater

Since the background prevalence of tuberculosis infection in adult foreign-born populations from high-incidence countries often exceeds 30%, it is important to stratify the infection rates by country of birth and/or length of residence and by age. For example, household contacts with a positive tuberculin skin test (TST) results are more likely to be infected recently (or as a result of exposure to the index patient) if the contacts are US-born children rather than adults born in high-incidence countries.

   - **b.** Evidence of second-generation transmission (i.e., from TB patients who were infected after exposure to the source patient)
   - **c.** TB disease in any contacts who had been assigned low priority
   - **d.** Infection in any contacts younger than five years old
   - **e.** Contacts with change in TST status from negative to positive
4. When results from an investigation indicate that it should be expanded, but resources are insufficient, seek assistance from the next higher public health administrative level.

In general, without evidence of recent transmission, do not expand an investigation to lower-priority contacts. When program evaluation objectives have not been met, expand a contact investigation only in exceptional circumstances, generally involving highly infectious cases with high rates of infection among contacts or evidence for secondary cases and secondary transmission. Derive the strategy for expanding an investigation

from the data obtained from the investigation to that point in time. Without data from the initial contact investigation to support evidence of transmission, there is little support to expand to lower-priority contacts. As in the initial investigation, review the incoming results of the expanded investigation at least weekly to reassess the strategy.

Sometimes the result from an investigation indicates a need for expansion, but resources do not permit this. In these situations, seek consultation and assistance from the next higher level in public health administration (e.g., the county health department consults with the state health department). Consultation offers an objective review of strategy and results, additional expertise, and the potential for personnel or funds for meeting unmet needs.

Contact your ISDH Regional TB Nurse Consultant, contact information in Section 1 – Introduction, to consult about expanding a contact investigation.

Record your decision and rationale for expanding a contact investigation on the ISDH Tuberculosis Contact Investigation Summary Report and Worksheet at http://www.in.gov/icpr/webfile/formsdiv/50007.pdf

Low-Priority Contacts

Use Table 12 to select evaluation, treatment, and follow-up activities for low-priority contacts. Evaluate low-priority contacts with medical and exposure history. Based on these histories, take the actions in the Table 12.

Table 12: EVALUATION, TREATMENT, AND FOLLOW-UP OF LOW-PRIORITY CONTACTS[54]

If evaluation or test results show that a contact has the following:		Then take this action or these actions:
Symptoms consistent with TB disease		Fully evaluate for TB disease
No symptoms consistent with TB disease	8–10 weeks since last exposure	Evaluate with a TST or IGRA
No symptoms consistent with TB disease	<8 weeks since last exposure	Wait 8–10 weeks after last exposure, and then evaluate with a TST or IGRA
No symptoms consistent with TB disease	1st TST* ≥5 mm or Positive IGRA	Evaluate with physical examination and CXR: ▪ If CXR is abnormal, fully evaluate for TB disease ▪ If CXR is normal, consider treatment for LTBI
No symptoms consistent with TB disease	1st TST <5 mm or Negative IGRA	No further evaluation or treatment required

Definitions of abbreviations: CXR = chest radiograph; IGRA = interferon gamma release assay; LTBI = latent tuberculosis infection; TB = tuberculosis; TST = tuberculin skin test.

* **Note:** An IGRA may be used in place of a TST.

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):22.

Data Management and Evaluation of Contact Investigations

Data collection related to contact investigations has three broad purposes:

1. Management of care and follow-up of individual index patients and contacts
2. Epidemiologic analysis of an investigation in progress as well as overall results of previous investigations
3. Program evaluation via performance indicators that reflect performance objectives

Reasons Contact Investigation Data Are Needed

Comprehensive Care

For each index patient and the associated contacts, a broad amount of demographic, epidemiologic, historical, and medical information is needed for providing comprehensive care. The care for these individuals can extend to longer than a year in some instances, so the information builds stepwise and has numerous longitudinal elements (e.g., clinic visits attended, treatment doses administered, and bacteriologic response to treatment).

Timeline Objectives

Many of these data elements also contribute to the other reasons for collecting data. Data on some process steps are necessary for monitoring whether the contact investigation is keeping to the timeline objectives (e.g., how soon after listing is the tuberculin skin test (TST) administered to a contact).

Completion of Investigation

When aggregated, the data from an investigation inform public health officials as to whether the investigation is on time and complete. The analysis of data also contributes to reassessments of the strategy used in the investigation (e.g., was the infection rate greater for contacts believed to have more exposure?).

Reassessment of Strategy

The data from a completed investigation and all investigations in a fixed period (e.g., six months) show achievements in meeting program objectives, such as observance of timelines and completion of therapy for infected contacts. These core measurements for program evaluation, however, cannot directly show why objectives were not met. If the data are structured and stored in formats allowing detailed retrospective review, then the reasons for problems can be studied.

To assess the overall activities of contact investigations, see the CDC's "Framework of Program Evaluation in Public Health" (*MMWR* 1999;48[No. RR-11]) at this hyperlink: ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4811.pdf.

Approach

Follow a systematic, consistent approach to data collection, organization, analysis, and dissemination.

1. Collect specific data elements on index patients and their contacts. The data elements should permit calculation of program performance indices.
2. Collect data on standardized (paper or electronic) forms.
3. Supply data definitions and formats for use by persons who collect, use, and interpret contact investigation data.
4. Whenever feasible, use data definitions and formats that are standard among jurisdictions.
5. Store data electronically for quick analysis of interim results.
6. Implement policies for data management that enable quick analysis of interim results.
7. Implement policies for data management and storage that specify the assignment of responsibilities.
8. Implement training and policies for data accuracy, completeness, and security.
9. Periodically summarize and review data during a particular contact investigation and for overall contact investigations.
10. Evaluate programs for contact investigation activities at least annually. Evaluation is an integral part of TB program responsibility.
11. Beyond standard data elements shown in these guidelines, specific additional elements can contribute to local program management.

Index Patient and Contact Data

For data required on each index patient and contact, See Table 13 and Table 14.

Table 13: DATA ABOUT THE INDEX PATIENT[55]

Identifiers/Demographic Information	▪ Case manager ▪ Name and aliases ▪ For minors and dependents: guardian information ▪ Date of birth ▪ Social security number ▪ Current locating information and emergency contacts ▪ Residences during infectious period if unstably housed ▪ Sex ▪ Race ▪ Ethnicity ▪ Country of birth ▪ Time in United States, if foreign born ▪ Primary language and preferred language ▪ Methods of translation or interpretation
Transmission Settings and Associated Time Frames	▪ Living situation(s) ▪ Employment or school ▪ Social/recreational activities ▪ Congregate settings (e.g., jail, homeless shelter) ▪ Substance abuse with social implications (e.g., crack cocaine)
Tuberculosis Information	▪ Healthcare provider for TB (e.g., public health, private, both, other) ▪ Anatomic site of disease ▪ Symptoms and their dates ▪ CXR results, presence of cavity ▪ TB medications with start and stop dates ▪ Bacteriologic results (sputum smear, culture, drug susceptibility) with dates ▪ Previous history of TB disease and treatment ▪ Infectious period (updated as new information arrives) ▪ HIV infection status ▪ HIV/AIDS registry number
Contact Investigation	▪ Date of initial interview with index patient ▪ Dates of follow-up interviews with index patient

Definitions of abbreviations: AIDS = acquired immunodeficiency syndrome; CXR = chest radiograph; HIV = human immunodeficiency virus; *RVCT* = *Reports of Verified Cases of Tuberculosis*; TB = tuberculosis.

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):21.

Table 14: DATA ABOUT EACH CONTACT[56]

Investigator and Dates	▪ Contact manager or investigator ▪ Date listed ▪ How or why the contact was listed (e.g., named by index patient) ▪ Dates of interviews ▪ Start and end dates for exposure (updated as new information arrives)
Identifiers	▪ Name and aliases ▪ For minors and dependents: guardian information ▪ Social security number ▪ Date of birth ▪ Locating information and emergency contacts ▪ Sex ▪ Race ▪ Ethnicity ▪ Country of birth ▪ Time in the United States, if foreign born ▪ Primary language and preferred language ▪ Methods of translation or interpretation
Exposure	▪ Relationship/connection to the index patient ▪ Social affiliations (e.g., work, school, church, clubs, activities) ▪ Environmental information about exposure settings (e.g., size, ventilation) ▪ Frequency, duration, and time frame of interactions
Medical History and Risk Factors	▪ Prior history of TB disease or LTBI, and documentation ▪ BCG vaccination and date ▪ Medical risk factors for progression of infection to TB disease ▪ Population risk factors for prevalent *M. tuberculosis* infection
Evaluation for Tuberculosis Disease and Latent Tuberculosis Infection	▪ Healthcare provider for TB (e.g., public health, private, both, other) ▪ Symptoms suggesting TB disease ▪ TSTs, with dates, reagents and lot numbers, reaction measurement ▪ IGRA results ▪ CXR results with dates ▪ Bacteriologic results with dates ▪ HIV infection status ▪ Final diagnostic classifications for LTBI or TB disease
Treatment Information for Contacts with Latent Tuberculosis Infection	▪ Dates of treatment ▪ Treatment regimen (medications, dosing schedule, any changes to these) ▪ Methods of supervising treatment (DOT, etc.) ▪ Adverse reactions (specify each) ▪ Interruptions in regimen and dates ▪ Outcome of treatment (completion, etc.) ▪ If treatment not completed, reason

Abbreviations: BCG = bacille Calmette-Guérin; CXR = chest radiograph; DOT = directly observed therapy; HIV = human immunodeficiency virus; IGRA = interferon gamma release assay; LTBI = latent tuberculosis infection; TB = tuberculosis; TST = tuberculin skin test.

Source: CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the N TCA and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):21.

Evaluation of a Contact Investigation

Summarize the results of a contact investigation to report by priority the total number of contacts who were identified, were tested, started therapy, and completed therapy.

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Record your summary on the ISDH **Tuberculosis Contact Investigation Summary Report and Worksheet** at http://www.in.gov/icpr/webfile/formsdiv/50007.pdf

For more information on using this evaluation framework, see the CDC Program Evaluation Workgroup's Web site at this hyperlink: http://www.cdc.gov/eval/framework.htm .

Outbreak Investigation

If data from a contact investigation or surveillance indicate a potential outbreak, conduct an outbreak investigation. A tuberculosis (TB) outbreak warns of potential extensive transmission. An outbreak implies that (1) a TB patient was contagious, (2) contacts were exposed significantly, and (3) the interval since exposure has been sufficient for infection to progress to disease. An outbreak investigation involves several overlapping contact investigations, with a surge in the need for public health resources. More emphasis on active case finding is recommended, which sometimes means that more contacts than usual should have chest radiographs and specimen collection for mycobacteriology.

Definition of a Tuberculosis Outbreak

Definitions for TB outbreak are relative to the local context. Outbreak cases can be distinguished from other cases only when certain associations in time, location, patient characteristics, or *Mycobacterium tuberculosis* attributes (e.g., drug resistance or genotype) become apparent. In low-incidence jurisdictions, any temporal cluster is suspicious for an outbreak. A working definition of a potential *TB outbreak* is helpful for planning and response, and may include any of the following six criteria:

Criteria based on surveillance and epidemiology:

1. An increase has occurred above the expected number of TB cases.
2. During and because of a contact investigation, two or more contacts are identified as having TB disease, regardless of their assigned priority (i.e., high, medium, or low priority).
3. Any two or more cases occurring within one year of each other are discovered to be linked, and the linkage is established outside of a contact investigation (e.g., two patients who received a diagnosis of TB disease outside of a contact investigation are found to work in the same office and only one or neither of the persons was listed as a contact to the other).
4. A genotype cluster leads to discovery of one or more verified transmission links that were missed during a contact investigation within the prior two years.

Criteria based on program resources:

5. Transmission is continuing despite adequate control efforts by the TB control program.
6. Contact investigation associated with increased cases requires additional outside help.

DNA Genotyping

Deoxyribonucleic acid (DNA) genotyping is a laboratory technique used by public health officials during a TB outbreak to distinguish between different strains of *M. tuberculosis* and to help assess the likelihood of TB transmission. Characterization of *M. tuberculosis* with DNA genotyping is a powerful tool for the following:

1. Surveillance of potential outbreaks
2. Confirming TB cases linked by traditional epidemiologic methods
3. Identifying clusters of patients infected with genetically related or identical strains of M. tuberculosis and determining common sources of infections
4. Guiding contact investigations and the appropriate use of preventive therapy
5. Identifying laboratory cross-contamination as the cause of misdiagnosis

When used to track the transmission of a specific strain, DNA genotyping can help assess the effectiveness of TB control programs, a particularly useful methodology for areas with low TB incidence as the United States approaches TB elimination.

Confirm the linkage between cases by genotyping results if isolates have been obtained. An outbreak increases the urgency of investigations and will put greater demands on the health department. Therefore, corroborate a suspected linkage between cases by genotyping results before intensifying an investigation. An epidemiologic investigation is required for determining probable transmission linkages even if genotypes match.

Any secondary case that is unexpectedly linked to a known index patient represents a potential failure in the contact investigation; in such cases, reassess the original investigation to determine whether the strategy for finding contacts was optimal and whether the priorities were valid. If a secondary case occurred because treatment for a known contact with latent tuberculosis infection (LTBI) was not started or completed, then review the strategies for treatment and completion.

For more information on Genotyping see Section 2 – Surveillance.

ISDH Tuberculosis Outbreak Response Plan

Purpose: To establish procedures to be followed in response to an outbreak of tuberculosis (TB) in a community.

Definition Outbreak: A situation that is consistent with one of the sets of the following criteria:

- An increase has occurred above the expected number of TB cases.
- During (and because of) a contact investigation, two or more contacts are identified as having active TB, regardless of their assigned priority.
- Any two or more cases occurring ≤ 1 year of each other are discovered to be epidemiologically linked, and the linkage is established outside of a contact investigation (e.g., two patients who received a diagnosis of TB outside of a contact investigation are found to work in the same office, and only one or neither of the persons was listed as a contact to the other).
- Three or more genotypically linked cases within a year that are either:
    a) Determined to be an uncommon genotype strain constituting ongoing transmission (determination can be performed using TB GIMS which can account for time, space and common behaviors.)
    b) New genotype cluster for the state of Indiana, with consideration of time, space and common behaviors.

Procedure: Tuberculosis outbreak investigations should follow the following procedures:

1. When an outbreak is identified, the Local Health Department (LHD) should lead the investigation and ensure that the appropriate reporting forms are completed and a contact investigation is initiated for each identified case. The Local Health Officer will exercise oversight at the local level, as well as serve as the primary liaison with the news media. Within 24 hours or one working day of identifying an outbreak, a meeting should be held. When possible, this meeting should be located at the Local Health Department. Members of the meeting should include the state TB Control Officer, state TB Epidemiologist, ISDH Regional Nurse, Director of Field Epidemiology, and the Local Health Officer and staff.

2. The purpose of the initial meeting is to establish a plan of action, outline responsibilities and determine a time line. The agenda will include: 1) Confirming the diagnosis of TB for all reported TB cases; 2) Determining the extent of exposure including possible sites and populations at risk; 3) Identifying any medical and case management problems so that they can be addressed; 4) Assuring that all active cases are receiving directly observed therapy (DOT); 5) Assuring that an appropriate contact investigation has been initiated for each active case; 6) Identify any additional resources that may be needed to help manage the investigation; 7) Consulting with the Centers for Disease Control and Prevention (CDC) after the initial meeting.

3. Site visits are complementary to interviewing. They add contacts to a list and are the most reliable source of information regarding transmission settings. The

personnel conducting the site visit should include a regional nurse consultant and TB Epidemiologist from ISDH. At the local level, the nurse case manager, outreach workers, health officer, and other administrative and clinical personnel as appropriate, should attend. ISDH will review the findings with the Local Health Officer.

4. Within five working days of the meeting with the LHD, the state TB Control Officer will notify the Division of TB Elimination (DTBE) at the Centers for Disease Control and Prevention. The state TB Control Officer will request assistance from the DTBE through the State Epidemiologist.

5. Within ten working days of the meeting with the LHD, an outbreak plan should be agreed upon and documented in writing. The plan need not be detailed, but should address responsibilities for medical management, case management, contact investigations and DOT.

6. The ISDH will assist LHDs to identify factors contributing to the outbreak so that community education and other control measures may be addressed. If additional resources are needed, the outbreak plan should state where they will come from and how they will be allocated.

7. The ISDH will continue to monitor progress toward outbreak control by monitoring new cases and by maintaining contact with the LHDs. The status of the outbreak control measures should be reviewed with the LHD on a biweekly basis. Adjustments may be made as needed.

When all identified contacts have been appropriately evaluated, local and state health departments will collaborate on a report. The report will document the findings of the investigation and assess the effectiveness of the response to the outbreak. The end of the outbreak will be determined by the state TB Control Officer, in coordination with the Local Health Officer and the State Epidemiologist. It will be based on (1) the successful treatment of the patients involved in the outbreak, (2) the cessation of new case reports for patients who are linked to the initial source or index cases and (3) public health deficiencies have been addressed.

Resources and References

Resources

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Laboratory Services

CONTENTS

Introduction

Purpose

Use this section to do the following:

- Obtain contact information for laboratories.
- Determine which tests are available and the tests' turnaround times.
- Identify which laboratory can perform a specific test.

The diagnosis of tuberculosis (TB), management of patients with the disease, and public health TB control services rely on accurate laboratory tests. Laboratory services are an essential component of effective TB control, providing key information to clinicians (for patient care) and public health agencies (for control services).[1]

Policy

Public health laboratories should ensure that clinicians and public health agencies within their jurisdictions have ready access to reliable laboratory tests for diagnosis and treatment of TB.[2]

Effective TB control requires timely, complete, and accurate communication among the laboratory system, TB control program, and healthcare provider.[3]

For roles and responsibilities, refer to the "Roles, Responsibilities, and Contact Information" topic in Section 1 - Introduction.

INDIANA

LAB: ISDH provides laboratory support for TB control and prevention by isolating, identifying, and performing susceptibility testing on clinical specimens from submitters pre-approved by our TB program. The lab also performs TB rule in/out testing on mycobacterium isolates from laboratories lacking this capability. However, speciation on non-tuberculosis (NTM) isolates will not be performed.

For pre-approval for submitting specimens to the ISDH TB Lab contact the ISDH TB/Refugee Division at 317.233.7434.

Labs shall report at least weekly AND shall submit all isolates of *Mycobacterium tuberculosis* to the ISDH Lab for further evaluation within 5 business days of isolation.

Refer to Section 2 – Surveillance AND the ***Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories*** for detailed information on reporting requirements.

Laboratory Contact Information

Indiana State Department of Health Laboratories
550 W 16th Street, Suite B
Indianapolis, IN 46202
CLIA 15D0662599

TELEPHONE NUMBERS

Operator	**317.921.5500**
After Hours Emergency	**317.233.1327**
State Emergency Operations Center	**800.669.7362**

Clinical Collection Kits and Shipping Containers **317.921.5875**
Containers@isdh.in.gov

LABORATORY SENIOR STAFF

Judith Lovchik,PhD, D(ABMM) **317.921.5808**
Laboratory Director jlovchik@isdh.in.gov

Lixia Liu, PhD, MP (ASCP) **317.921.5832**
Clinical Microbiology/Emergency Preparedness Division Director lliu@isdh.in.gov

LABORATORY OUTREACH CONTACTS

State Laboratory Training Information **317.921.5890**
Shelley Matheson - State Laboratory Training Coordinator smatheson@isdh.in.gov

State Laboratory Program Information **317.921.5556**
Ellie Carter - Laboratory Program Advisor ecarter@isdh.in.gov

MICROBIOLOGY

Reference Microbiology **317.921.5860**
Jon Radosevic – Supervisor jradosev@isdh.in.gov

Serology/TB **317.921.5858**
Jessica Gentry – Supervisor jgentry@isdh.in.gov

TB Laboratory **317.921.5892**

MICROBIOLOGY FAX NUMBERS: **317.927.7806** or **317.927.7804**

REFERENCE: http://www.in.gov/isdh/224423.htm

Available Laboratory Tests

INDIANA:

Submission of primary clinical specimens for Mycobacterium tuberculosis complex and isolates for Mycobacterium tuberculosis (page 11.5).

Primary clinical specimens for Mycobacterium tuberculosis complex

Specimen Requirements: Preferred specimen Sputum. Volume/Amount required >1-10 ml.

Sampling Materials: Collection/Preservation: Collect specimen in a clean, sterile, one-use, plastic, disposable container.

Procedural Notes:
1. Be sure to properly label the specimen tube with at least the patient's name and date of collection.
2. Check the expiration date on the tube to ensure product is acceptable and will continue to be acceptable once received at the ISDH laboratory.
3. Diagnostic Information: Collect sputum early in the morning before the patient eats or drinks. It should be raised from the lungs, not saliva, and deposited directly into the furnished plastic container. Identification is performed by HPLC testing, and drug susceptibility testing is performed on newly identified patients.

ISDH Provided Collection Kit: 6A
Category B UN3373, Triple contained in accordance with federal shipping regulations for infectious agents. 2-8C or ambient transport to the laboratory either by courier or by overnight mailing.

4. Complete a request form for each specimen with the following information:
a. Name, birth date, and sex of patient
b. Specimen type and date of specimen collection
c. Submitting clinic information-clinic name, address, phone number, fax number, contact name and email address (if available).

Shipping Requirements: In accordance with federal shipping regulations for diagnostic specimens.
Specimen Handling: Body fluids handled with standard precautions.
1. Tighten the specimen collection container or culture tube cap. Best to wrap tape around cap to help seal from any leakage.
2. Label clearly on the outside of the container/tube with the patient name and collection date.
3. Wrap this primary container with absorbent material. Place the primary container and absorbent material in the inner mailing container and tighten the cap securely.
4. The completed request form may be then wrapped around the sealed inner container and together enclosed securely in an outer shipping container clearly labeled with the senders name/address and recipients name/address.
5. Do not send culture isolates on Petri plates when submitting by mail.

Reporting: Test turn around 6 weeks. Reporting measure mail or fax.

Test Referral: Cultures identified as Mycobacterium tuberculosis will be sent to Michigan Department of Community Health for genotyping.

Required Request Form: Mycobacteriology Test Request form at
http://www.in.gov/icpr/webfile/formsdiv/13701.pdf

Reference: ISDH Available Tests, http://www.in.gov/isdh/24634.htm

SEE Algorithm for how to proceed after Initial Lab Result from ISDH Laboratory page 11.6

INDIANA:

Isolates for Mycobacterium tuberculosis

Specimen Requirements: Pure culture. Preferred specimen: Pure culture on LJ slant / appropriate media. Volume/amount required > one specimen per patient. Collection/Preservation: Organism must be kept at appropriate atmosphere conditions.

Sampling Materials: Specimen Handling: Infectious agent, biosafety level 3.

Procedural Notes:
1. Be sure to properly label the specimen tube with at least the patient's name and date of collection.
2. Check the expiration date on the tube to ensure product is acceptable and will continue to be acceptable once received at the ISDH laboratory.
3. Diagnostic Information: Confirmation testing is performed by HPLC testing, and drug susceptibility testing is performed on newly identified patients.
4. Complete a request form for each specimen with the following information:

a. Name, birth date, and sex of patient
b. Specimen type and date of specimen collection
c. Submitting clinic information-clinic name, address, phone number, fax number, contact name and email address (if available).

Shipping Instructions: In accordance with federal shipping regulations for infectious agents.

A. If an isolate is a known member of the Mycobacterium tuberculosis complex, or if highly suspected to be in this group, ship as a Category A Infectious Agent.
B. Complete the Shippers Declaration for Dangerous Goods documentation and include this information with the shipping address information on the outside of package.

1. Tighten the specimen collection container or culture tube cap. Best to wrap tape around cap to help seal from any leakage.
2. Label clearly on the outside of the container/tube with the patient name and collection date.
3. Wrap this primary container with absorbent material. Place the primary container and absorbent material in the inner mailing container and tighten the cap securely.
4. The completed request form may be then wrapped around the sealed inner container and together enclosed securely in an outer shipping container clearly labeled with the senders name/address and recipients name/address.
5. Do not send culture isolates on Petri plates when submitting by mail.
   Transport Temperature: Ambient

Reporting: Test turnaround time 1-7 days. Reporting measure mail or fax.

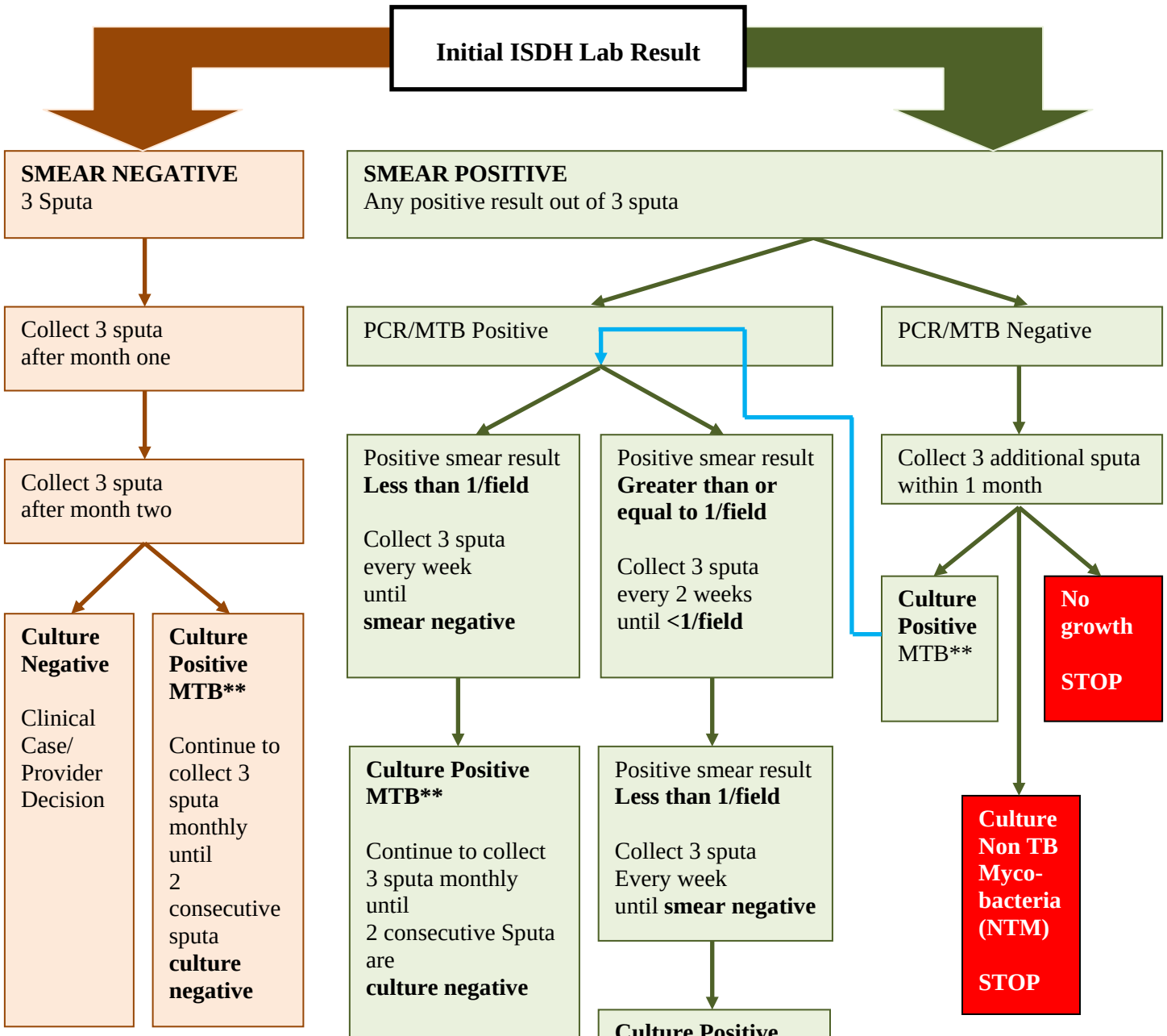
Test Referral: Cultures identified as Mycobacterium tuberculosis will be sent to Michigan Department of Community Health for genotyping.

Required Request Form: Mycobacteriology Test Request form at
http://www.in.gov/icpr/webfile/formsdiv/13701.pdf

Reference: ISDH Available Tests, http://www.in.gov/isdh/24634.htm

SEE Algorithm for how to proceed after Initial Lab Result from ISDH Laboratory page 11.6

TUBERCULOSIS SPUTUM COLLECTION*



*If you need to submit specimens outside of these parameters, please contact the ISDH TB/Refugee Division at 317.233.7434 or your TB Regional Nurse Consultant (contact information in Section 1 – Introduction).
**TB sputum collection algorithm does not apply to Non Tuberculous Mycobacteria (NTM)

Effective Date 11/16/2009

The laboratory tests listed below in Table 1 are available where noted.

When performing tests for the diagnosis of mycobacterial infection, acid-fast bacilli smear and culture **and** sensitivities must be ordered.

At the ISDH Laboratories, culture identification is automatically performed on any isolate, and first-line susceptibility testing is automatically performed on all initial *M. tb* complex isolates, and positive *M. tb* cultures are sent to the national genotyping laboratory.

All laboratories, other than ISDH Laboratories, are to send all positive *M. tb* culture(s) to the ISDH Microbiology Laboratory for referral to the national genotyping laboratory.

Table 1: AVAILABLE LABORATORY TESTS

Test	Laboratory	Turnaround Time
Diagnosis		
Acid-fast (AFB) bacilli smear	*ISDH Public Health Laboratory*	Within 24 hours from receipt in laboratory[4]
Culture	*ISDH Public Health Laboratory*	Mycobacterial growth detection by culture within 14 days from date of specimen collection Identification of cultured mycobacteria within 21 days from date of specimen collection[5,6]
Drug susceptibility	*ISDH Public Health Laboratory*	Within 30 days from date of specimen collection[7,8]
Nucleic acid amplification (NAA) test	*ISDH Public Health Laboratory*	Within 2 days from date of specimen collection[9,10]
Epidemiologic Monitoring		
Genotyping	Cultures identified as *M.tb* will be sent (by the ISDH Laboratory) to the Michigan Department of Community Health for genotyping	*1 – 7 days*

Specimen Collection

Sputum is phlegm from deep in the lungs. The important characteristics needed in sputum specimens are freshness and actual sputum, rather than saliva. An early morning specimen is best; therefore, when collecting a set of three sputum specimens, at least one of them should be an early morning specimen.

To isolate mycobacteria from clinical materials successfully, handle specimens carefully after collection. For optimal results, collect specimens in clean, sterile containers and keep them in refrigerated conditions to inhibit the growth of contaminating organisms, since most specimens will contain bacteria other than mycobacteria.[11]

INDIANA

Sputum should be collected for:

- all patients (adults and older children) suspected of having pulmonary or laryngeal TB
- patients diagnosed with extra-pulmonary TB who are coughing or who have an abnormal CXR
- patients being evaluated for a positive TST who are coughing or who have an abnormal CXR

Collect samples 8 - 24 hours apart

- prior to the initiation of TB medication; then
- collect 3 specimens every 2 weeks until the smear results are less than or equal to 1 per field ;
- once smear results are less than or equal to 1 per field, collect 3 sputum specimens every week until the smear results are negative;
- continue to collect 3 sputa monthly until 2 consecutive sputa results are culture negative

Specimens should be collected in either a well-ventilated area or a sputum collection booth. Health care workers collecting the sputum, regardless of the setting, must observe the appropriate infection control precautions. Collection of early morning specimens is preferred because of the overnight accumulation of secretions; however, you may collect specimens at any time for patients who have a deep cough that is readily productive.

Collect sputum in a sterile container for processing and examination. Sputum should be collected under direct observation, at least for the first time. This is to insure that the patient is being properly coached and is giving a good coughing effort, as well as insuring that uncooperative patients are producing their own sputum for examination.

Instruct the patient to breathe deeply and cough from deep down in the lungs. Instruct them that saliva and upper respiratory secretions are not sputum and are not acceptable specimens. For patients unable to bring up sputum, deep coughing may be induced by inhalation of an aerosol of warm, hypertonic (5%-15%) saline.

Remember the following: For public health planning purposes, the degree of infectiousness is determined by the presence of AFB in the *sputum*, not in bronchial washings, tracheal aspirates, or other pulmonary specimens. The presence of AFB in specimens other than sputum is not particularly useful for determining how soon and to what extent a contact investigation needs to be done. Therefore, regardless of the decision to perform a bronchoscopy or other diagnostic procedure, sputum should still be collected at the time the diagnostic evaluation is performed.

Reference: ISDH **Guidelines for Sputum Collection**, http://www.in.gov/isdh/19693.htm
Mycobacteriology Test Request form: http://www.in.gov/icpr/webfile/formsdiv/13701.pdf

During procedures in which aerosols may be produced, use appropriate respiratory protection and environmental controls. For more information, refer to the CDC's "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings, 2005" (*MMWR* 2005;54[No. RR-17]) at this hyperlink: http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

Table 2: SPECIMEN COLLECTION METHODS AND TYPES FOR PULMONARY TUBERCULOSIS

Pulmonary Tuberculosis Collection Method	Specimen Type
Spontaneous sputum collection occurs when the patient can cough up sputum without extra assistance.	▪ 5–10 ml of sputum from deep in the lung
Induced sputum collection should be considered if a patient needs assistance in bringing up sputum.*	▪ 5–10 ml of sputum from deep in the lung
Gastric aspirates (must be neutralized) can be submitted for the diagnosis of pulmonary tuberculosis (TB) in young children who cannot produce sputum.	▪ 50 ml of gastric contents
Bronchoscopy can be used in the following situations: ▪ If a patient cannot produce sputum by the above three methods[12] or ▪ If a patient has a substantial risk of drug-resistant TB and has initial routine studies that are negative[13] or ▪ In a patient in whom there is suspicion of endobroncheal TB[14] or ▪ If a variety of clinical specimens for the diagnosis of pulmonary TB or other possible diseases need to be obtained	▪ Bronchial washings ▪ Bronchoalveolar lavage ▪ Transbronchial biopsy
* It is important to specify if the sputum is induced or not, because induced sputum is "more watery" and appears to be just saliva. Some laboratories may throw out induced sputum and report it as an inadequate specimen.	

Refer to Table 3 for collection methods and specimen types for extrapulmonary TB.

Table 3: SPECIMEN COLLECTION METHODS AND TYPES FOR EXTRAPULMONARY TUBERCULOSIS

Extrapulmonary Tuberculosis		
Collection Method	Specimen Type	
Extrapulmonary specimen collection from tissue and other body fluids can be submitted for the diagnosis of extrapulmonary tuberculosis.	Examples of tissues (biopsy)* ▪ Lymph node ▪ Pleural ▪ Bone/joint ▪ Kidney ▪ Peritoneal ▪ Pericardial	Examples of fluids ▪ Pleural ▪ Cerebrospinal ▪ Blood ▪ Urine ▪ Synovial ▪ Peritoneal ▪ Pericardial
* Do not place specimens in formalin.		

How to Perform Spontaneous Sputum Collection at a Healthcare Facility

1. Collect the specimen in a specialized room or booth designed for cough-inducing procedures (negative air pressure).
2. Instruct the patient on how to collect the sputum sample.
   a. Put a mark at the 5 ml level on the sputum tube (if not already marked) to show the patient the minimum amount of sputum needed. (Most laboratories consider 5 to 10 ml an adequate amount.)
   b. Review with the patient how to collect sputum.
3. Make sure the specimen container and laboratory requisition are filled out completely before shipping.
   a. On the specimen container, record the patient name and the date and time of collection.
   b. Use the ISDH Laboratories **Mycobacteriology Test Request** form available at http://www.in.gov/icpr/webfile/formsdiv/13701.pdf

It is especially important to **specify if the sputum is induced or not,** because an induced sputum generally is “more watery” and appears to be just saliva. Some private laboratories may throw out the specimen and report it as an “inadequate specimen.”

4. Make sure the specimen and laboratory requisition are packaged into appropriate shipping containers, per laboratory instructions.
5. If possible, send the specimen on the day it is collected. If this is not possible, refrigerate the specimen until it is sent on the next day.
6. Do not delay sending specimens in order to send all three on the same day.
7. Use the most rapid transport to the laboratory: UPS (or other service that is specified by the ISDH TB Control program)

Make every effort to submit specimens to the laboratory within 24 hours of collection. Normal flora can overgrow any mycobacteria in the specimen and make it unusable. If specimens cannot be submitted within 24 hours, keep in mind that most laboratories will not run a specimen over five days old. Know how long it takes the specimen to get to the laboratory from the time it leaves your hands, and submit specimens accordingly.

How to Direct a Patient to Perform Spontaneous Sputum Collection at Home

If a patient will be collecting sputum specimens at home, provide the following guidance.

1. Put a mark at the 5 ml level on the sputum tubes (if not already marked) to show the patient the minimum amount of sputum needed. (Most laboratories consider 5 to 10 ml an adequate amount.)
2. Review with the patient how to collect sputum.
3. Make arrangements for a healthcare worker to pick up the specimen or for the patient, a family member, or a friend to drop off the specimen.

Induced Sputum Collection at a Healthcare Facility

If the patient cannot produce sputum spontaneously, then make arrangements for an induced sputum to be collected at a facility. Facilities where sputum can be collected include the respiratory therapy department of a local hospital, TB clinic, or laboratory. Facilities must have appropriate respiratory protection, environmental controls, and policies and procedures in place to prevent transmission of TB to other persons.

For further information regarding infection control during sputum collection refer to Section 16 – Infection Control, AND

CDC. "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings, 2005" (*MMWR* 2005;54[No. RR-17]) at this hyperlink: http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

How to Collect Gastric Aspirates

The following are basic guidelines for collecting gastric aspirates:

- Collect the specimen after the patient has fasted for eight to ten hours and, preferably, while the patient is still in bed.
- Collect a specimen daily for three days.

For additional information on how to collect a gastric aspirate and prepare the specimen for transport, see the guide and Francis J. Curry National TB Center's online video *Pediatric TB: A Guide to the Gastric Aspirate (GA) Procedure* at this hyperlink: http://www.nationaltbcenter.ucsf.edu/products/product_details.cfm?productID=ONL-06.

Bronchoscopy or Collection of Extrapulmonary Specimens

If TB staff are consulting with physicians before the specimens are collected, the physician should be reminded to send part of the specimen (not in formalin) to the microbiology laboratory for acid-fast bacilli (AFB) smear and culture, in addition to any other tests or pathology examinations the physician plans to obtain. In addition, a post-bronchoscopy sputum specimen should be sent for AFB smear and culture. Bronchoscopy and Extrapulmonary specimens will be collected by the physician and facility performing the procedure.

Specimen Shipment

INDIANA

Shipping Infectious Substances: Only trained personnel may package and ship infectious substances. International Air Transport Association regulations require recurrent training every 24 months and Department of Transportation regulations require recurrent training every 36 months. Shipping regulations change on an annual basis, and it is the shipper's responsibility to be knowledgeable about current regulations.

Please contact the Training Office if you are interested in shipping training. http://www.in.gov/isdh/22426.htm

Shipping Containers: Can be ordered from the ISDH Laboratories, for telephone and email

For transportation, there are two primary categories of infectious substances, and each category has different packaging requirements to provide increased levels of protection against leaks and contamination.

Pure mycobacterial cultures (or culture isolates suspected of being mycobacteria) are Category A Infectious Substances and can be transported only by a medical courier or shipped by private carrier as dangerous goods. Category A Infectious Substances cannot be mailed through the United States Postal Service (USPS).

Category B Infectious Substances (raw diagnostic specimens, such as sputum, blood, or tissue) can be mailed through the USPS, shipped by private carrier (e.g., Federal Express, Airborne Express, etc.), or transported by a medical courier.

Shipment of dangerous goods by the USPS is regulated by the United States Department of Transportation. Specific shipping instructions from the Centers for Disease Control and Prevention (CDC) can be found in the publication by the United States Department of Health and Human Services (DHHS) *Public Health Mycobacteriology: A Guide for the Level III Laboratory.* Packaging and shipment of specimens by USPS should meet the following regulations:

- Office of Health and Safety. "Interstate Shipment of Etiologic Agents" [Web page] (Centers for Disease Control and Prevention Website): http://www.cdc.gov/od/ohs/biosfty/shipregs.htm
- United States Postal Service. Domestic Mail Manual: http://pe.usps.com/text/dmm300/dmm300_landing.htm
- United States Postal Service. 135 Mailable Dangerous Goods (International Mail Manual): http://pe.usps.gov/text/Imm/immc1_013.htm

- National Archives and Records Administration. Code of Federal Regulations Title 39—United States Postal Service (U.S. Government Printing Office Website): http://www.access.gpo.gov/nara/cfr/waisidx_03/39cfrv1_03.html
- National Archives and Records Administration. Code of Federal Regulations Title 49—Transportation (U.S. Government Printing Office Website): http://www.access.gpo.gov/nara/cfr/waisidx_04/49cfrv2_04.html
- U.S. Department of Labor, Occupational Safety & Health Administration (OSHA):Occupational Health and Safety Standards 29 CFR 1910.1030: http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910 [15]

For shipments by private carriers, follow International Air Transportation Association (IATA) instructions. *Mycobacterium tuberculosis* pure cultures are defined as infectious substances/etiologic agents when shipped by private carrier and must be shipped in packaging approved by the United Nations (UN), according to IATA Packing Instruction 602: http://oregonstate.edu/vetmed/pdf/iata_602.pdf . Diagnostic specimens are defined as human or animal specimens, including excreta, secreta, blood and its components, tissue, tissue fluids, and cultures of nontuberculous mycobacteria being transported for diagnostic or investigational purposes. Diagnostic specimens must be packaged according to IATA Packing Instruction 650: http://www.iata.org/NR/ContentConnector/CS2000/SiteInterface/sites/whatwedo/cargo/file/PI650.pdf .[16]

Resources and References

Detailed descriptions of recommended laboratory tests; recommendations for their correct use; and methods for collecting, handling, and transporting specimens have been published. For more information on laboratory testing for tuberculosis (TB), see the following:

- ATS, CDC, IDSA. "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America" (*MMWR* 2005;54[No. RR-12]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5412.pdf .
- ATS, CDC, IDSA. "Diagnostic Standards and Classification of Tuberculosis in Adults and Children" (*Am J Respir Crit Care Med* 2000;161[4 Pt 1]). Available at: http://www.cdc.gov/tb/pubs/PDF/1376.pdf .
- National Committee for Clinical Laboratory Standards. *Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard* [Document no. M24-A] (Wayne, PA; 2003).

References

[1] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):18.

[2] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):19.

[3] Association of Public Health Laboratories. *The Future of TB Laboratory Services: A framework for integration/collaboration/leadership* [Association of Public Health Laboratories Web site]. 2004. Available at: http://www.aphl.org/docs/TBTaskForcewcover.pdf . Accessed November 1, 2006.

[4] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No RR-12):19; and Tenover, R., et al. The resurgence of tuberculosis: is your laboratory ready? *Journal of Clinical Microbiology*1993:767–770.

[5] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No RR-12):19; and Tenover, R., et al. The resurgence of tuberculosis: is your laboratory ready? *Journal of Clinical Microbiology* 1993:767–770.

[6] CDC. National plan for reliable tuberculosis laboratory services using a systems approach - recommendations from CDC and the Association of Public Health Laboratories Task Force on Tuberculosis Laboratory Services. *MMWR* 2005;54(No. RR-6):2.

[7] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No RR-12):19; and Tenover, R., et al. The resurgence of tuberculosis: is your laboratory ready? *Journal of Clinical Microbiology* 1993:767–770.

[8] CDC. National plan for reliable tuberculosis laboratory services using a systems approach - recommendations from CDC and the Association of Public Health Laboratories Task Force on Tuberculosis Laboratory Services. *MMWR* 2005;54(No. RR-6):2.

[9] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No RR-12):19; and Tenover, R., et al. The resurgence of tuberculosis: is your laboratory ready? *Journal of Clinical Microbiology* 1993:767–770.

[10] CDC. National plan for reliable tuberculosis laboratory services using a systems approach - recommendations from CDC and the Association of Public Health Laboratories Task Force on Tuberculosis Laboratory Services. *MMWR* 2005;54(No. RR-6):3.

[11] ATS, CDC, IDSA. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med*. 2000;161:1376–1395.

[12] Iseman, MD. *A Clinician's Guide to Tuberculosis, 2000*. 1st ed. Philadelphia, PA: Williams & Wilkins; 2000:135–136.

[13] Iseman, MD. *A Clinician's Guide to Tuberculosis, 2000*. 1st ed. Philadelphia, PA: Williams & Wilkins; 2000:135–136.

[14] Iseman, MD. *A Clinician's Guide to Tuberculosis, 2000*. 1st ed. Philadelphia, PA: Williams & Wilkins; 2000:135–136.

[15] National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory.* Denver, CO; March 2005:2.
[16] National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory.* Denver, CO; March 2005:5–7.

Patient Education

CONTENTS

Introduction

Purpose

Use this section to do the following:

- Determine what information to cover in education sessions.
- Educate patients about tuberculosis (TB).
- Educate patients about latent TB infection (LTBI).
- Identify which forms to use to document education efforts.

An important part in helping patients to adhere to treatment plans is to educate them about TB. This means talking to them about what causes TB, the way TB is spread, how TB is diagnosed, and their specific treatment plan.[1] Patients cannot be expected to adhere to treatment recommendations if they are not educated about TB and how it is treated, and patients who understand these concepts are more likely to adhere to treatment.

Patients with LTBI need to understand that they are infected with TB, that they may have specific risks for progressing to TB disease, and that they can take precautions to protect themselves, their family, and their friends. Patients with TB disease need to understand the seriousness of the disease and why it is important to adhere to treatment. In order to prevent relapse and drug resistance, clinicians must prescribe an adequate regimen and make sure that patients adhere to treatment.[2] To ensure completion of treatment, the public health department should thoroughly educate the patient, monitor the patient's adherence, and use incentives and enablers.[3,4,5]

General Guidelines

Table 1: GUIDELINES FOR THE EDUCATIONAL PROCESS

When Educating Tuberculosis Patients	
Do	**Don't**
▪ Find out what patients know and believe about tuberculosis (TB). Reinforce and provide correct TB information, and disabuse them of any misconceptions. ▪ Use good skills to interview and influence patients and to problem solve. ▪ Go through the educational material with patients. Use language appropriate to their level of understanding. If necessary, use an interpreter.	▪ Flood patients with information about TB and its effects without allowing them to participate in the discussion. ▪ Hand out pamphlets and brochures to patients without going through the materials with them.

Language and Comprehension Barriers

In the initial assessment, assess for and address any potential language and comprehension barriers.

1. Assess the patient's ability to speak and understand instructions, including potential barriers, such as not speaking English as primary language, deafness, speech deficit, or learning disability.
2. Assess literacy in the patient's primary language.
3. Provide all instructions and communications in the appropriate language.
4. Use interpreters, visuals, or other educational methods to promote understanding.
5. Provide educational materials appropriate to the patient's language and reading level.
6. Make referrals to an appropriate service and notify it of any language and comprehension concerns.

Education Topics

During the initial assessment, directly observed therapy (DOT/Videophone DOT) appointments, and monthly monitoring, educate the patient as needed on the topics that follow.

INDIANA

In Indiana the TB Case Manager has the primary responsibility for case management, which includes assuring that each TB patient is thoroughly educated about TB and its treatment. In some instances, this specific responsibility may be delegated to other trained persons, but the TB Case Manager still oversees the outcome.

Reference: ISDH, ***Tuberculosis Case Management***, 1999

For more information on case management activities, see Section 9 - Case Management.

Medical Diagnosis

In the initial interviews with the patient, provide information about TB and the patient's treatment plan. During DOT appointments and monthly monitoring, confirm and reinforce the patient's understanding of these topics.

1. Discuss the difference between TB disease and TB infection.
2. Explain the signs and symptoms of TB, how TB is transmitted, prevention activities, and treatment.
3. Explain that TB is both treatable and preventable.
4. Explain the importance of completion of treatment.
5. Discuss diagnostic procedures used to make diagnosis of TB, such as CXR, sputum microscopy, and TST. Stress the importance of testing and follow-up.
6. Discuss the current medical treatment plan and rationale. It is suggested that the patient sign a treatment plan and a DOT agreement (patient agreement forms can help to explain a process and/or collaboration and serve as a behavioral contract between the patient and the agency/provider).

   A sample DOT agreement can be viewed at New York City Department of Health and Mental Hygiene Tuberculosis Clinical Policies and Protocols, 4th Edition page 240, http://home2.nyc.gov/html/doh/downloads/pdf/tb/tb-protocol.pdf.

7. Explain the need for regular medical monitoring and follow-up during the disease process. Discuss how treatment will be monitored (i.e., sputum, blood tests, vision screening, weight check, etc.). Encourage the patient to be an active participant in care and treatment.
8. Discuss the roles of the patient (engage in treatment), the LDH (case management, monitoring, contact tracing, and supervision of treatment), and the private provider (treatment and monitoring). Encourage the patient to contact the case manager for issues and problems that arise during treatment.
9. Explain the risk of treatment relapse or failure and the need to complete treatment to prevent relapse.
10. Explain the signs and symptoms of possible relapse or failure and encourage the patient to report them immediately to the case manager.

Contact Investigation

When a contact investigation is necessary, educate the index patient about the process and confidentiality.

1. Discuss the contact investigation process.
2. Reinforce the confidentiality of investigation, but warn the patient of the potential for contacts to guess the patient's identity.

Isolation

If isolation is necessary, educate the patient about how to take proper precautions.

1. Explain isolation precautions and restrictions, if appropriate. It is suggested that the patient sign an isolation agreement (patient agreement forms can help to explain a process and/or collaboration and serve as a behavioral contract between the patient and the agency/provider).

   A sample Home Isolation Agreement can be viewed at New York City Department of Health and Mental Hygiene Tuberculosis Clinical Policies and Protocols, 4th Edition page 246, http://home2.nyc.gov/html/doh/downloads/pdf/tb/tb-protocol.pdf.

2. Explain the behavior changes needed for infection control. Discuss permitted and prohibited activities, limiting and excluding visitors, covering the mouth and nose when coughing and sneezing, and using a mask.
3. Explain the home environmental changes needed for infection control. Discuss ventilation and sunlight. Explain how to dispose of items soiled with potentially infectious material.
4. Discuss the requirements for release from isolation. Advise the patient that clearance is contingent upon clinical condition and continued compliance with the treatment regimen.

Side Effects and Adverse Reactions

Educate all patients on antituberculosis medications about the medications' potential side effects and adverse reactions.

1. Explain the names, dosages, and rationale for the drug treatment plan as well as the importance of treatment.
2. Explain the common side effects and methods to improve symptoms.
3. Explain signs and symptoms of drug toxicity.
4. Direct the patient on what actions to take if side effects or signs and symptoms of toxicity appear.
5. Explain potential effects of alcohol and/or drug use on treatment and the increased risk for side effects and toxicity.

Adherence

If a patient has the potential for not adhering to the treatment plan, educate the patient about the importance of treatment, the patient's responsibilities during treatment, and the consequences of nonadherence.

1. Explain the drug names and dosages and the rationale for the drug treatment plan.
2. Explain the importance of treatment and follow-up for active TB.
3. Explain the importance of regular monitoring visits.
4. Discuss the treatment plan and expectations. Advise the patient on the patient's responsibilities and expected behavior regarding treatment compliance and follow-up activities. As noted in **Medical Diagnosis**, it is suggested that the patient sign a treatment plan and DOT agreement (patient agreement forms can help to explain a process and/or collaboration and serve as a behavioral contract between the patient and the agency/provider).
5. Advise the patient on laws regarding TB disease and isolation.

Resources: Patient Education Materials

INDIANA

The ISDH Refugee Health Program has information available on their website including statistics, maps, and immigrant and refugee numbers by state.

Under the topic of "Culturally Competent Care", there are documents related to health issues for specific Indiana refugee populations (Burmese/Karen, Hmong, Somali, and Liberian).

Under the topic of "Health Education Materials for Refugees" there are documents related to health information for multiple languages, health information translations, select patient information in Asian Languages only, etc.

There is also a section on "Refugee Mental Health".

NOTE: There is some duplication of information in the Patient Education Materials list that follows.

To view or print these documents visit: http://www.in.gov/isdh/24668.htm

CDC

TOPICS:

- Get the facts about TB disease
- What you need to know about TB infection
- What you need to know about the TB skin test
- Protect your family and friends from TB
- Take steps to control TB When you have HIV

LANGUAGES:

The Spanish/English and Tagalog/English versions available only in *print* format. View at: http://www.cdc.gov/tb/publications/CulturalMaterials.htm

TO ORDER:
http://wwwn.cdc.gov/pubs/tb.aspx

New Jersey Medical School Global Tuberculosis Institute

TOPICS:

- Get the facts about TB disease
- What you need to know about TB infection
- What you need to know about the TB skin test
- Protect your family and friends from TB
- Take steps to control TB When you have HIV ***(same info as CDC above)***
- What Parents Need to Know About Tuberculosis (TB) Infection In Children (*online only – may be printed and distributed as is, or modified to include specific contact information for your clinic).*
- What You Need To Know About Tuberculosis Flipbook *(can be printed or ordered)*

LANGUAGES:

Spanish/English, Tagalog/English

TO ORDER (or print)**:**

www.umdnj.edu/globaltb/products/patienteduc.htm

See also: Regional Training and Medical Consultations Centers (RTMCCs)

Minnesota Department of Health

TOPICS:

- The TB Skin Test (Mantoux)
- Treatment for Latent TB Infection
- Instructions for Collecting Sputum for TB
- Active TB Disease
- TB Contact Investigations

LANGUAGES:

Amharic, Arabic, Bosnian/Croatian/Serbian, English, Hmong, Karen, Khmer (Cambodian), Laotian, Oromo, Russian, Somali, Spanish, Tibetan, Vietnamese

A variety of **Videotapes and DVDs** are also available.

TO ORDER:

www.health.state.mn.us/divs/idepc/diseases/tb/brochures.html

San Francisco City and County Tuberculosis Control Section

TOPICS:

- What is Tuberculosis:
- I Have Been Exposed to Tuberculosis (TB): What do I do now?
- What do I need to know about Latent Tuberculosis Infection?
- What do I need to know about Active TB Disease?

LANGUAGES:

Chinese, English, Russian, Spanish, Tagalog, Vietnamese

TO ORDER:

http://www.sfdph.org/dph/comupg/oservices/medSvs/TB/ click on “Public Information brochures”

Ethno Med

TOPICS:

- Teaching Tool for Somalis about TB and INH Treatment of LTBI (and audio recording)
- Tuberculosis: Get the Facts **-** A CDC pamphlet
- Pills to Prevent TB - A Washington State Dept. of Health publication
- Tuberculosis: Medications for the Treatment of Tuberculosis - Published by the Seattle-King County Department of Health
- The Tuberculosis Skin Test **-** Published by Harborview Medical Center and Ethnomed

LANGUAGES:

Somali

TO ORDER:

http://ethnomed.org/ethnomed/patient_ed/somali/index.html

Southeastern National Tuberculosis Center

TOPICS:

Country Guides (to help you employ a more culturally relativistic approach when working with foreign-born individuals and includes epidemiology, common misperceptions and beliefs about TB and HIV/AIDS, general practices and cultural courtesies for:

Brazil, Cambodia, Dominican Republic, Ecuador, el Salvador, Guatemala, Haiti, Honduras, India, Indonesia, Mexico, Myanmar (formerly Burma), Philippines, Somalia, Vietnam

TO ORDER:

http://sntc.medicine.ufl.edu/Products.aspx

See also: Regional Training and Medical Consultations Centers (RTMCCs)

FRANCIS J. CURRY NATIONAL TUBERCULOSIS CENTER

TOPICS:

- TB: have you been tested?

LANGUAGES:

English, Chinese, Spanish

http://nationaltbcenter.ucsf.edu/abouttb/patient_education.cfm

See also: Regional Training and Medical Consultations Centers (RTMCCs)

VIRGINIA HEALTH DEPARTMENT

TOPICS:

- Do I Need a TB Skin Test?
- Just the Facts About BCG and TB
- Stop TB Infection Before it Makes You Sick
- TB and HIV: A Dangerous Partnership
- TB Disease: You Need treatment to Make You Well
- What You Should Know About Taking Tuberculosis Medicines
- What is a TB Skin Test?
-

LANGUAGES:

Albanian, Amharic, Arabic, Chinese (Traditional Script), English, Farsi, Hindi, Indonesian, Korean, Russian, Somali, Spanish, Tagalog, Tigrinya, Urdu, Vietnamese

TO ORDER:

http://www.vdh.virginia.gov/epidemiology/DiseasePrevention/Programs/Tuberculosis/Patients/

Regional Training and Medical Consultation Centers'

Francis J. Curry National Tuberculosis Center
http://www.nationaltbcenter.edu

Heartland National Tuberculosis Center
http://www.heartlandntbc.org/

Southeastern National Tuberculosis Center
http://sntc.medicine.ufl.edu/

New Jersey Medical School Global Tuberculosis Institute
http://www.umdnj.edu/globaltb/home.htm

REGIONAL TB TRAINING AND EDUCATION PRODUCTS webpage:

http://sntc.medicine.ufl.edu/rtmccproducts.aspx

References

[1] CDC. Module 4: treatment of TB infection and disease. *Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]. 1999:12. Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules1-5/Default.htm . Accessed November 1, 2006.

[2] CDC. Module 4: treatment of TB infection and disease. *Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]. 1999:12. Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules1-5/Default.htm . Accessed November 1, 2006.

[3] CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49(No. RR-6):38–39.

[4] National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. *Tuberculosis Nursing: A Comprehensive Guide to Patient Care.* Atlanta, GA: 1997:64, 69, 74.

[5] CDC. Module 9: patient adherence to tuberculosis treatment. *Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]. 1999:9–11. Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/Default.htm . Accessed November 1, 2006.

Confidentiality and Legal Aspects of Patient Management

CONTENTS

Introduction

Purpose

Use this section to do the following:

- Determine what information and which records should be treated with confidentiality.
- Identify state policy for maintaining patient confidentiality.
- Take measures to ensure TB patients' confidentiality.
- Determine when it is permissible to share information for public health reasons.

The protection of private patient information is commonly referred to as confidentiality. Confidentiality involves the protection of information revealed during patient–healthcare worker encounters, including all written or electronic records of these encounters. Confidentiality is an essential issue in many different aspects of TB control. Healthcare workers need to be aware of confidentiality issues that are relevant to patient–healthcare worker encounters, as well as to the collection, management, and sharing of information gathered on TB patients.[1]

Policy

Healthcare workers should keep patient information in confidence and divulge it only with the legal consent of the patient, except as otherwise allowed by law.[2]

For roles and responsibilities, refer to the "Roles, Responsibilities, and Contact Information" topic in Section 1 - Introduction.

State Laws and Regulations

Confidentiality of medical and epidemiological information

All information obtained under the *Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories*, whether from patient records or other sources, is confidential.

Release shall be made of the medical records concerning an individual to:

1. The individual
2. A person authorized in writing by the individual to receive the medical records
3. A Coroner (under IC 36-2-14-21)

An individual may voluntarily disclose information about the individual's communicable disease.

Reference: Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories, 410 IAC 1-2/3-50, Effective November 30, 2009, Indiana State Department of Health, http://www.in.gov/isdh/files/comm_dis_rule(1).pdf

Indiana Program Standards

Protecting Patient Confidentiality

Confidentiality involves the protection of information revealed during encounters with the patient, including verbal, written, and electronic communication. Health care workers must keep patient information in confidence and only divulge it with the written consent of the patient, except as required by state laws and administrative rules. IC-16-41-8-1 deals with confidentiality as it pertains to patients with communicable diseases, and specifies under what conditions personal health information may be disclosed, as well as release of information to third parties. The privacy and confidentiality provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliment Indiana laws concerning the reporting of communicable diseases.

Confidentiality is a very important issue in TB control because the diagnosis of TB disease is potentially damaging for patients. Tuberculosis carries a stigma that is very pervasive among many cultures. A diagnosis of TB can result in the unfair loss of a job, rejection by friends, family, and co-workers, and even eviction from housing. There are some specific issues that require special attention by health care workers who work with TB patients:

- The patient has certain rights that must be respected. These include rights to privacy, autonomy, to be given information, and to give or withhold authorization of disclosures.

- State and local health departments have a responsibility to protect the public's health using certain effective TB control strategies.

- It is sometimes necessary to override certain patient rights in the interest of protecting the health and safety of the public (e.g., an uncooperative, infectious patient may be quarantined until he or she is no longer infectious; reporting by hospitals, physicians, and laboratories; sharing information with other TB control programs to ensure completion of treatment).

- Great care must be taken to ensure that patient rights, especially the right to privacy, are protected so that the patient-health care worker relationship is not compromised.

  Reference: Tuberculosis Control and Prevention Manual, 2003, ISDH

Health Insurance Portability and Accountability Act (HIPAA)

Confidentiality of patient information has long been a requirement in the healthcare field and now has its own set of regulations, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The regulations protect the privacy of certain individually identifiable health data, referred to as protected health information (PHI). PHI is individually identifiable health information that is transmitted or maintained in any form or medium (e.g., electronic, paper, or oral).

Centers for Disease Control and Prevention Guidance on HIPAA

The Centers for Disease Control and Prevention (CDC) published the report "HIPAA Privacy Rule and Public Health: Guidance from CDC and the US Department of Health and Human Services" (*MMWR* 2003;52 [S-2]:1–12 at this hyperlink: http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm), to provide guidance in implementing the HIPAA requirements. In this report, the US Department of Health and Human Services (DHHS) recognized the importance of sharing PHI to accomplish essential public health objectives and to meet certain other societal needs (e.g., administration of justice and law enforcement).

Covered entities—which are health plans, healthcare clearinghouses, and healthcare providers who transmit health information in electronic form in connection with certain transactions—are permitted by the Privacy Rule to do the following:

- Share PHI for specified public health purposes. For example, covered entities may disclose PHI, without individual authorization, to a public health authority legally authorized to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability.
- Make disclosures that are required by other laws, including laws that require disclosures for public health purposes.[3]

INDIANA

The Indiana State Department of Health (ISDH) is a hybrid entity under HIPAA. This means that while the primary purpose of the ISDH is not to be a health care provider, health care plan or health care clearinghouse some of its components meet those definitions. The programs that can be classified as meeting HIPAA definitions of covered entities must comply with HIPAA's regulations.

The ISDH HIPAA covered programs are:

- Breast and Cervical Cancer Program
- Children's Special Health Care Services Program
- Hemophilia Program
- HIV Medical Services Program
- Genomics/Newborn Screening Program

At the current time, other ISDH programs are not required to comply with HIPAA, although other laws may apply to them and require protection of individuals' information.

For more information refer to ISDH Office of Technology and Compliance (OTC)

http://www.in.gov/isdh/23500.htm

National Guidelines

The following guidelines for protecting tuberculosis (TB) patients' confidentiality are adapted from the National Tuberculosis Controllers Association's (NTCA's) and Centers for Disease Control and Prevention's (CDC's) "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC" (*MMWR* 2005;54[No. RR-15]).

Table 1: HOW TO PROTECT CONFIDENTIALITY

Conducting All Activities	▪ Make every attempt to ensure patient confidentiality.
Training	▪ Participate in training on maintaining confidentiality and obtaining informed consent in accordance with local/state laws.
Interviewing Patients	▪ Interview the tuberculosis (TB) patient in a private setting. ▪ Inform the patient about confidentiality rights. ▪ Explain to a human immunodeficiency virus (HIV)-infected patient that HIV status will be kept confidential. ▪ Consult with the patient to identify boundaries for confidentiality and obtain oral consent for any breaches in confidentiality. ▪ If written consent is required, present the consent form to the patient in an appropriate manner and retain a copy in the patient's medical record. If consent is refused, the TB program should develop a plan of action.
Conducting Site Investigations	▪ Plan site investigation procedures in advance of any visit, in consultation with and with the consent of the index patient, if possible. ▪ Obtain agreement to maintain confidentiality from any site personnel who receive information about the identity of the index patient.
Communicating with the Press	▪ Maintain confidentiality in communications with the press.

Indiana
Legal Aspects of Patient Management

The legal responsibility for ensuring the treatment and case management of TB patients rests with the local health department (IC 16-20-1-21). Treating the patient with tuberculosis not only cures the patient, but protects the public as well. The vast majority of TB patients are cooperative and adhere to their treatment regimens. It is when patients do not adhere to the prescribed plan that they become a threat to the health and safety of the public. Indiana has laws that enable local health officials to ensure that the non-adherent patient complies with the applicable communicable disease control laws.

When there is sufficient and compelling evidence that an individual may have infectious TB and poses a danger to public health, the local health officer may ask the patient to consent to testing. This testing could be a skin test, collecting sputum samples, or receiving a chest x-ray. If the patient refuses to undergo a medical examination, the local health officer may compel the testing or examination only upon a court order based on clear and convincing evidence of a serious and present health threat to others posed by the patient (see IC 16-41-6-2).

If a patient is *suspected* of having TB, you must have sufficient evidence to support your suspicion that the person has TB disease. Such evidence may include

- TB symptoms in a person who is a recent close contact to a case of infectious TB
- TB disease or infection in a child, in which case the family members and other adults in contact with the child need to be evaluated
- TB symptoms accompanied by a sputum smear that is positive for acid-fast bacilli

Before imposing restrictions, there must be either (1) a laboratory or a clinical diagnosis of pulmonary or laryngeal tuberculosis, or (2) a reasonable suspicion that an individual has tuberculosis in an infectious state. Disease in an extra-pulmonary site (except the larynx) without concurrent pulmonary involvement would not be considered a threat to the public

General Guidelines

- Maintain a patient file with all relevant information supporting a confirmed or suspected diagnosis of TB.
- Assess the situation first-hand, which means a visit to the home or wherever the patient may be found.

- Educate the patient and assure understanding. Be sure to repeat and reinforce your message so the patient knows what is expected.

- Attempt to gain voluntary cooperation from the patient. Use the educational approach, offer incentives or enablers, and document all interventions and patient responses.

- When a problem arises in managing a TB case or suspect, the public health nurse should advise the health officer of the patient's recalcitrant behavior and document all interventions. The key to managing any patient is documentation. Remember, if it's not documented, it wasn't done.

- If it is determined that the patient is not adhering to the treatment plan, or is refusing to cooperate, legal intervention may be necessary to assure compliance. After informing the health officer and county attorney of the situation, call the ISDH TB Control Program to report the difficulty and that more aggressive actions are being considered.

Documenting Non-compliant or Recalcitrant Behavior

Once the patient is shown to have suspected or confirmed TB, the next step is to demonstrate that the patient poses a health risk to the general public. Non-compliance means that the patient is not following the prescribed treatment plan for whatever reasons. Recalcitrance means that the patient knowingly refuses to follow the treatment plan and knowingly puts others at risk. If either situation occurs, the local health department must act to prevent further disease transmission.

A person with TB is a serious and present danger when:

- They refuse to take their medication;

- They engage repeatedly in behavior that has been demonstrated to transmit TB or that indicates a careless disregard for the safety others;

- The patient's past behavior or statements indicate that he or she will engage in behavior that transmits TB to others; or

- The patient fails to follow voluntary health restrictions to prevent disease transmission.

The public health nurse must thoroughly document all non-compliant or recalcitrant patient behavior. Key items in this summary should include, but not be limited to:

- Documentation of tuberculin skin test results, if done, as well as chest x-ray and laboratory results, including drug susceptibility tests;
- Clinical observations and symptoms;
- Contacts or evidence of transmission to contacts;
- Place and type of employment, if applicable;
- Treatment records, home visit records, and clinical progress notes, and a record of physicians' appointments;
- Social and family history;
- Interventions attempted by the nurse;
- Patient response to nurse's attempts to seek compliance;
- Anything else that demonstrates non-compliance with medical treatment.

Carefully document any statements the patient makes that would cause you to think he or she is not going to follow your instructions. For example, if the patient refused to produce a sputum sample or misses a physician's appointment, document it. Your nursing notes should also include non-verbal responses, such as a door being slammed in your face, missed appointments, or any other actions that could serve as indicators of future behavior. Document patient use of alcohol and drugs. These notes reflect the facts as you observed them, not hearsay from a third party. *In the event that court action is necessary, your nursing notes may become part of the legal record.*

This documentation must show that the patient poses a serious and present danger to health, has engaged in behavior that transmits TB to others, or that his or her behavior or past statements indicate that the patient will engage in such behavior.

Local Health Agreement

Before imposing formal health restrictions, the local health officer must meet with the patient and request that he or she voluntarily comply with the health restrictions. This request can be fairly informal at this point. An example would be a verbal or written agreement with the local health officer that the patient agrees to comply with the specified restrictions. Be sure to document this event if done verbally. Verbal agreements should be a routine part of the case management process.

A written health agreement can be issued by the county without state intervention. This agreement should be signed and dated by both the patient (and/or guardian) and the nurse or

health officer. A sample health agreement is available at the end of this section.

A health agreement is used to ensure that the patient has a basic understanding of TB, as well as the importance of adhering to the prescribed treatment plan. Often, this step is sufficient to gain cooperation and compliance since the patient agrees to very specific instructions. This step is also less intimidating than other measures.

Local Health Officer's Order

The local health officer is authorized by state statutes to take whatever measures are necessary to control the spread of communicable diseases. Examples of situations for which a local health officer may issue an order to the patient include:

- The patient refuses to remain isolated until he or she is no longer infectious;
- Refusal to take medications as directed;
- Refusal to provide follow-up sputum specimens;
- Refusal of a TB suspect to comply with a medical evaluation;
- Refusal to complete a course of curative therapy.

If a patient refuses to comply with the order, the local health officer may ask the court to impose any necessary restrictions on the patient, such as home isolation. The local health officer may undertake these initiatives without state intervention.

A health directive (see IC 16-18-2-166) is a written statement that is presented to a patient by a designated health official (see IC 16-18-2-93) outlining the restrictive measures that the patient must comply with. The local health officer may be appointed as the designated health official by either the State Health Commissioner or the designated Assistant Commissioner.

The health directive may provide for actions that the local health officer is authorized to perform independently. However, the difference between a health directive and an order issued independently by the local health officer is that the health directive may also provide for emergency detention without a hearing. Both the designated health official and the patient sign this document and copies are provided to both parties. If the patient refuses to sign the document, make a note such as "patient refuses to sign," and the nurse and health officer sign as a witness to that refusal.

The county attorney manages the legal portion of this process based on the facts provided by the health department. The ISDH Office of Legal Affairs is available for consultation. Other county officials are notified as necessary.

A health directive would be appropriate if the patient is a flight risk, has refused orders from the local health officer, or has violated court orders.

Filing a Petition for Restrictions

This part of the process involves the court system, and is used when other measures have failed. The local health official presents the case to a judge who decides if any restrictions should be imposed on the patient. The county attorney will be the best guide through the steps.

A petition for restrictions is based upon a showing of clear and convincing ($\geq$ 50% or more likely) evidence of the serious and present health threat posed by the individual. IC 16-41-6-2

The county attorney files an order to keep the pleadings confidential. This order ensures that the patient's name is not used in public documents.

Based on the relative threat the patient poses to public health, local health officials will determine the least restrictive, but medically necessary measures to take. Some specific medical procedures are listed in 410 IAC 1-2.3 (the Indiana Communicable Disease Reporting Rule). Some of the restrictions that the court may order include, but are not limited to, the following:

- Undergo medically necessary tests;
- Complete a course of curative therapy;
- Submit to directly observed therapy;
- Notify or appear before designated health officials to verify health status;
- Cease and desist conduct which constitutes a health threat to others;
- Be monitored by an electronic monitoring device;
- Live part-time or full-time in a supervised setting;
- Comply with any combination of the remedies considered appropriate by the local health officer.

A petition for restrictions may also require detention or isolation. If the situation warrants these measures, they may be included in this petition as well as the location where the action is to occur and for how long. Detention or isolation usually occurs in a hospital, the home, or other suitable facility.

When a petition for restrictions is filed, the patient is entitled to be represented by an attorney. A hearing date will be set and the patient will receive notice of the hearing. If the patient and the designated health official come to an agreement, the order may be carried out without going to a hearing. If there is no agreement, the matter will proceed to a hearing. The hearing shall be closed to the public at the patient's request.

The public health nurse or local health officer may be asked to testify in court or to sign an affidavit. The information needed will depend on the seriousness of the case and what restrictions are being requested. Nursing notes and other clinical documentation may be required as evidence in court and will be subject to examination along with possible testimony. The county attorney will advise you.

Imposition of Restrictions

- The judge issues an order and the order is carried out.
- If so ordered, the county health official may be required to submit progress notes to the court, especially in cases where detention has been ordered. Follow the court order very carefully.
- If the patient is already under detention and leaves the premises, the county sheriff is notified and requested to arrest and return the patient to the place of detention. Ensure that law enforcement personnel are aware of the need to wear personal respiratory protection.
- If the patient meets the criteria for release as specified in the court order, he or she is released from the restrictions by the judge. Release from restrictions may require a hearing or an attorney's report to the judge.
- The public health nurse continues to assess the patient's compliance with the court order and medical instructions. The goal is to render the patient non-infectious and continue medications until the disease is cured.
- Continue to document how the patient responds to the restrictions as well as clinical response.

Emergency Detention

IC 16-41-9-1.5 provides for emergency detention should it become necessary to act very quickly in order to protect the health of the public. Imposing emergency detention is an extremely serious matter. In these instances, the court may order a health officer or law enforcement officer to take a person into custody and transport the person to an appropriate facility for observation, testing, diagnosis, care, treatment, and if necessary, temporary detention. TB detention generally occurs in a hospital equipped to manage infectious TB patients. It is recommended that when imposing emergency detention requires a designated health official to be appointed by ISDH.

Emergency detention is not the first step in disease control, but at times it may become necessary. You should always seek voluntary compliance from the patient before resorting to more aggressive legal measures. This option is exercised only in cases of emergency when all other measures have failed. Because an emergency order is of very short duration by law, a regular petition for restrictions must also be filed at the time of the emergency petition or shortly thereafter.

If emergency detention is to be the course of action, or if it appears that this option should be made available to the county officials, you must:

- Contact the State TB Control Program prior to acting. You will be required to submit written documentation to support emergency detention.
- ISDH will provide a letter signed by the state health commissioner's authorized agent that designates the local health officer as the designated health official.
- A court order may be issued in an *ex parte* proceeding on an affidavit of the designated health official. An *ex parte* proceeding means that the patient does not have to be present at the hearing and the health official states what restrictions are necessary to protect public health. The affidavit must set forth the specific facts on which the order is sought and must be served on the patient immediately upon apprehension or detention.
- Once the court determines that there is probable cause of serious danger to the health of others and a risk of irreparable harm from the patient's actions, the court can immediately order any restrictions necessary to protect the public health.
- The patient must have a court hearing within 72 hours to determine if the detention should continue. These 72 hours exclude Saturdays, Sundays, and legal holidays.

- The patient must be served notice of the hearing at least 24 hours before the hearing is to occur. The notice must specify the time, date, and place of hearing; the grounds and underlying facts on which the emergency hold is sought; the patient's right to appear at the hearing and cross-examine witnesses; and the patient's right to court appointed counsel.

- The court may order a continuance of the emergency detention if the court finds that the patient poses an imminent health threat to others if released. However, the emergency hold may not continue longer than five (5) days unless a petition is filed to implement medically necessary procedures to protect the public's health. The hearing for the petition for restrictions must occur not more than five (5) days after the filing of the petition, excluding Saturdays, Sundays, and legal holidays.

Examples when emergency detention would be used include:

- A patient who is a flight risk

- Failure to comply with court-ordered restrictions

- If an infectious patient cannot be effectively isolated at home

- Threats of violence directed towards the health care personnel

Costs of Care or Treatment

If the patient cannot pay the full cost of care and other sources of public or private funding are not available, the county is responsible for the cost under IC 16-41-9-13. Even if the care, treatment, and/or detention is court-ordered, the county is still responsible for costs incurred.

Examples of Legal Documents

The next three pages contain examples of one Health Agreement and 2 Health Directives:

(YOUR LETTERHEAD)

TUBERCULOSIS HEALTH AGREEMENT

I, _____(Patient's Name)_____, Date of Birth ___(Patient's DOB)___understand the serious consequences of not taking medication for tuberculosis (TB), including the spread of disease to my family, friends, and others around me. I realize that if I take only some of my medicine, the germs may become resistant and difficult, if not impossible, to treat. Therefore, I do hereby agree to be present at the ___(Local Health Department's Name or Doctor's Name)___ clinic for my appointments and to take this medication:

DAILY _____ TWICE WEEKLY _____ THREE TIMES WEEKLY

ON: MONDAY ___ TUESDAY ___ WEDNESDAY ___ THURSDAY ___ FRIDAY

FOR: _____ WEEKS _____ MONTHS

I will notify this health department if I plan to move so that a referral can be made to the new county and state so that treatment can continue without interruption. If I move unexpectedly, I will go immediately to the health department in that city or state with my medicine bottles for refills.

Although it may not be possible to avoid all side effects, I will talk to the nurse if I think I may be having problems with the medication so that we can work together. Failure to comply with the health agreement may result in legal action.

Patient's (or Authorized Adult's) Signature Date

Name of Authorized Adult If Not Patient Relationship

Address, City, State, Zip Code

Public Health Nurse's Name Date

SAMPLE 1

CONFIDENTIAL

HEALTH DIRECTIVE

TO: ADDRESS:

RECEIVED:

You have been diagnosed with a dangerous communicable disease (as defined under 410 IAC 1-2.3-479d) namely pulmonary tuberculosis. Pursuant to the authority under IC 16-41-7-4 and 16-20-1-21, I am the public health authority in this matter.

Therefore, under the foregoing authority, I hereby issue this health directive and order you to:

1. Remain in isolation (in your hospital room with the door closed) until you no longer pose a public health risk. You must follow your physician's orders regarding treatment and medication. If for any reasons your medical condition requires you to leave your room, you must wear a mask covering your mouth and nose and be escorted by hospital personnel.

2. Upon release from the hospital, you must submit sputum samples as directed by your physician or personnel of the Public Health Division. You must take your medications as ordered by your physician under the direct supervision of the Public Health Nurse.

Your failure to comply with this Directive will result in court action against you.

Issued this _____ day of the month of _____ of the year _____.

_____ _____

Local Health Director Signature Patient Signature

Sample 2

CONFIDENTIAL

HEALTH DIRECTIVE

TO: ADDRESS:

RECEIVED:

You are hereby notified that it has been determined that your behavior is a serious and present danger to the health of others in that you have reportedly engaged in behavior that has been demonstrated epidemiologically to transmit a dangerous communicable disease, *Mycobacterium tuberculosis* (410 IAC 1-2.3-47(d)) and have engaged in behavior that indicates a careless disregard for the transmission of the disease to others. Further, your past behavior and statements indicate an imminent danger that you will continue to engage in behavior that transmits *Mycobacterium tuberculosis* to others.

Pursuant to the authority given under IC 16-41-7-4 and IC 16-20-1-21_____, this Health Directive is hereby issued:

You are prohibited from any act known epidemiologically to spread *Mycobacterium tuberculosis* and are hereby required to comply with the following directions:

1. Collecting three early morning sputum specimens on _____, _____, and _____ using containers provided by the County Health Department each morning as directed. You must also collect further specimens as required by the County Health Department.

2. Taking your medications as ordered by your physician under the direct supervision of the public health nurse.

3. Protecting others by remaining isolated in your residence; covering your mouth and nose when communicating with any person or when you leave your residence for necessary medical care.

If sputum specimens are positive, you must comply with your physician's recommendations to be admitted to the hospital at the time recommended and arranged by the physician.

Your failure or refusal to comply with this Health Directive may result in the filing of a court action under IC 16-41-9-1.5 to obtain an order for restrictions upon you to protect the public's health.

Issued this _____ day of the month of _____ of the year _____.

_____ _____

Local Health Authority Signature Patient Signature

Resources and References

Resources

- CDC. “HIPAA Privacy Rule and Public Health: Guidance from CDC and the US Department of Health and Human Services” (*MMWR* 2003;52[S-2]). Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm .
- CDC. Module 7: “Confidentiality in Tuberculosis Control” (*Self-Study Modules on Tuberculosis.* Division of Tuberculosis Elimination Web site; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/Default.htm .
- United States Department of Health and Human Services. “Health Insurance Portability and Accountability Act of 1996.” (Public Law 104-191 Web site). Available at: http://www.aspe.hhs.gov/admnsimp/pl104191.htm .
- United States Department of Health and Human Services. “Office for Civil Rights—HIPAA” [Office for Civil Rights Web site]. Available at: http://www.hhs.gov/ocr/hipaa/ .

References

[1] CDC. Module 7: confidentiality in tuberculosis control. *Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]. 1999:4. Available at: http://www.cdc.gov/tb/pubs/ssmodules/default.htm . Accessed November 1, 2006.

[2] CDC. Module 7: confidentiality in tuberculosis control. *Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]. 1999:4. Available at: http://www.cdc.gov/tb/pubs/ssmodules/default.htm . Accessed November 1, 2006.

[3] CDC. HIPAA privacy rule and public health: guidance from CDC and the US Department of Health and Human Services. *MMWR* 2003;52(S-2):1.

Interjurisdictional Transfer Notifications

CONTENTS

Introduction

Purpose

Use this section to do the following:

- Notify public health agency staff in another jurisdiction (within the state, between states, and out of the country) that a person is moving (or has moved) to their jurisdiction who is any of the following:
  - Verified or suspected case of tuberculosis (TB) disease
  - High-priority contact to a smear-positive Class 3 or Class 5 pulmonary case, contact to a smear-negative Class 3 pulmonary case, or contact to a highly suspect Class 5 pulmonary case
  - Documented convertor who has initiated treatment for latent tuberculosis infection (LTBI)
  - Class 2 or Class 4 patient who has initiated treatment for LTBI
  - Close associate to a Class 3 index case with clinical presentation consistent with recently acquired disease in a source-case investigation or close associate to a child with LTBI in a source-case investigation
- Follow up on notifications.

Making sure that TB patients complete their evaluation and treatment is a critical element of TB control.[1] Some patients receiving treatment for TB disease in the United States move from one jurisdiction to another before completing treatment. Notifying the receiving local and/or state jurisdiction of a patient's impending arrival will prevent care from being interrupted and improve treatment outcome.

The term *transfer notification* refers to a referral or follow-up report. Before the patient moves, or as soon as it becomes apparent that a patient has moved, the referring jurisdiction provides a referral to the receiving jurisdiction. After the patient has moved, the receiving jurisdiction then provides the referring jurisdiction with a follow-up report.

Policy

The ISDH TB/Refugee Health Division is responsible for coordination of transfer notifications between states, between other local jurisdictions within the state, and out of the country. The local public health jurisdiction should notify the state public health department when a patient plans or requests to transfer to another jurisdiction. The receiving and referring jurisdictions should stay in communication until final dispensation of the patient is known.

For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in Section 1 - Introduction.

State Laws and Regulations

Refer to Section 1 – Introduction for Indiana Laws and Rules that mandate infection control policy and/or procedures and Section 2 – Surveillance for Reporting requirements.

When to Initiate a Notification

For definitions of the "TB Classification System" see Section 5: Diagnosis of TB Disease.

Table 1: TRANSFER NOTIFICATIONS AND FOLLOW-UPS[2]

Referral Type	When to Initiate	Notes
Verified and suspected cases of TB disease	When notified that a Class 3 or 5 patient is moving or has moved from the area for 30 days or more	May also initiate to coordinate directly observed therapy (DOT) while patient is visiting another area.
Contacts	After identifying a: ▪ Medium or High-priority contact to a smear-positive Class 3 or Class 5 pulmonary case ▪ Contact to a smear-negative Class 3 pulmonary case ▪ Contact to a highly suspect Class 5 pulmonary case	Send individual referrals for each contact.
LTBI converters	When notified that a documented convertor who has initiated treatment is moving or has moved from the area for 30 days or more	
LTBI reactors	When notified that a Class 2 or 4 patient who has initiated treatment is moving or has moved from the area for 30 days or more	
Source case investigation for TB disease	After identifying a close associate to a Class 3 index case with clinical presentation consistent with recently acquired disease	Use primarily for associates to children under 5 years of age with TB disease. A younger age cut-off may be advisable because the focus would be on more recent transmission.[3]
Source case investigation for LTBI	After identifying a close associate to a child with LTBI	Use primarily for associates to children under 2 years of age with LTBI.[4]
Final disposition	When final status and/or outcome is known	

Source: NTCA. *Interjurisdictional Tuberculosis (TB) Notification—National Tuberculosis Controllers Association Recommendations.* Smyrna, GA: March 2002:1–5.

How to Issue a Notification

Inside the United States (within the state or between states), see Table 2: **Referrals in the United States**.

Outside the United States, contact the ISDH TB/Refugee Health Division at 317.233.7434. The Indiana TB Program will work with the country impacted to report the case.

Transfers Inside the United States

Transfers Within Indiana: Refer to the middle column in Table 2: **Referrals in the United States.**

Transfers Between States: An interjurisdictional tuberculosis (TB) notification system has been set up by the National Tuberculosis Controllers Association (NTCA) to facilitate and standardize communication between states. This system will enhance continuity and completeness of care and improve outcome evaluation of verified cases.[5] Refer to the right column in Table 2: **Referrals in the United States.**

NTCA's **Interjurisdictional Tuberculosis Notification** form is available online at: http://tbcontrollers.org/docs/IJ_Form_Page1.pdf .

NTCA's **Interjurisdictional TB Notification Follow-Up** form is available online at: http://tbcontrollers.org/docs/IJ_Form_Page2_Followup.pdf .

For more information on completing the NTCA forms, see the NTCA's *Interjurisdictional Tuberculosis (TB) Notification—National Tuberculosis Controllers Association Recommendations* (NTCA Web site; March 2002) at this hyperlink: http://tbcontrollers.org/docs/IJ_Instructions.pdf .

TABLE 2: Referrals in the United States[6]

Action	Transfers Within Indiana	Transfers Between States
Make a referral	The LHD from which the patient is transferring should do the following as soon as possible: ▪ Call the ISDH TB/Refugee Health Division at 317.233.7434 ▪ Copy the updated, complete LHD file on the patient, and send the copy to the jurisdiction receiving the patient ▪ Call the patient's private provider and arrange for transfer of the patient's records to the receiving physician (or to the jurisdiction receiving the patient if no receiving physician is designated)	The LHD from which the patient is transferring should do the following as soon as possible: ▪ Call ISDH TB/Refugee Health Division at 317.233.7434 ▪ Fill out the NTCA's "Interjurisdictional Tuberculosis Notification" form* ▪ Mail and fax the form to the ISDH TB/Refugee Health Division Fax: 317.233.7747 If more information is needed, ISDH will request it from the LHD from which the patient is transferring
Provide records to the patient	The LHD from which the patient is transferring should provide the patient a copy of the treatment records	The LHD from which the patient is transferring should provide the patient a copy of the referral and treatment records
Follow up on referrals	Not necessary	Complete the NTCA's Interjurisdictional TB Follow-Up form†

* The NTCA's Interjurisdictional Tuberculosis Notification form is available online at this hyperlink: http://tbcontrollers.org/docs/IJ_Form_Page1.pdf .

† NTCA's Interjurisdictional TB Notification Follow-Up form is available online at this hyperlink: http://tbcontrollers.org/docs/IJ_Form_Page2_Followup.pdf .

Source: NTCA. *Interjurisdictional Tuberculosis (TB) Notification–National Tuberculosis Controllers Association Recommendations.* Smyrna, GA: March 2002:1–5.

Transfers Outside the United States

Centers for Disease Control and Prevention International Notifications

The ISDH TB/Refugee Health Division is responsible for international transfer notifications. The LHD should notify the ISDH TB/Refugee Health Division when a patient moves outside the country. ISDH will complete the required CDC **International Tuberculosis Notification** form and forward to the proper authorities.

References

[1] CDC. International notification of tuberculosis cases [Division of Tuberculosis Elimination Web site]. Available at: http://www.cdc.gov/tb/pubs/International/default.htm . Accessed June 30, 2008.

[2] NTCA. *Interjurisdictional Resources* [NTCA Web site]. Available at: http://tbcontrollers.org/?p=9 . Accessed June 30, 2008.

[3] CDC, NTCA. Guidelines for the investigation of contacts of persons with infectious tuberculosis; recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):31.

[4] CDC, NTCA. Guidelines for the investigation of contacts of persons with infectious tuberculosis; recommendations from the National Tuberculosis Controllers Association and CDC, and guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15):31.

[5] NTCA. *Interjurisdictional Resources* [NTCA Web site]. Available at: http://tbcontrollers.org/?p=9 . Accessed June 30, 2008.

[6] NTCA. *Interjurisdictional Resources* [NTCA Web site]. Available at: http://tbcontrollers.org/?p=9 . Accessed June 30, 2008.

Infection Control

CONTENTS

Introduction

Purpose

Use this section to understand and follow national and state guidelines to do the following:

- Review the hierarchy of infection control measures and know where to go for further information.
- Alert local public health staff to the basic differences between masks and respirators.
- Estimate patients' infectiousness and determine when patients are noninfectious.
- Determine when to isolate patients, when to discharge them from hospitals, and when to permit them to return to work, school, or other settings.
- Review how to implement infection control measures in residential settings, patient care facilities, and transportation vehicles.
- Consult with facilities that are implementing infection control measures, including two-step testing.

In the 2005 guidelines, "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, Centers for Disease Control and Prevention, and the Infectious Diseases Society of America," one of the recommended strategies to achieve the goal of reducing tuberculosis (TB) morbidity and mortality is the identification of settings in which a high risk exists for transmission of *Mycobacterium tuberculosis* and application of effective infection control measures.[1]

As TB continues to decline in most areas of the United States, it is crucial that state and local public health agencies provide facilities with epidemiologic data on TB, as well as education and guidance in developing effective TB infection control programs.

Infection control measures are fundamental to reducing the spread of communicable diseases such as TB. Transmission of *M. tuberculosis* from person to person can occur in many locations, such as home, work, school, and healthcare facilities.[2] It is impossible to prevent all exposure; however, the goal is to reduce the amount of transmission.

Each agency's or facility's program should include a hierarchy of administrative controls, environmental controls, and personal respiratory protection. Because each patient care setting and patient's home is different, each program will incorporate a different combination of control activities. The extent to which each agency or facility implements its control activities is based on the results of its risk assessment. In areas where TB rates are lower, the TB risk is lower, and this should affect which elements of the TB infection control plan are utilized.

Policy

For infection control, state and local health department need to address TB control in these three areas:

1. Healthcare facilities, where persons with infectious TB disease would seek care[3,4]
2. Congregate settings and residential facilities, whose residents are at increased risk for TB disease[5,6]
3. The patient's home

To accomplish TB control activities, each local public healthcare agency should do the following:

1. Familiarize staff with the current CDC infection control guidelines for healthcare providers and settings.
2. Develop an infection control program for the TB staff that addresses these issues:
   - **a.** Assignment of responsibility for the program
   - **b.** Risk assessment
   - **c.** Persons (if any) who need baseline testing, including TB screening and counseling
   - **d.** Education and training
   - **e.** Case management (if direct patient care is provided)

   Designate a staff person to guide facilities that may need to set up TB infection control programs.

For roles and responsibilities, refer to the "Roles, Responsibilities, and Contact Information" topic in Section 1 - Introduction.

Effective TB Infection Control Programs

The CDC's "**Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005"** provide guidance for effective Infection Control Programs in Health-Care Settings. Setting is defined as any physical or organizational relationship where health-care workers share air space with person's with TB disease **or** might be in contact with clinical specimens. Setting is further divided into the three categories of:

- **Inpatient** – patient rooms, emergency departments, intensive care units, surgical suites, laboratories, laboratory procedure areas, bronchoscopy suites, sputum induction or inhalation therapy rooms, autopsy suites, and embalming rooms.

- **Outpatient** - TB treatment facilities, medical offices, ambulatory-care settings dialysis units, and dental-care settings

- **Nontraditional** - emergency medical service, medical settings in correctional facilities (e.g., prisons, jails, and detention centers) home-based health-care and outreach settings, long term care settings (e.g., hospices, skilled nursing facilities), and homeless shelters. Other settings might include cafeterias, general stores, kitchens, laundry areas, maintenance shops, pharmacies, and law enforcement settings.

A facility can fall into 1 or more of these setting types.

The **CDC "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005", is available at:** http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf. The Errata is available at: http://198.246.98.21/tb/publications/reportsarticles/mmwr/Errata09-25-06.pdf.

NOTE: In the remainder of this section this guideline will be referenced as: CDC, Guidelines… for Health-Care Settings, hyperlink on page 16.4.

State Laws and Regulations

Refer to Section 1 – Introduction for Indiana Laws and Rules that mandate infection control policy and/or procedures and Section 2 – Surveillance for Reporting requirements.

Hierarchy of Infection Control Measures

There are three types of infection control measures. The first are administrative controls, which are primarily aimed at early identification, isolation, and appropriate treatment of infectious patients. The second are environmental controls, which focus on preventing the spread and reducing the concentration of infectious droplet nuclei in the air.[7] The third is personal respiratory protection, which may provide additional protection for healthcare workers in high-risk settings such as isolation rooms and cough-inducing or aerosol-generating suites.

The activities described below are more relevant to infection control in healthcare or residential facilities. Home settings are discussed separately in the "Residential Settings" topic in this section.

Administrative Controls

Administrative control measures are the first of three levels of measures designed to reduce the risk of tuberculosis (TB) transmission. Administrative controls are the first level of infection control because they include a variety of activities to identify, isolate, and appropriately treat persons suspected of having TB disease.

An effective TB infection control plan contains measures for reducing the spread of TB that are appropriate to the risk of a particular setting.[8] Every healthcare setting should have a written TB infection control plan that is part of an overall infection control program.[9] **The specifics of the plan depend on whether a setting will provide health care or will triage and transfer patients with suspected or confirmed TB disease**. A written TB infection control plan helps to ensure prompt detection, airborne precautions, and treatment of persons who have suspected or confirmed TB disease.[10]

- **In TB infection control programs for settings in which patients with suspected or confirmed TB disease are expected to be encountered,** develop a written TB infection control plan that outlines a protocol for the prompt recognition and initiation of airborne precautions for persons with suspected or confirmed TB disease, and update it annually.[11]
- **In TB infection control program for settings in which patients with suspected or confirmed TB disease are NOT expected to be encountered,** develop a written TB infection control plan that outlines a protocol for the prompt recognition and transfer of persons who have suspected or confirmed TB disease to another healthcare setting. The plan should indicate procedures to follow to separate persons with suspected or confirmed infectious TB disease from other persons in the setting until the time of transfer. If your policy is to transfer patients you need documentation of intent from your collaborating facility. Evaluate the plan annually, if possible, to ensure that the setting remains one in which persons who have suspected or confirmed TB disease are not encountered and that they are promptly transferred.[12]

Administrative Activities[13]

Key activities to reduce the risk of transmission include the following:

1. **Assign responsibility** to a specific person for designing, implementing, evaluating, and maintaining a TB infection control program for that facility.
2. **Conduct a risk assessment.** The risk level of a particular facility is the basis for determining all other activities and will result in each facility having a plan designed specifically for that facility (a model worksheet is available in the **CDC, Guidelines… for Health-Care Settings, hyperlink on page 16.4).** Risk Classification, part of the Risk Assessment, determines the need for, and frequency of a TB Screening Program.
3. **Develop, implement, and enforce policies and procedures** to ensure early identification, evaluation, and treatment of infectious cases of TB.
4. **Provide prompt triage** and management in the outpatient setting of patients who may have infectious TB.
5. **Promptly initiate and maintain TB isolation** for persons who may have infectious TB and are admitted to an inpatient setting.
6. **Plan effectively for the discharge** of the patient, coordinating between the LHD and the healthcare provider.
7. **Implement environmental controls.** Develop, install, maintain, and evaluate the effectiveness of engineering controls.
8. **Implement a Respiratory Protection Program.** Develop, initiate, install, maintain, and evaluate the effectiveness of the respiratory protection program. The Respiratory Protection Program is a written set of site specific procedures outlining: who is in charge of the program, when respirators should be used, how respirators will be inspected, cleaned and stored (if they are not disposable), where records will be stored and how the program will be evaluated. Two critical elements of a respiratory protection program are how and when employees will be trained and when employees will be fit tested to be sure that the respiratory is right for them. The procedure for fit testing, a model framework for a medical questionnaire and a questionnaire for users of N95 respirators can be found in the **CDC, Guidelines… for Health-Care Settings, hyperlink on page 16.4).**
9. **Implement precautions for cough-inducing procedures.** Develop, implement, and enforce policies and procedures to ensure adequate precautions when performing cough-inducing procedures.
10. **Educate and train healthcare workers** about TB.
11. **Counsel and screen healthcare workers.** Develop and implement counseling and TB Screening Program (i.e., Mantoux skin test or IGRA) for healthcare workers.
12. **Promptly evaluate possible episodes of TB transmission.** Including testing and evaluation of healthcare workers who have been or may have been exposed to TB.
13. **Coordinate activities** between the state and LHDs.

Environmental Controls

TB is caused by an organism called *Mycobacterium tuberculosis.* When a person with infectious TB disease coughs or sneezes, tiny particles called droplet nuclei that contain *M. tuberculosis* are expelled into the air.[14] Environmental controls are used to prevent the spread and reduce the concentration of infectious droplet nuclei.[15] Each facility should use different combinations of environmental controls, based on the results of its risk assessment.

It is important to note, however, that without strong administrative controls, environmental controls are ineffective because cases would not be recognized or managed appropriately.

Table 1 describes the three main types of environmental controls.

Table 1: THREE TYPES OF ENVIRONMENTAL CONTROLS

Most Effective Control	Ventilation ▪ Controls direction of air flow to prevent contamination of air in areas surrounding a person with infectious tuberculosis (TB) ▪ Dilutes and removes contaminated air ▪ Exhausts contaminated air to the outside Local exhaust ventilation (external hoods, booths, tents) is used to capture contaminates before they are dispersed (like during cough inducing procedures). General Ventilation processes are designed to reduce the concentration in room air (e.g., negative pressure rooms).
Supplementary Controls	High-efficiency particulate air (HEPA) filtration ▪ Cleans the air of infectious droplet nuclei. HEPA units claim a minimum removal efficiency of 99.97% of particles 0.3 microns in size. HEPA filtration can be used to supplement other ventilation measures. Used alone, it doesn't provide outside air and doesn't provide negative pressure to the room. Ultraviolet germicidal irradiation (UVGI) ▪ Kills or inactivates TB bacilli in the air There are some short-term safety issues with UV radiation. It can cause redness of the skin and conjunctivitis (reversible conditions) and it is classified as probably carcinogenic to humans – so it's very important that is is designed and installed to ensure safe exposure levels for occupants.

Personal Respiratory Protection

Although administrative controls and environmental controls are most effective in controlling the spread of TB, they do not eliminate the risk of transmission entirely. Personal respiratory protection, the third level of infection control, is also used in higher-risk settings.

The purpose of a respirator is to reduce exposure by filtering out TB bacilli from room air before the air is breathed into a person's lungs. Respirators used for TB control should be approved for TB use by the National Institute for Occupational Safety and Health (NIOSH).

It is recommended that healthcare provider staff and visitors use personal respiratory protective equipment in settings that may be at higher risk for TB transmission, such as the following:

- Rooms where infectious TB patients are being isolated
- Areas where cough-inducing or aerosol-generating procedures are performed
- Other areas, which should be identified in the facility's risk assessment, where administrative and environmental controls are not likely to protect persons from inhaling infectious droplet nuclei

It is important to note that the precise level of effectiveness (of respiratory protection) in protecting healthcare workers from *M. tb* transmission in healthcare settings has not been determined.[16]

Surgical-type masks are to be used by persons who are infectious or are suspected cases of TB disease when they are out of TB respiratory isolation. The purpose of the mask is to reduce transmission by reducing the number of TB bacilli coughed out into the room air. The infectious patient should not wear a respirator. For more information, see Table 2: **Using Masks and Respirators.**

When TB respirators are used, a respiratory protection program should be developed and enforced.[17] For more information regarding respiratory protection programs, see the **CDC, Guidelines… for Health-Care Settings, hyperlink on page 16.4)** and the CDC Fact Sheet, **Respiratory Protection in Health-Care Settings** at http://www.cdc.gov/tb/publications/factsheets/prevention/rphcs.htm .

CDC guidelines recommend that healthcare facilities conduct annual training regarding multiple topics for healthcare workers (HCWs), including the nature, extent, and hazards of TB disease in the healthcare setting. The training can be conducted in conjunction with other related training regarding infectious disease associated with airborne transmission.

In addition, training topics should include the following:

1. Risk assessment process and its relation to the respirator program, including signs and symptoms used to indicate that respirators are required in certain areas and the reasons for using respirators
2. Environmental controls used to prevent the spread and reduce the concentration of infectious droplet nuclei
3. Selection of a particular respirator for a given hazard (See "Selection of Respirators" on p. 78 of the **CDC, Guidelines… for Health-Care Settings, hyperlink on page 16.4.**
4. Operation, capabilities, and limitations of respirators
5. Cautions regarding facial hair and respirator use
6. Occupational Health and Safety Administration (OSHA) regulations regarding respirators, including assessment of employees' knowledge

Trainees should be provided opportunities to handle and wear a respirator until they become proficient. Trainees should also be provided with copies or summaries of lecture materials for use as references and instructions to refer all respirator problems immediately to the respiratory program administrator.[18]

A fit test is used to determine which respirator fits the user adequately and to ensure that the user knows when the respirator fits properly. Fit testing provides a means to determine which respirator model and size fits the wearer best and to confirm that the wearer can don the respirator properly to achieve a good fit. Periodic fit testing for respirators used in TB environments can serve as an effective training tool in conjunction with the content included in employee training and retraining.[19]

The CDC recommends that, after a risk assessment to validate the need for respiratory protection, a healthcare facility should perform fit testing during the initial respiratory protection program training and periodically thereafter in accordance with federal, state, and local regulations.[20] Additional fit testing should be considered in the following situations: 1) risk of transmission of *M. tb,* 2) changes in facial features of the wearer, 3) development of a medical condition that would affect respiratory function, 4) change in the appropriate physical characteristics of the respirator (despite the same model number), or 5) change in the model or size of the assigned respirator.[21]

OSHA addresses general respiratory protection requirements and the need for the following:

- Respiratory protection program
- Amended medical evaluation
- Training and recordkeeping
- Annual fit testing
- Fit checking

Who Should Use a Mask or Respirator

Using masks and respirators properly can reduce transmission of *Mycobacterium tuberculosis* and exposure to TB. Refer to Table 2: **Using Masks and Respirators** to determine when to use masks and respirators. NOTE: the CDC does allow VISITORS to use disposable N-95 respirators with instruction.

Table 2: USING MASKS AND RESPIRATORS[22]

Mask (a regular "surgical" mask*)	Respirator (NIOSH-approved, N-95 or higher*)
Purpose To reduce transmission by capturing infectious droplet nuclei that an infectious patient releases before they get into the air.	Purpose To reduce exposure by filtering infectious droplet nuclei out of the air, before wearers breathe the air into their lungs.
Who should wear a mask? ▪ Patients with infectious TB or suspected infectious TB	Who should wear a respirator? ▪ Staff ▪ Visitors to TB isolation rooms (keep these visitors to a minimum)
A patient should wear a mask in a hospital setting when: ▪ Suspected of having infectious TB and not yet placed in respiratory isolation ▪ Leaving a respiratory isolation room for any reason Note: Infectious patients should NOT wear masks when in their TB isolation rooms. A patient should wear a mask in a health clinic setting when: ▪ Not in a TB isolation room ▪ Returning to the clinic for evaluation	A staff person or visitor should wear a respirator in a hospital or clinic setting when: ▪ Entering a TB isolation room ▪ Performing cough-inducing or aerosol-generating procedures ▪ Unlikely to be protected by administrative or environmental controls
A patient should wear a mask in a transportation setting when: ▪ Traveling in a vehicle with other persons	A staff person or visitor should wear a respirator in some transportation settings when: ▪ Riding in a vehicle with a patient with infectious TB
In the patient's home: Note: Infectious patients do NOT need to wear a mask when they are in their homes - there should NOT be any visitors (excluding protected healthcare workers) to the home until the patient is released from TB isolation.	A staff person or visitor* should wear a respirator in a patient's home when: ▪ Visiting the infectious patient inside the home/residence Note: There should NOT be any visitors (excluding protected healthcare workers) to the home until the patient is released from TB isolation.
Definition of abbreviations: NIOSH = National Institute for Occupational Safety and Health; TB = tuberculosis. * There are some devices, such as the 3M 1860, which are both N95 respirators and surgical masks.	

Source: CDC. Guidelines for preventing the transmission *of M. tb* in health-care facilities, 2005. *MMWR* 2005;54(No. RR-17):38–40.

Two-Step Tuberculin Skin Testing

Two-step testing is used to improve the interpretation of tuberculin skin tests (TSTs), especially in persons who are required to undergo periodic testing. Two-step testing should be used for the **initial** skin testing of adults who will be retested periodically, such as healthcare workers.[23]

In some persons who are infected with *M. tuberculosis,* delayed-type hypersensitivity to tuberculin may wane over the years. When these persons are skin tested many years after their infection, they may have a negative reaction.

However, the skin test may have stimulated (boosted) their ability to react to tuberculin, causing a positive reaction to subsequent tests. This boosted reaction may be misinterpreted as a new infection. The booster phenomenon may occur at any age, but its frequency increases with age and is highest among older persons. Boosted reactions may occur in persons infected with nontuberculous mycobacteria or in persons who have had a prior bacille Calmette-Guérin (BCG) vaccination.

A positive reaction to the second test should be interpreted as evidence for infection with *M. tuberculosis.* On the basis of this second test result, the person should be classified as previously infected and cared for accordingly. This would not be considered a skin test conversion.

If the first and second test results are negative, the person should be classified as uninfected. In these persons, a positive reaction to any subsequent test is likely to represent new infection with *M. tuberculosis* (a skin test conversion).

Schedule apppointments for two-step testing as shown below.

Refer to the topics on administration, measurement, and interpretation of the tuberculin skin test in the Diagnosis of LTBI section.

Table 3: FOUR APPOINTMENT SCHEDULE FOR TWO-STEP TESTING

Appointments	Tasks
First appointment	Apply the first tuberculin skin test (TST).
Second appointment 48 to 72 hours after applying the first TST	Measure the reaction. ▪ If the reaction is negative, schedule a third appointment. ▪ If the reaction is positive, do not repeat the TST. Obtain a chest radiograph.
Third appointment 1 to 3 weeks after measurement of the first TST	Re-apply the TST. ▪ Use the same dose and strength of tuberculin. Inject the tuberculin on the other forearm, or at least 5 cm from the original test site. ▪ If the reaction is negative and the patient returns over a week after the first TST was applied, apply the second TST.
Fourth appointment 48 to 72 hours after applying the second TST	Measure the reaction. ▪ If the reaction is negative, classify the individual as uninfected. ▪ If the reaction is positive, obtain a chest radiograph.

For more information on two-step testing, refer to the the **CDC, Guidelines… for Health-Care Settings, hyperlink on page 16.4.**

Isolation

To reduce disease transmission, a patient with tuberculosis (TB) disease may need to be isolated or have activities restricted.

Isolation: Isolation is used when people are ill. Isolation of people who have a specific illness separates them from healthy people and restricts their movement to stop the spread of that illness. Isolation allows for the focused delivery of specialized health care to people who are ill, and it protects healthy people from getting sick. People in isolation may be cared for in their homes, in hospitals, or at designated healthcare facilities. Isolation is a standard procedure used in hospitals today for patients with TB. In most cases, isolation is voluntary; however, many levels of government (federal, state, and local) have the basic legal authority to compel isolation of sick people to protect the public.[24]

Restricted Activities: Until determined to be noninfectious, the patient is not permitted to return to work, school, or any social setting where the patient could expose individuals to airborne bacteria.

Quarantine: Although TB control programs have used the word “quarantine” interchangeably with “isolation” and “restricted activities,” the word “quarantine” properly used is not a term applicable to TB control. Quarantine applies to people who have been exposed and may be infected but are not yet ill. Separating exposed people and restricting their movements is intended to stop the spread of illness. Quarantine is not an appropriate TB control measure for asymptomatic, exposed individuals. [25]

Infectiousness of TB

In general, patients with suspected or confirmed TB disease are considered infectious if they:

- Have cavitation on chest radiograph **OR**
- Have disease in their lungs, airway, or larynx **OR**
- Are coughing, **OR**
- Are undergoing cough-inducing or aerosol-generating procedures (e.g., sputum induction, bronchoscopy, airway suction) [26] **OR**
- Have positive acid-fast bacilli (AFB) sputum smear result(s)

AND

- Are not on anti-TB therapy, **OR**
- Have just started therapy, **OR**
- Have poor clinical or bacteriologic response to therapy

If a patient with one or more of these characteristics is on standard multidrug therapy with documented clinical improvement, usually in connection with smear conversion over several weeks, the risk of infectiousness is reduced.[27]

Extrapulmonary TB (TB outside of the lungs, e.g. brain, kidney, bone, lymph, etc.) is usually not infectious unless there is concomitant pulmonary disease, TB in the oral cavity or larynx, or an open abscess or lesion with high concentrations of organisms (especially if drainage is extensive or there is aerosolization during a procedure).

Determining Noninfectiousness

Use the following criteria as general guidelines to determine when during therapy a patient with pulmonary TB disease has become noninfectious. Decisions about infectivity of a person on treatment for TB should depend on the extent of illness and the specific nature and circumstances of the contact between the patient and exposed persons. These guidelines can and should be modified on a case-by-case basis by a qualified public health officer.

- The patient has negligible likelihood of multidrug-resistant TB (no known exposure to multidrug-resistant tuberculosis and no history of prior episodes of TB with poor compliance during treatment).
- The patient has received standard multidrug antituberculosis therapy for two to three weeks. (For patients with AFB sputum smear results that are negative or rarely positive, the threshold for treatment is four to seven days.)
- The patient has demonstrated complete adherence to treatment (e.g., is receiving directly observed therapy).

- The patient has demonstrated evidence of clinical improvement (e.g., reduction in the frequency of cough or reduction of the grade of the AFB sputum smear result).
- All close contacts of the patient have been identified, evaluated, advised, and, if indicated, started on treatment for latent TB infection. This criterion is critical, especially for children younger than five years of age and persons of any age with immunocompromising health conditions such as human immunodeficiency virus (HIV) infection.
- While in the hospital for any reason, patients with pulmonary TB should remain in airborne infection isolation until they:
  - Are receiving standard multidrug antituberculosis therapy
  - Have demonstrated clinical improvement
  - Have had 3 consecutive AFB-negative smear results from sputum specimens collected eight to 24 hours apart, with at least one being an early morning specimen

    Hospitalized patients returning to a congregate setting (e.g., a homeless shelter or detention facility) should have three consecutive AFB-negative smear results of sputum specimens collected more than eight hours apart before being considered noninfectious.[28] At least one of these specimens should be collected early in the morning.

Airborne Infection Isolation in a Healthcare Facility

In airborne infection isolation (AII), the patient is placed in an AII room, usually within a hospital or healthcare facility. The main characteristics of an AII room (for new or renovated buildings) are that it has negative air pressure relative to the hall and 12 or more air exchanges per hour, of which at least two exchanges are outside air. For existing structures, six or more air exchanges per hour are acceptable.[29]

The decisions to initiate and discontinue isolation are made by the patient's physician with input from the Infection Control Personnel of the hospital or healthcare facility. The LDH may also be consulted. Isolation decisions should be made on a case-by-case basis.

When to Initiate Airborne Infection Isolation

Suspected cases of laryngeal or pulmonary TB should be isolated immediately, before AFB sputum smear results are available.

Initiate TB AII precautions for any patient who meets the criteria in Table 4.

Table 4: INITIATION OF AIRBORNE INFECTION ISOLATION[30]

Criteria for Initiation of Airborne Infection Isolation		
The patient has signs or symptoms of pulmonary, laryngeal, or multidrug-resistant tuberculosis (MDR-TB) disease.	OR	▪ The patient has documented infectious pulmonary, laryngeal tuberculosis (TB) disease or MDR-TB disease. AND ▪ The patient has not completed treatment.

Source: CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR* 2005;54(No. RR-17):16, 44.

Patients with suspected or confirmed MDR-TB should remain in an AII room throughout their hospitalization or until culture conversion is documented, regardless of sputum smear results.

When to Discontinue Airborne Infection Isolation

High-risk patients should be carefully evaluated before discontinuing isolation. Hospitalized patients with suspected or confirmed MDR-TB should remain in an AII room throughout their hospitalization.

Suspected Tuberculosis Disease

For patients placed in AII due to suspected infectious TB disease of the lungs, airway, or larynx, AII can be discontinued when the criteria in Table 5 are met.

Table 5: DISCONTINUATION OF AIRBORNE INFECTION ISOLATION OF PATIENTS WITH SUSPECTED TUBERCULOSIS[31]

Criteria for Discontinuing Airborne Infection Isolation: Suspected Case of Tuberculosis of the Lungs, Airway, or Larynx		
Infectious tuberculosis (TB) disease is considered unlikely.	AND	Either ▪ Another diagnosis is made that explains the clinical syndrome. OR ▪ The patient has 3 negative acid-fast bacilli (AFB) sputum smear results,* has been on treatment delivered as directly observed therapy, and has demonstrated clinical improvement.
* Each of the 3 sputum specimens should be collected 8 to 24 hours apart, and at least 1 should be an early morning specimen (because respiratory secretions pool overnight). Generally, this will allow patients with negative AFB sputum smear results to be released from AII in 2 days.[32]		
 While in the hospital for any reason, patients with pulmonary TB should remain in airborne infection isolation until they (1) are receiving standard multidrug antituberculosis therapy; (2) have demonstrated clinical improvement; and (3) have had 3 consecutive AFB-negative smear results of sputum specimens collected 8 to 24 hours apart, with at least 1 being an early morning specimen.[33]		
 Because patients with TB disease who have negative AFB sputum smear results can still be infectious, patients with suspected disease who meet the above criteria for release from AII should not be released to an area where other patients with immunocompromising conditions or children <5 years are housed.[34]		

Sources: CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR* 2005;54(No. RR-17):16, 43; ATS, CDC. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):9.

Confirmed Tuberculosis Disease

A patient with drug-susceptible TB of the lung, airway, or larynx who is on standard multidrug antituberculosis treatment and who has had a significant clinical and bacteriologic response to therapy (e.g., reduction in cough, resolution of fever, and progressively decreasing quantities of AFB on smear results) is probably no longer infectious. However, because culture and drug susceptibility results are not usually known when the decision to discontinue AII is made, all patients with confirmed TB disease should remain in AII while hospitalized until all the criteria in Table 6 are met.[35]

Table 6: DISCONTINUATION OF AIRBORNE INFECTION ISOLATION OF PATIENTS WITH CONFIRMED TUBERCULOSIS[36]

Criteria for Discontinuing Airborne Infection Isolation: Hospitalized Patients with Confirmed, Drug-Susceptible Tuberculosis of the Lungs, Airway, or Larynx
▪ The patient has had 3 consecutive negative acid-fast bacilli (AFB) sputum smear results collected 8 to 24 hours apart, with at least 1 being an early morning specimen. AND ▪ The patient has received standard multidrug antituberculosis treatment by directly observed therapy (DOT). AND ▪ The patient has demonstrated clinical improvement.

Source: CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR* 2005;54(No. RR-17):43.

Hospital Discharge

The decision to discontinue isolation is made by the patient's physician with input from the Infection Control Personnel of the hospital or healthcare facility. The LDH may also be consulted.

The decisions to discharge an acid-fast bacilli (AFB) sputum smear-positive patient or an multidrug-resistant tuberculosis (MDR-TB) patient should be made in consultation with the LHD.

Drug-Susceptible Tuberculosis Disease

If a hospitalized patient who has suspected or confirmed drug-susceptible TB disease is deemed medically stable (including patients with positive AFB sputum smear results indicating pulmonary TB disease), the patient may be discharged from the hospital before converting AFB sputum smear results to negative if all the criteria in Table 7 are met.[37]

Table 7: HOSPITAL DISCHARGE OF PATIENTS WITH DRUG-SUSCEPTIBLE TUBERCULOSIS[38]

Criteria for Hospital Discharge to Home: Patients with Suspected or Confirmed Drug-Susceptible Tuberculosis
▪ A specific plan exists for follow-up care with the LHD. AND ▪ The patient has been started on a standard multidrug antituberculosis treatment regimen and directly observed therapy (DOT) has been arranged. AND ▪ No children aged <5 years or persons with immunocompromising conditions are present in the household. AND ▪ All immunocompetent household members have been previously exposed to the patient. AND ▪ The patient is willing to remain inside the home except for healthcare-associated visits until the patient has negative acid-fast bacilli (AFB) sputum smear results. NOTE: the patient must be educated about preventing TB transmission to others (this education should be documented)

Source: CDC. Guidelines for preventing the transmission *of Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR* 2005;54(No. RR-17):43–44.

Multidrug-Resistant Tuberculosis Disease

Patients with suspected or confirmed MDR-TB disease should remain in the hospital in AII until they meet all three of the criteria in Table 8.

Table 8: HOSPITAL DISCHARGE OF PATIENTS WITH MULTIDRUG-RESISTANT TUBERCULOSIS

Criteria for Hospital Discharge to Home: Patients with Suspected or Confirmed Multidrug-Resistant Tuberculosis
▪ The patient has had 3 consecutive negative acid-fast bacilli (AFB) sputum smear results collected 8 to 24 hours apart, with at least 1 being an early morning specimen. AND ▪ An appropriate treatment regimen has been devised and initiated. AND ▪ Suitable arrangements have been made so that the regimen can be continued and properly monitored on an outpatient basis, specifically by directly observed therapy (DOT).

Release Settings

Patients with suspected or confirmed infectious TB disease should not be released to healthcare settings or homes where the patient can expose others who are at high risk for progressing to TB disease if infected, such as HIV-infected persons or young children.[39] Hospitalized patients returning to a congregate setting (e.g., a homeless shelter or detention facility) should have three consecutive AFB-negative smear results of sputum specimens collected more than eight hours apart, with at least one being an early morning specimen, before being considered noninfectious.[40]

Patients who have positive AFB sputum smear results should **not** be directly discharged from the hospital to **any** of the following living environments:

- Congregate living site (e.g., shelter, nursing home, jail, prison, group home, another hospital)
- Living situation where infants and young children also reside
- Living situation where immunosuppressed persons (e.g., HIV-infected persons or those taking cancer chemotherapy) also reside
- Living situation where home health aides or other social service providers will be present in the home for several hours a day to care for the person or family member

Residential Settings

Patients suspected of having infectious tuberculosis (TB) either are diagnosed during an outpatient workup, or, if admitted to a hospital, are often sent home after starting treatment, even though they may still be infectious. Because patients are most likely to transmit TB to household members **before** TB has been diagnosed and treatment has rendered the patient noninfectious, it is important that TB patients and members of their households know what steps to take to prevent the spread of TB in the home until the patient becomes noninfectious.[41,42]

Administrative Controls in the Patient's Home

Establish a policy and procedure for managing infectious patients at home. To standardize care, the following information should be included:

1. **Definition of key terms:** Infectious case and noninfectious case
2. **Treatment of cases at home whenever possible:** Treat patients at home if their condition does not otherwise require hospitalization.
3. **Window period treatment policy:** Ensure that candidates for window period treatment in the home have completed their evaluation and are on medication before they are discharged home (or as soon as possible if they were not hospitalized).
4. **Education:** Educate infectious patients, family, care providers, and close contacts regarding the purpose of isolation, their responsibility to adhere to the isolation requirements, and the consequences of not voluntarily complying with isolation.
5. **Home isolation agreements:** Have infectious patients in isolation sign a home isolation agreement. This document should include any legal consequences should they fail to voluntarily comply.

   A sample Home Isolation Agreement can be viewed at New York City Department of Health and Mental Hygiene Tuberculosis Clinical Policies and Protocols, 4th Edition page 246, http://home2.nyc.gov/html/doh/downloads/pdf/tb/tb-protocol.pdf.

   Also refer to Section 13: Confidentiality and Legal Aspects of Patient Management

Environmental Controls in the Patient's Home

Generally, there are no special engineering recommendations. However, patients and their families can be advised to do the following:

- Have tissues available for patients to cover their mouths and noses when coughing or sneezing.
- Keep windows and doors open (weather permitting) to increase the ventilation and dilution of infectious droplet nuclei in the house.
- If a sputum sample needs to be collected at home, do so in a well-ventilated area away from other residents (e.g., bathroom with an exhaust fan). If possible, collect the sputum in an outdoor area away from open windows or doors.

Respiratory Protection in the Patient's Home

Patient: Mask

- Patients do not need to wear masks at home.
- Give patients regular surgical-type masks and advise them to wear them at medical appointments until they are no longer infectious.

For more information on the criteria for noninfectiousness, see the "Determining Noninfectiousness" topic in this section.

- Do not give patients respirators (N-95 or higher).

Healthcare Worker: Respirator

- Healthcare workers should wear respirators when entering the home or a closed area to visit with infectious patients.
- The respirators should be National Institute for Occupational Safety and Health (NIOSH)-approved (N-95 or higher).
- Healthcare workers should be provided with respirators after appropriate education and testing.

Other Residential Settings

Motels

Homeless persons with infectious TB may be housed in a motel that has outside access to rooms (not via hallways).

The motel manager must be advised of the following:

1. The patient is in respiratory isolation.
2. The manager should report to local public health agency staff if the manager becomes aware that the patient does not stay in the room or if the patient has guests.
3. The manager should advise motel staff that they are not to enter the room while the patient resides at the motel. (Arrangements should be made for weekly linen replacement in which the patient sets out linens that need to be replaced, and the staff knock on the door and leave the linens for the patient to make his or her own bed.)
4. Upon release from isolation, the room should be aired out for one day before staff enters to clean. Afterwards, routine cleaning done between guests is sufficient. There are no additional special cleaning requirements.
5. Local public health agency staff will be delivering medication to the patient (specify the frequency).
6. Arrangements have been made for food delivery to the patient.

Healthcare Facilities or Residential Settings

1. Patients with infectious TB should be in appropriate respiratory isolation (airborne infection isolation rooms) when housed in healthcare facilities or residential settings.
2. If a facility does not have the capability to provide appropriate respiratory isolation, the patient should be transferred to a facility that can accommodate respiratory isolation until the patient is noninfectious. Once noninfectious, the person may return to the original facility.

INDIANA

Admission of Patient with Confirmed or Suspected TB to a LTC facility requires a waiver from the ISDH Division of Long Term Care.

(See Section 2-Surveillance, page 2.15 for details on the Waiver Program)

Return to Work, School, or Other Social Settings

The decision of when to allow a patient to return to work, school, or other social settings should be made in consultation with the physician and the LHD.

The decision to permit a patient to return to work, school, or other social settings is based on the following:

- The characteristics of the patient with TB disease (e.g., whether the patient is likely to adhere to the regimen and follow treatment instructions)
- The characteristics of the TB disease itself (e.g., multidrug-resistant versus drug-susceptible TB, AFB sputum smear-positive versus smear-negative, cavitary versus noncavitary)
- The duration of current treatment (For example, the patient has received standard multidrug antituberculosis therapy for two-to-three weeks. However, for patients with sputum AFB smear results that are negative or rarely positive, the threshold for treatment is five-to-seven days.)[43]
- The environment(s) to which the patient will be returning

Drug-Susceptible Tuberculosis Disease

Patients with drug-susceptible TB are no longer considered infectious if they meet all the criteria in Table 9.

Table 9: RETURN TO WORK, SCHOOL, AND OTHER SETTINGS OF PATIENTS WITH DRUG-SUSCEPTIBLE TUBERCULOSIS[44]

Criteria for Return to Work, School, or Other Social Settings: Patients with Suspected or Confirmed Drug-Susceptible Tuberculosis
▪ The patient is on adequate therapy. AND ▪ The patient has had a significant clinical response to therapy. AND ▪ The patient has had 3 consecutive negative acid-fast bacilli (AFB) sputum smear results collected 8 to 24 hours apart, with at least 1 being an early morning specimen.

Source: CDC. Infectiousness. *Core Curriculum on Tuberculosis (2000)* November 2001.

Multidrug-Resistant Tuberculosis Disease

Regardless of their occupation, patients known or likely to have pulmonary MDR-TB may be considered for return to work or school only if they meet all four of the criteria in Table 10.

Table 10: RETURN TO WORK, SCHOOL, AND OTHER SETTINGS OF PATIENTS WITH MULTIDRUG-RESISTANT TUBERCULOSIS

Criteria for Return to Work, School, or Other Social Settings: Patients with Suspected or Confirmed Multidrug-Resistant Tuberculosis
▪ The resolution of fever and the resolution, or near resolution, of cough has occurred. AND ▪ The patient is on current treatment with an antituberculosis regimen to which the strain is known or likely to be susceptible.* AND ▪ The patient has had 3 consecutive negative acid-fast bacilli (AFB) sputum smear results collected 8 to 24 hours apart, with at least 1 being an early morning specimen. AND ▪ The patient has had a negative culture for *Mycobacterium tuberculosis.*
*In addition, directly observed therapy (DOT) should be strongly encouraged for patients with MDR-TB.

Tuberculosis Infection Control in Patient Care Facilities

Patients with suspected tuberculosis (TB) may present for care in many different settings. The CDC has written a comprehensive set of guidelines for TB infection control in acute care hospitals and other medical settings (**CDC, Guidelines… for Health-Care Settings, hyperlink on page 16.4**).[45] In addition to the CDC guidelines, various professional organizations or state regulations may have guidelines for managing TB patients.

The main focus in establishing a TB infection control program at a patient care facility is to do the following:

1. Assign responsibility for managing the program to a designated staff position.
2. Perform and establish a TB risk assessment for the facility.
3. Develop the TB infection control plan based on the level of TB risk identified in the assessment.

The main purpose for having an effective TB infection control plan in a facility is to assure that the activities necessary for TB control are addressed and that policies and procedures are developed to protect the healthcare workers, other patients, and visitors in the facility.

Table 11: **Guidelines for Tuberculosis Infection Control** lists references that provide the information needed to conduct a TB risk assessment and write a TB infection control plan to establish policies and procedures for TB control activities for inpatient care facilities.

Table 11: GUIDELINES FOR TUBERCULOSIS INFECTION CONTROL

Guidelines for Tuberculosis Infection Control

The following settings are addressed in the "Guidelines for Preventing the Transmission of *M. tb* in Health-care Facilities, 2005" (noted on the previous page). Some settings have additional guidelines as noted below.

Inpatient Settings

- Emergency departments and urgent care settings
- Intensive care units
- Surgical suites
- Laboratories
- Bronchoscopy suites
- Sputum induction and inhalation therapy rooms
- Autopsy suites and embalming rooms

Outpatient Settings

- Tuberculosis (TB) treatment facilities
- In Correctional and Detention facilities: Prevention and Control of Tuberculosis in Correctional and Detention Facilities, July 2006 at this hyperlink: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5509a1.htm
- Medical offices and ambulatory care settings
- Dialysis units

Nontraditional Facility-Based Settings

- Homeless shelter clinics: Prevention and Control of Tuberculosis Among Homeless Persons, April 1992 at this hyperlink: http://www.cdc.gov/mmwr/preview/mmwrhtml/00019922.htm
- Emergency medical services
- Home-based healthcare and outreach settings
- Long-term care facilities (e.g., hospices, skilled nursing facilities) at this hyperlink: http://www.cdc.gov/mmwr/preview/mmwrhtml/00001711.htm

Transportation Vehicles

To prevent the transmission of *Mycobacterium tuberculosis* while transporting patients, follow the respiratory precautions identified below.

Patient Self-Transport

1. The car windows should be opened, and any recirculating air controls should be turned off.
2. If possible, only household members should accompany the patient. Members of the patient's household who accompany the patient do not need to wear surgical masks.
3. If the only source for transport is a friend or relative who is not a member of the patient's household:
   a. The person accompanying the patient should be given a respirator (N-95) to wear during transport (due to the confined space and risk of ongoing exposure).
   b. The patient should sit in the back seat and wear a surgical mask.
   c. The car windows should be opened, and any recirculating air controls should be turned off.
4. The patient should wear a surgical mask after leaving the vehicle.[46]

Transport by Healthcare Workers

1. Healthcare workers should wear respiratory protection (N-95) while in the vehicle.
2. The patient should wear a surgical mask and sit in the back seat.
3. The car windows should be opened, and any recirculating air controls should be turned off. [47]

Transport by Emergency Medical Services

Emergency medical services staff may have specialized vehicles that have the ability to separate the driver's compartment from the transport compartment and/or may be equipped with rear exhaust fans. Recommendations for these vehicles and staff are addressed in the **CDC, Guidelines… for Health-Care Settings, hyperlink on page 16.4.**

Resources and References

Resources

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Glossary

acid-fast bacilli (AFB): Microorganisms that are distinguished by their retention of specific stains even after being rinsed with an acid solution. An AFB examination involves microscopic examination of a stained smear of a patient specimen (usually sputum) to determine if mycobacteria are present. The relative concentration of AFB per unit area on a slide (the smear grade) is associated with infectiousness. A presumptive diagnosis of pulmonary TB can be made with a positive AFB sputum smear result. However, approximately 50% of patients with TB disease of the lungs have negative AFB sputum smear results. The majority of AFB in patient specimens are mycobacteria, including species other than *Mycobacterium tuberculosis* complex. A positive nucleic acid amplification or culture result is needed for confirmation of *M. tuberculosis* complex.

administrative controls: Managerial measures that reduce the risk for exposure to persons who might have TB disease. Examples include coordinating efforts with the local or state health department; conducting a TB risk assessment for the setting; developing and instituting a written TB infection control plan to ensure prompt detection, airborne infection isolation, and treatment of persons with suspected or confirmed TB disease; and screening and evaluating healthcare workers who are at risk for TB disease or who might be exposed to *M. tuberculosis.*

air change rate: Ratio of the airflow in volume units per hour to the volume of the space under consideration in identical volume units, usually expressed in air changes per hour (ACH).

air changes per hour (ACH): Air change rate expressed as the number of air exchange units per hour.

airborne infection isolation (AII) precautions: The isolation of patients infected with organisms spread through airborne droplet nuclei 1–5 μm in diameter. This isolation area receives substantial air changes per hour (ACH) (≥12 ACH for new construction since 2001 and ≥6 ACH for construction before 2001) and is under negative pressure (i.e., the direction of the air flow is from the outside adjacent space [e.g., the corridor] into the room). The air in an AII room is preferably exhausted to the outside but can be recirculated if the return air is filtered through a high efficiency particulate respirator.

airborne infection isolation room (AII room): A room designed to maintain AII. Formerly called negative pressure isolation room, an AII room is a single-occupancy patient-care room used to isolate persons with suspected or

confirmed infectious TB disease. Environmental factors are controlled in AII rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. AII rooms should provide negative pressure in the room (so that air flows under the door gap into the room), have an air flow rate of 6–12 air changes per hour, and direct exhaust of air from the room to the outside of the building or recirculation of air through a high efficiency particulate respirator filter.

anergy: A condition in which a person has a diminished ability to exhibit delayed T-cell hypersensitivity to antigens because of a condition or situation resulting in altered immune function. Skin tests for anergy (i.e., control antigens) have poor predictive value and are not recommended.

asymptomatic: Neither causing nor exhibiting signs or symptoms of disease.

bacille Calmette-Guérin (BCG): Vaccines for tuberculosis named after the French scientists Calmette and Guérin. The vaccines are effective in preventing disseminated and meningeal TB disease in infants and young children. They might have approximately 50% efficacy for preventing smear diagnosed pulmonary TB in adults. They are used in multiple countries where TB disease is endemic.

baseline tuberculosis screening: Screening healthcare workers (HCWs) for latent TB infection and TB disease at the beginning of employment. TB screening includes a symptom screen for all HCWs and tuberculin skin tests (TSTs) or blood assays for *M. tuberculosis* (BAMTs) for those with previous negative test results for *M. tuberculosis* infection. The TST or BAMT is administered at the beginning of employment to newly hired HCWs. If the TST method is used for HCWs who have not had a documented negative test result for *M. tuberculosis* during the preceding 12 months, the baseline TST result should be obtained by using the two-step method. BAMT baseline testing does not need the two-step method.

blood assay for Mycobacterium tuberculosis (BAMT): A general term to refer to recently developed *in vitro* diagnostic tests that assess for the presence of infection with *M. tuberculosis*. This term includes, but is not limited to, interferon gamma (IFN-γ) release assays (IGRA). In the United States, the currently available IGRAs are the QuantiFERON®-TB Gold (QFT-G) test and the QuantiFERON®-TB Gold in-tube (QFT™) test.

boosting: When nonspecific or remote sensitivity to tuberculin (purified protein derivative [PPD] in the skin test) wanes or disappears with time, subsequent tuberculin skin tests can restore the sensitivity. This is called boosting or the booster phenomenon. An initially limited reaction size is followed by a larger

reaction size on a later test, which can be confused with a conversion or a recent *M. tuberculosis* infection. Two-step testing is used to distinguish new infections from boosted reactions in infection-control surveillance programs, but this method is not recommended for testing contacts.

bronchoscopy: A procedure for examining the lower respiratory tract in which the end of the endoscopic instrument is inserted through the mouth or nose (or tracheostomy) and into the respiratory tree. Bronchoscopy can be used to obtain diagnostic specimens. Bronchoscopy also creates a high risk for *M. tuberculosis* transmission to healthcare workers (HCWs) if it is performed on an untreated patient who has TB disease (even if the patient has negative acid-fast bacilli smear results) because it is a cough-inducing procedure.

case: A particular instance of a disease (e.g., TB), referring only to the disease, not to the person with the disease. A case is detected, documented, and reported.

cavity (pulmonary): A hole in the lung parenchyma, usually not involving the pleural space. Although a lung cavity can develop from multiple causes and its appearance is similar regardless of its cause, in pulmonary TB disease cavitation results from the destruction of pulmonary tissue by direct bacterial invasion and an immune interaction triggered by *M. tuberculosis*. A TB cavity substantial enough to see with a normal chest radiograph predicts infectiousness.

chest x-ray: See **radiography**.

clinical examination: A physical evaluation of the clinical status of a patient by a physician or equivalent practitioner.

cluster (TB): A group of patients with latent TB infection or TB disease that are linked by epidemiologic, location, or genotyping data. Two or more tuberculin skin test conversions within a short period can be a cluster of TB and might suggest transmission within the setting. A genotyping cluster is 2 or more cases with isolates that have an identical genotyping pattern.

confirmed TB: A diagnosis of TB disease based on positive cultures for *M. tuberculosis.* However, TB may also be diagnosed on the basis of clinical signs and symptoms in the absence of a positive culture. Positive cultures for *M. tuberculosis* confirm the diagnosis of TB; however, TB may also be diagnosed on the basis of clinical signs and symptoms in the absence of a positive culture. Culture examinations should be done on all specimens, regardless of acid-fast bacilli smear results.

contact: A person who has been exposed to *M. tuberculosis* infection by sharing air space with a person with infectious TB.

contact investigation: Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify latent TB infection or TB disease, and treatment of these persons, as indicated.

contagious: See **infectious**.

conversion: A change in the result of a test for *M. tuberculosis* infection that is interpreted to indicate a change from being uninfected to infected. With the tuberculin skin test, an increase of more than 10 mm in induration size during a maximum of 2 years is defined as a conversion. If blood assay for *M. tuberculosis* (BAMT) is used for testing, a conversion is a change from a negative to a positive BAMT result over a 2-year period. A conversion is presumptive evidence of new *M. tuberculosis* infection and poses an increased risk for progression to TB disease. The term is applied to contacts only when previous test results are available. A change in tuberculin status during the window period is not necessarily consistent with this definition.

conversion rate: The percentage of a population with a converted test result (tuberculin skin test or blood assay for *M. tuberculosis*) for *M. tuberculosis* within a specified period. This is calculated by dividing the number of conversions among eligible healthcare workers (HCWs) in the setting in a specified period (numerator) by the number of HCWs who received tests in the setting over the same period (denominator) multiplied by 100.

culture: Growth of microorganisms in the laboratory performed for detection and identification in sputum or other body fluids and tissues. This test usually takes 2 to 4 weeks for mycobacteria to grow (2 to 4 days for most other bacteria).

delayed-type hypersensitivity (DTH): Cell-mediated inflammatory reaction to an antigen, which is recognized by the immune system usually because of previous exposure to the same antigen or similar ones. Cell-mediated reactions are contrasted with an antibody (or humoral) response. DTH typically peaks at 48–72 hours after exposure to the antigen.

deoxyribonucleic acid (DNA) genotyping: A clinical laboratory technique used to distinguish between different strains *of M. tuberculosis* and to help assess the likelihood of TB transmission.

directly observed therapy (DOT): An adherence-enhancing strategy in which a healthcare worker or other trained person watches a patient swallow each dose of medication and is accountable to the public health system. DOT is the standard of care for all patients with TB disease and is a preferred option for patients treated for latent TB infection.

disseminated TB: See **miliary TB**.

droplet nuclei: Microscopic particles produced when a person coughs, sneezes, shouts, or sings. These particles can remain suspended in the air for prolonged periods and can be carried on normal air currents in a room and beyond to adjacent spaces or areas receiving exhaust air.

drug susceptibility test: A laboratory determination to assess whether an *M. tuberculosis* complex isolate is susceptible or resistant to anti-TB drugs that are added to mycobacterial growth medium or are detected genetically. The results predict whether a specific drug is likely to be effective in treating TB disease caused by that isolate.

enabler: A practical item given to a patient for making adherence (e.g., to treatment or to clinic appointments) easier.

environmental controls: Physical or mechanical measures (as opposed to administrative control measures) used to reduce the risk for transmission of *M. tuberculosis* by preventing the spread and reducing the concentration of infectious droplet nuclei in ambient air. Examples include ventilation, filtration, ultraviolet lamps, airborne infection isolation rooms, and local exhaust ventilation devices.

epidemiologic cluster: A closely grouped series of cases in time or place.

erythema: Abnormal redness of the skin. Erythema may develop around a tuberculin skin test (TST) site, but should not be read as part of the TST result.

exposure: The condition of being subjected to something (e.g., an infectious agent) that could have a harmful effect. A person exposed to *M. tuberculosis* does not necessarily become infected. Much of the work in a TB contact investigation is dedicated to learning who was exposed and, of these, who became infected.

exposure incident: A situation in which persons (e.g., healthcare workers, visitors, and inmates) have been exposed to a person with suspected or confirmed infectious TB disease (or to air containing *M. tuberculosis*) without the benefit of effective infection control measures.

exposure period: The coincident period when a contact shared the same air space as a person with TB during the infectious period.

exposure site: A location that the index patient visited during the infectious period (e.g., school, bar, bus, or residence).

extrapulmonary TB: TB disease in any part of the body other than the lungs (e.g., the kidney, spine, or lymph nodes). The presence of extrapulmonary disease does not exclude pulmonary TB disease.

false-negative tuberculin skin test (TST) or blood assay for *M. tuberculosis* (BAMT) result: A TST or BAMT result that is interpreted as negative in a person who is actually infected with *M. tuberculosis*.

false-positive tuberculin skin test (TST) or blood assay for *M. tuberculosis* (BAMT) result: A TST or BAMT result that is interpreted as positive in a person who is not actually infected with *M. tuberculosis*. A false-positive TST result is more likely to occur in persons who have been vaccinated with bacille Calmette-Guérin or who are infected with nontuberculous mycobacteria.

fit check: A procedure performed after every respirator is donned to check for proper seal of the respirator. Also called “user-seal check.”

fit test: The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on a person.

genotype: The deoxyribonucleic acid (DNA) pattern of *M. tuberculosis* used to discriminate among different strains.

healthcare workers (HCWs): All paid and unpaid persons working in healthcare settings.

hemoptysis: The expectoration or coughing up of blood or blood-tinged sputum—one of the symptoms of pulmonary TB disease. Hemoptysis can also be observed in other pulmonary conditions (e.g., lung cancer).

high efficiency particulate air (HEPA) filter: A portable or stationary filter that is certified to remove more than 99.97% of particles 0.3 μm in size, including *M. tuberculosis*-containing droplet nuclei. Use of HEPA filters in building ventilation systems requires expertise in installation and maintenance.

human immunodeficiency virus (**HIV) infection:** Infection with the virus that causes acquired immunodeficiency syndrome (AIDS). A person with both latent TB infection and HIV infection is at high risk for developing TB disease.

hypersensitivity: A state in which the body reacts with an exaggerated immune response to a foreign substance. Hypersensitivity reactions are classified as immediate or delayed, types I and IV, respectively. See **delayed-type hypersensitivity**.

immunocompromised and immunosuppressed: Conditions in which at least part of the immune system is functioning at less than normal capacity. According to some style experts, “immunocompromised” is the broader term, and “immunosuppressed” is restricted to conditions with iatrogenic causes, including treatments for another condition. Some immunocompromised conditions increase the likelihood that *M. tuberculosis* infection will progress to TB disease. Certain conditions also make TB disease or infection from *M. tuberculosis* more difficult to diagnose because manifestations of TB disease differ and tests for infection rely on an intact immune system.

incentive: A gift given to patients to encourage or acknowledge their adherence to treatment.

incidence: The number of new events or cases of disease that develop during a specified period.

index (TB): The first case or patient with TB disease that comes to attention as an indicator of a potential public health problem.

induration: The firmness in the skin test reaction produced by immune-cell infiltration in response to the tuberculin antigen that was introduced into the skin during a tuberculin skin test. Induration is measured transversely by palpation, and the result is recorded in millimeters. The measurement is compared with guidelines to determine whether the test result is classified as positive or negative.

infection control program (TB): A program designed to control transmission of *M. tuberculosis* through early detection, isolation, and treatment of persons with infectious TB. A hierarchy of control measures are used, including 1) administrative controls to reduce the risk for exposure to persons with infectious TB disease and screening for healthcare workers (HCWs) for latent TB infection and TB disease, 2) environmental controls to prevent the spread and reduce the concentration of infectious droplet nuclei in the air, and 3) respiratory protection in areas where the risk for exposure to *M. tuberculosis* is high (e.g., airborne infection isolation rooms). A TB infection control plan should include surveillance of HCWs who have unprotected high-risk exposure to TB patients or their environment of care.

infection: A condition in which microorganisms have entered the body and typically have elicited immune responses. *M. tuberculosis* infection might progress to TB disease. The expression “*M. tuberculosis* infection” includes both latent infection and TB disease. Latent *M. tuberculosis* infection or latent tuberculosis infection (LTBI) is an asymptomatic condition that follows the initial infection; the infection is still present but is dormant (and believed not to be currently progressive or invasive). TB disease is determined by finding anatomic changes caused by

advancing infection (e.g., shadows from infiltrates on a chest radiograph) or by noting symptoms (e.g., malaise, feverishness, or cough), and typically by both. Positive culture results for *M. tuberculosis* complex typically are interpreted as both an indication of TB disease and its confirmation, but infecting organisms can be obtained from patients who have no other evidence of disease.

infectious: Refers either to TB disease of the lungs or throat which has the potential to cause transmission to other persons, or to the patient who has TB disease.

infectious droplet nuclei: Droplet nuclei produced by an infectious TB patient that can carry tubercle bacteria and be inhaled by others. Although usually produced from patients with pulmonary TB through coughing, infectious droplet nuclei can also be produced by aerosol-generating procedures.

infectious period: The period during which a person with TB disease might have transmitted *M. tuberculosis* organisms to others. For patients with positive acid-fast bacilli (AFB) sputum smear results, the infectious period begins 3 months before the collection date of the first positive smear result or 3 months before the symptom onset date (whichever is earlier). The infectious period ends when the patient is placed into airborne infection isolation (AII) or the date of collection for the first of consistently negative smear results. For patients with negative AFB sputum smear results, the infectious period extends from 1 month before the symptom onset date and ends when the patient is placed into AII (whichever was earlier).

interferon-γ (gamma) release assay (IGRA): A type of an *ex vivo* test that detects cell-mediated immune response to this cytokine. In the United States, QuantiFERON®-TB Gold (QFT-G) and QuantiFERON®-TB Gold in-tube (QFT™) are the currently available IGRAs.

laryngeal TB: A form of TB disease that involves the larynx and can be highly infectious.

latent TB infection (LTBI): See **infection**.

Mantoux method: A skin test performed by intradermally injecting 0.1 mL of purified protein derivative tuberculin solution into the volar or dorsal surface of the forearm. This method is the recommended method for tuberculin skin testing.

mask: A device worn over the nose and mouth of a person with suspected or confirmed infectious TB disease to prevent infectious particles from being released into room air.

medical evaluation: An examination to diagnose TB disease or latent TB infection, to select treatment, and to assess response to therapy. A medical evaluation can

include medical history and TB symptom screen, clinical or physical examination, screening and diagnostic tests (e.g., tuberculin skin tests, chest radiographs, bacteriologic examination, and human immunodeficiency virus testing), counseling, and treatment referrals.

meningeal TB: A highly dangerous and difficult-to-diagnose form of TB disease with infectious invasion of the tissues covering the brain. Often indolent but uniformly fatal if untreated, at times it is diagnosed too late to save the patient's life or prevent permanent disability.

miliary TB: A dangerous, and difficult to diagnose, form of rapidly progressing TB disease that extends throughout the body. Uniformly fatal if untreated, sometimes it is diagnosed too late to save the patient's life. Derives its name from a pathognomonic chest radiograph, but certain patients with this condition have normal findings or ordinary infiltrates on the chest radiograph. Sometimes referred to as disseminated TB.

multidrug-resistant TB (MDR-TB): TB disease caused by an *M. tuberculosis* strain that is resistant to at least isoniazid and rifampin. Treatment regimens for curing MDR-TB are long, expensive, and difficult to tolerate. The cure rate depends on the susceptibility of *M. tuberculosis* to alternative chemotherapy.

mycobacteria other than tuberculosis (MOTT): See **nontuberculous mycobacteria**.

Mycobacterium tuberculosis: The namesake member organism of *M. tuberculosis* complex and the most common causative infectious agent of TB disease in humans. In certain instances, the species name refers to the entire *M. tuberculosis* complex, which includes *M. bovis* and *M. african, M. microti, M. canetii, M. caprae,* and *M. pinnipedii*.

N95 disposable respirator: An air-purifying, filtering-facepiece respirator that is more than 95% efficient at removing 0.3 *μ*m particles and is not resistant to oil. See also **respirator**.

negative pressure: The difference in air-pressure between two areas. A room that is under negative pressure has a lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas. Also used to describe a nonpowered respirator. See also **airborne infection isolation** and **airborne infection isolation room**.

nontuberculous mycobacteria (NTM): Refers to mycobacterium species other than those included as part of *M. tuberculosis* complex. Although valid from a laboratory perspective, the term can be misleading because certain types of NTM cause disease with pathologic and clinical manifestations similar to TB disease.

Another term for NTM is mycobacterium other than tuberculosis. NTM are environmental mycobacteria.

nucleic acid amplification (NAA): A laboratory method used to target and amplify a single deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) sequence for detecting and identifying (typically) a microorganism. NAA tests for *M. tuberculosis* complex are sensitive and specific; they can accelerate confirmation of pulmonary TB disease.

outbreak (TB): Relative to the local context. Outbreak cases can be distinguished from other cases only when certain associations in time, location, patient characteristics, or *M. tuberculosis* attributes (e.g., drug resistance or genotype) become apparent. In low-incidence jurisdictions, any temporal cluster is suspicious for an outbreak. A working definition of a potential "TB outbreak" is helpful for planning and response and may include any of the following 6 criteria:

Criteria based on surveillance and epidemiology:

- An increase has occurred above the expected number of TB cases.
- During and because of a contact investigation, 2 or more contacts are identified as having TB disease, regardless of their assigned priority, (i.e., high-, medium-, or low-priority).
- Any 2 or more cases occurring within 1 year of each other are discovered to be linked, and the linkage is established outside of a contact investigation (e.g., 2 patients who received a diagnosis of TB disease outside of a contact investigation are found to work in the same office and only 1 or neither of the persons was listed as a contact to the other).
- A genotype cluster leads to discovery of 1 or more verified transmission links which were missed during a contact investigation within the prior 2 years.

Criteria based on program resources:

- Transmission is continuing despite adequate control efforts by the TB control program.
- Contact investigation associated with increased cases requires additional outside help.

periodic fit testing: Repetition of fit testing performed in accordance with federal, state, and local regulations. Additional fit testing should be used when 1) a new model of respirator is used, 2) a physical characteristic of the user changes, or 3) when the user or respiratory program administrator is uncertain that the healthcare worker is obtaining an adequate fit.

potential ongoing transmission: A risk classification for TB screening, including testing for *M. tuberculosis* infection when evidence of ongoing transmission of *M.*

tuberculosis is apparent in the setting. Testing might need to be performed every 8–10 weeks until lapses in infection controls have been corrected and no further evidence of ongoing transmission is apparent. Use potential ongoing transmission as a temporary risk classification only. After corrective steps are taken, reclassify the setting as medium risk. Maintaining the classification of medium risk for at least 1 year is recommended.

powered air-purifying respirator (PAPR): A respirator equipped with a tight-fitting facepiece (rubber facepiece) or loose-fitting facepiece (hood or helmet), breathing tube, air-purifying filter, cartridge or canister, and a fan. Air is drawn through the air-purifying element and pushed through the breathing tube and into the facepiece, hood, or helmet by the fan. Loose-fitting PAPRs (e.g., hoods or helmets) might be useful for persons with facial hair because they do not require a tight seal with the face.

prevalence: The proportion of persons in a population who have a disease at a specific time.

pulmonary TB: TB disease that occurs in the lung parenchyma, usually producing a cough that lasts 2 to 3 weeks.

purified protein derivative (PPD) tuberculin: A material used in diagnostic tests for *M. tuberculosis* infection. In the United States, PPD solution (5 tuberculin units per 0.1 mL) is approved for administration as an intradermal injection as a diagnostic aid for *M. tuberculosis* infection (latent infection or TB disease).

QuantiFERON®-TB Gold in-tube (QFT™), QuantiFERON®-TB test (QFT), and QuantiFERON®-TB Gold test (QFT-G): Types of blood assays for *M. tuberculosis* that are *in vitro* cytokine assays that detects cell-mediated immune response to *M. tuberculosis* in heparinized whole blood from venipuncture. This test requires only a single patient encounter, and the result can be ready within 1 day. In 2005, QFT was replaced by QFT-G, and in 2007 the QFT™ was approved by the FDA. The QFT-G and QFT™ have greater specificity than the original QFT. QFT-G and QFT™ appear to be capable of distinguishing between the sensitization caused by *M. tuberculosis* infection and that caused by bacille Calmette-Guérin vaccination. The QFT™ test has an advantage over the QFT-G test in that the QFT™ allows longer time (3 days) between the blood specimen collection and its arrival at a qualified laboratory. The blood specimen for the QFT-G test must arrive at the laboratory within 12 hours of collection.

radiography: The diagnostic imaging techniques (including plain-film chest radiographs and computerized tomography) that rely on degrees of X-radiation transmission related to differences in tissue densities.

reinfection: A second infection that follows from a previous infection by the same causative agent. Frequently used when referring to an episode of TB disease resulting from a subsequent infection with *M. tuberculosis* and a different genotype.

resistance: The ability of certain strains of mycobacteria, including *M. tuberculosis*, to grow and multiply in the presence of certain drugs that ordinarily kill or suppress them. Such strains are referred to as drug-resistant strains and cause drug-resistant TB disease. See also **multidrug-resistant TB**.

respirator: A Centers for Disease Control and Prevention (CDC)/National Institute for Occupational Safety and Health (NIOSH)-approved device worn to prevent inhalation of airborne contaminants.

respiratory hygiene and cough etiquette: Procedures by which patients with suspected or confirmed infectious TB disease can minimize the spread of infectious droplet nuclei by decreasing the number of infectious particles that are released into the environment. Patients with a cough should be instructed to turn their heads away from persons and to cover their mouth and nose with their hands or preferably a cloth or tissue when coughing or sneezing.

respiratory protection: The third level in the hierarchy of TB infection control measures (after administrative and environmental controls) is the use of respiratory protective equipment in situations in which the administrative and environmental controls do not eliminate the risk that exposures can still occur (e.g., airborne infection isolation rooms and rooms where cough-inducing or aerosol-generating procedures are performed).

risk assessment (TB): An initial and ongoing evaluation of the risk for transmission of *M. tuberculosis* in a particular healthcare setting. To perform a risk assessment, the following factors should be considered: the community rate of TB, number of TB patients encountered in the setting, and the speed with which patients with TB disease are suspected, isolated, and evaluated. The TB risk assessment determines the types of administrative and environmental controls and respiratory protection needed for a setting.

screening (TB): An administrative control measure in which evaluation for latent TB infection and TB disease are performed through initial and serial screening of healthcare workers, as indicated. Evaluation might comprise tuberculin skin test, blood assay for *M. tuberculosis*, chest radiograph, and symptom screening. See also **symptom screen**.

secondary (TB) case: A new case of TB disease that is attributed to recent transmission as part of the scenario under investigation. The period for “recent” is

not defined but usually will be briefer than 2 years. Technically, all cases are secondary, in that they originate from other contagious cases.

smear: A laboratory technique for preparing a specimen so bacteria can be visualized microscopically. Material from the specimen is spread onto a glass slide (and typically dried and stained). Smear, stain, and microscopy methods for mycobacteria are specific to this genus. The slide can be scanned by light or fluorescent high-power microscopy. These methods require ongoing quality assurance for prompt and reliable results. The results for sputum acid-fast bacilli (AFB) smears typically are reported as numbers of AFB per high-powered microscopy field, or else as a graded result, from no AFB to 4+ AFB. The quantity of stained organisms is associated with degree of infectiousness. See **acid-fast bacilli**.

source: The person or case that was the original source of infection for secondary cases or contacts. The source case can be, but is not necessarily, the index case.

source case investigation: An investigation to determine the source case could be conducted in at least 2 circumstances: 1) when a healthcare setting detects an unexplained cluster of tuberculin skin test conversions among healthcare workers or 2) when TB infection or disease is diagnosed in a young child. The purposes of a source case investigation are to ascertain that the source case has been diagnosed and treated, to prevent further *M. tuberculosis* transmission, and to ensure that other contacts of that source case are also evaluated and, if indicated, provided treatment.

specimen: Any bodily fluid, secretion, or tissue sent to a laboratory for testing.

sputum: Mucus-containing secretions coughed up from inside the lungs. Tests of sputum (e.g., smear and culture) can confirm pulmonary TB disease. Sputum is different from saliva or nasal secretions, which are unsatisfactory specimens for detecting TB disease. However, specimens suspected to be inadequate should still be processed because positive culture results can still be obtained and might be the only bacteriologic indication of disease.

sputum induction: A method used to obtain sputum from a patient who is unable to cough up a specimen spontaneously. The patient inhales a saline mist, which stimulates coughing from deep inside the lungs.

susceptibility: See **drug susceptibility test**.

suspected TB: A tentative diagnosis of TB that will be confirmed or excluded by subsequent testing. Cases should not remain in this category for longer than 3 months.

symptom screen: A clinical evaluation procedure in which patients are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g., cough).

symptomatic: A term applied to a patient with health-related complaints (i.e., symptoms) that might indicate the presence of disease. In certain instances, the term is applied to a medical condition (e.g., symptomatic pulmonary TB).

targeted testing: A strategy to focus testing for infection with *M. tuberculosis* in persons at high risk for latent TB infection and for those at high risk for progression to TB disease if infected.

transmission: Any mode or mechanism by which an infectious agent is spread from a source through the environment or to a person (or other living organism). In the context of healthcare-associated TB infection control, transmission is the airborne conveyance of aerosolized *M. tuberculosis* contained in droplet nuclei from a person with TB disease, usually from the respiratory tract, to another person, resulting in infection.

tubercle bacilli: *M. tuberculosis* organisms.

tuberculin: A precipitate made from a sterile filtrate of *M. tuberculosis* culture medium.

tuberculin skin test (TST): A diagnostic aid for finding *M. tuberculosis* infection. A small dose of tuberculin is injected just beneath the surface of the skin (in the United States by the Mantoux method), and the area is examined for induration by palpation 48–72 hours after the injection. The indurated margins should be read transverse (perpendicular) to the long axis of the forearm. See also **Mantoux method** and **purified protein derivative (PPD) tuberculin**.

tuberculosis (TB) disease: Condition caused by infection with a member of the *M. tuberculosis* complex that has progressed to causing clinical illness (manifesting symptoms or signs) or subclinical illness (early stage of disease in which signs or symptoms are not present, but other indications of disease activity are present). The bacteria can attack any part of the body, but disease is most commonly found in the lungs (pulmonary TB). Pulmonary TB disease can be infectious, whereas extrapulmonary disease (occurring at a body site outside the lungs) is not infectious, except in rare circumstances. When the only clinical finding is specific chest radiographic abnormalities, the condition is termed “inactive TB” and can be differentiated from active TB disease, which is accompanied by symptoms or other indications of disease activity (e.g., the ability to culture reproducing TB organisms from respiratory secretions or specific chest radiographic finding). See also **infection**.

tuberculosis (TB) infection: See **infection**.

two-step (tuberculin) skin test: A procedure used for baseline skin testing of persons who will periodically receive tuberculin skin tests (TSTs) (e.g., healthcare workers or residents of long-term–care facilities). Two-step TSTs are used to reduce the likelihood of mistaking a boosted reaction for a new infection. If an initial TST result is classified as negative, a second test is repeated 1 to 3 weeks later. If the reaction to the second TST is positive, it should be interpreted as evidence of infection with *M. tuberculosis* and indicates that the infection was most likely in the past and not recent. If the second TST is also negative, the person is classified as not being infected. Two-step skin testing has no place in contact investigations or in other circumstances in which ongoing transmission of *M. tuberculosis* is suspected.

ultraviolet germicidal radiation (UVGI): An air-cleaning technology that can be used in a room or corridor to irradiate the air in the upper portion of the room (upper-air irradiation) and is installed in a duct to irradiate air passing through the duct (duct irradiation) or incorporated into room air-recirculation units. UVGI uses ultraviolet germicidal irradiation to kill or inactivate microorganisms.

wheal: A small bump that is produced when a tuberculin skin test (TST) is administered. The wheal disappears in approximately 10 minutes after TST placement.

window period: The interval between infection and detectable skin test reactivity is referred to as the window period and is estimated to be 2–12 weeks.

extensively drug-resistant tuberculosis (XDR-TB): The occurrence of TB in persons whose *M. tuberculosis* isolates are resistant to isoniazid and rifampin and also resistant to any fluoroquinolone and to at least 1 of 3 injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin).