Arizona

TUBERCULOSIS PROGRAM MANUAL

Tuberculosis Control Program
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Arizona Department of Health Services

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About the Arizona Tuberculosis Program Manual

Purpose

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. Arizona has a rate of 4.7 cases/100,000 population/year thus The *Arizona Tuberculosis Program Manual* adapted this manual to meet the needs of the case rate for Arizona.

The *Arizona Tuberculosis Program Manual* is based on a template created by an advisory group convened during CDC Task Order #6. The advisory group developed the template's format and created its content by reviewing other TB control manuals, current CDC guidelines, and needs in the four low-incidence states of Idaho, Montana, Utah, and Wyoming.

Audience

The audience for this manual includes city/county/regional public health nurses, outreach workers, physicians, and public health officers; Indian Health Services (IHS) staff; physician consultants; private sector physicians; infection control nurses in hospitals and other facilities; disease intervention specialists; state epidemiologists; and state TB program staff.

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 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 in the forms section

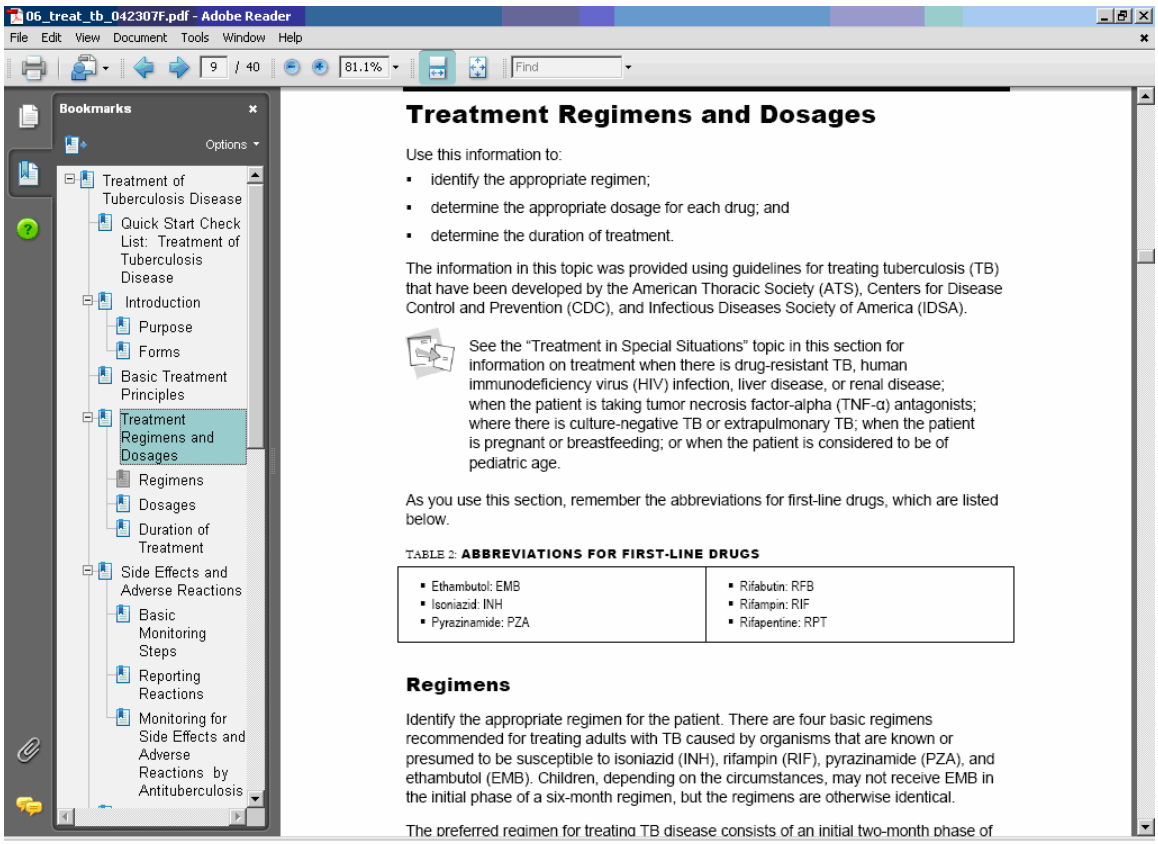
Bookmarks

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:

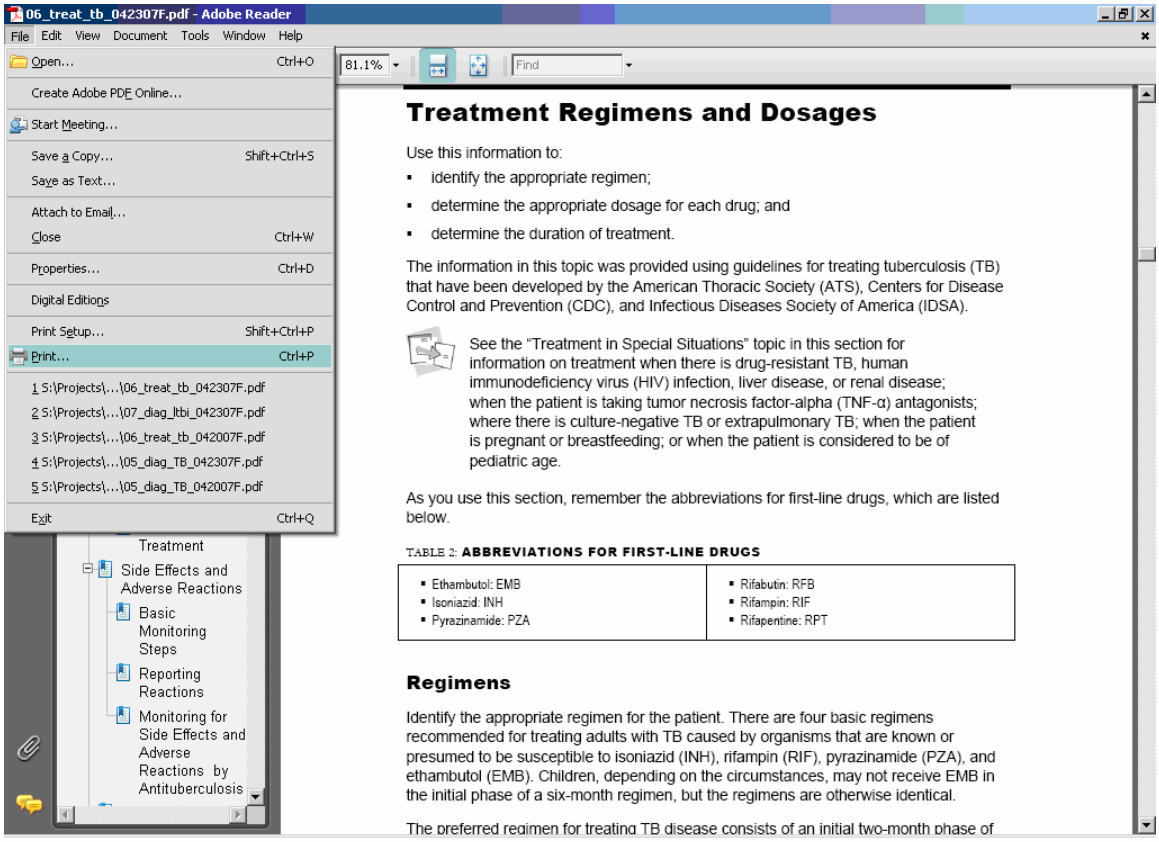
- Click + to see a more detailed list.
- Click – to hide the more detailed list.

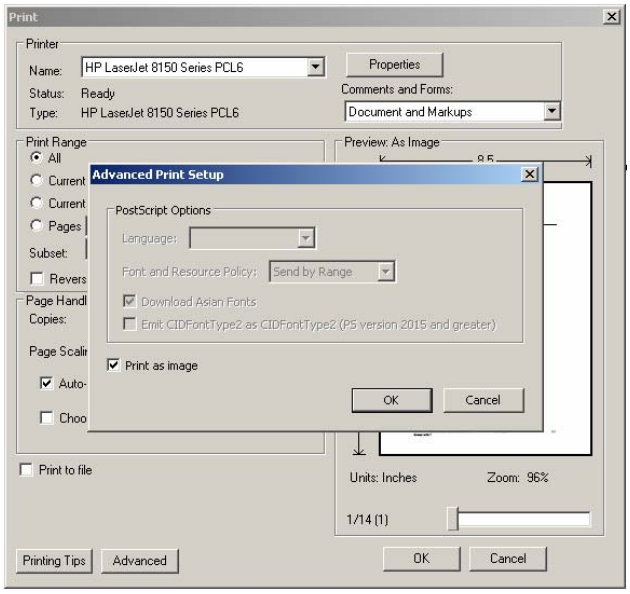
To go to a section or topic in the bookmarks list, point to its name and left-click.



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, click File/Print, click the Advanced button, check Print as Image, and then click OK. If you need further assistance with printing, call the ADHS TB Control Section at 602-364-4750 if you have any problems.

Icons

Throughout the manual, these icons quickly cue you about 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
DTBE	Division of Tuberculosis Elimination
DTH	delayed-type hypersensitivity
ED	emergency department
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
IDSA	Infectious Diseases Society of America
IGRA	interferon gamma release assay
INH	isoniazid
LTBI	latent tuberculosis infection
M. tuberculosis	*Mycobacterium tuberculosis*
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
NTNC	National Tuberculosis Nurse Coalition
NTM	nontuberculous mycobacteria
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
RFB	rifabutin
RFLP	restriction fragment length polymorphism
RIF	rifampin
RNA	ribonucleic acid
RPT	rifapentine
RVCT	*Report of Verified Case of Tuberculosis*
RZ	rifampin and pyrazinamide
TB	tuberculosis
TIMS	Tuberculosis Information Management System
TNF-α	tumor necrosis factor-alpha
TST	tuberculin skin test
TU	tuberculin units
USCIS	U.S. Citizenship and Immigration Services
UVGI	ultraviolet germicidal irradiation

Purpose of Tuberculosis Control

Tuberculosis (TB) is caused by a bacterial organism named *Mycobacterium tuberculosis.* (These organisms are sometimes called tubercle bacilli.) Mycobacteria can cause a variety of diseases. Some mycobacteria are called tuberculous mycobacteria because they cause TB or diseases similar to TB. These mycobacteria are *M. tuberculosis, M. bovis,* and *M. africanum.* Other mycobacteria are called nontuberculous mycobacteria (NTM) because they do not cause TB. One common type of nontuberculous mycobacteria is *M. avium* complex. Tuberculous mycobacteria readily spread from person to person; nontuberculous mycobacteria do not usually spread from person to person.

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

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

For information on the transmission of *M. tuberculosis* and on how LTBI progresses to TB disease, see the Centers for Disease Control and Prevention's (CDC's) online course *Interactive Core Curriculum on Tuberculosis* (2004) at http://www.cdc.gov/tb/webcourses/corecurr/index.htm .

The four fundamental strategies to reduce TB morbidity and mortality are

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; and
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 http://www.cdc.gov/MMWR/PDF/rr/rr5412.pdf .

Arizona Laws and Rules on Tuberculosis Control

Arizona laws and rules on tuberculosis (TB) are available by clicking on the following locations:

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizon Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

Contact the Arizona Department of Health Services TB Program at 602-364-4750 for assistance with interpreting laws and rules regarding TB control.

Objectives and Standards

Quality of Care

For tuberculosis (TB) programs, quality of care is measured by means of objectives and standards. Such objectives and standards are used as yardsticks to direct the program and measure its success.

Objectives reflect outcomes or results and program desires. Programs require objectives to define expected outcomes and results for case management activities.

Standards are an accepted set of conditions or behaviors that define what is expected and acceptable regarding job duties, performance, and provision of services. The TB control program works to achieve objectives through a series of standards.

In Arizona, TB program objectives and standards are established from the following:

State Laws and Regulations

See the above laws and regulations

TB Program Agreements, Plans, and Protocols

- Contracts between Arizona, TB Control and the local health agencies
- Centers for Disease Control and Prevention (CDC) Cooperative Agreement

National TB Guidelines

The national organizations or TB guidelines that help to establish the TB program's goals, objectives, and standards of performance include:

- American Thoracic Society (ATS)
- Infectious Diseases Society of America (IDSA)
- CDC Division of Tuberculosis Elimination (DTBE) guidelines

National Program Objectives

Below are national TB program objectives. The CDC program objectives are current as of December 2006.[4]

TABLE 1: PROGRAM OBJECTIVES AND PERFORMANCE TARGETS

Indicator		National Tuberculosis Program Objectives
1	Percent completion of treatment	Increase timely completion of treatment National Objective: At least 93% of patients with newly diagnosed tuberculosis (TB), for whom therapy for 12 months or less is indicated, will complete treatment within 12 months by 2015.
2	TB case rate	Decline in TB rates **a.** National Objective: The average yearly decline in TB rates in U.S. born will be >11%. **b.** National Objective: The average yearly decline in TB rates in foreign born will be >4%. **c.** National Objective: The TB rate in U.S. born will be <0.7 cases/100,000 by 2015. **d.** National Objective: The TB rate in foreign born will be <14 cases/100,000 by 2015. **e.** National Objective: The TB rate in U.S.-born black non-Hispanics will be <1.3 cases/100,000 by 2015. **f.** National Objective: The TB rate in children <5 years of age will be <0.4/100,000 by 2015.

Indicator		National Tuberculosis Program Objectives
3	Thorough contact investigations	Improve contact identification, evaluation, and treatment **a.** National Objective: All sputum-AFB-smear-positive TB cases will have at least one contact listed by 2015. **b.** National Objective: At least 93% of contacts to sputum-AFB-smear-positive TB cases will be evaluated for infection and disease by 2015. **c.** National Objective: At least 88% of infected contacts will start treatment by 2015. **d.** National Objective: At least 79% of contacts who start treatment will complete treatment.
4	Timely laboratory reporting	Ensure timely laboratory reporting **a.** National Objective: State public health labs will report 100% of results of culture identification of M. tuberculosis complex to submitter and state TB program within 21 days of receipt of specimen by 2015. **b.** National Objective: Increase the percentage of TB patients with initial positive cultures who also are tested for and receive drug susceptibility results to 100% by 2015.

Source: National TB Indicators Project. *Initial Indicators and Performance Targets.* Atlanta, GA: CDC Division of Tuberculosis Elimination; November 1, 2006. [Cleared by CDC but unpublished as of December 2006.]

In addition to the national program objectives listed above, the CDC has two goals (listed below) that do not have national program objectives established at this time. Specific objectives relating to these two goals will be established in the future. In the meantime, states should review the following two goals and establish objectives that are specific, measurable, and time phased, if applicable. National Goal 2 is listed for reference; it does not apply to low-incidence areas.

1. National Goal: Increase the percentage of immigrants and refugees designated as Class A, B1, or B2 who are appropriately evaluated and treated. Refer to the following Web link, pages 2-6, for classification descriptions: http://www.cdc.gov/ncidod/dq/pdf/ds-forms-instructions.pdf.

2. National Goal: For jurisdictions with greater than 50 reported cases of TB occurring annually in U.S.-born African Americans, decrease the case rate.

Standards

Program standards are what the stakeholders of the TB program would consider to be "reasonable expectations" for the program. For TB, standards have been established by nationally accepted authorities, such as ATS, IDSA and CDC, and generally recognized TB control experts, such as the National Tuberculosis Nurse Coalition (NTNC) and National Tuberculosis Controllers Association (NTCA). Many state programs, and some local TB control programs, have established their own standards and objectives for case management. As of late 2007, the NTNC currently is revising its Tuberculosis Nursing manual, which will contain the most current program, structural, and patient care standards that the NTNC recommends. Check for updates at http://www.ntca-tb.org.

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:

- 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 .
- ATS, CDC, IDSA. "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .
- CDC, NTCA. "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]). Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf .
- 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 .
- 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 .

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/nchstp/tb/pubs/mmwrhtml/Maj_guide/List_categories.htm .

Roles, Responsibilities, and Contact Information

The TB Control Section (TBCS) has the overall responsibility for surveillance, containment, management and assessment of TB activities in the state. Specific duties include the formulation and distribution of guidelines for TB control and prevention in Arizona, utilizing established recommendations from the CDC and ATS. The responsibilities of TBCS include:

a) Providing epidemiological, technical, medical, nursing, and programmatic consultative services regarding TB prevention and control to public and private health care providers, including local and Native American public health departments, public and private physicians and nurses, and public and private health care facilities,
b) Providing training upon request or identified need for individuals and groups with responsibility for diagnosing/evaluation and treating persons with Tb disease and LTBI,
c) Providing technical assistance as necessary,
d) Providing notification to the local health departments of any information received by the Refugee Health Program,
e) Providing reports as necessary to the CDC,
f) Working with Arizona State Laboratory to ensure quality TB laboratory services are provided in the state,
g) Ensuring that reporting regulations are met and assists local health departments in enforcing commitment laws when necessary,
h) Verification and accurate count of all new and recurrent cases of TB disease and known LTBI in children < six (6) years of age within the state,
i) Maintaining a registry for all known persons with LTBI who have been placed on preventive treatment, including contacts to persons with infectious TB disease,
j) Aggregating non-patient specific information and transmitting this information to CDC for inclusion in national statistics on the incidences of TB, as well as data on the utilization of recommended control and prevention measures,
k) Maintaining a registry of TB cases with drug resistant organisms, and provides drug resistance incidence data and technical advice regarding appropriate treatment regimens to health care providers throughout the state,
l) Providing case management consultation to local and district health departments and other health care providers,
m) Developing and distributing epidemiological data on the incidence and location of TB disease in Arizona,
n) Providing/assisting local health departments' TB programs with program evaluations, chart audits,
o) Initiating, developing, approving and monitoring contracts with local and district health departments to provide TB services.
p) Providing on-site evaluations of TB control programs in each local health department, and
q) Evaluating the TB control program and providing that information to CDC semiannually.

Roles and Responsibilities of the Local Health Departments

The basic role of the Local Tuberculosis Control Programs is to assure the provision of comprehensive TB prevention and control services to persons with known or suspected TB disease or latent TB infection, with as little disruption in their daily lives as possible. Each program is expected to ensure their practices are current based on the CDC guidelines. Local TB clinics have a major responsibility to prevent unnecessary hospitalization by performing, when possible, necessary screening and diagnostic testing along with providing appropriate treatment on an outpatient basis. The local health departments' responsibilities include:

a) Physician evaluation, including medical history;
b) Tuberculin skin test (Mantoux only) administration, reading and interpretation;
c) Chest x-rays (on-site or at a reasonable convenient location for the patient);
d) Chest x-rays reading and interpretation by a radiologist;
e) Collection of sputum specimens – natural and/or induced (on-site or at a reasonable convenient location for the patient);
f) Ensuring that persons on therapeutic or preventive regimens take their medication to completions, including directly observed therapy (DOT);
g) Monitoring persons on therapeutic or preventive regimens;
h) Contact identification, notification, and examination, with appropriate follow-up;
i) Consultation to other health care providers regarding TB control and prevention methods;
j) TB educational services for patients and their families, other health care providers, and the general public, as requested or required; and
k) Referral to appropriate agencies for assistance with identified problems/needs.

TB Nurses/Coordinators in the Local Health Department

The TB nurse/coordinators at the local health department have a major responsibility for a successful TB control program. They are the prime link in effective TB prevention and control for all persons in the community, whether hospitalized or on an outpatient basis. The responsibilities include:

a) Instructing the patient on the importance of continuous and uninterrupted drug therapy and precautions to take to prevent the transmission of infection
b) Case management to ensure the patient successfully completes anti-TB chemotherapy and treatment of LTBI.
c) Monitoring of the patient's clinical status and obtaining liver function studies monthly
d) Ensuring compliance with treatment
e) Collecting specimens as necessary
f) Ensuring other testing is completed as necessary
g) Referring patient to other appropriate agencies as necessary
h) Working with the physician to maintain standards of care for each patient
i) Contacting any health care provider (i.e. outpatient departments, infirmaries of state and local correctional and mental health institutions, federal facilities, and private physicians) to monitor the current status of the TB patient

j) Maintaining surveillance for TB within the community, an
k) Serving as a liaison between local health care providers and facilities and the TBCS.

Specific responsibilities include:

a) Initial patient visit – within 3 working days after receiving the report of a newly diagnosed or suspected case of TB. This visit is often the key to eventual successful completion of adequate treatment for the patient.
b) Assessment of the patient (See Case Management Section)
c) Development of the Nursing Care Plan (See Case Management Section)
d) Observation for infectiousness, i.e. coughing, general hygiene (if patient covers their cough, disposes of tissues, and collection of specimens without contamination,
e) Current and prior medical history, i.e., contacts with other TB cases or a previous history of TB of LTBI, length of illness, other chronic conditions, current medications (including over the counter and herbal), HIV status (or risk factors if not known),
f) Coping skills i.e., reaction of the patient and family regarding present condition. Identification of barriers to care in order to develop a plan of care,
g) Assessment of the patient's environment i.e. home, school work to determine shared environments with others. Also note the climate, central heating and air conditions, confined spaces, air movement within a home, office, classroom, etc., all may be factors to be taken into consideration,
h) Contact identification, ensuring all contacts are examined and appropriately managed. Identification of contacts to a smear positive TB case/suspect is a high priority activity and should begin within 3 working days of notification;
i) Initial contact evaluation, examination of close contacts of current infectious cases of pulmonary or laryngeal TB is the most productive method of case finding and initial evaluations should be completed within 10 working days of the initial report of the TB case/suspect. Tuberculin skin tests (TSTs) to household contacts and other close contact within one week of notification of the case. Standing orders may be used. If the TB suspect later prove to have disease caused by a mycobacterium other than tuberculosis (MOTT), the contacts with documented TSTs, $\geq$ 10 mm should be re-evaluated and determination made regarding preventive treatment. If the TST is $\geq$ 10 mm, it is appropriate to continue preventive treatment of LTBI to completion if the TB clinician, the primary health care provider and the patient agree.
j) Patient and family education, focusing on achieving an understanding of:
    - The disease process
    - The reason for chemotherapy for the patient and preventive treatment for contacts
    - The importance of continuous and uninterrupted therapy
    - The importance of maintaining regular medical supervision
    - The signs and symptoms of potential side effects of the prescribed medications and what course of action to follow should these occur
    - Transmission of TB and methods of prevention
    - The importance of covering the nose and mouth with tissue every time when coughing or sneezing whether alone or with others, and proper disposal of tissue
    - The probable duration of the infectious period

- The need for adequate ventilation
- The fact that dishes, linens, and other fomites require no special precaution
- The potential benefit of sleeping apart from the rest of the family during the infectious period
- The reason for contact identification and examination.

k) Medication orders for anti-tuberculosis chemotherapy from the primary health care provider and/or the TB clinician for the local health department. Directly observed therapy (DOT) is the standard of care. Rarely, there may be times when self administered therapy (SAT) is an acceptable option. For patients who are on SAT, only a one (1) month supply of medication may be given to the patient at any time. Monitoring for potential side effects of the medication is provided at each does for patients on DOT, and at least monthly for patients on SAT. If any prescription calls for a dose or method of administration which is different from what the CDC and or the ATS recommends the TB nurse/coordinator should consult with TBCS, the TB clinician for the local health department and/or the local health officer.

l) Specimen collection containers should be provided along with mailing tubes and instructions to the patient for collecting routine laboratory specimens and referral to a local health care provider for sputum induction may be necessary.

m) Contact follow-up is the responsibility of the TB nurse/coordinator when a TB case or suspect is identified in any long term care facility, including state or federal correctional institutions. Usually the institution is responsible to test contacts residing or employed within the institution and the local health department to test contacts outside the facility. The TB nurse/coordinator assures that the contact investigation has begun, assists in the investigation if requested, administers TSTs to contacts identified outside the institution but within that county and notifies TBCS of contacts requiring examination but residing in other jurisdictions. Contacts are to be evaluated and managed according to current recommendations as noted in this manual. Contacts on preventive therapy for LTBI must be followed and monitored at least monthly. Results of the contact investigation are sent to TBCS using the approved ADHS TB Prevention Registry form (see forms section), no later than four (4) months after the report of the index case.

n) Documenting records and reports in the patient's folder including components of the home, hospital, or clinic visits, contact examination results and follow-up treatment regimen, collection of specimens, smear and culture results, chest x-ray reports, other laboratory reports, assessment of compliance, and any other information pertinent to the appropriate case management of the patient in a timely manner and forwarded to TBCS. Examples of some of the forms include, Report of Verified Case of Tuberculosis (RVCT), RVCT Follow-up 1 & 2 forms and the ADHS TB Prevention Registry form (See the Forms Section).

o) Isolation assistance should be requested from the local deputy TB control office and/or the local health office and enforced, when necessary.

p) Quarantine enforcement should be used only in consultation with the local deputy TB control office and/or the local health officer and must by in compliance with the Arizona statues and/or rules to protect the health of the public. TBCS will assist the local TB nurse/coordinator with this responsibility as necessary and when requested (See page 1.10 on Arizona TB laws/rules)

Local Health Departments' Tuberculosis Program

Apache County Health Department
PO Box 1952, Springerville, AZ 85938
(928) 333-2475

Cochise County Health Department
1415 W. Melody Lane, Bldg A, Bisbee, AZ 85603
(520) 432-9464

Coconino County Health Department
2625 N. King Street, Flagstaff, AZ 86004
(928) 522-7108

Gila County Health Department
1400 E. Ash, Globe, AZ 85501
(928) 402-8848

Graham County Health Department
826 W. Main, Safford, AZ 85546
(928) 428-0110

Greenlee County Health Department
PO Box 936, Clifton, AZ 85533
(928) 865-2601

La Paz County Health Department
1112 Joshua St. #204, Parker, AZ 85344
(928) 669-1100

Maricopa County Health Department
1645 E. Roosevelt, Phoenix AZ 85006
(602) 506-6643 or (602) 506-6661

Mohave County Health Department
PO Box 7000, Kingman AZ 86401
(928) 753-0714, ext. 4281

Navajo County Health Department
117 E. Buffalo, PO Box 639, Holbrook, AZ 86025
(928) 535-6050

Navajo Nation TB Program
Gallup Indian Medical Center
(505) 722-1589
Public Health Nursing Department #39
PO Box 1337, Gallup NM 87301

Pima County Health Department
150 W. Congress, Tucson, AZ 85701

(520) 740-8613

Pinal County Health Department
188 S. Main St. Coolidge, AZ 85228
(520) 866-7362

Santa Cruz County Health Department
91 E. La Castellana Dr. Nogales, AZ 85621
(520) 375-5046

Tohono O'odham Health Department
PO Box 815, Sells, AZ 85634
(520) 383-6200

Yavapai County Health Department
930 Division St. Prescott, AZ 86301
(928) 771-3134

Yuma County Health Department
2200 W. 28th St. Yuma, AZ 85364
(928) 317-4585

Health Care Providers

Health care providers, including general hospital, outpatient departments, infirmaries of state and local correctional and mental institutions, federal facilities, as well as local health departments and private providers in the community, carry out the roles of evaluation, diagnosing, prescribing, and monitoring the medical care of those persons with TB disease or LTBI.

Health care providers and operators of homeless shelters in Arizona who know of a person who has or is suspected of having tuberculosis, are required by Arizona Revised Statues (ARS 36-723D, Section X.1) to notify the state TB control officer or the local health officer, and to cooperate in any investigation conducted as a result of the notification. Notification shall include, if known, the name, address and physical location of the person who has or is suspected of having TB. If the person reporting is a licensed physician, the report shall also include the condition of the person and the status of the disease.

According to Arizona Administrative Code (AAC R9-6-202A), a physician or an administrator of a health care facility or any authorized representative, shall report within twenty-four (24) hours to the local health agency by telephone or other equally expeditious means, any suspected or confirmed TB disease in any person, as well as any LTBI in a child less than six (6) years of age.

The reporting of each person with known or suspected new or recurrent TB disease and each child less than six (6) years of age with LTBI allows the resources of the local health department and TBCS to become available to assist the provider in the appropriate management of the patient. Epidemiological services are available to identify and examine source cases and contacts. The local health department may have chest x-ray availability on site, or will have arrangements made with other nearby health care facilities to provide x-ray services, including reading and interpretation. Some local health department may have laboratory services and local medical consultation. All local health departments have a Deputy TB Control Officer to assist the provider in the treatment and follow-up of each TB patient. All local health departments are also able to link the health care provider with all services provided by ADHS.

Close cooperation between health care providers and the local health department is imperative for the optimal outcome for the patient, contacts, and the community as a whole. Physicians and other providers described above are required to cooperate with the local health department when a report is requested on the follow-up care being given to a patient (ARS 36-723D). Periodic updates are required to monitor the patient's bacteriological, radiological, and chemotherapy status, or status of treatment for LTBI. Physicians and other health care providers are required to promptly report to the local health department if the patient ceases to or refuses to comply with medical

recommendations for voluntary examination, isolation, monitoring, quarantine or treatment for active TB (ARS 36-723E).

Any treating, screening or attending health care provider, clinical laboratory, or an operator of a homeless shelter, who knowingly fails or refuses to perform a duty or legal responsibility regarding known or suspected tuberculosis disease is guilty of a class 3 misdemeanor (ARS 36-737A).

Any person who knowingly obstructs, impairs or hinders an investigation into known or suspected tuberculosis disease is guilty of a class 3 misdemeanor (ARS 36-737D).

Any person who knowingly makes a false report of tuberculosis to the tuberculosis control officer or the local health officer is guilty of a class 3 misdemeanor (ARS 36-737E).

Clinical Laboratories

A clinical laboratory director, or authorized representative**,** in accordance with Arizona Administrative Code (AAC R9-6-202D), shall submit to the Arizona Department of Health Services a weekly written or electronic report of positive laboratory findings for *Mycobacterium tuberculosis* and its drug sensitivity patterns. AAC R9-6-202E requires that the written or electronic laboratory report shall include the patient's name, address and telephone number (if available), date of birth, reference number, specimen type, date of collection, type of test, test results, and the ordering physician's name and telephone number. This required report includes the findings of any test that is suggestive of tuberculosis, most specifically positive smears for acid-fast bacilli (AFB) as well as positive cultures for *Mycobacterium tuberculosis.*

In addition, in order to provide epidemiological data and information regarding TB in Arizona including drug-resistance patterns, all clinical laboratories are strongly encouraged to provide an isolate of all cultures positive for *Mycobacterium tuberculosis* to the Arizona State Laboratory, 250 N. 17th Ave., Phoenix, Arizona, 85007, telephone (602) 542-1188.

The following is from "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings Facilities, 2005/1994" published in Morbidity and Mortality Weekly Report, Vol. 5 434, No. RR 1713, December 30, 2005.

"Prompt laboratory results are crucial to the proper treatment of the TB patient and to early initiation of infection control measures. To ensure timely results, laboratories performing mycobacteriologic tests should be proficient at both the laboratory and administrative aspects of specimen processing. Laboratories should use the most rapid methods available (e.g., fluorescent microscopy for AFB smears; radiometric culture

methods for isolation of mycobacteria, nucleic acid probes, or high-pressure liquid chromatography (HPLC) for species identification; and radiometric methods for drug susceptibility testing). As other more rapid or sensitive tests become available, practical, and affordable, such tests should be incorporated promptly into the mycobacteriology laboratory. Laboratories that rarely receive specimens for mycobacteriologic analysis should refer the specimens to a laboratory that more frequently performs these tests."

Arizona State Laboratory

The Arizona State Laboratory processes sputum and other specimens for tuberculosis diagnostic and monitoring purposes as submitted by local health departments, private health care providers, health care facilities, and other laboratories at no charge to the patient, health care provider or facility, laboratory, or local health department. The results of acid-fast bacilli (AFB) smears, direct identification of mycobacteria from clinical specimens (rapid method), mycobacterial cultures, anti-tuberculosis drug sensitivity studies, and mycobacterial organism identification are included in the services provided. The laboratory serves as the tuberculosis reference laboratory for the entire state.

Specimen containers and mailing tubes may be obtained at no charge to patients or local health departments by calling (800) 542-3156, extension 1195, or (602) 542-1188.

Governmental and Voluntary Agencies

The Centers for Disease Control and Prevention (CDC) and the American Thoracic Society (ATS**)**, formerly the medical Section of the American Lung Association (ALA), provide official recommendations and guidelines for the control of tuberculosis, including standards of care for persons with known or suspected tuberculosis infection or disease, diagnostic methods, effective and appropriate anti-tuberculosis drug regimens, laboratory standards, contact identification, examination and follow-up, and methods for the prevention of transmission of tuberculosis within health care facilities and long-term care institutions. Both agencies also provide education, consultation and technical assistance as necessary to the Arizona Department of Health Services, Tuberculosis Control Section (TBCS), as well as public and private health care providers throughout the state upon request.

The CDC also provides a portion of the funds for the prevention and control of tuberculosis in Arizona. These funds are provided by an ongoing cooperative agreement between TBCS and the CDC, as well as special grants.

Cooperative agreement funds provide for salaries and travel funds for some TBCS staff, and supplemental contracted tuberculosis control services for the major tuberculosis incidence areas of the state, including three Mexican border areas, as well as mycobacterial laboratory services.

The State of Arizona provides General Revenue funds for contracts for tuberculosis services in local health departments, salaries for some TBCS staff, and laboratory services at the Arizona State Laboratory.

The American Lung Association of Arizona, through contracts with TBCS, provides continuing education offerings, and leadership in the Arizona TB-Free Coalition.

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.
[4] CDC Division of Tuberculosis Elimination. November 1, 2006. Cleared by CDC but unpublished as of December 2006.

Surveillance

CONTENTS

Introduction

Purpose

Use this section to

- 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 form
- Understand how the computerized TB registry works, and
- 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

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, and
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 Centers for Disease Control and Prevention's (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., defining the infectious period, settings, risk groups, mode of transmission, contact identification, and follow-up). However, long-term activities require continued active surveillance.

For more information on outbreak investigations, see the "Outbreak Investigation" topic in the Contact Investigation section.

Contact investigation: Collecting, analyzing, interpreting, and disseminating data on contacts and contact investigations are necessary for prioritizing the highest-risk

contacts, resulting in focused 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 on surveillance in contact investigations, see the Contact Investigation section.

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, to prevent subsequent progression to TB disease. Targeted testing and treatment of LTBI is best accomplished through cost-effective programs aimed at patients and populations identified on the basis of local surveillance data as being at increased risk for TB.[8]

For more information on surveillance and targeted testing, see the 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 on surveillance and targeted testing, see the Targeted Testing section. For more information on updated LTBI treatment recommendations, see the CDC's "Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection—United States, 2003" (*MMWR* 2003;52[31];735–739) at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5231a4.htm .

Policy

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

For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the Introduction.

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

Laws and Rules

Arizona laws and rules on tuberculosis (TB) are located by clicking the appropriate section below:

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizon Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations

Contact the Arizona TB Program at 602-364-4750 for assistance with interpreting state laws and rules regarding TB control.

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 Centers for Disease Control and Prevention (CDC) reports that delays in reporting cases of pulmonary TB are one of the major challenges to successful control of TB.[10] 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.[11] Also, by Arizona law and regulation, a case of TB disease in the United States must be reported to the local public health agency.

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."[12] These criteria are listed below in Table 1.[13]
- **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.[14]
- **Confirmed:** A case that meets the clinical case definition or is laboratory confirmed, as described below in Table 1.[15]

Table 1: CASE DEFINITIONS[16]

Clinical Case Definition	Laboratory Criteria for Diagnosis
A case that 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.[17]

For more information on suspected pulmonary TB, see the Diagnosis of Tuberculosis Disease section.

Mandatory and timely case reporting from community sources (e.g., providers, laboratories, hospitals, and pharmacies) 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.[18]

Prompt reporting (prior to culture confirmation) allows the state and local public health agency 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[19]

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.[20]

Reporting gives physicians access to resources provided by the local public health agency. Private physicians are encouraged to work collaboratively with their local public health agency 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 public health services may be available to assist physicians with managing their TB cases:

- Epidemiologic investigation, including identification and examination of contacts
- Chest radiographic services
- Antituberculosis medications
- Local public health agency laboratory services and consultation: The actual *M. tuberculosis* isolate should be sent to the state laboratory so that genotyping can be performed when needed. [21]

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

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

Reporting Suspected or Confirmed Cases of Tuberculosis to the Local Public Health Agency

Healthcare providers and laboratories should report suspected or confirmed cases of TB using the information in Table 2.

Table 2: WHEN TO REPORT TUBERCULOSIS

What Condition/ Test Result	Who Reports	When to Report	How to Report
Confirmed or suspected cases of tuberculosis (TB) disease Confirmation by laboratory tests is not required. This includes pulmonary and extrapulmonary cases.	▪ Physicians ▪ Other healthcare providers ▪ Hospitals ▪ Other similar private or public institutions ▪ 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.	Within one working (1) day	Telephone Contact the local health department
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: The laboratory must report even if the attending physician or other healthcare provider is also reporting.	Within one day	

* Note: Preliminary report of cultures growing AFB without confirmation of *M. tuberculosis* complex; final report of cultures that are demonstrated to be positive for *M. tuberculosis* complex.

The local health departments are to use the Report of Verified Case of Tuberculosis (RVCT) to report confirmed cases of TB to the state.

Healthcare Providers

Healthcare providers should report the following information on confirmed or suspected cases of TB.

Reporting Healthcare Provider
- Name
- Address
- Phone number
- Date of report

Patient Information
- Name
- Address
- Phone numbers
- Marital status
- Employment information
- Hospital admission information (name of hospital if applicable, date of admission)
- Type of isolation arrangements (if applicable, home, hospital, other)

Demographic and Social Information
- Date of birth
- Sex
- Race/ethnic origin
- Country of birth/date of arrival in the U.S.
- Drug and alcohol use
- Homeless within past year?
- Diagnosed in a correctional facility or long-term care facility?

Medical Information
- Reason for test
- Symptoms/onset
- Disease site
- Comorbid health conditions
- Human immunodeficiency virus (HIV) testing information
- Results of QuantiFERON®-TB Gold (QFT-G) or tuberculin skin test (TST) (TST in mm) and date of test
- Chest radiograph results and dates (if applicable)
- Bacteriology results, date(s), and name of laboratory performing test(s)
- Drug therapy (medications used, dates given, mode of treatment)

Laboratories

Laboratories should complete a Report of a Positive Laboratory Finding for Mycobacteria and submit to the Arizona Department of Health, TB Control Section with the following information on test results. All appropriate data fields need to be completed. If you need additional reporting forms contact the Arizona Department of Health, TB Control Section at 602-364-4750.

Required Reports from Local Public Health Agencies to to the Arizona Tuberculosis Program

Local public health agencies are required to complete and submit the reports listed in Table 3 to the TB Control Program at the Arizona Department of Health Services:

Table 3: REQUIRED REPORTS

ADHS Prevention Registry Form
Report of Verified Case of Tuberculosis (RVCT)
RVCT Initial Drug Susceptibility Report
RVCT Case Completion Report
RVCT Addendum Form
Report of a positive laboratory finding for mycobacteria

The ADHS registry form is available in the Forms Sections. To obtain the other forms for the above required reports, contact ADHS at 602-364-4750.

The Report of Verified Case of Tuberculosis (RVCT) forms are designed to collect information on cases of TB. Data obtained from RVCT forms are entered into the Tuberculosis Information Management System (TIMS) by the Arizona Department of Health Services, TB Control Program and then transferred electronically to the CDC. While a case of TB is required to be reported to the CDC only if active disease is verified and the case is to be part of the annual morbidity count, the CDC encourages the use of the RVCT forms and TIMS for the collection of data on suspected cases of TB. Verification of suspect cases can be accomplished through period updates of the records in TIMS.[22]

Data Collection

Forms

It is recommended that the following standardized forms (or similar forms developed by local public health agencies) be completed and placed in the patient's chart if and when the related activities are performed.

Table 4: RECOMMENDED FORMS FOR A TUBERCULOSIS PATIENT'S CHART

Chart of a Patient on Treatment for Tuberculosis Disease	
Tuberculosis (TB) Disease Treatment/Case Management Patient Education Confidentiality and Medical Records	Contact Investigation B Notifications Transfer Notifications

The following forms (or similar forms developed by local public health agencies) should be completed and placed in files for LTBI treatment and contact investigations.

Table 5: RECOMMENDED FORMS FOR A LATENT TUBERCULOSIS INFECTION PATIENT'S CHART AND FOR A CONTACT INVESTIGATION FILE

Chart of a Patient on Treatment for Latent Tuberculosis Infection	
Latent Tuberculosis Infection (LTBI) Treatment Contact Investigation Form	Transfer Notifications

To download forms for the above required reports, go to the Forms Section

Computerized Tuberculosis Registry

To carry out mandatory community public health responsibilities, the state TB control program maintains a computerized record system (case registry) with up-to-date information on all current clinically active and suspected TB cases in the community.[23] The TB case registry should ensure that laboratory data, including all initial diagnostic tests, are promptly reported, if applicable, to the healthcare provider and local and state TB control programs. 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. Providing this information supports education and advocacy and facilitates their collaboration in the planning process.

To ensure appropriate follow-up of all TB patients and persons suspected of having TB, the following registry information is updated by the Arizona Department of Health Services on a continuing basis:[24]

- Acid-fast bacilli smear results
- Culture results
- Drug susceptibility results
- Clinical status
- Chest radiograph results
- Doses of medications being administered

Document Retention

State Laws and Regulations

http://www.azleg.gov/FormatDocument.asp?inDoc=/ars/12/02297.htm&Title=12&DocType=ARS

http://www.lib.az.us/records/pdf/State_RD.pdf

The Arizona TB Program will maintain all state TB public health records for five (5) years.

Radiographs are not stored by the state. Radiographs are held by the principle healthcare provider or radiology office where the radiographs were obtained.

Case management health information and other TB records should be maintained at the local public health agency according to current applicable record retention rules and regulations.

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).

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 Arizona Department of Health Services, TB Control Program reviews all genotype results for clusters and contacts the appropriate local health agency or others as necessary.

For more information on genotyping, see the National Tuberculosis Controllers Association/Centers for Disease Control and Prevention Advisory Group on Tuberculosis Genotyping's *Guide to the Application of Genotyping to Tuberculosis Prevention and Control* (2004) at http://www.cdc.gov/tb/genotyping/manual.htm .

All positive *M. tuberculosis* cultures should be sent to your state public health laboratory for referral to the appropriate national genotyping laboratory.

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.

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.

For more information see the CDC's "Updated Guidelines for Evaluating Public Health Surveillance Systems" (*MMWR* 2001;50[No RR-13]) at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5013a1.htm .

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):10.

[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):10.

[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):10.

[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):15.

[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):5.

[6] 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):39.

[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):39.

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

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Targeted Testing for Latent Tuberculosis Infection

CONTENTS

Introduction

Purpose

Use this section to understand and follow national and the Arizona Department of Health Services guidelines to conduct targeted testing to screen for latent tuberculosis infection (LTBI).

In the 2005 guideline "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America," one of the recommended strategies to achieve the goal of reduction of tuberculosis (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]

For information on treatment, refer to the Treatment of Tuberculosis Disease and Treatment of Latent Tuberculosis Infection sections.

Reducing LTBI in high-risk populations is an important strategy to control TB. With an estimated 9.5–14.7 million persons with LTBI in the United States, continued progress toward eliminating TB in the United States and reducing TB among foreign-born persons requires effective strategies to meet this challenge.[2] Targeted testing for LTBI is a strategic component of TB control that identifies persons at high risk for developing TB who would benefit by treatment of LTBI, if detected. Persons with increased risk for developing TB include those who have had recent infection with *Mycobacterium tuberculosis* and those who have clinical conditions that are associated with an increased risk for progression of LTBI to active TB.[3]

Policy

In Arizona:

- 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.

- 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 a list of groups at high risk, refer to Table 1: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease**.

For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the Introduction.

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

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[4]

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.

High-Risk Groups

Certain factors identify persons at high risk for tuberculosis (TB) infection and/or for progression to TB disease. Persons in the high-risk groups listed in Table 1: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease** are candidates for tuberculin skin testing in Arizona.

Persons with risk factors from both columns may be at much higher risk than those with risk factors in only one column. For example, 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 2: Persons at high risk for Tuberculosis Infection and Progression to Tuberculosis Disease[5]

For Tuberculosis Infection	For Progression to Tuberculosis Disease[6]
▪ 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 U.S. 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 idea 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.

When to Conduct Targeted Testing

Targeted testing programs should be conducted only among groups at high risk, and testing should be discouraged for groups at low risk.[7] High-risk groups include persons with increased risk for developing tuberculosis (TB) and those who have clinical conditions that are associated with an increased risk for progress of latent TB infection (LTBI) to TB disease.

Factors that identify persons at high risk of LTBI infection and/or progressing to TB disease are listed in Table 1: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease.**

Evaluate high-risk patients for LTBI as specified in the Diagnosis of Latent Tuberculosis Infection section.

Offer treatment of LTBI to infected persons, irrespective of age, who are considered to be at high risk for developing active TB.[8] See the Treatment of Latent Tuberculosis Infection section.

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.[9]

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 or diabetes mellitus) that also confers a risk for acquiring TB. This approach depends on a person's risk profile for TB.[10]

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.[11]

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 the Arizona Department of Health Services TB Program at 602-364-4750.

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),[12] as determined in its TB risk assessment (both 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 .

In Arizona facilities such as hospitals should follow the Occupational Safety and Health Administration (OSHA) located at the following web-site: http://www.osha.gov/SLTC/tuberculosis/standards.html

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).

References

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[12] CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR* 2005;54(No. RR-17):10.

B Notifications

CONTENTS

Introduction

Purpose

Use this section to:

- Follow up on B1 and B2 notifications and
- Evaluate and treat immigrants with B1 and B2 notifications.

B notifications are sent by the Centers for Disease Control and Prevention (CDC) to the Arizona Department of Health Services Tuberculosis (TB) Program as follow-up to the screening mandated by US 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, domestic follow-up evaluation of immigrants and refugees with Class B1 and B2 TB notification status should be given highest priority by all TB control programs.[2] Legal immigrants and refugees with Class B1 and B2 TB notification status are also a high-priority subpopulation for screening for latent TB infection (LTBI).[3]

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.[4]

Not all foreign-born persons who enter the United States go through the same official channels or through the screening process.[5] 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**.

Persons entering in the nonimmigrant category do not require pre-entry screening, but as a condition of entry, persons migrating as immigrants, refugees, and asylees are required to be screened outside the United States for diseases of public health significance, including TB.[6,7] Applicants for immigration who plan to relocate permanently to the United States are required to have a medical evaluation prior to entering the country. Visa applicants 15 years or older must have a chest radiograph performed overseas as part of that medical evaluation. If the chest radiograph is suggestive of pulmonary TB disease, sputa for acid-fast bacilli (AFB) smears must be obtained.

Table 1: NUMBERS OF FOREIGN-BORN PERSONS WHO ENTERED THE UNITED STATES, BY IMMIGRATION CATEGORY, 2002[8,9]

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.	132,000	0.46%	Yes
Nonimmigrants are aliens granted temporary entry to the United States for a specific purpose (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.[10]			

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.

Applicants who are identified as having abnormalities in their chest radiographs consistent with TB are classified according to the criteria in Table 2: **Classification of Immigrants and Refugees in the B Notification Program**. An applicant whose chest radiograph is compatible with active TB but whose sputum AFB smear results are negative is classified as having Class B1 status and may enter the United States. If the chest radiograph is compatible with inactive TB, no sputum specimens are required, and the applicant enters the country with Class B2 status.[11] If abnormalities are present in a chest radiograph and if sputum AFB smears are positive, the applicant must receive a

Class A waiver before entry into the United States. Very few persons with A waivers enter the United States, so A waivers are not covered in these guidelines.

The Class B notification system follows up on medical screenings of persons with B1 and B2 classifications after their arrival in the United States.[12,13] Immigrants with a Class A waiver or with Class B1 or B2 status are identified at ports of entry to the United States by the US Citizenship and Immigration Services (USCIS) on entry to the United States and reported to CDC's Division of Global Migration and Quarantine (DGMQ). The DGMQ notifies state and local health departments of refugees and immigrants with TB classifications who are moving to their jurisdiction and need follow-up evaluations. Persons with a Class A waiver are required to report to the jurisdictional public health agency for evaluation or risk deportation. For persons with Class B1 and B2 status, however, the stipulated evaluation visits to the health agency are voluntary.[14]

Table 2: CLASSIFICATION OF IMMIGRANTS AND REFUGEES IN THE B NOTIFICATION PROGRAM[15]

Immigrant/ Refugee Classification	Overseas Chest Radiograph	Overseas Sputum Acid-Fast Bacilli Smears	Restrictions
A Waiver*	Abnormal, suggestive of active tuberculosis (TB) disease	Positive	May not enter the United States unless started on antituberculosis therapy and sputum smears are negative and apply for a waiver signed by the local health department in their intended US destination (A Waiver) or ▪ Complete TB therapy overseas
B1	Abnormal, suggestive of active TB disease	Negative	Instructed to voluntarily report to the local health department in the United States for further medical evaluation within 30 days of arrival
B2	Abnormal, suggestive of inactive TB disease	Negative	Same as above
* Very few persons with A waivers enter the United States, so they are excluded from these guidelines.			

Source: 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* [CTCA Web site]. September 1999:1. Available at: http://www.ctca.org/guidelines/IIA7bnotification.pdf . Accessed November 1, 2006.

Policy

Newly arrived refugees and immigrants with Class B1/B2 TB will receive thorough and timely TB evaluations and appropriate treatment to ensure prompt detection of TB disease and prevention of future cases.[16]

For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the Introduction.

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

Follow-up of B1 and B2 Tuberculosis Arrivals

Division of Global Migration and Quarantine Forms

The Centers for Disease Control and Prevention (CDC) Division of Global Migration and Quarantine (DGMQ) generates the following Class B notification forms:

- CDC 75.17: “Notice of Arrival of Alien with Tuberculosis”
- DS-2053: “Medical Examination for Immigrant or Refugee Application”
- DS-3024: “Chest X-Ray and Classification Worksheet”

The DGMQ sends the notifications to the state TB program. 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 United States.[17]

The Class B notification forms are then faxed and mailed to the appropriate local health departments.

Data Entry

Enter all immigrants’ names and addresses in the logbook or registry at the state TB program.

Patient Follow-up

The immigration paperwork may make it appear that a patient has had a complete evaluation for TB disease. However, the overseas evaluation is designed only to detect abnormal radiographs and determine infectiousness at the time of travel and does not rule out disease. Remember that all B1 and B2 arrivals need a new diagnostic evaluation for active disease, including a tuberculin skin test and new chest radiograph. Even if active TB disease is ruled out, most B1 and B2 arrivals are priority candidates for treatment of latent TB infection.

Follow-up on each B1 and B2 arrival is described below.

1. Check to see if the immigrant has already visited the health department or a private provider.
2. If not, then 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 health department and/or arrange for the patient to see a private provider. Whenever possible, communications should be made in the immigrant's first language.
3. If the immigrant does not visit the health department 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. Whenever possible, communications should be made in the immigrant's first language.
4. If the immigrant does not visit the health department 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. Take a representative who speaks the immigrant's first language if at all possible (if needed).
5. Every effort should be made to locate B1 or B2 arrivals as these immigrants are considered high risk for TB disease. Call the Arizona Department of Health Services TB Program for consultation when an immigrant is not located.
6. Complete Class B follow-up within one month.
7. Complete and return the B notification form CDC 75.17 to the Arizona Department of Health Services TB Program.[18] This form is essential for the Arizona Department of Health Services TB Program to conduct statewide surveillance and follow-up on all B1 and B2 arrivals and report results to the CDC.

Evaluation of B1 and B2 Tuberculosis Arrivals

Evaluation Activities

B1 arrivals had negative sputum acid-fast bacilli results overseas and have overseas chest radiographs that are abnormal and suggestive of **active TB disease**

B2 arrivals had negative sputum acid-fast bacilli results overseas and have overseas chest radiographs that are abnormal and suggestive of **inactive TB disease**.

Refer to Table 3 to determine which evaluation tasks should be done for B1 and B2 arrivals.

Table 3: EVALUATION ACTIVITIES FOR B1 AND B2 ARRIVALS[19]

Evaluation Activities	B1 Active TB	B2 Inactive TB
Determine tuberculin skin test (TST) status. If documentation is not available, administer a TST. A reaction of ≥5 mm is considered significant for persons with an abnormal chest radiograph.	Yes	Yes
Review the chest radiograph. Even if patients have their overseas chest radiographs available for comparison, a new chest radiograph generally should be taken.	Yes	Yes
Review tuberculosis (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 chest radiograph result, collect sputum specimens if the patient is symptomatic.	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. Collect sputum for testing, at the provider's discretion, based on the evaluation. Remember that a chest radiograph does not rule out TB disease with certainty. Regardless of chest radiograph result, collect sputum specimens if the 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.

Treatment

Prescribe medications as appropriate. *Do not start patients on single-drug therapy for latent TB infection (LTBI) until tuberculosis (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 chest radiograph 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 chest radiograph. Reevaluation in the United States may show the patient to actually have old, healed TB. According to current CDC/American Thoracic Society (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.[20]

For more information on treatment, see the Treatment of Latent Tuberculosis Infection and Treatment of Tuberculosis Disease sections.

Resources and References

Resources

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Diagnosis of Tuberculosis Disease

CONTENTS

Introduction

Purpose

Use this section to understand and follow national and Arizona guidelines to

- 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; and
- Diagnose TB disease.

It is important to understand when a person should be evaluated further for TB disease. Not recognizing TB symptoms promptly will lead 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, receipt of 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] The majority of pulmonary TB cases continue to be diagnosed at an advanced stage. Earlier diagnosis would result in less individual morbidity and death, 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. 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.

Policy

In Arizona:

- 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 the Introduction.

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

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[7]

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.

High-Risk Groups

Certain factors identify persons at high risk for tuberculosis (TB) infection and/or for progression to TB disease. Persons in the high-risk groups listed in Table 2: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease** are candidates for tuberculin skin testing in Arizona.

Persons with risk factors from both columns may be at much higher risk than those with risk factors in only one column. For example, 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 2: Persons at high risk for Tuberculosis Infection and Progression to Tuberculosis Disease[8]

For Tuberculosis Infection	For Progression to Tuberculosis Disease[9]
▪ 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 U.S. 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 idea 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.

Case Finding

Identifying Suspected Tuberculosis Cases

The majority of tuberculosis (TB) cases are detected during the medical evaluation of symptomatic illnesses. 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.[10] Professionals in the primary healthcare sector, including hospital and emergency department clinicians, should be trained to recognize patients with symptoms consistent with TB.[11]

Be alert for cases of TB among persons who have not sought medical care during evaluation of contacts of patients with pulmonary TB and of other persons with newly diagnosed infection with *Mycobacterium tuberculosis.* Perform screening for TB also 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, prisons, and other correctional facilities.[12]

Suspect pulmonary TB and initiate a diagnostic investigation when the historic features, signs, symptoms, and radiographic findings listed in Table 3 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.[13]

Note that 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[14] 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 mask and tissues.

Table 3: WHEN TO SUSPECT PULMONARY TUBERCULOSIS IN ADULTS[15]

Historic Features	▪ Exposure to a person with infectious tuberculosis (TB) ▪ Positive test result for *Mycobacterium tuberculosis* infection ▪ 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†,[16]
Signs and Symptoms Typical of TB	▪ Prolonged coughing (≥2–3 weeks) with or without production of sputum that might be bloody (hemoptysis)§,[17] ▪ Chest pain[18] ▪ Chills[19] ▪ Fever ▪ Night sweats ▪ Loss of appetite[20] ▪ Weight loss ▪ Weakness or easy fatigability[21] ▪ Malaise (a feeling of general discomfort or illness)[22]
Chest Radiograph: Immunocompetent patients	▪ Classic findings of TB are upper-lobe opacities, frequently with evidence of contraction fibrosis and cavitation¶
Chest Radiograph: Patients with advanced HIV infection	▪ Lower-lobe and multilobar opacities, hilar adenopathy, or interstitial opacities might indicate TB

* See Table 2: Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease.

† 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 symptom 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.

Extrapulmonary Tuberculosis

If a patient has a positive tuberculin skin test or interferon gamma release assay (IGRA), consider signs and symptoms of extrapulmonary TB.

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 4: **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.[23]

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

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 the Infection Control section of this manual.

Laboratories should report positive smears or positives cultures, and primary healthcare providers should report suspected or confirmed cases of TB to the health department, as specified in the "Reporting Tuberculosis" topic in the Surveillance section. Prompt reporting allows the health department to organize treatment and case management services and to initiate a contact investigation as quickly as possible.[24]

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 or interferon gamma release assay
- Chest radiography
- Bacteriologic examination

When a suspected case of pulmonary TB is identified, refer to Table 4 for guidelines for the initial steps of TB case detection in five clinical scenarios encountered by providers of primary healthcare, including those serving in medical emergency departments.[25]

Table 4: GUIDELINES FOR THE EVALUATION OF PULMONARY TUBERCULOSIS IN ADULTS IN FIVE CLINICAL SCENARIOS[26]

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[27]
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.[28]

† See Table 2: Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease.

§ 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 3: **When to Suspect Pulmonary Tuberculosis in Adults,** Table 4: **Guidelines for the Evaluation of Pulmonary Tuberculosis in Adults in Five Clinical Scenarios,** and Table 5: **Symptoms of Tuberculosis Disease**)
- Previous TB infection or disease
- Risk factors (as listed in Table 2: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease**)
- 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 pulmonary or laryngeal 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, such as ruling out a cancer diagnosis (e.g., through a chest radiograph given to patients before surgery).

The symptoms in Table 5 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 3: **When to Suspect Pulmonary Tuberculosis in Adults**.

Table 5: SYMPTOMS OF TUBERCULOSIS DISEASE[29]

Pulmonary	General: Pulmonary and Extrapulmonary	Extrapulmonary
▪ Coughing ▪ Coughing up sputum or blood ▪ Pain in the chest when breathing or coughing	▪ Chills[30] ▪ Fever ▪ Night sweats ▪ Loss of appetite[31] ▪ Weight loss ▪ Weakness or easy fatigability[32] ▪ Malaise (a feeling of general discomfort or illness)[33]	The symptoms depend on part of body affected by tuberculosis (TB) disease: ▪ TB of the spine may cause pain in the back. ▪ TB of the kidney may cause blood in the urine. ▪ Meningeal TB may cause headaches or psychiatric symptoms. ▪ Lymphatic TB may cause swollen and tender lymph nodes, often at the base of the neck.

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.

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 recur, 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 2: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease**.)[34] 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 2: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease**.

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.[35]

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[36]

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.[37]

Tuberculin Skin Test and Interferon Gamma Release Assays

Use the Mantoux 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. However, an IGRA can be done if there is suspicion that the TST result was a false positive.

Blood assay for *Mycobacterium 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 IGRAs. The IGRA currently approved by the Food and Drug Administration (FDA) and available on the market is QuantiFERON®-TB Gold (QFT-G), which can be used in all circumstances in which the TST is used. QFT-G usually can be used in place of the TST.[38] Other cytokine-based immunoassays are under development and may also become useful in the diagnosis of *M. tuberculosis* infection. Future FDA-licensed products, in combination with Centers for Disease Control and Prevention (CDC)-issued recommendations, may provide additional diagnostic alternatives.[39]

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.[40] In addition, the QFT-G test appears to be less affected by past Bacille of Calmette-Guérin (BCG) vaccination than the TST and may eliminate the unnecessary treatment of patients with BCG-related false-positive results.[41] However, the QFT-G test has practical limitations that include the need to draw blood and to ensure its receipt in a qualified laboratory in time for testing. For QFT-G tests, the blood must be incubated with the test antigens less than12 hours after collection, while the lymphocytes are viable.[42] Refer to www.quantiferon.com for available test sites. Refer to the Celestis web-site http://cellestis.com/ for additional information regarding a.new QuantiFERON®-TB Gold In-Tube (IT) test that has recently been approved by the FDA.

For both the TST and IGRA, additional tests, such as chest radiography and bacteriologic examination, are required to confirm TB disease.[43]

Persons with a positive QFT-G result or a positive TST result, regardless of symptoms and signs, should be evaluated for TB disease before LTBI is diagnosed. At minimum, a chest radiograph should be examined for abnormalities consistent with TB disease.[44]

A negative TST does not rule out TB disease[45]—as many as 20% of patients with TB disease have a negative TST reaction.[46] A negative TST result or a negative QFT-G 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.[47]

For more information on the Mantoux TST, see the Diagnosis of Latent Tuberculosis Infection section. For more information on IGRAs and the QuantiFERON®-TB Gold (QFT-G) Test, see the CDC's "Guidelines for Using the QuantiFERON®-TB Gold Test for Detecting *Mycobacterium tuberculosis* Infection, United States" (*MMWR* 2005;54[No. RR-15]) at http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf .

Chest Radiography

A posterior-anterior 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 5 years of age should receive posterior-anterior and lateral radiographs.[48]

Certain abnormalities on chest radiographs 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 chest radiograph. 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.[49]

For more information on chest radiography, see the Francis J. Curry National Tuberculosis Center's *Radiographic Manifestations of Tuberculosis: A Primer for Clinicians* (2006) at http://www.nationaltbcenter.edu/products/product_details.cfm?productID=EDP-04 .

Bacteriologic Examination

Refer to Table 6 below to determine the types of specimens needed to assist in the diagnosis of TB.

Table 6: 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.
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 ▪ Blood (heparinized)

Refer to Table 7 below for information on the bacteriology tests used to diagnose TB.

Table 7: BACTERIOLOGY TESTS USED IN DIAGNOSING TUBERCULOSIS DISEASE[50]

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).[51]
Nucleic Acid Amplification (NAA) Assay[52]	▪ 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.[53]	▪ Within 48 hours from specimen collection[54,55]
Culture	▪ Usually necessary for species identification of all clinical specimens suspected of containing mycobacteria. ▪ Is 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 [56,57]
Drug Susceptibility Testing	▪ For first-line drugs: Is performed on initial isolates of all patients to identify an effective antituberculosis regimen. ▪ For both first-line and second-line drugs: Is repeated on interim isolates when a patient remains culture-positive after 3 months of treatment.[58,59]	▪ 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 report positive smears or positives cultures, and primary healthcare providers should report suspected or confirmed cases of TB to the health department, as specified in the “Reporting Tuberculosis” topic in the Surveillance section. Prompt reporting allows the health department to organize treatment and case management services and to initiate a contact investigation as quickly as possible.[60]

For information on reporting, see the “Reporting Tuberculosis” topic in the Surveillance section.

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

For laboratory services available in Arizona contact the state lab at (602) 542-1188.

Resources and References

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Treatment of Tuberculosis Disease

CONTENTS

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. Successful treatment of TB has benefits both for the individual patient and the community in which the patient resides.

Use this section to understand and follow national and Arizona guidelines to

- 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; and
- hospitalize and coordinate hospital discharges of patients with infectious TB.

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]

Policy

Patients with TB disease in Arizona or who move to Arizona with reported TB disease should receive and complete treatment in accordance with the national guidelines set forth in this manual and in accordance with the following Arizona laws and regulations.

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

Forms

Required and recommended forms are available in the forms section.

For roles and responsibilities, refer to the chapter on “Roles, Responsibilities, and Contact Information,”

Basic Treatment Principles

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

Table 1: BASIC TREATMENT PRINCIPLES FOR TUBERCULOSIS DISEASE

Phase	Principles
At Start of Treatment	**Patient-centered care and directly observed therapy** (DOT). An adherence plan should tailor treatment and supervision to each patient by considering his or her clinical and social circumstances (patient-centered care), as well as emphasizing DOT.
	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.
	Human immunodeficiency virus (HIV) testing. HIV testing should be offered to all patients with TB disease.
	Medical supervision. Patients with confirmed or suspected tuberculosis (TB) disease must be under the supervision of a medical provider.
	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 isoniazid (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).

Phase	Principles
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

Use this information to:

- Identify the appropriate regimen;
- Determine the appropriate dosage for each drug; and
- Determine the duration of treatment.

The information in this topic was provided using guidelines for treating tuberculosis (TB) that have been developed by the American Thoracic Society (ATS), Centers for Disease Control and Prevention (CDC), and Infectious Diseases Society of America (IDSA).

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.

As you use this section, remember the abbreviations for first-line drugs, which are listed below.

Table 2: ABBREVIATIONS FOR FIRST-LINE DRUGS

▪ Ethambutol: EMB ▪ Isoniazid: INH ▪ Pyrazinamide: PZA	▪ Rifabutin: RFB ▪ Rifampin: RIF ▪ Rifapentine: RPT

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. Per the 2003 Red Book, American Academy of Pediatrics, page 653 "When drug resistance is suspected, …initial therapy should include a fourth drug, either ethambutol or an aminoglycoside, until drug susceptibility results are available. If an isolate from the pediatric case under treatment is not available, drug susceptibilities can be inferred by the drug susceptibility pattern of rates of single and multiple drug resistance can be helpful. Data may not be available for foreign-born children or in circumstances of foreign travel. If this information is not available, a 4-drug initial regimen is recommended."

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 the next page in Table 3.

For consultation regarding the treatment of TB, contact the Arizona Department of Health Services TB Control at 602-364-4750. Additional information can be obtained by contacting the Heartland National TB Center at 800-839-5864.

Table 3: DRUG REGIMENS FOR CULTURE-POSITIVE PULMONARY TUBERCULOSIS CAUSED BY DRUG-SUSCEPTIBLE ORGANISMS[2]

Initial Phase			Continuation Phase			Range of total doses (minimal duration)	Rating* (evidence)†	
Regimen	Drugs	Interval and doses‡ (minimal duration)	Regimen	Drugs	Interval and doses‡ § (minimal duration)		HIV–	HIV+
1	INH RIF PZA EMB	Seven days/week for 56 doses (8 wk) or 5 d/wk for 40 doses (8 wk)¶	1a	INH RIF	Seven days/week for 126 doses (18 wk) or 5 d/wk for 90 doses (18 wk)¶	182–130 (26 wk)	A (I)	A (II)
			1b	INH RIF	Twice weekly for 36 doses (18 wk)	92–76 (26 wk)	A (I)	A (II)#
			1c**	INH RPT	Once weekly for 18 doses (18 wk)	74–58 (26 wk)	B (I)	E (I)
2	INH RIF PZA EMB	Seven days/week for 14 doses (2 wk), then twice weekly for 12 doses (6 wk) or 5 d/wk for 10 doses (2 wk),¶ then twice weekly for 12 doses (6 wk)	2a	INH RIF	Twice weekly for 36 doses (18 wk)	62–58 (26 wk)	A (II)	B (II)#
			2b**	INH RPT	Once weekly for 18 doses (18 wk)	44–40 (26 wk)	B (I)	E (I)
3	INH RIF PZA EMB	Three times weekly for 24 doses (8 wk)	3a	INH RIF	Three times weekly for 54 doses (18 wk)	78 (26 wk)	B (I)	B (II)
4	INH RIF EMB	Seven days/week for 56 doses (8 wk) or 5 d/wk for 40 doses (8 wk)¶	4a	INH RIF	Seven days/week for 217 doses (31 wk) or 5 d/wk for 155 doses (31 wk)¶	273–195 (39 wk)	C (I)	C (II)
			4b	INH RIF	Twice weekly for 62 doses (31 wk)	118–102 (39 wk)	C (I)	C (II)

Definitions of abbreviations: DOT = directly observed therapy; EMB = ethambutol; INH = isoniazid; HIV = human immunodeficiency virus; PZA = pyrazinamide; RIF = rifampin; RPT = rifapentine.

* Definitions of evidence ratings: A = preferred; B = acceptable alternative; C = offer when A and B cannot be given; D = should generally not be offered; E = should never be given.

† Definition of evidence ratings: I = randomized clinical trial; II = data from clinical trials that were not randomized or were conducted in other populations; III = expert opinion.

‡ When DOT is used, drugs may be given 5 days/week and the necessary number of doses adjusted accordingly. Although 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 chest radiograph and positive cultures at completion of 2 months of therapy should receive a 7-month (31 week; either 217 doses [daily] or 62 doses [twice weekly]) continuation phase.

¶ Five-day-a-week administration is always given by DOT. Rating for 5 day/week regimens is rated AIII.

Not recommended for HIV-infected patients with CD4+ cell counts <100 cells/microliter.

** Options 1c and 2b should be used only in HIV-negative patients who have negative sputum smears at the time of completion of 2 months of therapy and who do not have cavitation on initial chest radiograph. For patients started on this regimen and found to have a positive culture from the 2-month specimen, treatment should be extended an extra 3 months.

Source: ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):3.

Dosages

For consultation regarding the treatment of TB, contact the Arizona Department of Health Services at 602-364-4750.

Once the appropriate regimen has been identified, refer to the following tables for instructions on dosages for each drug. First-line antituberculosis medications should be administered together; split dosing should be avoided.

The following drugs are available in the State of Arizona for treating TB disease. These drugs are provided free of charge upon approval of the TB Program.

- Isoniazid (INH)
- Rifampin (RIF)
- Rifabutin (RFB)
- Rifapentine (RPT)
- Ethambutol (EMB)
- Pyrazinamide (PZA)

For information regarding second-line drugs, contact the local health department.

Table 4: 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)	—

Drug	Preparation	Adults/children	Doses			
			Daily	1x/wk	2x/wk	3x/wk
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 intravenous use of INH, please consult with the Arizona Department of Health Services, TB Control Section at 602-364-4750.

‡ 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.

Table 5: SUGGESTED PYRAZINAMIDE DOSES, USING WHOLE TABLETS, FOR ADULTS WEIGHING 40 TO 90 KILOGRAMS[4]

Interval	Weight (kg)*		
	40–55 kg	56–75 kg	76–90 kg
Daily, mg (mg/kg)	1,000 (18.2–25.0)	1,500 (20.0–26.8)	2,000 † (22.2–26.3)
Thrice weekly, mg (mg/kg)	1,500 (27.3–37.5)	2,500 (33.3–44.6)	3,000 † (33.3–39.5)
Twice weekly, mg (mg/kg)	2,000 (36.4–50.0)	3,000 (40.0–53.6)	4,000 † (44.4–52.6)

* Based on estimated lean body weight.

† Maximum dose regardless of weight.

Source: ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):5.

Table 6: SUGGESTED ETHAMBUTOL DOSES, USING WHOLE TABLETS, FOR ADULTS WEIGHING 40 TO 90 KILOGRAMS[5]

Interval	Weight (kg)*		
	40–55 kg	56–75 kg	76–90 kg
Daily, mg (mg/kg)	800 (14.5–20.0)	1,200 (16.0–21.4)	1,600 † (17.8–21.1)
Thrice weekly, mg (mg/kg)	1,200 (21.8–30.0)	2,000 (26.7–35.7)	2,400 † (26.7–31.6)
Twice weekly, mg (mg/kg)	2,000 (36.4–50.0)	2,800 (37.3–50.0)	4,000 † (44.4–52.6)

* Based on estimated lean body weight.

† Maximum dose regardless of weight.

Source: ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):5.

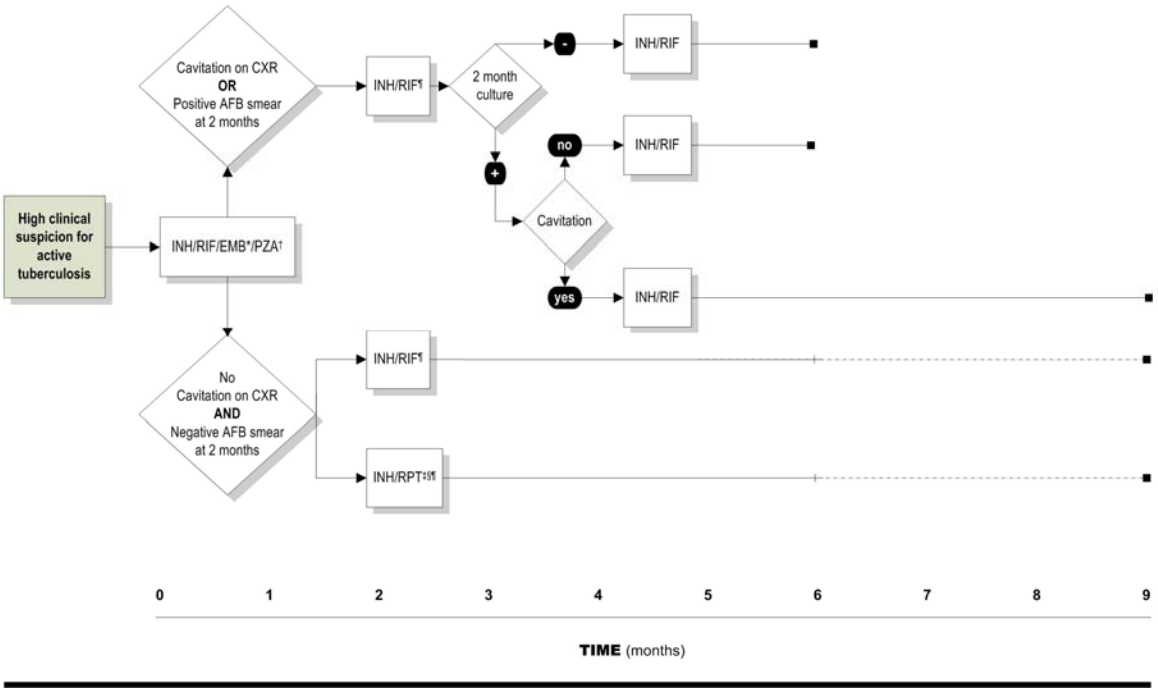
Duration of Treatment

Use the treatment algorithm in Figure 1: **Treatment Algorithm for Tuberculosis** to determine the duration of treatment. The four recommended regimens for treating patients with TB caused by drug-susceptible organisms have a duration of six to nine months. Each regimen has an initial phase of two months, followed by a continuation phase of either four or seven months.

Figure 1 gives directions for treating patients with pulmonary and extrapulmonary TB. The standard duration of treatment for pulmonary TB should be six months unless **both** cavitation is present **and** the patient is still culture positive after two months, in which case nine months is recommended. Note that there are three exceptions to the standard six-month duration of treatment.

1. For tuberculous meningitis, the optimal length of therapy has not been established, although some experts recommend 9 to 12 months.[6]
2. Treatment for bone or joint TB may need to extend to nine months.[7]
3. In HIV-negative, culture-negative patients, treatment for four months may be adequate if there is clinical or radiographic improvement and no other etiology identified.[8] However, HIV-infected patients with culture-negative pulmonary TB should be treated for a minimum of six months.[9]

Figure 1. TREATMENT ALGORITHM FOR TUBERCULOSIS[10]



Definition of 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 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 tuberculosis. *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 weekly 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. See Clinical Care Pathway and 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.[11]

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.[12] 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.[13] In addition, proper management of more serious adverse reactions often requires expert consultation.[14]

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/default.htm 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 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 clinic immediately.
    a. If a patient reports a potentially serious adverse reaction, call the patient's provider immediately and alert the state TB program by calling 602-364-4750.
    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 602-364-4750.
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, side effects, and adverse reactions (and any labs that were drawn)
    b. Education given
    c. Refill provided
    d. Description of any problems encountered and action taken for that visit
    e. Next appointment

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 7.

If a patient reports to a healthcare worker a potentially serious adverse reaction, the healthcare worker should call the patient's provider immediately and alert the state TB program by calling 602-364-4750.

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

Table 7: REPORTING REACTIONS TO ANTITUBERCULOSIS MEDICATIONS[15]

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

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

Table 8 is based upon national guidelines.

Table 8: MONITORING AND INTERVENTIONS FOR SIDE EFFECTS AND ADVERSE REACTIONS[16,17,18]

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 neurophathy 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/default.htm 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) or other standard 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

For consultation regarding a patient's response to treatment, contact 602-364-4750.

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. 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 after 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 tuberculosis (TB) medical expert should be consulted. Contact the Arizona Department of Health Services, TB Control Section at 602-364-4750 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.[19]

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.[20]

For consultation regarding the treatment of tuberculosis (TB) in a patient with negative cultures, contact the local health department, TB Control Section.

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.[21]

For consultation regarding completion of therapy or considerations for retreatment, contact the local health department, TB Control Section.

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.[22]

For consultation regarding post-treatment evaluation, contact the local health department, TB Control Section.

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
- Liver disease
- Renal insufficiency and end-stage renal disease (ESRD)
- TB associated with tumor necrosis factor-alpha (TNF-α) antagonists
- Culture-negative pulmonary TB
- Extrapulmonary TB
- Pregnancy and breastfeeding
- TB in children

For consultation regarding treatment in the following situations, contact the Arizona Department of Health Services, TB Control Section at 602-364-4750.

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.[23]

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.[24]

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.[25]

For consultation regarding the treatment of drug-resistant TB, contact the Arizona Department of Health Services, TB Control Section at 602-364-4750.

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. "Drug-Resistant Tuberculosis" (*TB Elimination Fact Sheet;* accessed April 23, 2007). Available at: http://www.cdc.gov/tb/pubs/TBfactsheets.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 [26]

Patients with HIV-related TB may experience a temporary exacerbation of symptoms, signs, or radiographic manifestations (paradoxical reactions) of TB while receiving antituberculosis treatment.[27]

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/PDF/wk/mm5302.pdf .
- 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 .

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.[28]

For all patients with preexisting liver disease, frequent clinical and laboratory monitoring should be performed to detect drug-induced hepatic injury.[29]

Resources

- ATS, CDC, IDSA. “Treatment of Tuberculosis” (*MMWR* 2003;52[No. RR-11]:11, 65). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .

For consultation regarding patients with preexisting liver disease, contact the Arizona Department of Health Services, TB Control Section at 602-364-4750.

Renal Insufficiency and End-Stage Renal Disease

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. To facilitate DOT (three times per week) and avoid premature removal of the drugs, administer all antituberculosis drugs immediately after hemodialysis.[30]

Resources

- ATS, CDC, IDSA. “Treatment of Tuberculosis” (*MMWR* 2003;52[No. RR-11]:10–11, 63–65). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .

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.[31]

Patients should be screened for risk factors for *M. tuberculosis* infection and tested for infection before initiating immunosuppressive therapies, including TNF-α antagonists.[32]

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.[33]

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.[34]

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.[35] However, HIV-infected patients with culture-negative pulmonary TB should be treated for a minimum of six months.[36]

For consultation regarding the treatment of TB in a patient with negative cultures, contact the local health department, TB Control Section.

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.[37] **Exceptions:** For bone or joint TB, use a six- to nine-month regimen.[38] For the meninges, use a 9- to 12-month regimen.[39]
- Consider prolonging therapy for patients with TB in any site that is slow to respond.[40]

Note: Affected lymph nodes may enlarge while patients are receiving appropriate therapy or after treatment has ended without any evidence of bacteriological relapse. On occasion, new nodes can appear during or after treatment as well.[41]

For consultation to discuss length of treatment, contact the local health department, TB Control Section.

Resources

- ATS, CDC, IDSA. "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]:10, 56–61). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .
- Division of Tuberculosis Elimination. *Fact Sheets* (Division of Tuberculosis Elimination Web site; accessed February 2007). Available at: http://www.cdc.gov/tb/pubs/TBfactsheets.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 .

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.[42]

Pyridoxine supplementation (25 mg/day) is recommended for all women taking INH who are either pregnant or breastfeeding.[43]

Resources

- ATS, CDC, IDSA. "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]:11, 62–63). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .
- CDC. *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/Default.htm .

Tuberculosis in Children

A pediatric patient is a person below six (6) years of age.

Because of the high risk of disseminated TB in infants and children younger than 5 years of age, treatment should be started as soon as the diagnosis of TB is suspected.[44]

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.[45]
- Duration of treatment in children is six months.
  Exception: For disseminated disease and TB meningitis, use a 9- to 12- month regimen.[46] For other exceptions, refer to "Duration of Treatment" in the "Treatment Regimens and Dosages" topic in this section.
- DOT should always be used in treating children.[47]

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.[48]

Resources

- ATS, CDC, IDSA. “Treatment of Tuberculosis” (*MMWR* 2003;52[No. RR-11]:9–10, 55–56). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .
- CDC. *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/Default.htm .
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- CDC. *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/Default.htm .

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[4] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):5.
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[6] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):57
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[8] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):6–7.
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[16] CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49(No. RR-6):26–29, 38–39.
[17] CDC. Module 4: treatment of tuberculosis and tuberculosis infection. *Self-Study Modules on Tuberculosis* [Division of Tuberculosis Elimination Web site]. 1999:8–9, 15–17. Available at: http://www.cdc.gov/tb/pubs/ssmodules/default.htm . Accessed July 3, 2006.
[18] 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.
[19] CDC. Response to treatment. In: 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/default.htm . Accessed November 20, 2006.
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[22] CDC. Response to treatment. In: 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/default.htm . Accessed November 20, 2006.
[23] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):68–69.
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[33] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):61.
[34] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):61.
[35] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):6, 61.
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[45] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):55–56.
[46] ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):56.
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Diagnosis of Latent Tuberculosis Infection

CONTENTS

Introduction

Purpose

Use this section to understand and follow national and Arizona guidelines to

- 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 the Contact Investigation section. For information on treatment, refer to the Treatment of Latent Tuberculosis Infection section.

Policy

In Arizona:

- 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 the Contact Investigation section.

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

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

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[2]

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

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.

High-Risk Groups

Certain factors identify persons at high risk for tuberculosis (TB) infection and/or for progression to TB disease. Persons in the high-risk groups listed in Table 2: **Persons at High Risk for Tuberculosis Infection and Progression to Tuberculosis Disease** are candidates for tuberculin skin testing in Arizona.

Persons with risk factors from both columns may be at much higher risk than those with risk factors in only one column. For example, 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 2: PERSONS AT HIGH RISK FOR TUBERCULOSIS INFECTION AND PROGRESSION TO TUBERCULOSIS DISEASE[3]

For Tuberculosis Infection	For Progression to Tuberculosis Disease[4]
▪ High-priority contacts such as housemates or coworkers or contacts of persons who have smear-positive pulmonary or laryngeal tuberculosis (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 U.S. 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 idea 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 been traditionally been based upon results of tuberculin skin testing. However, the QuantiFERON®-TB Gold test (QFT-G), a whole-blood interferon gamma release assay (IGRA), is now another option for detecting LTBI.

Use the Mantoux tuberculin skin test (TST) or the QFT-G to test for *Mycobacterium tuberculosis* infection. QFT-G can be used in all circumstances in which the TST is used, and the QFT-G usually can be used in place of (and not in addition to) the TST.[5]

For information on testing methods available in Arizona, refer to the Laboratory Services section.

Mantoux Tuberculin Skin Testing

The Mantoux method of tuberculin skin testing is used to detect infection with *Mycobacterium 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).[6] 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.[7] 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
- Greater than or equal to 10 mm
- Greater than or equal to 15 mm of induration[8]

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,[9] persons who have previously been vaccinated with Bacille Calmette-Guérin (BCG),[10] 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.

If the person being tested is a contact, follow the procedures outlined in the Contact Investigation section.

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.

Diagnosis and treatment of LTBI should be considered for BCG-vaccinated persons with a TST reaction of equal to or greater than 10 mm induration, especially if they are

- continually exposed to populations with a high prevalence of TB (e.g., some healthcare workers, employees and volunteers at homeless shelters, and workers at drug treatment centers);
- born or have lived in a country with a high prevalence of TB; or

- exposed to someone with infectious TB, particularly if that person has transmitted TB to others.[11]

Evaluate these patients for symptoms of TB. If a patient has symptoms of TB disease, obtain chest radiography and (if the patient is coughing) collect sputum specimens.

Anergy Testing

Anergy testing is not routinely recommended in conjunction with TST for HIV-infected persons in the U.S.[12]

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.[13] Persons who are symptomatic should receive a chest radiograph.

Live-Virus Vaccines

The Mantoux TST can be administered in conjunction with all vaccines. However, the measles (MMR) vaccine—and possibly mumps, rubella, varicella, and live attenuated influenza vaccines—may transiently suppress the response to PPD.[14] Therefore, if a vaccine containing live virus (e.g., measles, smallpox) has already been given, the TST should be deferred until (or repeated) at least four weeks after the vaccine was administered.

When giving the TST and the MMR, one of the following three sequences should be used:

- Apply the TST at same visit as the MMR
- Delay the TST at least four weeks if the MMR is given first
- Apply the TST first and then give the MMR when the TST is measured[15]

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.

Table 3: BEFORE YOU BEGIN TO ADMINISTER A TUBERCULIN SKIN TEST

Before You Begin to Administer a TST	
Review Information	CDC. *Mantoux Tuberculin Skin Test Facilitator Guide at* http://www.cdc.gov/tb/pubs/Mantoux/guide.htm Infection control procedures (including hand washing before and after the procedure and the use of gloves and a sharps container).
Gather Equipment	▪ Gloves ▪ Alcohol pads or alternative skin cleanser ▪ Safety needle ▪ Tuberculin syringe (Do not pre-draw tuberculin into syringes prior to test.) ▪ Purified protein derivative (PPD) (Tubersol® or Aplisol®: See the warning in the text below in this table.) ▪ Sharps container Note: Opened PPD tuberculin vials must be dated and discarded after 30 days. See the package insert for appropriate storage information.

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 http://www.cdc.gov/tb/notes/TBN_1_05/Errors_mix_up.htm .

How to Administer a Tuberculin Skin Test

1. If the patient's written consent is required, obtain it, per health department requirements.
2. Inject air into the vial air space (not into the solution). Injection of air into the air space in the vial prevents creation of negative pressure within the vial, allowing the antigen to be withdrawn easily. Injecting air into the solution creates bubbles and may interfere with withdrawing the correct amount of antigen.[16]
3. The injection should be placed on the palm-side-up surface of the forearm, about two to four inches below the elbow. Your local institutional policy may specify the right or 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, tattoos, or scars.
4. 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.
5. Using a disposable tuberculin safety needle and syringe, inject 0.1 ml of PPD tuberculin containing 5 tuberculin units (TU) intradermally with the needle bevel facing upward. 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.
6. The injection should produce a discrete, pale elevation of the skin (a wheal) 6 to 10 mm in diameter. **Note:** If a 6- to10-mm wheal is not produced, repeat the test on the opposite arm or the same arm, 2 inches from the original site.
7. Record the date and time of TST administration, location of injection site, dose, name of person who administered the test, name and manufacturer of tuberculin product used, lot number, expiration date, and reason for testing.[17]

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 the Infection Control section.

Before you measure a TST, review information in the CDC’s *Mantoux Tuberculin Skin Test Facilitator Guide* at http://www.cdc.gov/tb/pubs/Mantoux/guide.htm .

How to Measure a Tuberculin Skin Test

1. Measure the TST site crosswise to the axis of the forearm.
2. Induration is a hard, dense, raised formation. Measure only induration hardness and not swelling around the site of the injection. Do **not** measure erythema (redness). A TST with erythema, but no induration, is nonreactive.
3. Record the test result in mm, not as “positive” or “negative.” An exact reading in mm may be necessary to interpret whether conversions occur on a subsequent test. Record a TST with no induration as “0 mm.” Where there is induration, do not round off the reading, but record it exactly as read.
4. 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 http://www.fda.gov/medwatch/ .

Interpretation of the Tuberculin Skin Test

TSTs should be interpreted by a trained healthcare worker. Use Table 4 below to interpret TSTs.

Call the medical director regarding TST reactions when interpretation and medical follow-up are unclear.

Before you interpret a TST, review information in the CDC's *Mantoux Tuberculin Skin Test Facilitator Guide* at http://www.cdc.gov/tb/pubs/Mantoux/guide.htm .

How to Interpret a Tuberculin Skin Test

Use the table below to determine when a reaction is positive.

Table 4: 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 of 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) antagonists
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, Russia, 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

Induration Size	Considered Positive For:
15 mm or more	▪ Persons with no known risk factors for TB

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:

- Anergy

See “Anergy Testing” under “Candidates for Mantoux Tuberculin Skin Testing” in this section.

- Recent TB infection (within the past 10 weeks)
- Very young age (less than 6 months of age, because the immune system is not fully developed)
- Overwhelming TB disease
- Vaccination with live viruses (e.g., measles, mumps, rubella, varicella, oral polio, or yellow fever).

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)
- Corticosteroids or other immunosuppressive agents given for two or more weeks

False-positive reactions may be due to the following:[19]

- Nontuberculous mycobacteria (NTM) or mycobacterium other than tuberculosis (MOTT)
- BCG vaccination

See “Bacille Calmette-Guérin Vaccine” under “Candidates for Mantoux Tuberculin Skin Testing” in this section.

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

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 the Diagnosis of Tuberculosis Disease section. Refer to Table 3: **When to Suspect Pulmonary Tuberculosis in Adults**.

If the person is a contact, follow the procedures for testing and evaluation in the Contact Investigation section.

If the person is a participant in two-step screening, see the topic titled "Two-Step Tuberculin Skin Testing" in the Infection Control section.

If the TST result is positive, a chest radiograph should be obtained for the patient, as specified in the "Chest Radiography" topic in this section.

Interferon Gamma Release Assays

An interferon gamma release assay (IGRA) is another method to test for *M. tuberculosis* infection. For patients with a previous documented positive TST reaction, an IGRA can be done. Refer to www.quantiferon.com for available test sites. Refer to the Celestis web-site http://cellestis.com/ for additional information.

Blood assay for *Mycobacterium tuberculosis* (BAMT) is a general term referring to recently developed in vitro diagnostic tests that reveal the presence of infection with *M. tuberculosis*. This term includes, but is not limited to IGRAs. The IGRA currently approved by the Food and Drug Administration (FDA) and available on the market is QuantiFERON®-TB Gold (QFT-G), which can be used in all circumstances in which the TST is used. QFT-G usually can be used in place of the TST.[21] Other cytokine-based immunoassays are under development and may also become useful in the diagnosis of *M. tuberculosis* infection. Future FDA-licensed products, in combination with CDC-issued recommendations, may provide additional diagnostic alternatives.[22]

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.[23] In addition, the QFT-G test appears 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.[24] However, the QFT-G test has practical limitations that include the need to draw blood and to ensure its receipt in a qualified laboratory in time for testing. For QFT-G tests, the blood must be incubated with the test antigens <12 hours after collection, while the lymphocytes are viable.[25] .[26] Refer to www.quantiferon.com for available test sites. Refer to the Celestis web-site http://cellestis.com/ for additional information regarding a.new QuantiFERON®-TB Gold In-Tube (IT) test that has recently been approved by the FDA.

Additional tests, such as chest radiography and bacteriologic examination, are required to confirm TB disease. [27]

Persons with a positive QFT-G result or a positive TST result, regardless of symptoms and signs, should be evaluated for TB disease before LTBI is diagnosed. At minimum, a chest radiograph should be examined for abnormalities consistent with TB disease. [28]

Negative QFT-G results 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.[29]

For more information on IGRAs and the QFT-G test, see the CDC's "Guidelines for Using the QuantiFERON®-TB Gold Test for Detecting *Mycobacterium tuberculosis* Infection, United States" (*MMWR.* 2005;54[No. RR-15]) at http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf .

For information on laboratories that provide QFT-G testing services for Arizona, go to www.quantiferon.com. For supplies to draw and ship the blood samples, see the "Specimen Collection and Shipment Supplies" topic in the Supplies, Materials and Services section.

Chest Radiography

All individuals being considered for LTBI treatment should undergo a chest radiograph 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 5 to determine when to obtain a chest radiograph and what follow-up is required for chest radiograph results.

A posterior-anterior 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 5 years of age should receive posterior-anterior and lateral radiographs.[30]

For more information on chest radiography, refer to the Francis J. Curry National Tuberculosis Center's *Radiographic Manifestations of Tuberculosis: A Primer for Clinicians* (Francis J. Curry National Tuberculosis Center Web site; 2006) at http://www.nationaltbcenter.edu/products/product_details.cfm?productID=EDP-04 .

For persons recently exposed to TB, follow the procedures for testing and evaluation in the Contact Investigation section.

Table 5: 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?	Follow-up Action
Yes	Positive or negative	Yes or no	Normal or abnormal	▪ Classify as Class 5. ▪ Evaluate for TB disease. Refer to the Diagnosis of Tuberculosis Disease section.
No	Negative	No	CXR not recommended unless the patient has HIV infection or other forms of immunosuppression are present	▪ Classify as Class 0.
No	Positive	No	Normal	▪ Classify as Class 2. ▪ Consider treatment for LTBI. Refer to the Treatment of Latent Tuberculosis Infection section.
			Abnormal: Noncalcified fibrotic lesions suggestive of old, healed TB; comparison film available and stable	▪ Classify as Class 4 or 5. ▪ Consider evaluating for TB disease. Refer to the Diagnosis of Tuberculosis Disease section.
			Abnormal: Consistent with TB disease; no comparison film	▪ Classify as Class 3 or 5. ▪ Evaluate for TB disease. Refer to the Diagnosis of Tuberculosis Disease section.

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.

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Treatment of Latent Tuberculosis Infection

CONTENTS

Introduction

Purpose

Use this section to understand and follow national and Arizona guidelines to

- 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; and
- 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. Treatment of LTBI is essential to controlling and eliminating TB in the United States. LTBI treatment substantially

reduces the risk that TB infection will progress to disease.[4] Depending upon adherence and length of treatment, completing treatment for LTBI can reduce the risk of TB disease by 65–90%.[5]

Policy

Treatment should be considered for all persons who are determined to be candidates for the treatment of LTBI.

For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the Introduction.

Whom to Treat

Determine whom to treat for latent tuberculosis infection (LTBI). 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, which follow in this topic. For more information on targeted testing, see the Targeted Testing for Latent Tuberculosis Infection section.

High-risk contacts (under 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 the Contact Investigation section.

Several treatment regimens are available for the treatment of LTBI, and providers should discuss treatment options with their patients.[7]

For more information on treatment of LTBI, see the "Treatment Regimens and Dosages" topic in this section and the Centers for Disease Control and Prevention (CDC) publication "Treatment of Latent Tuberculosis Infection (LTBI)" (*TB Elimination Fact Sheet;* April 2006) at http://www.cdc.gov/tb/pubs/tbfactsheets/treatmentLTBI.pdf .

For consultation regarding the treatment of LTBI, contact the local health agency, TB program or the Arizona Department of Health Services, TB Control Section at 602-364-4750.

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.[8] 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 had TB disease.[9] Persons who are susceptible and/or vulnerable to TB disease are candidates for window period treatment, which is treatment for presumptive TB infection during the interval between infection and detectable skin test reactivity. The National Tuberculosis Controllers Association (NTCA) and the CDC recommend that the window period be estimated at 8 to 10 weeks.[10]

The following contacts with initially negative TST results should receive treatment for LTBI after TB disease has been ruled out by clinical examination and chest radiograph:

1. Contacts younger that 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 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 not necessary. 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. Less than 5 years old;
2. Aged 5–15 years, at the clinician's discretion; or
3. HIV-seropositive or otherwise immunocompromised.[11]

Persons known to be or suspected of being immunocompromised, such as HIV-infected persons, should be given treatment for LTBI regardless of the TST reaction.[12]

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 radiograph that is consistent with old TB

- Persons with organ transplants and other immunosuppressed patients (receiving the equivalent of 15 mg or more/day of prednisone for at least one month)[13]

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 Russia)
- 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 5 years of age and adolescents exposed to adults at high risk for developing TB disease[14]

Tuberculin Skin Test Results of 15 mm or More[15]

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[16]

* For healthcare workers (HCWs) who are otherwise at low risk for LTBI and progression to TB disease if infected and who received baseline testing at the beginning of employment as part of a TB infection-control screening program, a TST result of ≥15 mm (instead of ≥10 mm) is considered to be positive. Although a result of ≥10 mm on baseline or follow-up testing is considered a positive result for HCWs for the purposes of referral for medical and diagnostic evaluation, if the TST result is 10–14 mm on baseline or follow-up testing, the referring clinician might not recommend treatment of LTBI.[17]

Treatment Regimens and Dosages

Select appropriate treatment durations, regimens, and dosages. Treatment of latent tuberculosis infection (LTBI) is an essential part of the strategy to eliminate tuberculosis (TB) in the United States. Persons with LTBI who are considered at increased risk for TB should be offered treatment.[18]

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.

For a list of high-risk groups, see the “Whom to Treat” topic in this section.

High-risk contacts (under 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 the Contact Investigation section.

Regimens

Identify an appropriate regimen for the patient using the national guidelines provided in Table 1 below.

Table 1: RECOMMENDED DRUG REGIMENS FOR TREATMENT OF LATENT TUBERCULOSIS INFECTION IN ADULTS[19]

Drug	Interval and Duration	Comments	Rating* (evidence)†	
			HIV–	HIV+
INH	Daily for 9 months‡ §	In HIV-infected patients, INH may be administered concurrently with nucleoside reverse transcriptase inhibitors (NRTIs), protease inhibitors, or non-nucleoside reverse transcriptase inhibitors (NNRTIs).	A (II)	A (II)
	Twice weekly for 9 months‡ §	DOT must be used with twice-weekly dosing.	B (II)	B (II)
INH	Daily for 6 months§	This duration of therapy is not indicated for HIV-infected persons, those with fibrotic lesions on chest radiographs, or children.	B (I)	C (I)
	Twice weekly for 6 months§	DOT must be used with twice-weekly dosing.	B (II)	C (I)
RIF	Daily for 4 months in adults Daily for 6 months in children	RIF is used for persons who are contacts of patients with INH-resistant, RIF-susceptible TB. Some antiretroviral drugs, such as the protease inhibitors and NNRTIs, have interactions with the rifamycins. Clinicians should consult Web-based updates or experts for the latest specific recommendations. The optimal length of RIF therapy in children with LTBI is not known; however, the American Academy of Pediatrics recommends 6 months of treatment.[20]	B (II)	B (III)
Definitions of abbreviations: DOT = directly observed therapy; HIV = human immunodeficiency virus; INH =				

isoniazid; LTBI = latent tuberculosis infection; RIF = rifampin.

* Strength of recommendation: A = Preferred, B = Acceptable alternative, C = Offer when A and B cannot be given.

† Quality of evidence: I = Randomized clinical trial data, II = Data from clinical trials that are not randomized or were conducted in other populations, III = Expert opinion.

‡ Recommended regimen for children <18 years of age.

§ Recommended regimen for pregnant women.

Source: CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49(No. RR-6):31.

The regimen of rifampin (RIF) and pyrazinamide (PZA) for two months 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 American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC) Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection" (*MMWR* 2003;52[No. 31]:735) at http://www.cdc.gov/mmwr/PDF/wk/mm5231.pdf .

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.

The following drugs are available in the State of Arizona for treating LTBI. These drugs are provided free of charge by Arizona upon approval of the TB Program.

- Isoniazid (INH)
- Rifampin (RIF)

Table 2: RECOMMENDED DOSAGES[21,22]

Drug	Preparation	Adults/ Children	Daily	Twice a Week
INH	Tablets (50 mg, 100 mg, 300 mg); elixir (50 mg/5 ml)	Adults (max.)	5 mg/kg (300 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	Adults (max.)	10 mg/kg (600 mg)	10 mg/kg (600 mg)
		Children (max.)	10–20 mg/kg (600 mg)	10–20 mg/kg (600 mg)
Definitions of abbreviations; INH = isoniazid; RIF = rifampin.				

Source: ATS, CDC, IDSA. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11):4; CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49(No. RR-6):28–29.

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 are maple syrup, Nutella, spinach baby food, and chocolate whipped cream. Layer the food and drug on a spoon, and teach the child to take the contents of the spoon without chewing.[23]

Ann Loeffler, M.D. pediatrician and faculty consultant with the Francis J. Curry National Tuberculosis Center suggests the following for methods to deliver the drugs:

"Mix with soft vehicle and deliver in one or two spoonfuls – followed by food without medicine to clear the palate. The best vehicles seem to be strong flavored and darkly colored.

- Chocolate sauce, pudding, fudge sauce, ice cream, etc.
- Jelly or marmalade (the texture hides the powder granularity
- Apple sauce or berry-sauce (better to hide the red rifampin color)
- Nutella or peanut butter
- Cream cheese or chili con carne
- Whatever the family can make work."

For information on ordering drugs, see the Supplies, Materials, and Services section.

For consultation 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 Arizona Department of Health Services, TB Control Section at 602-364-4750.

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. 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 is associated with a predictable incidence of adverse effects, some mild, some serious.[24]

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.[25] 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.[26] In addition, proper management of more serious adverse reactions often requires expert consultation.[27]

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 latent tuberculosis infection (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 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 http://www.cdc.gov/tb/default.htm 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 every months 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 clinic immediately.

a. If a patient reports a potentially serious adverse reaction, call the patient's provider immediately and alert the state TB program by calling the Arizona TB Control Program at 602-364-4750.

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 4: **Monitoring and Interventions for Side Effects and Adverse Reactions** below.

b. Consult with the patient's provider and contact the Arizona TB program for more information by calling 602-364-4750.

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, side effects, and adverse reactions (and any labs that were drawn)

b. Education given

c. Refill provided

d. Description of any problems encountered and action taken for that visit

e. Next appointment

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.

If a patient reports to a healthcare worker a potentially serious adverse reaction, the healthcare worker should call the patient's provider immediately and alert the Arizona TB Program by calling 602-364-4750.

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

TABLE 3: REPORTING REACTIONS TO ANTITUBERCULOSIS MEDICATIONS[28]

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 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.[29]

At present, the 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 Arizona TB Program by calling 602-364-4750 to report severe adverse events.

Monitoring for Side Effects and Adverse Reactions by Antituberculosis Drug

Refer to Table 4**: Monitoring and Interventions for Side Effects and Adverse Reactions** to

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

Table 4: MONITORING AND INTERVENTIONS FOR SIDE EFFECTS AND ADVERSE REACTIONS[30,31,32]

Antituberculosis 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 neurophathy 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.

Antituberculosis 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 every month throughout treatment.[33] It is difficult to identify who will and who will not be adherent.[34] 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 clinician 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 on 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 the Patient Education section.

Directly Observed Therapy

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 progressing 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 the Case Management section.

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 http://www.umdnj.edu/globaltb/downloads/products/PediatricGuidelines.pdf.

Completion of Therapy

Determine whether and when therapy is completed based on 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 at completion, willingness to continue, etc.)

Give nonadherent patients 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.[35]

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 a healthcare provider at least every month or more often. Incentives and enablers are recommended as aids to adherence, and the healthcare provider should educate the patient about TB, its treatment, and the signs of adverse drug effects at each patient encounter.[36]

Table 5 describes the duration of therapy and the number of doses that patients are required to take to complete therapy and the time frame within which the total number of doses must be administered for completion of therapy.

Table 5: RECOMMENDED REGIMENS FOR COMPLETION OF THERAPY[37]

Regimen	Age	Duration of Therapy	Number of Doses	Must be Administered Within
INH daily	Adult and child	9 months	270	12 months
INH daily	Adult	6 months	180	9 months
INH twice weekly	Adult and child	9 months	76	12 months
INH twice weekly	Adult	6 months	52	9 months
RIF daily	Adult Child	4 months 6 months	120 180	6 months 9 months
Definitions of abbreviations: INH = isoniazid; RIF = rifampin.				

Sources: CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49(No. RR-6):26–27; CDC. Regimens. In: Chapter 6: treatment of LTBI. *Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]. Updated November 2001. Available at: http://www.cdc.gov/tb/pubs/corecurr/index.htm . Accessed February 1, 2007

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.[38]

For consultation regarding completion of therapy and considerations to examine when restarting treatment in noncompliant patients, contact the Arizona, TB Control Section at 602-364-4750.

Treatment in Special Situations

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 Arizona, TB Control Section at 602-364-4750 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 the Contact Investigation section.

Resources

- CDC. "TB Guidelines: HIV/AIDS" (DTBE Web site; accessed February 2007). Available at: http://www.cdc.gov/tb/pubs/mmwr/Maj_guide/HIV_AIDS.htm .
- ATS, CDC. "Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection" (*MMWR* 2000;49[No. RR-6]:33). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf .
- CDC. "Prevention and Treatment of Tuberculosis among Patients Infected with Human Immunodeficiency Virus: Principles of Therapy and Revised Recommendations" (*MMWR* 1998;47(No. RR-20). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4720.pdf .
- CDC. "Updated Guidelines for the Use of Rifabutin or Rifampin for the Treatment and Prevention of Tuberculosis among HIV-infected Patients Taking Protease Inhibitors or Nonnucleoside Reverse Transcriptase Inhibitors" (*MMWR* 2000;49[No. 9]:185). Available at: http://www.cdc.gov/mmwr/PDF/wk/mm4909.pdf

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. Extensive use of 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.[39]

Resources and References

Resources

Whom to Treat

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Treatment Regimens and Dosages

- 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
- CDC. “Update: Adverse Event Data and Revised American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC) Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection” (*MMWR* 2003;52[No. 31]). Available at: http://www.cdc.gov/tb/pubs/mmwr/mmwr_updates.htm .
- CDC. *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 .

Side Effects and Adverse Reactions

- CDC. “Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection” (*MMWR* 2000;49[No. RR-6]:26–29, 38–39). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf .
- National Tuberculosis Controllers Association–National Tuberculosis Nurse Consultant Coalition. *Tuberculosis Nursing: A Comprehensive Guide to Patient Care* (Atlanta, GA;1997:47–51, 63–64).
- 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://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/Default.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 (rewards) and enablers (things that remove barriers for patients)
  - Using directly observed therapy (DOT)
- CDC. *Improving Patient Adherence to Tuberculosis Treatment.* (1994)
- National Tuberculosis Controllers Association–National Tuberculosis Nurse Consultant Coalition. *Tuberculosis Nursing: A Comprehensive Guide to Patient Care* (Atlanta, GA; 1997:69–84).

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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 Arizona's guidelines to

- Conduct initial assessments;
- Develop treatment plans for case management activities;
- Conduct monthly ongoing assessments;
- Monitor adverse reactions to anti-tuberculosis 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; and
- 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 should undertake 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]

For roles and responsibilities, refer to “Roles, Responsibilities, and Contact Information” topic in Chapter 1 Introduction.

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

Acknowledgments

The authors want to acknowledge the extensive use of two non–Centers for Disease Control and Prevention (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.

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]

- To document assessment data, use the appropriate form in the Chapter on Forms

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 http://www.nationaltbcenter.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 http://www.healthlaw.org/library.cfm?fa=download&resourceID=89928&appView=folder&print .

- 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 http://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/m9/9-12.htm .

Patient's Medical Records

The case manager needs all medical records 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 judgments in medical management.[14]

Assessment Site

The case manager (or designee) should make an initial hospital visit within one business day of a referral or case report to assess the condition of the patient and begin the contact investigation.

If the patient is hospitalized, conduct the initial assessment during the patient's hospitalization. If the patient is not hospitalized, conduct the initial assessment at the first clinic visit or during a home visit within three business days after discharge.

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 hospital stay
- Monitor the TB medication regimen
- Identify any barriers or obstacles to adherence
- Review psychosocial status
- Identify and document a good 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 his or her family at one time.

Obtain or review demographic information, including the name, address, telephone number(s), birth date, Social Security number, and health insurance provider's name, address, and identifying information.[17]

Ascertain the extent of TB illness, including acuity and length of symptoms, bacteriology and radiographic findings, laboratory analyses, tuberculin skin 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.

The responsible physician and/or program medical consultant should be consulted within one business day of receipt of a suspect report. Within seven business days of a case report, a tuberculin skin test should be placed, measured, and interpreted; and a chest radiograph should be taken and interpreted. Also within seven business days of a case report, a minimum of three consecutive sputum specimens of good quality should be collected 8–24 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 chest radiographs 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 chest radiograph.

Obtain and review the patient's health history to determine concurrent medical problems, including human immunodeficiency virus (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 history of treatment for TB infection and/or disease, especially for patients 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 are contraindicated when a patient is taking birth control pills. For more information, see the "Side Effects and Adverse Reactions" topic in the Treatment of Tuberculosis Disease section.

Determine infectiousness or potential infectiousness. To determine where and whom to initiate 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 5 years, the contact investigation should focus on determining the source case of TB, since young children are not likely to transmit TB. Dates of exposure and most recent information concerning the infectiousness of the source case should be documented.

- For more information on the period of infectiousness and contact investigations, see the Contact Investigation section.

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 in working with children. When dealing 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. A clinician should initiate medical treatment within one business day of positive acid-fast bacilli (AFB) sputum smear results (unless there is evidence that the AFB is not *M. tuberculosis* complex, e.g., by direct test of sputum) or a presumptive diagnosis. A clinician should complete medical evaluations within seven days of a referral. Within one business day of receipt of medical orders which document drugs, dose, route, frequency, and duration, the case manager should order drugs. The case manager then should initiate treatment within one business day of receiving the drugs.

Monitor the TB medication regimen. The case manager should ensure that medications and dosages are prescribed according to current American Thoracic Society (ATS)/Centers for Disease Control and Prevention (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]

	For more information on treatment regimens and dosages contact the Arizona Department of Health Services TB Control at 602-364-4750 or see the Treatment of Tuberculosis Disease section. Additional information can be obtained by contacting the Heartland National TB Center at 800-839-5864.
	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 good 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. 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 patient 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. A contact investigation should begin within three days of a case/suspect report and be completed within 10 days.

For more information, see the Contact Investigation section.

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 anti-tuberculosis 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 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 anti-tuberculosis 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 and 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 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 should be the standard of care for all TB cases and suspects.

Establish time frames in the treatment plan to monitor the plan and patient response. Monitoring should be done at least every 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
- Evaluate and locate needed services relating to TB treatment
- Negotiate a plan for DOT or self-administration evaluation
- 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 assessed for HIV risk and 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.

Evaluate and 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. It is important to schedule or assist the patient in scheduling appointments and to monitor the patient's adherence to the appointment and the results. 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] Help 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 or self-administration evaluation. DOT should be the 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]

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. To be effective, incentives and enablers should be meaningful and specific for a particular patient.[37] Incentives and enablers should be considered for use with all patients.

Ongoing Assessment and Monitoring

Conduct ongoing assessments and monitor patients at least every month, 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, or are non-adherent 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]

- For ongoing assessment and monitoring, refer to the sample forms located in the forms section. For the reporting schedule, see Table 3: **Required Reports** in the "Required Reports from Local Public Health Agencies to the Arizona's Tuberculosis Program" topic in the Surveillance section.

Ongoing Assessment Activities

To complete an ongoing assessment, perform the following activities:

- Monitor the clinical response to treatment
- Determine human immunodeficiency virus (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, bacteriology reports, and radiographic results, including drug susceptibility results and TB symptoms, and comparing them to previous documented findings. This review is an important measurement of clinical improvement, worsening, or stabilization of the patient's condition. The case manager should collect a sputum sample for acid-fast bacilli (AFB) sputum smear and culture every month until sputum smear conversion. Thereafter, sputum samples should be collected every month until there are two negative cultures. If a patient is on DOT, no further specimen collected is indicated unless the patient becomes symptomatic. A clinician should complete a medical evaluation every month until treatment is completed, and periodically based on patient condition or review of diagnostic information, patient chart, and chest radiographs. If the patient's condition is worsening, interview the patient to determine the potential cause(s) for the worsening condition. List all bacteriological reports in chronological order, and correlate them with the patient's current symptoms history and chest radiograph report to ensure accuracy. Also, conduct this review at 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 manager. [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. [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 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 at the correct time, and in the correct dosage. Review the patient's treatment plan and chart, and correct the medications as necessary.

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 every one to two weeks 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 orders from the provider. See Table 8**: Monitoring and Interventions for Side Effects and Adverse Reactions** in the Treatment of Tuberculosis Disease section.

- 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. 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 or if there is suspicion of non-adherence if the case is on self-administered therapy. 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. 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. It is important not to send a mixed message to a patient by not promptly responding to missed DOT doses. A preventable interruption in treatment can be avoided if the case manager is notified immediately, rather than when the monthly DOT rate is calculated. Regularly monitor the effectiveness of enhancement methods (i.e., incentives, enablers, behavioral contracting, or behavior modification).[48] 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. DOT should be initiated if adherence is compromised, as evidenced by missed pill pick-up appointments, inaccurate pill counts, etc., in persons at high risk of developing TB disease.

The case manager should ensure that the patient is informed about the consequences of non-adherence, including legal interventions. Changes in the patient's attitude

toward the healthcare worker should be noted and verified with the patient.[49]

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.[50]

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.[51] The case manager should provide patient and family education every month and until satisfactory recall is obtained.

For more information, see the Patient Education section.

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 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.[52]

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.[53] A contact investigation should begin within three days of a case/suspect report and be completed within 10 days. 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 every one to two weeks 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 per orders from the provider See Table 8**: Monitoring and Interventions for Side Effects and Adverse Reactions** in the Treatment of Tuberculosis Disease section.

As is true with all medications, combination chemotherapy for tuberculosis is associated with a predictable incidence of adverse effects, some mild, some serious.[54]

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.[55] 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. [56]

- Instruct patients to report the side effects and adverse reactions listed in the “Side Effects and Adverse Reactions” topic in the Treatment of Tuberculosis Disease section.

- To record information from monitoring for side effects and adverse reactions, refer to the sample forms in the forms section.

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
- Assess the patient for side effects and adverse reactions
- Ensure patient contact information is updated monthly for effective case management

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.[57]

Assess the patient for adverse reactions and side effects. For patients on self-administered therapy, the case manager ensures that patients are assessed for adverse effects to TB medications at least every month and at each visit. If the patient is on DOT or pill counts, staff should assess patients for side effects and adverse reactions on each visit by performing a symptom review. If indicated, (such as fatigue, rash, poor appetite, nausea, bloating, vomiting, abdominal pain, jaundiced, dark urine, light stools, or neurological problems), 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 .[58]

Monitoring Bacteriologic Improvement

Assess and document response to treatment. The case manager should collect sputa for AFB sputum smear and culture every month until sputum smear conversion. Thereafter, a sputum sample should be collected every month until there are two negative cultures. If a patient is on DOT, no further specimen collection is indicated unless the patient becomes symptomatic. [59]

To record information from monitoring for bacteriologic and clinical improvement refer to the sample forms in the forms section.

Activities to Monitor for Bacteriologic and Clinical Improvement

To monitor for response to treatment, perform the activities described below.

For more information on discontinuing isolation, see the Infection Control section.

Acid-Fast Bacilli Sputum Smear Negative

If a patient is AFB sputum smear negative, place laboratory reports promptly in the patient's chart. If previously AFB sputum smear positive and now AFB sputum smear negative on three separate consecutive days, consider discontinuing isolation.[60]

Acid-Fast Bacilli Sputum Smear Positive

If a patient is AFB sputum smear positive **and**

- **Prior positive:** Place a report in the patient's chart. Repeat sputum smears every month until three consecutive negative sputum smears have been documented from different days.
- **Has new AFB sputum smear positive results and is diagnosed with pulmonary TB:** Notify the TB controller and provider and initiate isolation. Repeat sputa smears at appropriate intervals (and at least every monthly until three consecutive negative sputa smears have been documented from different days.[61]

Culture-Positive Pulmonary Tuberculosis

For patients with culture-positive pulmonary TB, collect two or more sputum specimens every month for smears and cultures until persistently negative cultures are documented. [62]

Continued Positive Sputum Smears or Positive Cultures

	If sputum smears are positive after two months, call the ADHS TB Control Section at 602-364-4750.

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 within one day after obtaining documentation of a positive/suspect TB case. The case manager should do the following:

1. Review and confirm the patient's medication compliance.
2. Place the patient on DOT, if not already on DOT.
3. Reconfirm the appropriateness of the medication regimen, based on drug susceptibility results and other considerations.
4. If additional anti-tuberculosis 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.
5. Consider serum drug levels.
6. Repeat cultures and repeat drug susceptibility testing.[63]

Culture Negative or No Specimens

If a patient is culture negative or no specimens were collected:

1. Review the medications that the patient was on at the time TB medications were started, particularly other antibiotics.
2. If applicable, obtain follow-up chest radiograph reports to determine improvement.
3. Review the patient's symptoms for improvement, if applicable.
4. Review the patient's tuberculin skin testing 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 manager or the ADHS TB Control Section, if necessary at 602-364-4750 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.
2. If a patient's TB organism is drug resistant:
    a. Notify the provider for adjustment of medications
    b. Confirm the appropriateness of regimen within one day of provider notification

c. If the regimen is inappropriate, immediately notify the clinician and the manager or the ADHS TB Control Section, if necessary at 602-364-4750.

d. Initiate DOT

3. If isoniazid-resistant or multidrug-resistant TB (MDR-TB):

a. Place contacts on appropriate latent TB infection (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. Contact ADHS TB Control Section at 602-364-4750 for consultation regarding the treatment of drug-resistant TB

Multidrug-Resistant Tuberculosis

If a patient has MDR-TB, the case manager should:

1. Notify his or her supervisor and the ADHS TB Control Section at 602-364-4750, and the patient's provider the same day that MDR-TB findings are reported/known.

2. Confirm initiation of an appropriate regimen **within one day.** If the provider is unwilling to institute an appropriate regimen, notify the case manager's supervisor and the ADHS TB Control Section at 602-364-4750 on the same day.

3. For consultation regarding the treatment of drug-resistant TB, contact the ADHS TB Control Section at 602-364-4750

4. Initiate transfer of patient care to a more appropriate provider, if necessary. The case manager, with TB clinician/ADHS TB Control Section at 602-364-4750 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. Initiate DOT and maintain accurate DOT records. If the patient is non-adherent with DOT, the case manager must document attempts to correct the situation and notify his or her supervisor.

7. Provide

a. Patient education, including information regarding second-line TB drugs;

b. Attempts to provide DOT at the patient's convenience;

c. Use of incentives and enablers; and

d. Legal orders.

Clinical Response to Treatment

The case manager should monitor/evaluate a patient's clinical response to treatment. Some indicators are:

1. Lessening or resolution of TB symptoms
2. Weight gain
3. Progressive improvement in the chest radiograph, 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. [64]

	For more information on isolation and quarantine, refer to the Infection Control section.

Closing a Case

If the patient is not to be reported as case, notify the provider that the patient is closed to TB control program services. The patient can be closed to TB Registry.

	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 Arizona's and the Centers for Disease Control and Prevention (CDC) goal and important measurement of the effectiveness of tuberculosis (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 RVCT Completion of Therapy Form.

Verifying Adequate Course of Treatment

Most cases of active TB can be successfully treated using the standard short course (six 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.

- **If 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 six-month course. See "Duration of Treatment" in the "Treatment Regimens and Dosages" topic in the Treatment of Tuberculosis Disease section.
- **HIV-negative, culture-negative patients:** See "Duration of Treatment" in the "Treatment Regimens and Dosages" topic in the Treatment of Tuberculosis Disease section.
- **Relapse of TB following treatment for TB with pan-susceptible organisms.** Treatment may be prolonged to nine months or more. (Current drug susceptibility testing must be performed and the regimen adjusted if resistance has developed.)[65]

Calculating Completion of Therapy

So that doses missed due to nonadherence or other treatment interruptions are still given after treatment is resumed, the 2003 revised TB treatment guidelines "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]) at http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf recommend basing 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).[66]

- For the total number of doses recommended for completion of regimens using first-line drugs, refer to the "Treatment Regimens and Dosages" topic in the Treatment of Tuberculosis Disease section.

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 Arizona TB Program 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 three documented good faith 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."[67] Continue to follow up with contacts.

Ensure that the contact investigation on the case is also completed. For more information, see the Contact Investigation Chapter.

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?

	There are cohort review forms available on the Washington State Department of Health's Website at http://www.doh.wa.gov/cfh/tb/guidelines.htm

Evaluation Activities

To evaluate case management, perform the following activities:

- Monitor the multidisciplinary care plan at least every month
- Identify strengths or weaknesses in the healthcare system
- Conduct a cohort analysis at least every three months
- Monitor the regulatory reporting mechanism and the contact investigation

Monitor the treatment plan at least every month, 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.[68]

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 month 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."[69] With the information learned from the evaluation, the case manager can make changes to improve patient care outcomes.[70]

Monitor reports to ensure that the TB case reports are accurate and updated according to state standards and that the contact investigation is complete.[71]

Directly Observed Therapy

Provide directly observed therapy (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.

DOT is a component of case management that helps to ensure that patients receive effective treatment and adhere to it. The American Thoracic Society (ATS), the Centers for Disease Control and Prevention (CDC), and Arizona recommend that every tuberculosis (TB) patient be considered for DOT.[72] DOT is implemented because

- 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;[73] and
- 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 Directly Observed Therapy

DOT *should be* the standard of care for all TB cases and suspects. In Arizona many public health agencies, DOT *is* the standard of care. That is, it is their 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.[74] Consider DOT for all patients with TB disease, and *ensure* that medications are delivered by DOT for the following patients:

- All patients being treated for active TB disease
- Patients with multidrug-resistant TB (MDR-TB)
- Immunocompromised persons on treatment for LTBI
- Pediatric contacts on treatment for LTBI
- Household contacts on treatment for LTBI

How to Deliver Directly Observed Therapy

Who Can Deliver Directly Observed Therapy?

- Usually TB clinic personnel, such as a nurse or other healthcare worker
- Staff at other healthcare settings, such as outpatient treatment centers

- Other responsible persons, such as school personnel, employers, others trained by the local health jurisdiction

Who Cannot Deliver Directly Observed Therapy?

- *F*amily members[75]

Principles of Directly Observed Therapy

- 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.[76,77]

Directly Observed Therapy 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 the Treatment of Tuberculosis Disease section.

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.[78]

5. Document the visit.

	Refer to the forms section for a sample DOT form Another sample of DOT form from Snohomish County in the State of Washington. The location is http://www.doh.wa.gov/cfh/TB/2004_guidelines/case_management/Snohomish%20DOT%20Form.pdf

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[79]

- For more information, refer to the Patient Education section and the "Incentives and Enablers" topic in this section.

Adherence to Directly Observed Therapy

Patient Education

The case manager should ensure that education is provided in the patient's primary language and is culturally appropriate.[80]

- For more information, see the Patient Education section. 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 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:

http://www.umdnj.edu/globaltb/downloads/products/PediatricGuidelines.pdf
.

Agreements

It may be useful to develop a letter of agreement or acknowledgment 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.[81]

Incentives and Enablers

Incentives and enablers may be appropriate to help patients adhere to DOT.

- For more information, see the "Incentives and Enablers" topic in this section.

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.[82] Incentives and enablers are used to improve patient attitudes and to foster good health behaviors.[83] They help patients stay with and complete treatment.[84]

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. [85] **Enablers** are those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties.

Eligible Patients

The following patients may receive incentives and/or enablers:

- Patients qualify for incentives and enablers as needed.

Available Incentives and Enablers

The following incentives and enablers are available in Arizona:

Table 1: AVAILABLE INCENTIVES AND ENABLERS

Incentives	Enablers

▪ Food and beverages
▪ Movie passes
▪ Restaurant/fast food vouchers
	▪ Transportation
	  • Bus pass
	  • Cab fare
	▪ 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

- To obtain incentives and enablers, see the “Incentives and Enablers” topic in the Supplies, Materials, and Services section.

State Laws and Regulations

For Arizona laws and rules on tuberculosis (TB), see the following:

- ARS§36-725. Orders to cooperate; emergency custody.
- ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
- ARS§36-727. Hearings; procedure; confidentiality.
- ARS§36-728. Judicial action.
- ARS§36-729. Amended orders for intervention and transport of afflicted persons.
- ARS§36-730. Appointment of guardian or conservator.
- ARS§36-731. Confinement; selection; jails; prohibition.
- ARS§36-732. Early release from court ordered treatment.
- ARS§36-733. Choice of physician and mode of treatment.
- ARS§36-734. Treatment; exemption.
- ARS§36-735. Notification of rights.
- ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
- ARS§36-737. Violation; classification.
- ARS§36-738. Qualified immunity.

Arizon Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

R9-3-303 Child Care Group Homes

R9-5-301 Child Care Facilities

R9-10-206 Hospitals Health Care Institutions: Licensing

R9-10-207 Medical Staff

R9-10-229 Infection Control

R9-10-503 Adult Day Health Care Facilities personnel

R9-10-706 Assisted Living Facilities – Personnel Qualifications and Records

R9-10-805 Hospice Staff

R9-10-905 Nursing Care Institutions Staff

R9-10-1103 Home Health Agencies Personnel

R9-10-1404 Recovery Care Centers, Personnel

R9-10-1704 Outpatient Surgical Centers

R2-20-204 Behavioral Health Service Agencies: Licensure

Understand when and how to use legal orders, if necessary, for adherence to therapy. Non-adherent 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.[86]

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 Non-adherent Patients**. Progressive intervention should begin with learning the possible reasons for non-adherence 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.[87]

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.[88]

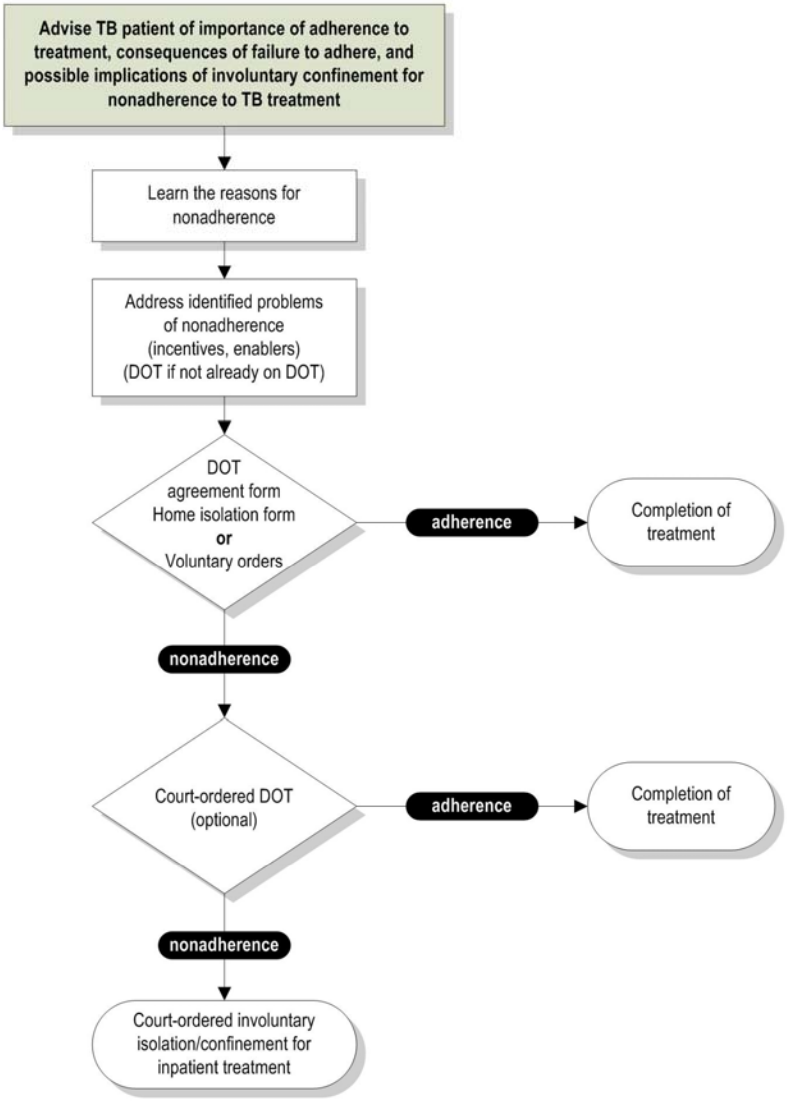
Use a DOT agreement form and home isolation form with a patient who is likely to comply with treatment requirements. With a patient who may need more encouragement to adhere to treatment, complete a voluntary orders form. Voluntary orders are not legal orders but serve to clarify the mutual understanding 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.

See the sample forms section. To ensure that they are effective, a state's voluntary orders forms should be developed in collaboration with court personnel.

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.[89]

Under normal circumstances, patients with extra-pulmonary 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. For additional information contact the Arizona Department of Health Services TB Program at 602-364-4750.

Figure 1: PROGRESSIVE INTERVENTIONS FOR NONADHERENT PATIENTS[90]



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.

- Criteria for starting isolation and discontinuing isolation are provided in the Infection Control section.

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 .
- 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 .
- 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). Available at: http://www.ctca.org/guidelines/IIA6casemgmt.pdf .
- 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.edu/catalogue/epub/index.cfm?uniqueID=1&tableName=DOTE .

Incentives and Enablers Resources

- CDC. "Adherence" in 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/Chapter_7_Adherence.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 .

Legal Orders Resources

- 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 .
- New Jersey Medical School National Tuberculosis Center. *Implementing Legal Interventions for the Control of Tuberculosis* (New Jersey Medical School Global Tuberculosis Institute Web site; 2005). Available at: http://www.umdnj.edu/globaltb/products/legalinterventions.htm .
- State of Washington. *Washington State TB Guidelines—Revised* (Washington State Department of Health; October 2004). Available at: http://www.doh.wa.gov/cfh/TB/guidelines.htm .

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[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):32.

[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.

[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):14.

[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):17.

[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):17.

[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.

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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 *Mycobacterium tuberculosis* due to recent exposure to a newly diagnosed or suspected case of pulmonary, laryngeal, or pleural tuberculosis (TB).

The primary goal of a contact investigation is to

- Identify persons who were exposed to an infectious case of TB
- Ensure that contacts receive
  - Testing for *M. tuberculosis* infection;
  - Screening for TB disease;
  - Medical evaluation, if indicated;
  - Prompt initiation of treatment for latent tuberculosis infection (LTBI) if at high risk (younger than 5 years of age or immunocompromised); and
  - Complete, standard course of treatment, unless medically contraindicated.[1]

Secondary goals of a contact investigation are to

- Stop transmission of *M. tuberculosis* by identifying persons with previously undetected infectious TB; and
- 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 Arizona's guidelines to do 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 Centers for Disease Control and Prevention (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 Arizona should be directed to meeting 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 prompt identification of contacts of 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 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]: 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 United States.[5]

The evaluation of contacts of cases of infectious TB is one of the most productive methods of identifying adults and children with LTBI at high risk for progression to TB disease and persons in the early stages of TB disease. Contact investigations, therefore, serve as an important means of detecting 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;
- Respiratory specimens that have acid-fast bacilli (AFB) on microscopy;
- Especially both.[8]

Persons with AFB sputum smear negative results are less likely to be infectious, but are still capable of infecting others.

For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the previous chapter.

Forms

For each investigation, complete the ADHS Prevention Registry Form on the reporting schedule in Table 3: **Required Reports** in the “Required Reports from Local Public Health Agencies to the Arizona Tuberculosis Program” topic in the Surveillance section. Forms are available in the sample forms section.

Persons with AFB sputum smear negative results are less likely to be infectious, but are still capable of infecting others.

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 for 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 about 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 pragmatic 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 on 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 10 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 5 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 5 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

This evaluation 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 rate of decrease cannot be predicted for individual patients, and an arbitrary determination is required for each.

Treatment After Exposure to Drug-Resistant Tuberculosis

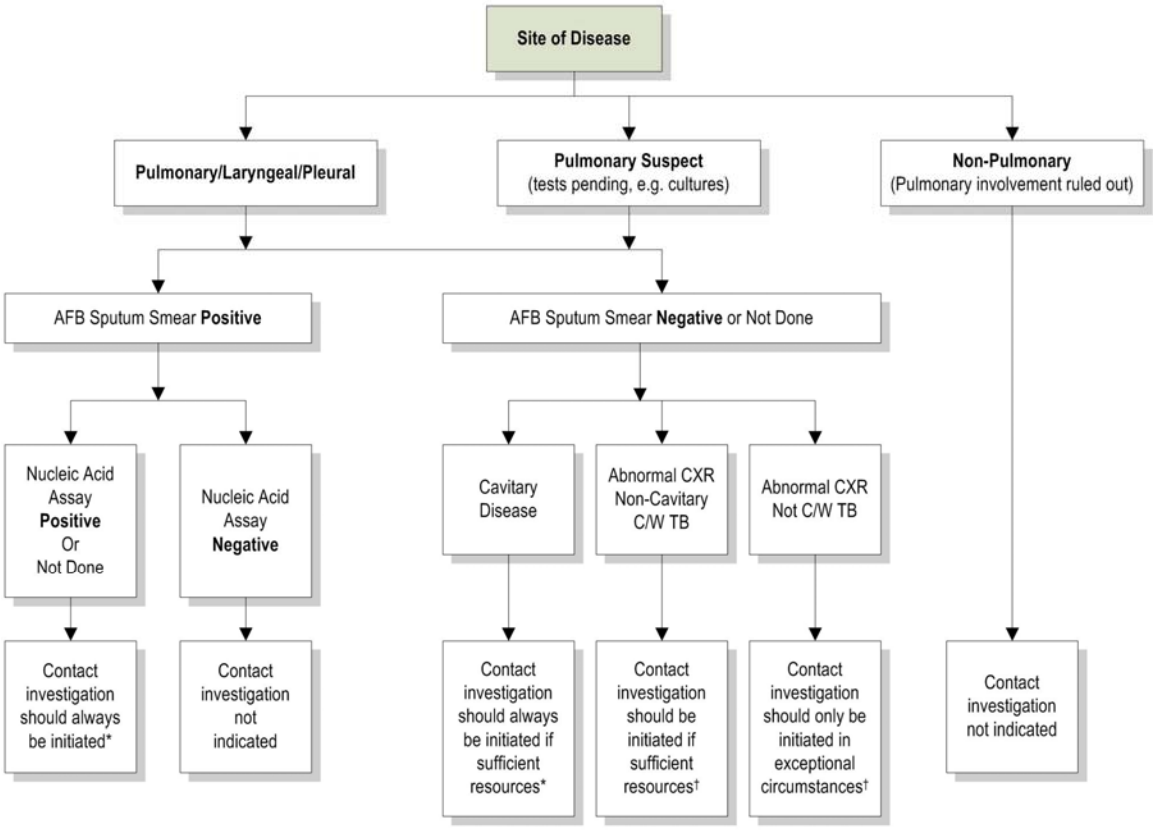
Drug susceptibility results for the *M. tuberculosis* isolate from the index patient (i.e., the presumed source of infection) are absolutely necessary for selecting the treatment regimen.

Resistance to only isoniazid (INH) leaves the option of four months of daily rifampin (RIF), but additional resistance to 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 can 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.

  For more information on outbreak investigations, see the "Outbreak Investigation" topic in this section.

- **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 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 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 as well as the duration and circumstances of the exposure, and the vulnerability/susceptibility of the contacts to disease from *Mycobacterium tuberculosis* infection.

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)	**≤1 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 First Interview**	**3 Business Days After 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 First Interview**	**1 or 2 Weeks After First Interview**
Reassessment of 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.

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 mycobacteriology 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 tuberculin skin test (TST) if contact is initially TST-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-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 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 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	To provide epidemiologic analysis of investigations and to measure performance using indicators that reflect performance objectives[27]	Ongoing
Collect data to complete the *Aggregate Reports for Tuberculosis Program Evaluation (ARPE)* form	To report on investigation to the Centers for Disease Control and Prevention	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 mycobacteriology 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 consultation regarding the appropriateness of a third TST, call the Arizona Department of Health at 602-364-4750.

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 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 are the approximate dates that TB symptoms were noticed, bacteriology 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						Recommended Beginning of Likely Period of Infectiousness
Tuberculosis Symptoms		Positive Acid-Fast Bacilli Sputum Smear Results		Cavitary Chest Radiograph		
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.

- 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 with pulmonary or laryngeal TB returning to a congregate living setting or to any setting in which susceptible persons might be exposed should meet the following criteria for noninfectiousness.

1. Have had three consecutive AFB-negative results from sputum specimens collected 8 to 24 hours apart, with at least one being an early morning specimen, and

2. Have been on antituberculosis therapy for two weeks, and

3. Diminished symptoms.

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 specific care for the 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 is at home, to obtain further information and answer additional questions.[32]

TB Interviewing for Contact Investigation: A Practical Resource for the Healthcare Worker (New Jersey Medical School Global Tuberculosis Institute Web site; 2004) at http://www.umdnj.edu/globaltb/products/tbinterviewing.htm offers specific suggestions on how to prepare for and conduct the interviews.[33]

Record information on the index patient and contacts on the ADHS Prevention Registry Form available in the forms section.

Pre-interview 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 who reported the case
- 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.[34]

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 ascertain 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.[35]
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 http://www.nationaltbcenter.edu/catalogue/epub/index.cfm?uniqueID=2&tableName=DOTE .

For assistance with language issues, see the *Language Services Resource Guide for Health Care Providers* (The National Health Law Program Web site; 2006) at http://www.healthlaw.org/library.cfm?fa=download&resourceID=89928&appView=folder&print .

Field Investigation

A field investigation includes visiting the patient's home or shelter, workplace (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 place in which exposure occurred. The field investigation may provide additional information for the risk assessment and identify additional contacts.[36]

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 dilute 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.[37]
- **Identify additional contacts** (especially children) and their locating information, such as phone numbers and addresses.
- **Look for evidence of other contacts** that 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** that are present and arrange for reading of the 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 sputum collection.[38]

For field investigation, use the ADHS Prevention Registry Form available in the sample form section.

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.[39]

For more information on infection control, see the Infection Control section.

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[40]

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.[41] Priority-ranking contacts for 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 disease from *Mycobacterium tuberculosis* infection.[42]

Use the assigned priorities to allocate resources to complete all investigative steps for the high- and medium-priority contacts.[43] 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).[44]

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[45]

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 per unit time established by the health department for high-priority contacts*	• Contacts not in high-priority groups • Contacts 5–15 years old • Contacts whose exposure exceeds duration/environment limits per unit time established by the health department for medium-priority contacts*	• Contacts not in high-priority groups • Contacts not in medium-priority groups

* 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.[46]

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 by the local TB control program for medium-priority contacts	• Contacts not in high-priority groups • Contacts not in medium-priority groups

* 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. [48]

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, 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 [49]

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.[50]

Use the tables on the following pages to determine the evaluation activities for contacts in these different risk groups and priority rankings:

- Table 9: **Immunocompromised Contacts and Children Younger than 5**
- Table 10: **Immunocompetent Adults and Children 5 and Older (High- and Medium-Priority Contacts)**
- Table 11: **Contacts with Prior Positive Tuberculin Skin Tests**

For the evaluation of low-priority contacts, see the "When to Expand a Contact Investigation" topic.

During the contact evaluation, treatment, and follow-up, use the ADHS Prevention Registry Report available in the forms section.

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.[51]

Immunocompromised Contacts and Children under 5

Use Table 9 to select evaluation, treatment, and follow-up activities for contacts who are immunocompromised and/or under 5 years old.

Evaluate contacts who are immunocompromised or under 5 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 5 YEARS OLD[52]

If evaluation or test results show that a contact has		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 chest radiographs	1st TST* ≥5 mm	Complete a full course of treatment for LTBI
	1st TST <5 mm 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 and <8 weeks since last exposure	Begin treatment for LTBI and retest 8–10 weeks post exposure
	2nd TST ≥5 mm	Complete a full course of treatment for LTBI
	2nd TST <5 mm	• 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 5 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 5 years of age or older. Evaluate high- and medium-priority contacts who are immunocompetent and/or 5 years of age or older, with medical history, exposure history, and tuberculin skin test (TST) or interferon gamma release assay (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 5 YEARS AND OLDER (HIGH- AND MEDIUM-PRIORITY CONTACTS)[53]

If evaluation or test results show that a contact has		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	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 and 8–10 weeks since last exposure	No further evaluation or treatment required
No symptoms consistent with TB disease	1st TST <5 mm and <8 weeks since last exposure	Retest 8–10 weeks post exposure
No symptoms consistent with TB disease	2nd TST ≥5 mm	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	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.

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 [54]

If evaluation or test results show that a contact has		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 U.S.-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 5 years old
   e. Contacts with change in TST status from negative to positive

- 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 needs.

Contact the Arizona Department of Health Services TB Program at 602-364-4750 to consult about expanding a contact investigation.

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 [55]

If evaluation or test results show that a contact has		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
No symptoms consistent with TB disease	<8 weeks since last exposure	Wait 8–10 weeks after last exposure, and then evaluate with a TST
No symptoms consistent with TB disease	1st TST* ≥5 mm	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	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. Epidemiological analysis of an investigation in progress and overall 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, epidemiological, historical, and medical information are 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 bacteriological 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 the 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.

CDC's "Framework of Program Evaluation in Public Health" (*MMWR* 1999;48[No. RR-11]), at ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4811.pdf , is recommended for assessing the overall activities of contact investigations.

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

Use the Report of Verified Case of Tuberculosis Form to collect the data each index patient and the ADHS Prevention Registry Form to collect the data on individual contacts.

Evaluation of a Contact Investigation

Statewide contact investigation data are compiled and summarized by the Arizona TB Program and provided to the Centers for Disease Control and Prevention (CDC) for national surveillance purposes. The data are also used to evaluate local and state program activities. The Arizona TB Program provides summarized contact investigation data to the CDC using the *Aggregate Report for Program Evaluation (ARPE)* form. [56] In addition, the CDC's Framework for Program Evaluation in Public Health is recommended for assessing the overall activities of contact investigations. [57]

For information about the *ARPE* form, see the CDC's *Aggregate Reports for Tuberculosis Program Evaluation: Training Manual and User's Guide*. (Atlanta, GA: US Department of Health and Human Services, CDC; 2005) at http://www.cdc.gov/tb/pubs/PDF/ARPEs_manual.pdf .

For more information on using this evaluation framework, see the CDC Program Evaluation Workgroup's Web site at 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 a contact investigation (e.g., two patients who received a diagnosis of TB disease outside 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:

- Transmission is continuing despite adequate control efforts by the TB control program
- Contact investigation associated with increased cases requires additional outside help

Deoxyribonucleic Acid 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.

Resources and References

Resources

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[53] 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):17.

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Laboratory Services

CONTENTS

Introduction

Purpose

Use this section to

- Get contact information for laboratories;
- Determine which tests are available and the tests' turnaround times; and
- 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 the Introduction.

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

Laboratory Contact Information

To locate and contact a laboratory, refer to Table 1: **Laboratory Contact Information**. For the list of the tests performed at each laboratory, refer to Table 2: **Available Laboratory Tests**.

Table 1: LABORATORY CONTACT INFORMATION

Roles and Responsibilities	Contact Information
State Laboratory Provides consultation as needed and	Arizona State Laboratory 250 N. 17th Avenue Phoenix, AZ 85007 (602) 542-1188 (602) 542-0760 Fax
Private Laboratories To be used as determined by specific contracts	

Available Laboratory Tests

The following laboratory tests are available:

Table 2: AVAILABLE LABORATORY TESTS

Test	Laboratory	Turnaround Time
Diagnosis		
QuantiFERON®-TB Gold (QFT-G)	Contact Maricopa Medical Center at: 602-344-5240 For additional sites go to: www.quantiferon.com	Up to two weeks
Acid-fast (AFB) bacilli smear	Arizona State Laboratory	Within 24 hours from receipt in laboratory[4]
Culture	Arizona State 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	Arizona State Laboratory	Within 30 days from date of specimen collection[7,8]
Nucleic acid amplification (NAA) test	Arizona State Laboratory	Within 2 days from date of specimen collection[9,10]
Treatment Monitoring		
Hepatic enzymes or up to 8 clinical, multichannel chem panel (that includes aspartate aminotransferase [AST], alanine aminotransferase [ALT], lactate dehydrogenase [LDH], total and direct bilirubin, alkaline phosphatase, uric acid, and calcium)	Contracted laboratory	varies

Test	Laboratory	Turnaround Time
Uric acid	Contracted laboratory	varies
Complete blood count (CBC) and platelets	Contracted laboratory	varies
Kidney function	Contracted laboratory	varies
Epidemiologic Monitoring		
Genotyping	Arizona State Laboratory sends the specimen out to the appropriate laboratory	varies

Laboratories should report positive smears or positive cultures, and primary healthcare providers should report suspected or confirmed cases of TB to the health department, as specified in the “Reporting Tuberculosis” topic in the Surveillance section (Chapter 2.11). Prompt reporting allows the health department to organize treatment and case management services and to initiate a contact investigation as quickly as possible.[11]

For information on reporting, see the “Reporting Tuberculosis” topic in the Surveillance section.

For laboratory services available in Arizona contact the Arizona TB Control Program at 602-364-4750.

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, so 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 conditions that inhibit the growth of contaminating organisms, since most specimens will contain bacteria other than mycobacteria.[12]

Refer to Table 3 to review the methods used to collect various specimens and the type of specimens obtained for pulmonary tuberculosis (TB).

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 http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

Table 3: 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 can be submitted for the diagnosis of pulmonary tuberculosis (TB) in young children who cannot produce sputum (make sure to alkalinize the specimen)	▪ 50 ml of gastric contents
Bronchoscopy can be used in the following situations: ▪ If a patient cannot produce sputum by the above three methods[13] or ▪ If a patient has a substantial risk of drug-resistant TB and has initial routine studies that are negative[14] or ▪ In a patient in whom there is suspicion of endobroncheal TB[15] or	▪ Bronchial washings ▪ Bronchoalveolar lavage ▪ Transbronchial biopsy

▪ If a variety of clinical specimens for the diagnosis of pulmonary TB or other possible diseases need to be obtained	
* 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 4 for collection methods and specimen types for extrapulmonary TB.

Table 4: 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.
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 appropriate laboratory form.

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.

Refer to the "Specimen Collection and Shipment Supplies" topic in the Supplies, Materials, and Services section, and see the "Specimen Shipment topic," which follows.

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 keep specimens to send all three on the same day.

7. Use the most rapid transport to the laboratory: yourself, courier, overnight carrier, or US mail.

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 should have appropriate respiratory protection, environmental controls, and policies and procedures.

How to Collect Gastric Aspirates

The following are basic guidelines for collecting gastric aspirates:

- Collect the specimen after the patient has fasted for 8 to 10 hours and, preferably, while the patient is still in bed.
- Collect a specimen daily for three days.
- Make sure the specimen is alkalinized at the time of collection.

For additional information on how to collect a gastric aspirate and prepare the specimen for transport, see the guide and Francis J. Curry National Tuberculosis Center's online video *Pediatric TB: A Guide to the Gastric Aspirate (GA) Procedure* at http://www.nationaltbcenter.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:** Refer the patient to a local specialist.
- **Extrapulmonary specimens:** These specimens will be collected by the physician performing the diagnostic work-up.

Specimen Shipment

There are three main categories of transportation methods: medical couriers, ground transportation, and air transportation. Category B Infectious Substances (raw diagnostic specimens, such as sputum, blood, or tissue) can be mailed through the US Postal Service (USPS), shipped by private carrier (e.g., Federal Express, Airborne Express, etc.), or transported by a medical courier. 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 US Postal Service. Each category requires different packaging requirements to provide increased levels of protection against leaks and contamination.

Shipment of dangerous goods by USPS is regulated by the US Department of Transportation. Specific shipping instructions from the Centers for Disease Control and Prevention (CDC) can be found in the publication by the US 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:

- Public Health Service/CDC: 42 CFR, Part 72—Interstate Shipment of Etiologic Agents at http://www.cdc.gov/od/ohs/biosfty/shipregs.htm
- USPS: 39 CFR and USPS Domestic Mail Manual C023.1.1, International Mail Manual 135, and USPS Publication 52
- US Department of Transportation: 49 CFR, Parts 171–180 (August 14, 2002) at http://www.access.gpo.gov/nara/cfr/waisidx_04/49cfrv2_04.html
- The Department of Labor, Occupational Safety and Health Administration (OSHA): 29 CFR 1910.1030[16]

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. 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.[17]

Refer to the shipping regulations that are listed under “Resources and References” at the end of this section. Personnel who handle, package, and ship infectious materials must be trained in these procedures.

For more information, contact the State of Arizona Laboratory at (602) 542-1188.

To obtain specimen collection and transport supplies, see the topic on "Specimen Collection and Shipment Supplies" in the Supplies, Materials, and Services section.

Resources and References

Resources for Laboratory Services

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).

Resources for Specimen Collection and Shipment

- 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 .
- CDC. *Public Health Mycobacteriology: A Guide for the Level III Laboratory* (Atlanta, GA; 1985).
- Francis J. Curry National Tuberculosis Center. *Pediatric TB: A Guide to the Gastric Aspirate (GA) Procedure* (Francis J. Curry National Tuberculosis Center Web site). Available at: http://www.nationaltbcenter.edu/products/product_details.cfm?productID=ONL-06 .
- International Air Transport Association (IATA). IATA Web site. Available at: http://www.iata.org/index.htm .
- National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory* (Denver, CO: March 2005).
- National Jewish Medical and Research Center. *Instructions (for Patients) for Collecting and Mailing Sputum Specimens* (Denver, CO: March 2005).
- National Tuberculosis Controllers Association—National Tuberculosis Nurse Consultant Coalition. *Tuberculosis Nursing: A Comprehensive Guide to Patient Care* (Atlanta, GA; 1997):39–42.

- US Department of Transportation. Hazardous Materials: Revision to standards for infectious substances. Part III 49 CFR Part 171. Federal Register (August 14, 2002).
- USPS. *Mailing Standards of the United States Postal Service: Domestic Mail Manual* (USPS Web site). *Available* at: http://pe.usps.com/

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[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] CDC. Diagnostic microbiology. In: Chapter 5: diagnosis of TB. *Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]. Updated November 2001. Available at: http://www.cdc.gov/tb/pubs/corecurr/index.htm . Accessed November 1, 2006

[12] ATS, CDC, IDSA. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med*. 2000;161:1376–1395.

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[14] Iseman, MD. *A Clinician's Guide to Tuberculosis, 2000*. 1st ed. Philadelphia, PA: Williams & Wilkins; 2000:135–136.

[15] Iseman, MD. *A Clinician's Guide to Tuberculosis, 2000*. 1st ed. Philadelphia, PA: Williams & Wilkins; 2000:135–136.

[16] National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory.* Denver, CO; March 2005:2.

[17] 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

- Determine what information to cover in education sessions;
- Educate patients about tuberculosis (TB);
- Educate patients about latent TB infection (LTBI); and
- Identify which forms to use to document education efforts.

An important part of helping patients take their medicine is educating them about TB. This means talking to them about the cause of 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]

Policy

The Arizona Department of Health Services uses the CDC guidelines in regards to the content for TB education that should be provided to patients with TB disease and LTBI (see resources at the end of this chapter).

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

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 educate 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.

Education Topics

During the initial assessment, directly observed therapy (DOT) appointments, and monthly monitoring, educate the patient as needed on the topics that follow.

For more information on case management activities, see the Case Management section.

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.

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 http://www.nationaltbcenter.edu/catalogue/epub/index.cfm?uniqueID=2&tableName=DOTE .

For assistance with language issues, see the *Language Services Resource Guide for Health Care Providers* (The National Health Law Program Web site; 2006) at http://www.healthlaw.org/library.cfm?fa=download&resourceID=89928&appView=folder&print .

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 chest radiography, sputum microscopy, and tuberculin skin testing. Stress the importance of testing and follow-up.
6. Discuss the current medical treatment plan and rationale. Have the patient sign the treatment plan and a DOT agreement.
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 health department (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. Have the patient sign an isolation agreement.
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.

For more information on side effects and adverse reactions, see the "Side Effects and Adverse Reactions" topic in the Treatment of Tuberculosis Disease section or the Treatment of Latent Tuberculosis Infection section.

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 importance of treatment and follow-up for active TB.
2. Explain the importance of regular monitoring visits.
3. Discuss the treatment plan and expectations. Advise the patient on the patient's responsibilities and expected behavior regarding treatment compliance and follow-up activities. Have the patient sign the treatment plan and a DOT agreement.
4. Advise the patient on laws regarding TB disease and isolation.

Patient Education Materials

The Centers for Disease Control and Prevention (CDC) offers the following patient education materials online (as of January 2007).

- *Get the Facts About TB Disease*
  http://www.cdc.gov/tb/pubs/pamphlets/TB_disease_EN_rev.pdf
- *Protect Your Friends and Family from TB: The TB Contact Investigation*
  http://www.cdc.gov/tb/pubs/pamphlets/TB_contact_investigation.pdf
- *Questions and Answers About TB 2005*
  http://www.cdc.gov/tb/faqs/pdfs/qa.pdf
- *Staying on Track with TB Medicine*
  http://www.cdc.gov/tb/pubs/pamphlets/TB_trtmnt.pdf
- *Stop TB*
  http://www.cdc.gov/tb/pubs/Posters/images/StopTB.pdf
- *Tuberculosis: General Information*
  http://www.cdc.gov/tb/pubs/tbfactsheets/tb.htm
- *Tuberculosis: Get the Facts!*
  http://www.cdc.gov/tb/pubs/pamphlets/TBgtfctsEng.pdf
- *What You Need to Know About TB Infection*
  http://www.cdc.gov/tb/pubs/pamphlets/TB_infection.pdf
- *What You Need to Know About the TB Skin Test*
  http://www.cdc.gov/tb/pubs/pamphlets/TB_skin_test.pdf

For other sources of patient education materials, consult the resources at the end of this section.

Resources and References

Resources

Patient Education Information for Healthcare Workers

- 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 ; and Updates available at: http://www.cdc.gov/tb/pubs/mmwr/mmwr_updates.htm
- ATS, CDC, IDSA. “Treatment of Tuberculosis” (*MMWR* 2003;52[No. RR-11]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf .
- CDC. *Self-Study Modules on Tuberculosis* (Division of Tuberculosis Elimination Web site; 1999). Available at: http://www.phppo.cdc.gov/phtn/tbmodules/Default.htm .
  - Module 9: “Patient Adherence to Tuberculosis Treatment.” Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/Default.htm .
  - Module 4: “Treatment of Tuberculosis Infection and Disease, Adherence to Treatment.” Available at: http://www.phppo.cdc.gov/phtn/tbmodules/modules1-5/Default.htm .
- CDC. *TB Elimination: Now Is the Time! 2007* (Division of Tuberculosis Elimination Web site; 2007). Available at: http://www.cdc.gov/tb/pubs/nowisthetime/default.htm .

Patient Education Materials for Patients

- CDC. *TB Education and Training Resources* [TB Education and Training Resources Web site]. Available at: http://www.findtbresources.org/scripts/index.cfm .
- CDC, Division of Tuberculosis Elimination. *Education and Training Materials* [Division of Tuberculosis Elimination Web site]. Available at: http://www.cdc.gov/tb/pubs/default.htm .
- Minnesota Department of Health. *Tuberculosis: Patient Education Materials* [Minnesota Department of Health Web site]. Available at: http://www.health.state.mn.us/divs/idepc/diseases/tb/brochures.html .
- University of Washington Harborview Medical Center. *Patient Education Resources: All Languages* [EthnoMed Web site]. Available at: http://ethnomed.org/ethnomed/patient_ed/index.html#tuberculosis .

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

CONTENTS

Introduction

Purpose

Use this section to

- 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; and
- 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 tuberculosis (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 permission of the patient, except as otherwise required by law.[2]

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

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

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 new 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), but excludes certain educational and employment records.

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 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]

Arizona HIPAA Policies

Click on the following link for information regarding the Arizona Department of Health Services HIPAA web-link: http://www.azdhs.gov/its/hipaa/index.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]).

To create a consent form, refer to the CDC's form "Example of an Authorization for Disclosure of Medical Record Information" at http://www.phppo.cdc.gov/phtn/tbmodules/modules6-9/m7/7-11.htm#fig7.1 .

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.
Breaching Confidentiality	▪ Breach confidentiality only with approval of TB program administrators and with the consent of the TB patient, when possible.

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.

Transfer Notifications

CONTENTS

Introduction

Purpose

Use this section to do the following:

- Notify public health agency staff in another jurisdiction that a person is moving (or has moved) to their jurisdiction who is a
  - 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; or
  - 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.
- Make CURE-TB referrals for TB patients and contacts who move between the U.S. and Mexico;
- Enroll mobile TB patients in the TBNet tracking and referral service.

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 Arizona Department of Health Services is responsible for coordination of transfer notifications between states and other local jurisdictions within the state. 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 chapter on “Roles, Responsibilities, and Contact Information”

When to Initiate a Notification

For a definition of tuberculosis (TB) patient classifications, see the "Tuberculosis Classification System" topic in the Diagnosis of Tuberculosis Disease section.

Table 1: TRANSFER NOTIFICATIONS AND FOLLOW-UPS[2]

Referral Type	When to Initiate	Notes
Verified and suspected cases of tuberculosis (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: ▪ 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.
Latent TB Infection (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]

Follow-Up Type	When to Initiate	Notes
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

How a notification is made depends upon whether the transfer occurred:

- Inside the United States
- Outside the United States

Transfers Inside the United States

Transfers Within Arizona Refer to 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 Table 2: **Referrals in the United States.**

The local health departments and the State of Arizona, Department of Health Services should take the following steps to send a referral to notify another jurisdiction to which a patient has moved or another jurisdiction in which a contact/associate is identified.

Table 2: REFERRALS IN THE UNITED STATES[6]

Action	Transfers Within Arizona	Transfers Between States
Make a referral	The public health agency from which the patient is transferring should do the following as soon as possible: ▪ Call the Arizona Department of Health Services at 602-364-4750. ▪ Copy the updated, complete local public health 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 public health agency from which the patient is transferring should do the following as soon as possible: ▪ Call the Arizona Department of Health Services at 602-364-4750. ▪ Fill out the NTCA's "Interjurisdictional Tuberculosis Notification" form* ▪ Mail and fax the form to the Arizona Department of Health Services, TB Control Section at: • Mail: 150 N. 18th Avenue, Suite 140 Phoenix, AZ. 85007 • Fax: 602-364-3267 If more information is needed, the Arizona Department of Health Services will request it from the public health agency from which the patient is transferring

Action	Transfers Within Arizona	Transfers Between States
Provide records to patient	The public health agency from which the patient is transferring should provide the patient a copy of the treatment records	The public health agency from which the patient is transferring should provide the patient a copy of the referral and treatment records
Send the referral form	Not necessary	Use the NTCA's "Interjurisdictional TB Notification Follow-Up" form†

* The NTCA's "Interjurisdictional Tuberculosis Notification" form is available online at http://bluewinkle.com/ntca/themes/connections/ntca_files/IJ_Form_Page1.pdf

† NTCA's "Interjurisdictional TB Notification Follow-Up" form is available online at http://bluewinkle.com/ntca/themes/connections/ntca_files/IJ_Form_Page2_Followup.pdf

Source: NTCA. *Interjurisdictional Tuberculosis (TB) Notification–National Tuberculosis Controllers Association Recommendations.* Smyrna, GA: March 2002:1–5.

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 http://bluewinkle.com/ntca/themes/connections/ntca_files/IJ_Instructions.pdf.

Transfers Outside the United States

Centers for Disease Control and Prevention International Notifications

The Arizona Department of Health Services is responsible for international transfer notifications. The local health jurisdiction should notify the state health department when a patient moves outside the country.

Local healthcare agency staff: The information below is provided for your information only. State program staff will fill out these forms.

A process for international notification of TB cases has been developed by the CDC to provide information to TB control staff in the country of the patient's destination.[7] The CDC notification process covers the following regions:

- African Region
- Americas Region
- Eastern Mediterranean Region
- European Region
- Southeast Asia Region
- Western Pacific and East Asia Region

In Arizona send these referrals directly to the destination country and the Arizona Department of Health Services, TB Control Section as soon as possible after receiving information about the patient's move or identifying a contact/associate.

To make an international referral through CDC:

1. Complete the International Tuberculosis Notification Form http://www.cdc.gov/nchstp/tb/pubs/international/PDF/internat_proces.pdf
2. Forward a copy of the notification by fax to the destination country and the Arizona Department of Health Services, TB Control Section. For contact information, see the CDC Website at http://www.cdc.gov/nchstp/tb/pubs/international/international.htm

3. Provide the patient with
    a. A copy of the referral and treatment records.
    b. Enough medication for one week if the patient is going out of the country.

CURE-TB: Transfers to Mexico

Instead of the CDC notification, make referrals through CURE-TB (http://www.curetb.org), a referral program for TB patients and their contacts moving between the U.S. and Mexico. This program provides direct guidance to patients and facilitates the exchange of information between providers in both countries. Services are available to patients and providers all over the U.S. and Mexico.[8]

Referrals accepted by the CURE-TB program include the following:

- **Patients** with suspected or confirmed TB disease who are moving or spending more than one month in Mexico
- **Contacts who move** between the U.S. and Mexico
- **Contacts living in Mexico** who have been exposed to a confirmed case living in the U.S.
- **Source case finding** for an index case in the U.S. when there is reasonable suspicion of TB disease in a person living in Mexico
- **Requests for a patient's clinical history** while living in Mexico, if sufficient locating information regarding the Mexican provider is supplied
- The local health department or the Arizona Department of Health Services initiates a CURE-TB referral within as soon as possible after receiving information about the patient's move or identifying a contact/associate.

To make a CURE-TB referral:

1. Complete the CURE-TB Referral Form (http://www2.sdcounty.ca.gov/hhsa/documents/BinationalReferralForm111.pdf)
2. Forward a copy of the referral form by fax to CURE-TB and the Arizona Department of Health Services
    a. The CURE-TB fax number is 1-619-692-8020. CURE-TB can be reached by telephone at 1-619-542-4011 or 1-619-542-4015.
    b. There is a Binational Card available from Immigration Custom Enforcement (ICE) and the local health departments for deportees. This card gives the deportees information on how to contact CURE-TB for assistance.

3. Provide the patient with:
   a. The CURE-TB telephone numbers to call (1-800-789-1751 in the U.S.; 001-800-789-1751 in Mexico) for questions about their care or about accessing care on either side of the border;[9]
   b. A copy of the referral and treatment records;
   c. A one-week supply of medication for patients going out of the country.

TBNet: International Transfers in Mobile, Underserved Populations

TBNet (http://www.migrantclinician.org/network/tbnet) is a multinational TB patient tracking and referral project for mobile, underserved populations. Although the program was originally created for migrant farm workers, it is expanding to include any patient who might be mobile during their treatment, such as the homeless, immigration detainees, or prison parolees.[10]

TBNet offers the following services:

- **Portable, wallet-sized treatment records.** TBNet supplies TB clinics with records that summarize a patient's TB treatment and can easily be carried by the patient.
- **Toll-free line (1-800-825-8205) for healthcare providers and patients.** Healthcare providers from the U.S. or Mexico can call to request an up-to-date copy of medical records of patients enrolled in TBNet. Patients can call for help with locating treatment facilities at their next destination.

The local health department or the Arizona Department of Health Services initiates a TBNet referral as soon as possible after the start of treatment.

To enroll a patient in TBNet:

1. Call the TBNet Program Manager, at 1-800-825-8205 to begin the referral process.
2. Complete the TBNet Patient History and Brief Medical Information Form. (http://www.migrantclinician.org/_resources/TBNet_Pt_History___Med_Info.pdf)
3. Fax the form and copies of the chest radiograph and all laboratory reports to TBNet at 1-512-327-6140.[11]
4. Provide the patient with the portable, wallet-sized treatment record and TBNet's toll free number (1-800-825-8205).

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 July 7, 2006.

[2] NTCA. *Interjurisdictional Tuberculosis (TB) Notification—National Tuberculosis Controllers Association Recommendations* [NTCA Web site]. March 2002:1–5. Available at: http://bluewinkle.com/ntca/themes/connections/ntca_files/IJ_Instructions.pdf . Accessed July 6, 2006.

[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 Tuberculosis (TB) Notification—National Tuberculosis Controllers Association Recommendations* [NTCA Web site]. March 2002:1–5. Available at: http://bluewinkle.com/ntca/themes/connections/ntca_files/IJ_Instructions.pdf . Accessed July 6, 2006.

[6] NTCA. *Interjurisdictional Tuberculosis (TB) Notification—National Tuberculosis Controllers Association Recommendations* [NTCA Web site]. March 2002:1–5. Available at: http://bluewinkle.com/ntca/themes/connections/ntca_files/IJ_Instructions.pdf . Accessed July 6, 2006.

[7] NTCA. *Interjurisdictional Tuberculosis (TB) Notification—National Tuberculosis Controllers Association Recommendations* [NTCA Web site]. March 2002:1–5. Available at: http://bluewinkle.com/ntca/themes/connections/ntca_files/IJ_Instructions.pdf . Accessed July 6, 2006.

[8] NTCA. *Interjurisdictional Tuberculosis (TB) Notification—National Tuberculosis Controllers Association Recommendations* [NTCA Web site]. March 2002:1–5. Available at: http://bluewinkle.com/ntca/themes/connections/ntca_files/IJ_Instructions.pdf . Accessed July 6, 2006.

[9] NTCA. *Interjurisdictional Tuberculosis (TB) Notification—National Tuberculosis Controllers Association Recommendations* [NTCA Web site]. March 2002:1–5. Available at: http://bluewinkle.com/ntca/themes/connections/ntca_files/IJ_Instructions.pdf . Accessed July 6, 2006.

Supplies, Materials, and Services

CONTENTS

Introduction

Use this section find out what resources are available and how to access them.

The Arizona Tuberculosis Program has resources available to assist local agencies. The following tables explain the resources that are available and how to obtain them:

- Table 1: **Mantoux Tuberculin Skin Testing**
- Table 2: **Interferon Gamma Release Assay**
- Table 3: **Chest Radiographs**
- Table 4: **Specimen Collection and Shipment**
- Table 5: **Antituberculosis Medications**
- Table 6: **Incentives and Enablers**
- Table 7: **Medical Interpretation Services**
- Table 8: **Healthcare Staff Training and Education**

For information on obtaining laboratory tests, see the Laboratory Services section.

Mantoux Tuberculin Skin Testing Supplies

Table 1: MANTOUX TUBERCULIN SKIN TESTING SUPPLIES

Availability	Mantoux Tuberculin Skin Testing is available at: • Every local health agency
How to Obtain	Order Mantoux Tuberculin Skin Testing supplies through your approved supplier:

Interferon Gamma Release Assay

Table 2: INTERFERON GAMMA RELEASE ASSAY

Availability and Contact information	Interferon Gamma Release Assay: ▪ The only place available in Arizona that is doing Quantaferon is Maricopa Integrated Health System (MIHS).
	▪ Contact MIHS at 602-344-5240 for further information or go to www.quantiferon.com .

Chest Radiographs

Table 3: CHEST RADIOGRAPHS

Availability	In the following circumstances: ▪ Chest Radiographs are available at your provider's office or the local health agencies as needed

Table 4: SPECIMEN COLLECTION AND SHIPMENT

Availability	The State TB laboratory provides the following specimen supplies at no charge: ▪ Specimen containers ▪ Packaging for shipment
How to Obtain	To order these supplies from the state laboratory: ▪ Call (602) 542-1188

Antituberculosis Medications

Table 5: ANTITUBERCULOSIS MEDICATIONS

Availability	In the following circumstances: When a patient has been diagnosed with tuberculosis and does not have any insurance medication for tuberculosis can be obtained at the local health agency. The local health agencies provides the following antituberculosis medications at no charge: ▪ Isoniazid (INH) ▪ Rifampin (RIF) ▪ Rifapentine (RPT) ▪ Ethambutol (EMB) ▪ Pyrazinamide (PZA) Note: Pyridoxine (vitamin B-6) is also provided to patients who have conditions associated with neuropathy such as nutritional deficiency, diabetes, human immunodeficiency virus (HIV) infection, renal failure, alcoholism, and pregnant/ breastfeeding women. Second-line antituberculosis medications are provided for patients with drug-resistant TB.

Incentives and Enablers

Table 6: INCENTIVES AND ENABLERS

Availability and Cost	In the following circumstances: The local health agencies may provide the following incentives/enablers for people with tuberculosis in certain situations:

Incentives

- Food and beverages

Enablers

- Transportation (bus pass, cab fare, car battery, gas)
- Obtaining and shipping specimens for the patient
- Assisting the patient with getting medication refills
- Assisting the patient with completing paperwork to get food/housing assistance
- Assisting the patient with getting substance treatment

Medical Interpretation Services

Table 7: MEDICAL INTERPRETATION SERVICES

Availability	In the following circumstances: The local health agencies have medical interpretation services at no charge to the patient who has been diagnosed with tuberculosis. For other patients, other agencies may fund interpretation services, or interpretation services may be obtained on a fee-for-service basis.
How to Obtain	The following may be helpful to obtain Medical Interpretation Services ▪ Diversity Rx page on Interpreter Associations: http://diversityrx.org/HTML/MOASSO.htm ▪ Yellow pages under "Translators & Interpreters" ▪ Medicaid-funded interpreters ▪ State refugee services program ▪ Local community organizations

Healthcare Staff Training and Education

Table 8: HEALTHCARE STAFF TRAINING AND EDUCATION

Availability and Cost	The local health agencies and/or the Department of Health Services, TB Control Section give free training and education based on need and availability of staff.
How to Obtain	For more information, call the local health agency or the Arizona Department of Health Services at 602-364-4750.

Infection Control

CONTENTS

Introduction

Purpose

Use this section to understand and follow national and Arizona guidelines to

- 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 reduction of 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 U.S., it is crucial that state and local public health agencies provide facilities with epidemiological 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 f*rom 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

Three main areas of infection control that need to be addressed by state and local public healthcare agencies are TB control in

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 Centers for Disease Control and Prevention (CDC) infection control guidelines for healthcare providers and settings.
2. Develop an infection control program for the county or state TB staff, focusing on
   a. Assignment of responsibility for program;
   b. Risk assessment;
   c. Persons (if anyone) who need baseline testing, including TB screening and counseling;
   d. Education and training;
   e. Case management (if direct patient care is provided).
3. 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 the Introduction.

State Laws and Regulations

Arizona Laws/Rules Regarding Tuberculosis Control
Arizona Revised Statutes. Title 36: Public Health and Safety; Chapter 6: Public Health Control; Title 6: Tuberculosis Control. (ARS§36-711 through §36-738)
ARS§36-711. Definitions.
ARS§36-712. Administration by the department.
ARS§36-714. Tuberculosis control officer.
ARS§36-715. Costs; removals; proceedings.
ARS§36-716. Payment of assistance.
ARS§36-717. Responsibility for care or treatment by counties.
ARS§36-718. Contracting for care of afflicted persons.
ARS§36-721. Rules.
ARS§36-723. Investigation of tuberculosis cases.
ARS§36-724. Voluntary control measures.
ARS§36-725. Orders to cooperate; emergency custody.
ARS§36-726. Petition for court ordered examination, monitoring, treatment, isolation or quarantine.
ARS§36-727. Hearings; procedure; confidentiality.
ARS§36-728. Judicial action.
ARS§36-729. Amended orders for intervention and transport of afflicted persons.
ARS§36-730. Appointment of guardian or conservator.
ARS§36-731. Confinement; selection; jails; prohibition.
ARS§36-732. Early release from court ordered treatment.
ARS§36-733. Choice of physician and mode of treatment.
ARS§36-734. Treatment; exemption.
ARS§36-735. Notification of rights.
ARS§36-736. Administrative procedures act; judicial review of administrative procedures; exemption; appeals.
ARS§36-737. Violation; classification.
ARS§36-738. Qualified immunity.

Arizona Administrative Code. Title 9. Chapter 6. Department of Health Services Communicable Diseases and Infestations.

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 TB infection control plan that is part of an overall infection control program.[9] 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. 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 will affect the extent of all other activities and will result in each facility having a different plan.
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. **Initiate promptly 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 local public health agency 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.
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 screening program for healthcare workers about TB disease and latent TB infection (LTBI).
12. **Evaluate promptly possible episodes of TB transmission.**
13. **Coordinate activities** between the state and local public healthcare agencies.

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
Supplementary Controls	High-efficiency particulate air (HEPA) filtration ▪ Cleans the air of infectious droplet nuclei Ultraviolet germicidal irradiation (UVGI) ▪ Kills or inactivates TB bacilli in the air

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 the 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. tuberculosis* 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.[1,17] For more information respiratory protection programs, see the Centers for Disease Control and Prevention's (CDC's) "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings, 2005" (*MMWR* 2005;54[No. RR-17]:75–79) at http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

The new 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 symbols 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.)
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] The frequency of periodic fit testing should be supplemented by the occurrence of 1) risk for transmission of *M. tuberculosis,* 2) facial features of the wearer, 3) medical condition that would affect respiratory function, 4) physical characteristics of respirator, or 5) model or size of the assigned respirator.[21]

The OSHA also developed its own TB Rule, although it was withdrawn in 2003. However, OSHA has addressed TB in their general respiratory protection requirements, which includes the need for the following:

- Respiratory protection program
- Amended medical evaluation
- Training and recordkeeping
- Annual fit testing
- Fit checking

For regulations in your area, refer to state and local regulations and contact your local OSHA office. A directory of OSHA offices may be found at http://www.osha-slc.gov/html/RAmap.html.[22]

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.

Table 2: USING MASKS AND RESPIRATORS[23]

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 the wearer breathes 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. 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.	A staff person or visitor* should wear a respirator In a patient's home when: ▪ Visiting the infectious patient inside a 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 Mycobacterium tuberculosis* 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 need to receive serial tests. Two-step testing should be used for the **initial** skin testing of adults who will be retested periodically, such as healthcare workers.[24]

In some persons who are infected with *Mycobacterium 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 section on Finding and Diagnosing Tuberculosis Disease and Latent Tuberculosis Infection.

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.
Second or 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.
Third or 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 CDC's "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Facilities, 2005" (*MMWR* 2005;54[No. RR-17]) at http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

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 and certain other infectious diseases. 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.[25]

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. [26]

For information on diagnosis and laboratory tests, refer to the sections on diagnosis of tuberculosis disease and latent tuberculosis infection. For information on guidelines for infection control in the patient’s residence, group settings, and during transportation of a patient, see the subtopics that follow.

Estimating Infectiousness

In general, patients who have suspected or confirmed TB disease and who are not on antituberculosis treatment should be considered infectious if characteristics include the following:

- Presence of cough
- Cavitation on chest radiograph
- Positive acid-fast bacilli (AFB) sputum smear result
- Respiratory tract disease with involvement of the lung or airways, including larynx
- Failure to cover the mouth and nose when coughing
- Undergoing cough-inducing or aerosol-generating procedures (e.g., sputum induction, bronchoscopy, airway suction) [27]

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.[28]

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 or health officer.

- 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).
- 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, threshold for treatment is four to seven days.)
- Patient has demonstrated complete adherence to treatment (e.g., is receiving directly observed therapy).
- 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 5 years of age and persons of any age with immunocompromising health conditions such as human immunodeficiency virus (HIV) infection.
- While in 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 three consecutive AFB-negative smear results of 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.[29]

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.[30]

The decisions to initiate and discontinue isolation should be made in consultation with the TB Control Department at the local health agency or the TB Control Officer at the Arizona Department of Health Services at 602-364-4750. 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[31]

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

Prior to discontinuing isolation, call the local health agency. 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 SUSPECTED CASES OF TUBERCULOSIS[32]

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.[33]		
While in 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.[34]		
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.[35]		

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.[36]

Table 6: DISCONTINUATION OF AIRBORNE INFECTION ISOLATION OF CONFIRMED CASES OF TUBERCULOSIS[37]

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 decisions to discharge an AFB sputum smear-positive patient or an MDR-TB patient should be made in consultation with the TB Control Department at the local health agency or the TB Control Officer at the Arizona Department of Health Services at 602-364-4750.

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 can be discharged from the hospital before converting AFB sputum smear results to negative if all the criteria in Table 7 are met.[38]

Table 7: HOSPITAL DISCHARGE OF DRUG-SUSCEPTIBLE CASES OF TUBERCULOSIS[39]

Criteria for Hospital Discharge to Home: Patients with Suspected or Confirmed Drug-Susceptible Tuberculosis
▪ A specific plan exists for follow-up care with the local TB control program 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 not travel outside the home except for healthcare-associated visits until the patient has negative acid-fast bacilli (AFB) sputum smear results

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 MULTIDRUG-RESISTANT CASES OF TUBERCULOSIS

Criteria for Hospital Discharge to Home: Patients with Suspected or Confirmed Multidrug-Resistant TB
▪ 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.[40] 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.[41]

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. Patients are sent home, even though they may still be infectious, because they are most likely to transmit TB to household members **before** TB has been diagnosed and treatment has started. However, TB patients and members of their household can take steps to prevent the spread of TB in their home until the patient becomes noninfectious.[42,43]

Administrative Controls in the Patient's Home

Have 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 cases in isolation sign a home isolation agreement. This document should include any legal consequences should they fail to voluntarily comply.

Refer to the sample "Home Isolation Agreement" in the Appendix.

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 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 that once a week, the patient sets out linens that need to be replaced. The staff can 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 enter to clean. Afterwards, routine cleaning done between guests is sufficient, and 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.

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 TB Control Department at the local health agency or the TB Control Officer at the Arizona Department of Health Services at 602-364-4750.

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 (e.g., the patient has received standard multidrug antituberculosis therapy for two-to-three weeks or, if the patient AFB sputum smear that are negative or rarely positive, the threshold for treatment is four-to-seven days)[44]
- The environment(s) to which the patient will be returning

Prior to notifying a patient that he or she is able to return to work or school, call the TB Control Department at the local health agency or the TB Control Officer at the Arizona Department of Health Services at 602-364-4750.

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 DRUG-SUSCEPTIBLE CASES OF TUBERCULOSIS[45]

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 (MDR-TB) 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 MULTIDRUG-RESISTANT CASES OF TUBERCULOSIS

Criteria for Return to Work, School, or Other Social Settings: Patients with Suspected or Confirmed Multidrug-Resistant TB
▪ 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) must be done 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 Centers for Disease Control and Prevention (CDC) has written a comprehensive set of guidelines for TB infection control in acute care hospitals and other medical settings.[46] 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:

1. Assign responsibility for managing the program to a designated staff position;
2. Perform and establish a TB risk assessment for the facility; and
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 inpatient care facilities.

Call the TB Control Department at the local health agency or the TB Control Officer at the Arizona Department of Health Services at 602-364-4750.if you have any questions when consulting with institutions on infection control measures.

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 *Mycobacterium tuberculosis* in Health-care Facilities, 2005" (MMWR 2005;54[No. RR-17]) at http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf Some settings have additional guidelines as noted below.

Inpatient Settings

- Emergency departments and urgent care settings
- Intensive care units
- Surgical suits
- Laboratories
- Bronchoscopy suites
- Sputum induction and inhalation therapy rooms
- Autopsy suites and embalming rooms

Outpatient Settings

- Tuberculosis (TB) treatment facilities
- Medical settings in correctional facilities: Prevention and Control of Tuberculosis in Correctional Facilities. (ACET) (*MMWR* 1996;45[No. RR-8]) at http://www.cdc.gov/nchstp/tb/pubs/mmwrhtml/Maj_guide/Correctional.htm
- Medical offices and ambulatory care settings
- Dialysis units

Nontraditional Facility-Based Settings

- Homeless shelter clinics: Prevention and Control of Tuberculosis Among Homeless Persons (ACET) (*MMWR* 1992;41[No. RR-5]) at 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): Prevention and Control of Tuberculosis in Facilities Providing Long-Term Care to the Elderly (*MMWR* 1990;39[No. RR-10]) at http://www.cdc.gov/mmwr/preview/mmwrhtml/00001711.htm

Transportation Vehicles

To prevent the transmission of *M. 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. Any 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 lack 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.[47]

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. [48]

Transport by Emergency Medical Services

Emergency medical services staff have specialized vehicles that may have the ability to separate the driver's compartment from the transport compartment and rear exhaust fans. Recommendations for these vehicles and staff are addressed in the Centers for Disease Control and Prevention (CDC) "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Facilities, 2005" (*MMWR* 2005;54[No. RR-17]:25–26, 88, 127) at http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

Resources and References

Resources

- CDC. “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
- CDC. “Guidelines for Environmental Infection Control in Health-care Facilities“ (*MMWR* 2003;52[No. RR-10]) at http://www.cdc.gov/mmwr/PDF/rr/rr5210.pdf
- CDC. *Interactive Core Curriculum on Tuberculosis* at http://www.cdc.gov/nchstp/tb/webcourses/CoreCurr/index.htm
- CDC. “Respiratory Protection in Health-Care Settings” (*TB Elimination Fact Sheet* April 2006) at http://www.cdc.gov/nchstp/tb/pubs/tbfactsheets/rphcs.pdf
- CDC. Module 4: “Treatment of TB Infection and Disease” (*Self-Study Modules on Tuberculosis 1999*) at http://www.phppo.cdc.gov/phtn/tbmodules/modules1-5/m4/4-m-04b.htm
- CDC. Module 5: “Infectiousness and Infection Control” (*Self-Study Modules on Tuberculosis 1999*) at http://www.phppo.cdc.gov/phtn/tbmodules/modules1-5/Default.htm
- NIOSH. “Respiratory Protection” [Web page] at http://www.cdc.gov/niosh/npptl/topics/respirators/
- OSHA. “Tuberculosis: OSHA Standards” [Web page] at http://www.osha.gov/SLTC/tuberculosis/standards.html

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[12] CDC. Guidelines for preventing the transmission *of Mycobacterium tuberculosis* in health-care facilities, 2005. *MMWR* 2005;54(No. RR-17):9.
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Prevention Registry Form

(Primary Use: Record information on Contacts and Targeted and Other Testing Clients)

DEMOGRAPHICS

Date Entered into Registry: ___/___/____ Provider Code _____ (see provider code list) Provider Group _____ (generated by the software) Clinic Name _____ (only applicable in limited, special investigation situations)

Event ID:_____ (generated by Registry) Local ID/ ADC #: _____ (ex: Medical Record # or Booking #) Other ID: _____ (for local information) County:_____ (of current residence)

Last Name: _____ First Name: _____ Initial ____ A.K.A.: _____

Street Address: _____ City: _____ State: _____ ZIP Code: _____

Telephone (include area code): Home: _____ Work: _____ Other: _____

Mailing Address (if different than Street Address): _____ City: _____ State: _____ ZIP Code: _____

Service Origin Date ___/___/_____ Date of Birth: ___/___/_____ ☐ **This Client is/was a TB Suspect** ☐ Start ☐ Stop ☐ Change / Update

(1st date of initial contact)

Gender	Race	Ethnicity	Reason For Testing	Population Risk	Residence	Country of Birth
☐ Female ☐ Male	☐ White ☐ Asian ☐ Native Hawaiian or Pacific Islander ☐ Black or African American ☐ American Indian or Alaska Native Tribe _____ ☐ Other _____	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown	These reasons should be considered sequentially. ☐ Contact Investigation ☐ Symptoms/Diagnostic ☐ Immigrant ☐ Refugee ☐ Day Care/School ☐ Screening ☐ Work Requirement ☐ Public Relations ☐ CDC Special Project _____ (CDC project code) ☐ Referred ☐ Reactor Associate ☐ Local Special Project	☐ None ☐ Low Income ☐ Migrant Worker ☐ Foreign Born ☐ Health Care Worker ☐ Correction Facility Worker ☐ Frequent visitor to a high risk country ☐ Other_____	☐ Private residence ☐ Homeless/Shelter ☐ Jail/Prison Inmate ☐ Nursing Home / Long Term Care ☐ Treatment Center ☐ Other _____	☐ United States ☐ Mexico ☐ Other _____ Entered U.S. ___/___/___

MEDICAL HISTORY

Diabetes	Chemical Use	HIV Status	Lung Disease	G.I./G.U.	Cancer/Chemo	Hepatitis	Medications
☐ None Known ☐ Diet Only ☐ Oral Meds ☐ Insulin ☐ Uncontrolled	☐ None Known ☐ Injected Drugs ☐ Other Drugs ☐ Excess Alcohol ☐ >2 Drinks/Day ☐ Binge Drinking ☐ Current Tobacco Amt. _____	☐ Unknown ☐ Negative ☐ Positive ☐ Undetermined ☐ Result Pending Test Offered: ☐ Yes ☐ No ☐ Refused	☐ None Known ☐ Asthma ☐ Silicosis ☐ Pneumonia ☐ Other _____	☐ None Known ☐ Gastrectomy ☐ Intestinal Bypass ☐ Pregnancy EstDD ___/___/___ ☐ Post-partum ☐ End stage renal disease ☐ Under Ideal Wt.	☐ None Known ☐ Leukemia/ Lymphomas/ Malignancies ☐ Immuno-suppressive Therapy ☐ Other _____	☐ None Known ☐ Hep A ☐ Hep B ☐ Hep C ☐ Unknown Type	☐ None Known ☐ Corticosteroids ☐ AntiConvulsants ☐ Immunosuppressants ☐ Birth Control ☐ AntiRetroviral ☐ Other _____ ☐ Allergies _____

CURRENT CLINICAL STATUS

Prior TB Therapy	Symptoms	Skin Test Results	Chest X-Ray	Laboratory Tests
☐ None Known ☐ Prior Prevention ☐ Incomplete PT ☐ Undergoing PT ☐ Active TB Year _____ ☐ Hx BCG Year _____	☐ None ☐ Prod. Cough ☐ S.O.B. ☐ Weight Loss ☐ Night Sweats ☐ Hemoptysis ☐ Fever ☐ Other _____ Wt.(lb)_____ Wt(kg)_____	At Current Evaluation: Date PPD1 placed: ___/___/____ Date PPD1 read: ___/___/____ Results PPD1:_____ mm (record results in millimeters only) Date PPD2 placed: ___/___/____ Date PPD2 read: ___/___/____ Results PPD2:_____ mm (record results in millimeters only) Last Known Neg. Test _____ Known Positive Reactor: ☐ KPR Date___/___/____ Results(mm)_____ Quantiferon Testing: Date Blood Drawn ___/___/____ Final Results: ☐ Positive ☐ Negative ☐ Indeterminate ☐ Conditionally Positive	At Current Evaluation: Date X-Ray ___/___/____ ☐ Normal ☐ Within Normal Limits ☐ Limited to calcified granuloma ☐ Abnormal ☐ Perihilar adenopathy ☐ Evidence of old inactive TB ☐ Suspect active tuberculosis Status: ☐ Stable ☐ Worsening ☐ Improving ☐ Other _____ ☐ Not Done/Refused Additional Chest X-Ray: Date X-Ray ___/___/____ Results: ☐ Normal ☐ Abnormal If abnormal, Status: ☐ Stable ☐ Worsening ☐ Improving ☐ Other _____	Source of specimen: _____ Date / Smear / Culture 1) ___/___/____ ☐ Pos ___+ ☐ Pos; ☐ Neg ☐ Neg; ☐ Not done ☐ Not done; ☐ Pending ☐ Pending 2) ___/___/____ ☐ Pos ___+ ☐ Pos; ☐ Neg ☐ Neg; ☐ Not done ☐ Not done; ☐Pending ☐ Pending 3) ___/___/____ ☐ Pos ___+ ☐ Pos; ☐ Neg ☐ Neg; ☐ Not done ☐ Not done; ☐ Pending ☐ Pending Other _____ Blood Work date: ___/___/____ results: _____ date: ___/___/____ results: _____ date: ___/___/____ results: _____ date: ___/___/____ results: _____ date: ___/___/____ results: _____

Questions about this Form?
Call: (602) 364-4750 or Fax: (602) 364-3267

Arizona Department of Health Services
Tuberculosis Control Program

ASSOCIATED CASES/SOURCE CASE INVESTIGATIONS

Information about the TB Case/Suspect	Source Case Investigation
Complete this section if the reason for testing is Contact Investigation: For non AZ cases, complete the following: ☐ Non AZ Case For AZ cases, complete the following: TIMS # (State Case #)_____ Year Counted_____ TB Case's Last Name:_____ TB Case's First Name:_____ TB Case's D.O.B.___/___/____ Date TB Case was Interviewed ___/___/____ Date TB Case was Reported to the LHD ___/___/____ Type of Contact: ☐ Close ☐ Casual Relationship of Contact to TB Case: ☐ Household ☐ Work ☐ Social ☐ Other:_____ Last date contact was exposed to TB case (may differ with each contact): ___/___/____ Sputum Smear (TB case) Sputum Culture (TB case) ☐ Positive ☐ Positive ☐ TB Ruled Out ☐ Negative ☐ Negative ☐ Not Done ☐ Not Done If contact to a second TB case within the same year, list that second TB case's TIMS # (State Case#):_____ & Name: _____	Complete this section if the reason for testing is Reactor Associate (which includes child converters and other source case investigations): Record below information about the person for whom the source case investigation is being done: Last Name:_____ First Name:_____ D.O.B.___/___/____ Reason for source case investigation: _____ _____ _____ _____ _____

CURRENT THERAPY

Reason for Therapy	Therapy	Duration	Therapy Started
Select choice from a or b but not from both. **a. For the choices listed below, complete at least the Therapy, Duration, and Therapy Started Sections:** **These reasons should be considered sequentially.** ☐ Contact, to recent TB case/suspect ☐ Converter (only if documented negative TST within last 2 years) ☐ Medical High Risk ☐ Old TB Disease ☐ Reactor ☐ Suspect Active TB ☐ Transferred in for completion of therapy **b. If this choice is selected, do not complete the Therapy, Duration, and Therapy Started sections:** ☐ Not a candidate for therapy	Select choice from a or b but not from both. a. Medication: Also complete the Duration and Therapy Started Sections ☐ Isoniazid (INH) ☐ Rifampin (RIF) ☐ RIF/PZA (LTBI therapy, only) ☐ Pyrazinamide (PZA) ☐ Ethambutol (EMB) ☐ Other _____ Is this a Change in Therapy? ☐ Change in Therapy **OR** b. Medication was not started because: ☐ Not Recommended ☐ Therapy Refused ☐ Therapy Deferred-Also enter the Anticipated Start Date	Select the recommended duration of therapy only if medication was started. ☐ 2 Months ☐ 4 Months ☐ 6 Months ☐ 9 Months ☐ 12 Months Method(s) used to deliver Therapy: ☐ DOPT (LTBI) ☐ DOT (Suspects) ☐ Self Admin. ☐ Both For suspects, **only**, is suspect improving on therapy for TB disease? ☐ Yes ☐ No	Enter medication start date only if medication was actually started. Initial Start Date: ___/___/____ Provider: _____ *OR* If medication was recommended but deferred, enter the anticipated medication start date here. Anticipated Start Date: ___/___/____ Signature: _____ case manager: _____ ordering physician: _____

OUTCOME

Classification	ReStart and Stopped Therapy Date(s) and Reason(s) for Stop	**Comments:**
All contacts/clients/suspects must be classified; please select the choice that best describes the outcome of the evaluation. ☐ 0 (Not Exposed, Not Infected) ☐ 1 (Exposed, Not Infected) ☐ 2 (Newly Infected, No Current Disease) ☐ 2K (Known Positive Reactor, No Current Disease) ☐ 2P (Infected, Provider Diagnosed) ☐ 3 (TB Clinically Active) RVCT Required ☐ 3M (Disease, not Tuberculosis) If MOTT:_____ ☐ 4 (TB Not Clinically Active) ☐ 5 (Tuberculosis Suspected) ☐ 6 (Client did not Return to Complete Evaluation) ☐ 7 (Education Only, No Evaluation) Please enter the date that the classification became final. Date Classification final: ___/___/____	Use these field(s) only if the client has a break in therapy. Start Date Stop Date Reason Provider ___/___/____ ___/___/____ _____ _____ ___/___/____ ___/___/____ _____ _____ ___/___/____ ___/___/____ _____ _____ Enter the final therapy stop date and reason below. Final Therapy Stop Date: ___/___/____ Provider: _____ Final Reason Therapy was Stopped: ☐ Completed Therapy ☐ Patient Choice (AMA) ☐ Moved ☐ Adverse Reaction ☐ Lost ☐ Died of TB Disease ☐ Died / Other ☐ Not Infected ☐ Provider Decision ☐ Active TB Disease ☐ Released from prison ☐ Transferred to another prison If the Client leaves from your jurisdiction, please complete the following: Address Moved/Released/Transferred to: _____ _____ _____ Date moved/released/transferred ____/____/_____	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Signature:_____ (Chart Format ADHS Rev 5A: 6/05)

Optional Information

Last Name: ___________________________ First Name: ____________________ Initial ____ Date of Birth: ___/___/_____ Local ID/ADC #: _______________

Telephone: ______________ Mailing Address: ______________________________________ City: ________________ State: ______ ZIP Code: _____________

CLIENT MANAGEMENT

date	medications/comments	adverse reactions reported	Next Clinic Appointment	Reason for next Appt.
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________
____/____/____	____	____________________________	date: ____/____/______	____________________

ANNUAL SKIN TESTS

In order for clients who receive annual skin tests to be counted in the Standard Reports, the following must be done. Change the Service Origin Date (located in the Demographics Section on page 1) to the date of the current service. Move the skin testing information currently in the Skin Test Results Section (located in the Current Clinical Status Section on page 1) to this Section. Enter the current skin testing information into the now empty Skin Test Results Section (located in the Current Clinical Status Section on page 1).

TB Skin Test #1
Pt. Signature: ___________________
☐ Copy of Informed Consent to Pt.
☐ Screening Questionnaire Completed
Date PPD placed: ___/___/____
Lot #: ________ Initials: __________
Date PPD read: ___/___/____
Results PPD:_____ mm
Initials: __________

TB Skin Test #2
Pt. Signature: ___________________
☐ Copy of Informed Consent to Pt.
☐ Screening Questionnaire Completed
Date PPD placed: ___/___/____
Lot #: ________ Initials: __________
Date PPD read: ___/___/____
Results PPD:_____ mm
Initials: __________

TB Skin Test #3
Pt. Signature: ___________________
☐ Copy of Informed Consent to Pt.
☐ Screening Questionnaire Completed
Date PPD placed: ___/___/____
Lot #: ________ Initials: __________
Date PPD read: ___/___/____
Results PPD:_____ mm
Initials: __________

TB Skin Test #4
Pt. Signature: ___________________
☐ Copy of Informed Consent to Pt.
☐ Screening Questionnaire Completed
Date PPD placed: ___/___/____
Lot #: ________ Initials: __________
Date PPD read: ___/___/____
Results PPD:_____ mm
Initials: __________

TB Skin Test #5
Pt. Signature: ___________________
☐ Copy of Informed Consent to Pt.
☐ Screening Questionnaire Completed
Date PPD placed: ___/___/____
Lot #: ________ Initials: __________
Date PPD read: ___/___/____
Results PPD:_____ mm
Initials: __________

TB Skin Test #6
Pt. Signature: ___________________
☐ Copy of Informed Consent to Pt.
☐ Screening Questionnaire Completed
Date PPD placed: ___/___/____
Lot #: ________ Initials: __________
Date PPD read: ___/___/____
Results PPD:_____ mm
Initials: __________

TB Skin Test #7
Pt. Signature: ___________________
☐ Copy of Informed Consent to Pt.
☐ Screening Questionnaire Completed
Date PPD placed: ___/___/____
Lot #: ________ Initials: __________
Date PPD read: ___/___/____
Results PPD:_____ mm
Initials: __________

TB Skin Test #8
Pt. Signature: ___________________
☐ Copy of Informed Consent to Pt.
☐ Screening Questionnaire Completed
Date PPD placed: ___/___/____
Lot #: ________ Initials: __________
Date PPD read: ___/___/____
Results PPD:_____ mm
Initials: __________

EDUCATION FOR CLIENTS WITH POSITIVE TB SKIN TEST

Please check all educational information presented/given to client (initial and date each item presented/given, if desired)

☐ Information on “What Having a Positive TB Skin Test Means”
☐ Need for medical evaluation, including a Chest X-Ray
☐ TB disease vs. TB infection
☐ Risk Factors for progression to TB disease
☐ Need for treatment of latent TB infection
☐ Medication(s), length of treatment, and side effects
☐ Need for monthly face-to-face evaluation
☐ Completion of Treatment for Latent TB Infection card given

County/Nation Specific Information

YAVAPAI COUNTY TB CASE/SUSPECT HOME ASSESSMENT SUMMARY

Initial Assessment DATE: ___/___/___ TIMS/RVCT _____

Patient's Name_____ DOB ___/___/___ Social Security # _____-____-_____

AKA/Legal _____ Parent/Guardian (if applicable) _____

Where Patient Interviewed: _____ Language _____ Translator? YES NO

Support Person _____ Phone (____)_____-_____

Emergency Contact/Address _____ Phone (____)_____-_____

Health Insurance: _____ Type: PPO HMO Medicare

Prior Authorization needed YES NO Phone _____

Housing: House Apt Nsg Home Shelter Hotel/Motel Institution Name/Address _____

Shares Sleeping Space: YES NO Ventilation: GOOD POOR Household Contacts? YES NO # _____

Medical Risks of Contacts: YES NO Explain _____ Children: YES NO # _____ Ages _____

_____

BARRIERS TO COMPLIANCE: NONE ____ LEVEL OF UNDERSTANDING RE: TB: Good ____ Needs Education ____

Transient Living Situation	Psychiatric Problems	Family Non-acceptance
Homeless @ Assessment	Alcohol Problems: Current Past	Language Difficulties
Homeless w/in past year	Non-injecting drug use @ Dx	Inaccessible Medical Resource
Unsanitary Living Situation	Type: _____	Long Work Hours
Chronic Incarceration	Injection drug use w/in Past Year	Transportation Problems
Incarceration w/in Past Year	Type: _____	Inadequate Finances
Correctional Facility @ Dx	Recovery/Rehab w/in Past year	Poor Nutrition
Type: Fed State City County	Resistance to Treatment	Lack of Nutritious Food
Resident Long Term Care @ Dx	Resistance to DOT	
Type: Hospital Nsg Home Psych	Cultural Non-Acceptance of TB	

Immigration status upon US entry: Refugee Student Visa Immigrant Class A Class B1 Class B2 H1/H4
Political Asylum Tourist Visa Undocumented Parolee Other:_____

Actions Taken: Masks: YES NO Sputums to be Collected: YES NO Needs Provided for: YES NO
Sent for Induction: YES NO Where: _____

Recommend Discharge to Home: YES NO Discharge to another Facility: YES NO Isolation: YES NO Type:_____

DOT Recommended: YES NO Reason: _____ Start Date: _____ DOT Location: _____

Initial Assessment Identified Needs/PLAN: _____

_____

_____

_____

_____

_____

PHN Signature/Date: _____

TRATAMIENTO DE ISONIAZID PARA LA INFECCIÓN DE TB

El doctor ha comprobado su expediente. Su reacción a la prueba de la piel de TB y sus medios de la radiografía del pecho usted tiene infección de TB (LTBI). LTBI significa que están durmiendo los gérmenes de TB. Usted no es enfermo. Usted no puede pasar los gérmenes a otros. El doctor recomienda que usted toma el isoniazid (INH) para esta infección. INH reducirá su riesgo de convertirse enfermo con enfermedad de TB en el futuro. Los gérmenes de TB son muy fuertes. Muchos gérmenes mueren enseguida después de usted comienzan a tomar su medicina, pero algunos permanecen vivo en su cuerpo un largo plazo. El oficial del control de TB ordenó INH por 9 meses.

Los efectos secundarios a INH incluyen:

- Dolor del estómago, calambres, náusea, o un malestar estomacal
- Dolores o el calambres en sus dedos o dedos del pie
- Orina oscura
- Pérdida de apetito
- Erupción/picazón
- vomito
- Piel y/o ojos amarillos

La mayoría de la gente puede tomar INH sin ninguno de estos problemas.

Antes de comenzar el INH, necesitaremos saber si usted tiene o ha tenido enfermedad del riñón, diabetes, o problemas del hígado. Traiga una lista de todas las medicaciones que usted está tomando actualmente. Si usted es embarazado o que intenta conseguir embarazada, por favor, déjenos saber.

Esté enterado que usted no debe beber alcohol mientras que toma esta droga

Muchas veces el doctor pedirá la vitamina B6 para ser tomado junto con el INH.

Usted puede necesitar examen de sangre para probar su hígado al principio del tratamiento. Las pruebas del hígado serán hechas, según lo necesitado, durante el tratamiento. No hay honorario a usted para esta prueba.

Si usted ve a un doctor o a dentista por cualquier razón mientras que usted está tomando INH, dígale que usted esta tomando INH para la infección de TB y no para la enfermedad de TB. Puede llamar al Departamento de Salud al 928-442-5559, si tienen preguntas.

Cómo tomar INH: Tome su INH al mismo tiempo diario. Si usted se olvida de una dosis, NO TOME UNA DOSIS ADICIONAL. INH trabaja tomado lo más mejor posible en un estómago vacío; usted puede tomar con el alimento si es necesario prevenir dolores del estómago. Evite de tomar a antiácidos 2 horas antes de tomar INH y 1 hora después.

INH es dado gratuitamente por Yavapai County. Usted necesitará visitar la clínica cada mes. Las visitas son para comprobar y saber si hay cualquier problema con tomar el INH y conseguir otra botella del medicamento.

Para comenzar el tratamiento de INH:

En Cottonwood
639-8132

En Prescott:
771-3134

Si usted tiene preguntas o problemas, llame:

En Cottonwood
Kay Beddall, RN en 649-5058

En Prescott:
Jo Ann French, RN en 771-3134

TB CONTROL PROGRAM
SAMPLE LETTER FOR LTBI

ISONIAZID TREATMENT FOR TB INFECTION

The doctor has checked your record. Your reaction to the TB skin test and your chest x-ray means you have TB infection (LTBI). LTBI means the TB germs are sleeping. You are not sick. You can't pass the germs to others. The doctor recommends that you take isoniazid (INH) for this infection. INH will reduce your risk of becoming sick with TB disease in the future. The TB germs are very strong. Many germs die just after you start taking your medicine, but some stay alive in your body a long time. The TB Control Officer has order INH for 9 months.

Side effects to INH include:

- Stomach pain, cramps, nausea, or an upset stomach
- Aches or tingling in your fingers or toes
- Dark urine
- Loss of appetite
- Rash/itching
- Vomiting
- Yellow skin and/or eyes

Most people can take INH without any these problems.

Before starting the INH, we will need to know if you have or have ever had kidney disease, diabetes, or liver problems. Bring a list of all the medications you are currently taking. If you are pregnant or trying to get pregnant, please let us know.

Be aware that you should not drink alcoholic while taking this drug

Many times the doctor will order vitamin B6 to be taken along with the INH.

You may need to have blood drawn to test your liver at the beginning of treatment. Liver tests will be done, as needed, during treatment. There is no fee to you for this testing.

If you see a doctor or dentist for any reason while you are taking INH, tell them that you are taking INH for TB infection and not for TB disease. They can call Communicable Disease at the Health Department, at 928-771-3134, if they have questions.

How to take INH: Take your INH at the same time every day. If you forget a dose, DO NOT TAKE AN EXTRA DOSE. INH works best taken on an empty stomach; you may take with food if needed to prevent stomach pains. Avoid taking anti-acids 2 hour before taking INH and 1 hour after.

INH is given free of charge by Yavapai County. You will need to visit the clinic each month. The visits are to check for any problems with taking the INH and to get another bottle of pills.

To start INH treatment contact:

If you have questions or problems, call:

Template from YAVAPAI COUNTY COMMUNITY HEALTH SERVICES

Revised: 12/4/07

TRATAMIENTO DE ISONIACIDA PARA LA INFECCIÓN DE TUBERCULOSIS (TB)

El doctor ha comprobado su expediente. Su reacción a la prueba de la piel de TB y su radiografía del pecho muestran que usted tiene infección latente de TB. Latente significa que están durmiendo los gérmenes de TB. Usted no está enfermo. Usted no puede pasar los gérmenes a otros. El doctor recomienda que usted tome un medicamento llamado isoniacida para esta infección. Isoniacida reducirá su riesgo de ponerse enfermo con TB en el futuro. Los gérmenes de TB son muy fuertes. Muchos gérmenes mueren en seguida después de que usted comience a tomar el medicamento, pero algunos permanecen vivos en su cuerpo por un largo plazo. El oficial del control de TB ordenó que usted tome isoniacida por 9 meses.

Los efectos secundarios de la isoniacida pueden incluir:

- Dolor del estómago, calambres, náusea, o malestar estomacal
- Dolores o el calambres en sus dedos
- Orina oscura
- Pérdida de apetito
- Sarpullio o picazón de la piel
- vómitos
- Piel amarilla y/o ojos amarillos

La mayoría de la gente puede tomar la isoniacida sin ninguno de estos problemas.

Antes de comenzar la isoniacida, necesitaremos saber si usted tiene o ha tenido enfermedad del riñón, diabetes, o problemas del hígado. Traiga una lista de todos los medicamentos que usted está tomando actualmente. Si usted está embarazada o está intentando estar embarazada, por favor, déjenos saberlo.

Esté enterado que usted no debe beber alcohol mientras que tome este medicamento.

Muchas veces el doctor recitará que tome la vitamina B6 junto con la isoniacida

Al principio del tratamiento, es posible que necesite un examen de sangre para probar su hígado. Las pruebas del hígado serán hechas durante el tratamiento según sea necesario. No hay costo a usted para esta prueba.

Si usted vaya a un doctor o dentista por cualquier razón mientras que usted esté tomando la isoniacida, dígale que usted está tomando isoniacida para la infección de TB y no para la enfermedad de TB. Puede llamar al Departamento de Salud al 928-442-5559, si tienen preguntas.

Cómo tomar la isoniacida: Tome la isoniacida al mismo tiempo diario. Si usted se olvida de una dosis, NO TOME UNA DOSIS ADICIONAL. Es mejor que tome la isoniacida con un estómago vacío. Sin embargo, usted puede tomarla con comida si sea necesario prevenir dolores del estómago. Evite de tomar antiácidos 2 horas antes de tomar la isoniacida y 1 hora después.

Se le proporcionará la isoniacida sin ningún costo por Yavapai County. Usted necesitará visitar a la clínica cada mes. Las visitas son para averiguar si hay cualquier problema al tomar la isoniacida, y también para conseguirle otra botella del medicamento.

Para comenzar el tratamiento de isoniacida, llame:

En Cottonwood	En Prescott:
639-8132	771-3134

Si usted tiene preguntas o problemas, llame:

En Cottonwood	En Prescott:
Kay Beddall, RN en 649-5058	Jo Ann French, RN en 771-3134

TRATAMIENTO DE ISONIACIDA PARA LA INFECCIÓN DE TUBERCULOSIS (TB)

El doctor ha comprobado su expediente. Su reacción a la prueba de la piel de TB y su radiografía del pecho muestran que usted tiene infección latente de TB. Latente significa que están durmiendo los gérmenes de TB. Usted no está enfermo. Usted no puede pasar los gérmenes a otros. El doctor recomienda que usted tome un medicamento llamado isoniacida para esta infección. Isoniacida reducirá su riesgo de ponerse enfermo con TB en el futuro. Los gérmenes de TB son muy fuertes. Muchos gérmenes mueren en seguida después de que usted comience a tomar el medicamento, pero algunos permanecen vivos en su cuerpo por un largo plazo. El oficial del control de TB ordenó que usted tome isoniacida por 9 meses.

Los efectos secundarios de la isoniacida pueden incluir:

- Dolor del estómago, calambres, náusea, o malestar estomacal
- Dolores o el calambres en sus dedos
- Orina oscura
- Pérdida de apetito
- Sarpullio o picazón de la piel
- vómitos
- Piel amarilla y/o ojos amarillos

La mayoría de la gente puede tomar la isoniacida sin ninguno de estos problemas.

Antes de comenzar la isoniacida, necesitaremos saber si usted tiene o ha tenido enfermedad del riñón, diabetes, o problemas del hígado. Traiga una lista de todos los medicamentos que usted está tomando actualmente. Si usted está embarazada o está intentando estar embarazada, por favor, déjenos saberlo.

Esté enterado que usted no debe beber alcohol mientras que tome este medicamento.

Muchas veces el doctor recitará que tome la vitamina B6 junto con la isoniacida

Al principio del tratamiento, es posible que necesite un examen de sangre para probar su hígado. Las pruebas del hígado serán hechas durante el tratamiento según sea necesario. No hay costo a usted para esta prueba.

Si usted vaya a un doctor o dentista por cualquier razón mientras que usted esté tomando la isoniacida, dígale que usted está tomando isoniacida para la infección de TB y no para la enfermedad de TB. Puede llamar al Departamento de Salud al 928-442-5559, si tienen preguntas.

Cómo tomar la isoniacida: Tome la isoniacida al mismo tiempo diario. Si usted se olvida de una dosis, NO TOME UNA DOSIS ADICIONAL. Es mejor que tome la isoniacida con un estómago vacío. Sin embargo, usted puede tomarla con comida si sea necesario prevenir dolores del estómago. Evite de tomar antiácidos 2 horas antes de tomar la isoniacida y 1 hora después.

Se le proporcionará la isoniacida sin ningún costo por Yavapai County. Usted necesitará visitar a la clínica cada mes. Las visitas son para averiguar si hay cualquier problema al tomar la isoniacida, y también para conseguirle otra botella del medicamento.

Para comenzar el tratamiento de isoniacida, llame:

En Cottonwood	En Prescott:
639-8132	771-3134

Si usted tiene preguntas o problemas, llame:

En Cottonwood	En Prescott:
Kay Beddall, RN en 649-5058	Jo Ann French, RN en 771-3134

Med Start for TB Infection

Medications currently taking Prescribed and OTC		
Medical treatments		
Risk of advancing to TB disease		
Benefits of treatment for this client		
Length of Treatment 4 6 9 Months	**Alcohol use**	**S/S** of TB No Yes
Adverse reactions of treatment **Stop medication and call if any of the following occur**	Taking INH	Taking RIF
Rash related to medication intake	Tingling/burning in hands and feet	Weakness lasting >3 days
Loss of appetite no reason		Fever lasting >3 days
Tiredness for no reason		Joint Pain
Weight loss for no reason		Easy bruising
Stomach pain		Easy bleeding
Jaundice		Orange colored tears, sweat
Nausea		Staining of contacts
Vomiting		
Dark urine		
If you become pregnant		
Method of birth control (RIF)		
Today's Weight	**Blood draws**	
Refill procedure		
Health Clearance		
Questions?		
Handouts given		

☐ Completed **TB history card** given to client
☐ **Medication** given Lot # _____ Exp Date ___/___
☐ **Appointment** for refill Date _____Time _____
☐ **Consent** signed to be scanned Site _____
☐ CC **Consent** to client
☐ CC **Med Start** to client

_____ _____

Name _____

Date of birth _____

Nurse Date

Interjurisdictional Follow-up Form

30 day status: □ located □ not located

Return to:

Name _____ Fax number _____

Jurisdiction _____ Phone number _____

Patient name_____ Date of birth ____/___/___
Last First Middle

New address _____
Number Street/Apt. City State Zip Code

New telephone ( )_____ Sex □ Male □ Female

□ **Case:** (Send RVCT F/U2 to reporting jurisdiction)

□ Completed: ____/____/____ □ Moved to: city _____ county _____ state _____

□ Died □ Lost (after initially located) □Never located

□Uncooperative or refused □Not TB □Other_____

□**Suspect:**

□Verified by lab □Verified by clinical

□Verified by provider □Not verified

□Other:_____

If verified, and original jurisdiction submits RVCT, complete case outcome above.

□**Contact:**

□No follow-up performed □Never located

□Evaluated: □ Class II □ Class III □Class IV □No infection

□ Started treatment □Continuing treatment □Other:_____

□**LTBI/Convertor:**

□No follow-up performed □Never located □Started treatment

□ Continuing treatment □Other:_____

Interjurisdictional Tuberculosis Notification

Referring Jurisdiction city _____ county _____ state _____ Date sent ____/____/____

Contact person _____ Phone ( ) _____ FAX ( ) _____

□ Verified case→State where reported: _____ RVCT# _____ (attach RVCT) □Not reported _____

□ Suspect case □Close contact □Reactor LTBI □Convertor □Source case investigation

Patient name _____ Sex □Male □Female
Last First Middle

Date of birth ____/____/____ Interpreter needed? □No □Yes, specify language _____

New address _____ Hispanic □No □Yes
Number/Street/Apt.

Race □ White □Black □Asian
□Am.Indian/Nat.Alaskan.
□Other: _____

_____
City/State/ZipCode

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

New health provider: □ Unknown □Known (name, address, phone) _____

Insurance source: □None □Medicaid □Private □Medicare □Other _____

Emergency contact: Name _____ Phone _____

Laboratory information for □ this referred case/suspect □index case for this contact □not applicable

Date	Specimen type	Smear	Culture	Susceptibility	Chest X-ray	Other pertinent labs

Site(s) of disease: □ Pulmonary □Other(s) specify all _____

Date 1st negative smear ____/____/____ □Not yet Date 1st negative culture ____/____/____ □Not yet

TB skin test #1:Date ____/____/____ Result ____mm TB skin test #2: Date ____/____/____ Result____mm

Contact/LTBI Information **TB Skin test** □Not Done

TST #1 Date ____/____/____ Result ____mm TST#2 Date ____/____/____ Result____mm

CXR □ Not Done Date ____/____/____ □Normal □Other: _____

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

Medications π this referred case/suspect π this referred contact/LTBI

Drug	Dose	Start date	Stop date

Planned completion date ____/____/____

DOT □No □Yes: start date ____/____/____

□Daily □1x W □2x W □3x W

Last DOT Date ____/____/____

Adherence problems/significant drug side effects:

_____

_____

_____

Comments _____

_____

_____

Case Follow-Up In 30 days report to referring jurisdiction if located or not located and report final outcome.

Other Follow-Up □ Follow-up requested (form attached) □No follow-up requested

TB CONTACT INVESTIGATION REPORT

CASE MANAGER:

INDEX CASE: _____INFECTIOUSNESS OF CASE: ☐ SPUTUM SMEAR+ ☐ SPUTUM CX+ ☐ CAVITY ON CXR

STATE CASE #: _____ ☐ PAN SENITIVE ☐ RESISTANT TO: _____

DOB: __/__/__ DATE ASSIGNED: _____

INFECTIOUS PERIOD:_____TO_____ GROUP NAME/ CONTACT PERSON: _____

% OF INFECTIVITY OF HIGH RISK CONTACTS:_____ REASON CI NOT EXPANDED: _____

Contact Name/ Address/ Phone	DOB / Age / Sex / Race// Ethnicity	Relationship	Priority of Contact (High, Medium, Low)	Medical Risk	Symptoms	Date of Last Exposure	Country of Birth / Date of Arrival in US	Prior Positive PPD (date) mm's	Prior TB Treatment (Y/ N)/ End Date	Date Initial PPD's mm's	Date F/U PPD mm's	CXR Date Results	Medications Start and Stop Dates	Reason Therapy was Stopped	Outcome
													Start __/__/__ Stop__/__/__ INH RIF Other		
													Start __/__/__ Stop__/__/__ INH RIF Other		
													Start __/__/__ Stop__/__/__ INH RIF Other		
													Start __/__/__ Stop__/__/__ INH RIF Other		
													Start __/__/__ Stop__/__/__ INH RIF Other		
													Start __/__/__ Stop__/__/__ INH RIF Other		

Race:
W-White
B- Black
A- Asian/ Pacific Islander
I- American Indian
O- Other

Ethnicity:
H- Hispanic
N- Non- Hispanic
U- Unknown

Medical Risks:
1- Diabetes
2- Substance Use
3- HIV
4- Lung
5- Kidney/ G.I.
6- Cancer Imm Supp
7- Hepatitis
8- Hx of TB Disease

Symptoms:
0- None
1- Prod. Cough
2- S.O.B.
3- Weight Loss
4- Night Sweats
5- Hemoptysis
6- Fever/ Chills

CXR:
1- Normal
2- Limited to calcified granulomas
3- Abnormal
4- Perihilar adenopathy
5- Evidence of old TB
6- Suspect active TB

Reason Why Therapy was Stopped:
1- Completed Therapy
2- Patient Choice (AMA)
3- Moved
4- Adverse Reaction
5- Lost
6- Died of TB Disease
7- Died/ Other
8- Not Infected
9- Provider Decision
10- Active TB Disease
11- Released from Prison
12- Transferred to another prison

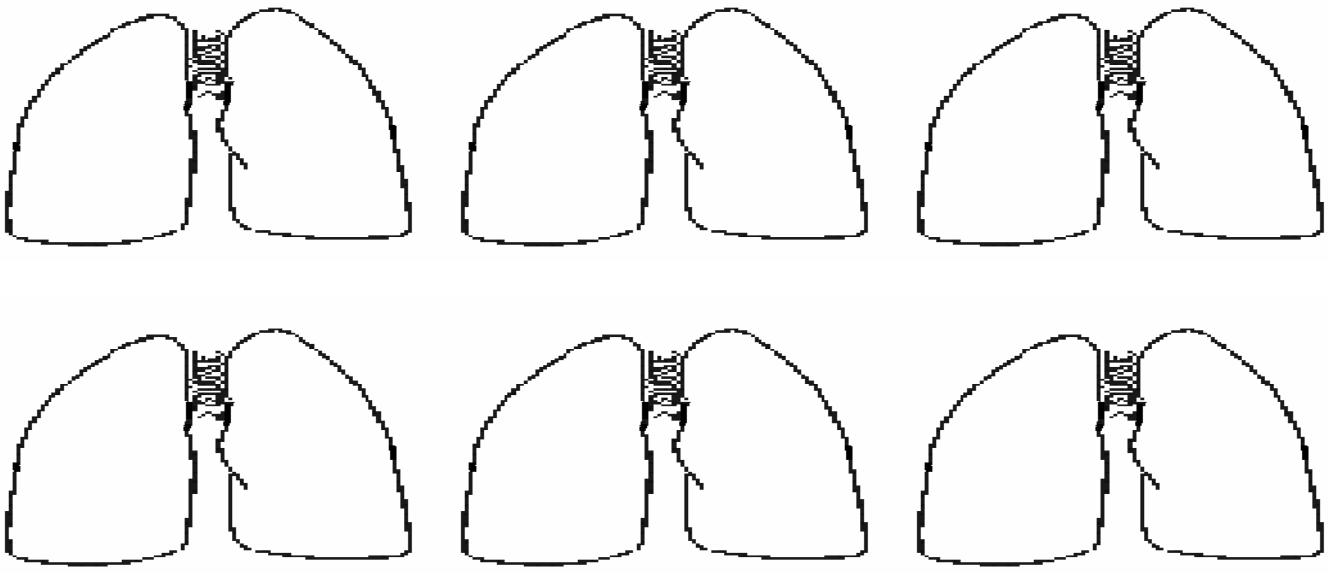
Outcome:
0- Not Exposed/ Not Infected
1- Exposed, Not Infected
2- Newly Infected, No Current Disease
2K- Known Positive Reactor, No Disease
2p- Infected- Provider
3- TB Clinically Active (TVCT Required)
3M- Disease not TB
4- TB Not Clinically Active
5- Tuberculosis Suspect
6- Client did not Return to Complete Evaluation

Maricopa County Public Health Department
Tuberculosis Program CXR Flow Sheet
1645 Roosevelt Street
Phoenix, AZ 85006

Name: _____
DOB: _____
PID No: _____
Sex: ☐ Male ☐ Female

TB Site ☐ Pulmonary ☐ Extra Pulmonary ☐ Suspect _____ ☐ Other _

	INITIAL CXR #1	MNTH#__	MNTH#__	MNTH#__	MNTH#__	MNTH#__	MNTH#__
Date							
Normal							
Primary Complex							
Abnormal-Cavitry							
Abnormal-Non Cavitry C/W Tuberculosis							
Abnormal not C/W Tuberculosis							
Stable							
Worse							
Improved							
Comments							
CT Scan							



Maricopa County Public Health Department
Tuberculosis Program Laboratory Flow Sheet
1645 Roosevelt Street
Phoenix, AZ 85006

Name: _____
DOB: _____
PID No: _____
Sex: ☐ Male ☐ Female

TB Site ☐ Pulmonary
☐ Extra Pulmonary
☐ Suspect
☐ Other

Mycobacteriology: ☐ Sputum _____
☐ Bx/BAL _____
☐ Other _____

Sensitivities: ☐ Pansensitive ☐ Resistant: _____

Date Ordered												
Weight												
Visual Acuity L												
R												
Color Vision												
T.Bilirubin												
Alk. Phosphatase												
ALT												
AST												
HIV												
BUN												
Creatnine												
Glucose												
Uric Acid												
WBC												
HCT												
Platelet												
PMN												
Cocci Serology												
QFT-G												
Other												

Maricopa County Public Health Department
Tuberculosis Program Medication Flow Sheet
1645 Roosevelt Street
Phoenix, AZ 85006

Name: _____
DOB: _____
PID No: _____
Sex: ☐ Male ☐ Female

Medication/Dosage: I = Isoniazid_____ mg SM = Streptomycin_____ mg
R = Rifampin mg PZA = Pyrazinamide mg
E = Ethambutol mg Other
B_6 = Pyridoxine mg

Drug Allergy: ☐ NKA ☐ Specify Allergy to Drug or Food:

TB Site ☐ Pulmonary **Mycobacteriology**: ☐ Sputum
☐ Extra Pulmonary ☐ Bx/BAL
☐ Other ☐ Suspect

		AGENT							METHOD		Total Dosages	Missed Dosages	Comments
DATE	WEEK	INH	RIF	EMB	PZA	B_6	SM	Other	M-F	2 x wk			
	1												
	2												
	3												
	4												
	5												
	6												
	7												
	8												
	9												
	10												
	11												
	12												
	13												
	14												
	15												
	16												
	17												
	18												
	19												
	20												
	21												
	22												
	23												
	24												
	25												
	26												

Maricopa County Public Health Department
Tuberculosis Program Medication Flow Sheet
1645 Roosevelt Street
Phoenix, AZ 85006

Name: _____
DOB: _____
PID No: _____
Sex: □ Male □ Female

Medication/Dosage: I = Isoniazid_____ mg SM = Streptomycin_____mg_____
R = Rifampin mg PZA = Pyrazinamide _____
B_6 = Pyridoxine mg Other_____mg_____
E = Ethambutol mg _____

Drug Allergy: □ NKA □ Specify Allergy to Drug or Food: _____

		AGENT							METHOD		Total Dosages	Missed Dosages	Comments
DATE	MONTH	INH	RIF	EMB	PZA	B_6	SM	Other	M-F	2 x wk			
	7												
	8												
	9												
	10												
	11												
	12												
	13												
	14												
	15												
	16												
	17												
	18												
	19												
	20												
	21												
	22												
	23												
	24												
CATCH UP DOSAGES													
							b						

Maricopa County Public Health Department
Tuberculosis Program Mycobacteriology Flow Sheet
1645 Roosevelt Street
Phoenix, AZ 85006

Name: _____
DOB: _____
PID No: _____
Sex: ☐ Male ☐ Female

Drug Allergy: ☐ NKA ☐ Specify Allergy to Drug or Food: _____

TB Site ☐ Pulmonary **Mycobacteriology**: ☐ Sputum
☐ Extra Pulmonary ☐ Bx/BAL
☐ Suspect ☐ Other
☐ Other

Mycobacteriology								
Date	Rx Week	Source	Spec. Number	SMEAR (+)	SMEAR (-)	CULTURE (+)	CULTURE (-)	Sensitive	Resistant	Histology

COUNTY and TRIBE DON and TB NURSE COORDINATORS as of 11/30/2007

Apache County Health Department
PO Box 1952, Springerville 85938

Jennifer Foote, RN
928-333-2415
djfoote@co.apache.az.us

Cochise County Health Department
1415 W. Melody Lane, Bldg A, Bisbee 85603

Cindy Berry, RN
520-432-9468
cberry@co.cochise.az.us

Coconino County Health Department
2625 N. King St, Flagstaff 86004

Linus Nienstadte, MPH
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lnienstadte@coconino.az.gov

Gila County Health Department
1400 E. Ash, Globe 85501

Lorraine Dalrymple, RN, DON
Susan Koepf, RN
928-402-8807
928-402-8808
ldalrymp@co.gila.az.us
skoepf@co.gila.az.us

Graham County Health Department
826 W. Main, Safford 85546

Kellie Konrad, RN
928-428-0110
kkonrad@graham.az.gov

Greenlee County Health Department
PO Box 936, Clifton, 85533

Michelle Scott, RN, DON
928-865-2601
928-865-2505
mscott@co.greenlee.az.us

Debbie Breshears, LPN
928-865-2601
928-865-2505
dbreshears@co.greenlee.az.us

La Paz County Health Department
1112 Joshua Ave, Ste 204, Parker 85344

Diana Grazier, RN, DON
928-669-1100
dgrazier@co.la-paz.az.us

Maricopa County Health Department
1645 E. Roosevelt, Phoenix 85006

Walter Palmer, MPH
602-506-6643
walterpalmer@mail.maricopa.gov

Mohave County Health Department
PO Box 7000, Kingman 86401

Christy Bronston, RN, DON
928-753-0714 x4281
christine.bronston@co.mohave.az.us

COUNTY and TRIBE DON and TB NURSE COORDINATORS as of 11/30/2007

Navajo County Health Department
251 N. Penrod Rd #1, Show Low 85901

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tracy.letcher@co.navajo.az.us

Navajo Nation TB Program
Gallup Indian Medical Center
Public Health Nursing Department #39
PO Box 1337, Gallup, NM 87301

Sarah Yazzie
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Pima County Health Department
150 W. Congress, Tucson 85701

Anne Davis, RN
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Pinal County Health Department
P.O. Box 2945, Florence, 85232

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graham.briggs@pinal.az.us

Artie Cordova
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Santa Cruz County Health Department
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Gail Randolph, RN DON
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gairan@mariposachc.net

Tohono O'odham Health Department
PO Box 810, Sells 85634

Lavina Harris, LPN
520-383-6200
lavina.harris@tonation-nsn.gov

Yavapai County Health Department
1090 Commerce Dr, Prescott 86305

JoAnn French, RN
928-442-5499
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Yuma County Health Department
2200 W. 28th St, Yuma 85364

Maria Nunez, RN
928-317-4585
maria.nunez@co.yuma.az.us

Maricopa County Public Health Department
Tuberculosis Program Summary Sheet
1645 Roosevelt Street
Phoenix, AZ 85006

Name: _____
DOB: _____
PID No: _____
Sex: ☐ Male ☐ Female

TB Site ☐ Pulmonary ☐ Extra Pulmonary ☐ Suspect ☐ Other

Mycobacteriology: ☐ Sputum ☐ Bx/BAL ☐ Other

Allergies:

Sensitivities: ☐ Pansensitive ☐ Resistant:

ACTION ITEMS	Yes	No	Results	Date Completed	Provider Notified
TST Results					
Initial W/U completed					
HIV Testing done					
Contact Investigation/Source Case Investigation					
Culture Report Positive					
Sensitivity Report Received					
Ethambutol stopped?					
On treatment 8 weeks (specify date), Should PZA be stopped?					
Sputum Conversion Date					
Discharge: (6 months course -26 wks) (9months course-39 wks)					
Post Rx Follow-up @ 6mon @ 18 mon					

Action Items	Date	Date	Date	Date	Date	Date	Date	Date
Repeat Sputum								
Repeat Blood Work								
Provider Visits								
Repeat CXR								
Visual Acuity								
Color Vision								
Temp/Weight/VS/Ht								
DOT								
Precautions (Mask or Universal)								
Taxi								
Other								

ACTION ITEMS	Date Collected	Date Started	Date Due	Date Completed	Date Sent
RVCT Pages 1&2					
RVCT Follow-up Report 1					
RVCT Follow-up Report 2 completed & sent					
ADHS Form Completed					

Created on 1/2/2008 8:09:00 AM

Texas Department of State Health Services
TB Case and Suspect Management Plan

Patient's Name: _____ **Initial Report Date:** _____

Nurse Case Manager: _____ **Case Management Team:** _____

Directions: Blank boxes indicate week(s) TB service is to be provided. ***Document date and initials of the provider in the appropriate box when the task is completed.*** Document comments in progress notes.

Action: **Interval:**		**0** **Begin**	**2** **Wks**	**4** **Wks**	**8** **Wks**	**12** **Wks**	**16** **Wks**	**20** **Wks**	**24** **Wks**	**26** **Wks**
Date		/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /
Responsibility	Assign nurse case manager; establish team; document in client's record									
Medical Evaluation	Obtain medical history; document on TB-202									
	Obtain release (L-30); request previous medical records									
	MD evaluation									
	RN evaluation									
	Mantoux skin test (if not previously done)									
	Chest X-ray									
	Supervised sputum for AFB smear/culture according to protocol									
	HIV screening for risk factors; counseling and testing									
	Nutritional assessment									
Treatment	Drug regimen according to protocol or specific order									
	Initiate DOT on all cases/suspects: Daily X2 weeks, 2X/week (Mon/Thurs or Tues/Fri) or 3X/week (Mon/Wed/Fri) til completion of adequate therapy; document DOT on TB-206									
	Pyrazinamide X2 months and ethambutol X2 months (or until susceptibilities are reported and client's organism is known to be pan sensitive)									
	Vitamin B6 (if pregnant, diabetic, at risk for peripheral neuropathy)									
	Obtain Informed Consent form TB-411 (TB-411A, if Spanish speaking, only) initially and for any drugs added to regimen.									
Consultation	Obtain expert consult for drug resistant cases, complicated adult/pediatric cases or client who remains symptomatic or sputum positive after 2 months therapy; written consult in client record									
Toxicity/ Clinical Assessment	Clinical assessment according to protocol; document (TB-205 and progress note as appropriate)									
	Visual acuity (Snellen) and color discrimination (Ishihara Plates) initially and monthly if on EMB or rifabutin; document (TB-205)									
	Hearing sweep check initially and monthly if on amikacin, capreomycin, kanamycin or streptomycin; document (TB-205)									

TB Case and Suspect Management Plan for Outpatient Care

Action: / Interval:		0 Begin	2 Wks	4 Wks	8 Wks	12 Wks	16 Wks	20 Wks	24 Wks	26 Wks
Date		/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /
Adherence	Issue Order to Implement Measures for a Client With Tuberculosis form TB-410 (TB-410A, if Spanish speaking, only) on all cases/suspects									
	Follow-up missed appointments within 1 working day; initiate court-ordered management according to TDH policy (see TB Policy Manual, Section 5) and notify Regional office									
	Evaluate barriers to treatment									
Isolation	Conduct **site visit** to assess living situation; isolate from congregate living situation and exclude from work or school, if infectious									
	Allow to return to work/school following 2 wks appropriate therapy, 3 consecutive negative smears on different days and an improvement of symptoms									
Education	Appropriate client education provided initially and monthly per protocol; written instructions and review of medication side effects, monthly and document on TB-203									
Public Health/ Contact Investigation	Interview case/suspect and contacts; plan contact investigation using the "Concentric Circle" approach									
	Initiate contact investigation within 3 working days; interview and evaluate (skin test/reading, CXR, medical evaluation) within 7 days; document on TB-340									
	Expand contact investigation if >30% of close high-risk contacts have positive Mantoux skin tests									
	Provide second skin test 8-10 weeks after break in contact with the case to all contacts who were skin test negative on the initial test; document on TB-340									
	Provide education and counseling for contacts									
Reporting	Report suspect/case to state designated case registry within 1 working day of notification									
	Submit TB-400A and TB-400B (all data fields complete) within 7 days of diagnosis; submit TB-400B at least quarterly and at the time of closure									
	Submit TB-340 within 14 working days of initiating contact investigation and after second testing of negative contacts is complete									
Quality Assurance Review	Clinical supervisor or TB Program Manager reviews and evaluates contact investigation									
	Team review of client record									
Social Services	Enroll in Medicaid, if eligible; make appropriate referrals to drug/alcohol treatment programs and refer for HIV services, if necessary									

PRINTED NAME:_____ **SIGNATURE:**_____ **INITIALS:**_____

PRINTED NAME:_____ **SIGNATURE:**_____ **INITIALS:**_____

PRINTED NAME:_____ **SIGNATURE:**_____ **INITIALS:**_____

PRINTED NAME:_____ **SIGNATURE:**_____ **INITIALS:**_____

Texas Department of State Health Services
Tuberculosis Education/Counseling Record

NAME: _____ **D.O.B.:** ____/____/____ **SS#:** ____/____/____

Instructions: υ Provide appropriate Education/Counseling to **ALL** TB clients. υ Each client must have an education/counseling plan based on individual assessment and need. υ This tool serves as a guideline but education/counseling should not be limited to this information only. υ **Initial each box** as education/counseling is performed. υ The (**Y**) indicates when instruction should occur. υ Standardized printed materials (in client's preferred language, if available) are provided to client on the initial visit. υ All staff providing client education must be familiar with reference information listed in the TB standing delegation orders.	**Comments:**									
	Initial Visit	**1 Mo Date**	**2 Mo Date**	**3 Mo Date**	**4 Mo Date**	**5 Mo Date**	**6 Mo Date**	**7 Mo Date**	**8 Mo Date**	**9 Mo Date**
TRANSMISSION/PATHOGENESIS: ρ Signs/symptoms of TB ρ Airborne disease ρ Infectiousness of case ρ Shared airspace ρ PPD(+) 2-10 weeks after initial infection ρ 10% of infected will develop disease ρ TB infection vs. disease	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
INFECTION CONTROL MEASURES: □ ρ Proper use of masks ρ Isolation/return to work ρ 3 negative smears, clinically improved, DOT X2 weeks ρ Use of tissues for coughing/sneezing ρ Sputum collection	Y	Y	Y	Y						
EVALUATION: ρ PPD testing/significance ρ CXR results ρ No further PPD testing if + (always +)	Y						Y			
HIGH RISK GROUPS/FACTORS: ρ Diabetics ρ Alcohol/drug abuse (IVDU) ρ Silicosis ρ Corticosteroids ρ Gastric resection ρ HIV+ ρ Foreign born ρ Resident of correctional or long term care facility	Y	Y	Y							
MEDICATION: ρ Possible side effects, actions to take if side effects occur ρ Increased risk of side effects if post-partum, alcohol abuse, kidney or liver disease ρ Benefits = cure of disease or prevention of infection/disease ρ Administration = dosage/frequency, length of treatment, DOT/DOPT	Y	Y	Y							
DRUG INTERACTIONS: ρ INH: Dilantin ρ Rifampin: prednisone, digoxin, quinidine, Coumadin, methadone, estrogen, oral contraceptives, protease inhibitors, Remicade	Y									
ADHERENCE: ρ Case = control order, quarantine, MDR-TB, death ρ LTBI = disease later, DOPT	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
RATIONALE FOR DOT/DOPT: ρ Assure compliance and adherence ρ DOT = prevents drug resistance and is Standard of Care ρ DOPT = children <5, HIV+, contacts to MDR-TB, other high risk	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

TEXAS Department of State Health Services

Tuberculosis Education/Counseling Record

	Initial Visit	1 Mo Date	2 Mo Date	3 Mo Date	4 Mo Date	5 Mo Date	6 Mo Date	7 Mo Date	8 Mo Date	9 Mo Date
RATIONALE FOR MONTHLY MONITORING: ρ Assess improvement/worsening of symptoms ρ Toxicity/symptom review ρ Medication refill ρ LFTs/other lab per protocol	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
LAB RESULTS: ρ LFTs/other lab per protocol ρ Sputum per protocol ρ Evaluation of sputum conversion	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
HIV ρ HIV pre/post test counseling	Y									
SPUTUM/SPECIMEN COLLECTION: □ ρ Early morning specimen ρ One supervised monthly ρ Weekly, till 3 consecutive negative smears ρ Monthly, till 2 consecutive months negative cultures ρ Collect outdoors or in room with negative air pressure	Y	Y	Y	Y	Y					
CONTACT INVESTIGATION: □ ρ Rationale = find new disease, early detection and treatment of new LTBI ρ 2nd testing of negative contacts, 10-12 weeks after break date ρ Concentric circle approach	Y		Y							
CONSENTS/AUTHORIZATIONS: ρ Consents explained ρ Copies given to patient	Y									
PROVIDER INFORMATION: ρ Clinic address/phone number ρ Nurse case manager=s name/phone number	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Provider Initials:										
Next Appointment:										

ρ **Provided at Indicated Month**

□ **Cases/Suspects Only**

PROVIDER NAME (Please Print)	PROVIDER SIGNATURE	INITIALS	DATE

TB-203 Education/Counseling Record – 08/04

Texas Department of State Health Services
Clinical Assessment for Tuberculosis Medication Toxicity

NAME: _____ **D.O.B.:** _____ /_____ /_____ **SS#:** _____ /____ /_____

Toxicity Assessment:
Ask questions **(1-18)** when patient is on first-line drugs and ask questions **(1-28)** if any second-line drugs are added to patient's regimen. Document **[+]** results in the progress notes and notify the physician.
Results: [+] = If Present [-] = If Denies [NA] = If Not Applicable

Toxicity Symptoms	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**
Weight									
Temperature									
Blood Pressure									
Are you experiencing any of the following now or since you have been on treatment?									
1. Loss of Appetite									
2. Nausea/Vomiting									
3. Urine Color Change (Dark)									
4. Skin Rashes/Dry									
5. Numbness/Tingling (Hands/Feet, Face/Mouth)									
6. Change in Vision									
7. Eye Pain/Irritation									
8. Jaundice (Yellow Skin/Eyes)									
9. Flu-like Symptoms									
10. Fatigue									
11. Headaches									
12. Fever									
13. Joint Pains/Swelling									
14. Urine Output ↕									
15. Bleeding (Nose Bleeds, Hemoptysis)									
16. Vertigo/Dizziness/Fainting									
Teeter/Fall to Left or Right When Standing (With Eyes Closed)									
Weave/Stagger When Walking (Normal Gait)									
17. Hearing Loss/Ears Ringing/Fullness									
18. Nervousness/Giddiness/Restlessness									
19. Increased Gas/Stomach Cramps									
20. Abdominal Pain/Diarrhea									
21. Sleep Problems									
22. Mood Changes/Depression									
23. Change in Heart Rate									
24. Convulsions									
25. Memory Loss									
26. Abnormal Behavior									
27. Skin Discoloration									
28. Allergic Reaction									

Drug Issued	**Mfg/Lot#/Exp**	**Route/ Frequency**	**Amt. Given**	**Amt. Given**	**Amt. Given**	**Amt. Given**	**Amt. Given**	**Amt. Given**	**Amt. Given**	**Amt. Given**	**Amt. Given**
Initials*/Title											
Next Appt.											

*** See Provider Signature Sheet**

TEXAS Department of State Health Services

Texas Department of State Health Services
Vision/Hearing Screening Form

NAME: _____

Red/Green Color Discrimination:
The **(X)** mark indicates the plate cannot be read. Screen all 14 plates. Client must pass 10 of the first 11 plates for the test to be regarded as normal. Refer for evaluation if ≤ 7 plates are read as normal.
Results: [N] = Normal [A] = Abnormal

Ishihara Plate #	Normal Reading	Red/Green Deficiency				Date	Date	Date	Date	Date	Date	Date	Date	Date
1	12	12												
2	8	3												
3	5	2												
4	29	70												
5	74	21												
6	7	X												
7	45	X												
8	2	X												
9	X	2												
10	16	X												
11	Traceable	X												
		Protan		**Deutan**										
		Strong	**Mild**	**Strong**	**Mild**									
12	35	5	(3) 5	3	3 (5)									
13	96	6	(9) 6	9	9 (6)									
14	Can trace 2 lines	Purple	Purple (Red)	Red	Red (Purple)									
Results														
Initials														

Visual Acuity:
If initial screen was conducted with corrective lenses (glasses or contacts), follow-up screens must be done the same. A change of 1 or more lines from the initial screen in either one or both eyes must be reported to the physician immediately.
Results: [P] = Pass [F] = Fail [U] = Unscreenable Chart Used: [ ] Letter [ ] "E" [ ] Other, Specify:_____
Corrective Lenses: [ ] = Yes [ ] = No

Distance Acuity	Date	Date	Date	Date	Date	Date	Date	Date	Date
Right Eye	20/	20/	20/	20/	20/	20/	20/	20/	20/
Left Eye	20/	20/	20/	20/	20/	20/	20/	20/	20/
Both Eyes	20/	20/	20/	20/	20/	20/	20/	20/	20/
Results									
Initials									

Hearing Sweep Check:
When patient is taking amikacin, capreomycin, kanamycin, or streptomycin, for each of the four frequencies listed, record the lowest level in decibels (dB) at which the person responds. Record the findings for both the right and left ear. Refer to an appropriately licensed professional if any two of the four frequencies are recorded as greater than 25 dB in either ear or the same ear or if there is a change of decreased hearing level from baseline. Start with 40 dB, if heard decrease by 10 dB until no response is obtained or until 20 dB is reached. If 20 dB is heard, record as 20 dB. Once no response is obtained, increase the dB level by 5 until a response is obtained and recorded. If a response is not heard at 40 dB, record as 40+ dB.
Results: [P] = Pass [R] = Refer [O] = Observe Ear: [R] = Right [L] = Left

Frequency	Date		Date		Date		Date		Date		Date		Date		Date		Date	
Ear	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**
500 Hz																		
1000 Hz																		
2000 Hz																		
4000 Hz																		
Initials																		

Texas Department of State Health Services
Tuberculosis Directly Observed Therapy Log

Name:	**DOB:**	**Sex:**
Address:	**Telephone:**	
Classification: ☐ **Class II** ☐ **Class III** ☐ **Class V** **DOT Ordered By:**	**DOT Initiated:** / /	

Date Ordered:	Medication/Dosage (Amount Given/Frequency)/Manufacturer/Lot Number/Expiration Date:	Date Discontinued:

Toxicity Screen: **+ = Yes** **- = No** **(To be completed for each client DOT encounter before patient takes medication)**

MONTH/YEAR:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Headaches (chronic)																
Joint Pain (chronic) - PZA																
Ears Ringing/Fullness - AK, CAP, KM, SM																
Numbness/Tingling																
****Skin Rashes/Itching**																
****Visual Problems** - Ethambutol																
****Dark Urine (coffee-colored)**																
****Jaundice (yellow skin/eyes)**																
****Abdominal Pain**																
****Nausea/Vomiting**																
****Malaise/Fatigue**																
****Fever (more than 3 days duration)**																
****Convulsions**																
****Unusual Bleeding** (nose, gums, stool, urine, etc. or easy bruising) - RIF																
Other:																
Other:																
Provider Initials																
Interpreter Initials																

**** = Do not give DOT Dose. Contact Nurse/Physician for further instructions.**

Date	DOT Adm	Self Adm	Dose Missed	DOT Provider's Initials	Client's Initials	Comments/Notes
/01/						
/02/						
/03						
/04/						
/05/						
/06/						
/07/						
/08/						
/09/						
/10/						
/11/						
/12/						
/13/						
/14/						
/15/						
/16/						

TEXAS Department of State Health Services

Tuberculosis Directly Observed Therapy Log

Toxicity Screen: + = Yes - = No (To be completed for each client DOT encounter before patient takes medication)

MONTH/YEAR:	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Headaches (chronic)																
Joint Pain (chronic) - PZA																
Ears Ringing/Fullness - AK, CAP, KM, SM																
Numbness/Tingling																
****Skin Rashes/Itching**																
****Visual Problems** - Ethambutol																
****Dark Urine (coffee-colored)**																
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Other:																
Other:																
Provider Initials																
Interpreter Initials																

**** = Do not give DOT Dose. Contact Nurse/Physician for further instructions.**

Date	DOT Adm	Self Adm	Dose Missed	DOT Provider's Initials	Client's Initials	Comments/Notes
/17/						
/18/						
/19/						
/20/						
/21/						
/22/						
/23/						
/24/						
/25/						
/26/						
/27/						
/28/						
/29/						
/30/						
/31/						

DOT SUMMARY:

# Targeted DOT Doses	# DOT Doses Given	% DOT Doses Given	# Self-Administered Doses	# Missed Doses

Compliant: ☐ Yes ☐ No Comment:

Quarantine Advised: ☐ Yes ☐ No Date of Control Order: Date of Court Action:

CLIENT/DOT PROVIDER AGREEMENT:

We agree to meet at _____ (Location) on (check all days that apply)

☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday ☐ Sunday

at _____ (Time) AM / PM for DOT medication, unless alternate arrangements are made in advance by either party.

Change in Location:_____ Day(s):_____ Time:_____

Client's Signature:_____ Client's Initials:_____

DOT Provider's Signature:_____ DOT Provider's Initials:_____

DOT Provider's Signature:_____ DOT Provider's Initials:_____

SAMPLE

DEPARTAMENTO DE SALUD DEL CONDADO DE YAVAPAI
PROGRAMA PARA EL CONTROL DE LA TUBERCULOSIS

TRATAMIENTO PARA PREVENCIÓN DE LA TUBERCULOSIS
Rifampicina

Su prueba positiva de tuberculosis enseña que usted está infectado con los microbios de la tuberculosis. Usted no está contagioso y no puede pasar este microbio a otra persona.

Después de revisar su historia médica y su radiografía, el doctor ha recomendado que usted tome un tratamiento. Este tratamiento baja su riesgo a la tuberculosis en el futuro.

Para matar éstos microbios, usted tiene que tomar una medicina muy fuerte cada día por bastante tiempo. Ésta medicina se llama "Rifampicina," o "RIF," y se toma por caurto meses. Reacciones de la RIF posiblemente pueden incluir problemas con el hígado. Otros síntomas son los siguientes:

- Cansancio excesivo
- Dolor del estómago
- Nausea
- Ojos amarillos, o la piel amarilla
- Orina oscura
- Pérdida de apetito
- Pérdida de peso sin razón
- Salpullido con comezón
- Vómitos
- Fiebre por 3 días o más
- Sangrado fácil
- Dolor en las articulaciones
- Mareos
- Magulladuras o moretones por lesiones pequeñas

Mucha gente no tienen éstos síntomas. Si usted tiene algunos de éstos síntomas, por favor, llame a la clínica y hable con una enfermera.

Los siguientes efectos adversos son problemas menores. Si experimenta alguno de los siguientes efectos adversos, puede seguir tomando su medicina.

- La Rifampicina puede hacer que la orina o las lágrimas se tiñan de anaranjado. Es posible que el médico o la enfermera le aconsejen no usar lentes de contacto suaves porque pueden mancharse.

- La Rifampicina puede hacerlo más sensible al sol. Esto significa que debe usar buenos protectores de rayos solares y cubrir las partes expuestas al sol para que no se queme. Si anticipa estar expuesto al sol, debe protegerse con lociones o cremas para bloquear el sol (sunblock).

- La Rifampicina puede disminuir la efectividad de las pastillas anticonceptivas así como algunos implantes de prevención de embarazo. Las mujeres que toman Rifampicina deben usar otras formas de contracepción.

- Si está tomando Rifampicina al mismo tiempo que la metadona (usada para tratar la adicción a las drogas), es posible que experimente síntomas de remoción. Su médico o enfermera quizá considere la posibilidad de ajustar la dosis de metadona.

Es importante vigilar la salud del hígado antes y durante el tiempo que usted tome la medicina. Para los adultos, sacamos la sangre antes de empezar la medicina, y si ellos desarrollan síntomas de algún problema. Para los niños bajo la edad de 15 años, solamente si ellos desarrollan síntomas de algún problema.

Durante el tiempo que usted está tomando la medicina RIF, es mejor no tomar alcohol de ningún tipo, especialmente todos los días. El alcohol aumenta la posibilidad que usted tenga problemas con la medicina.

Si usted tiene que visitar el doctor o el dentista dígale que usted está tomando la medicina RIF – es importante que usted le de el nombre de la medicina y que usted está tomando la medicina para prevenir la tuberculosis.

Es muy importante que cualquier mujer fértil no se quede embarazada durante el tiempo que está tomando la medicina RIF. Si usted necesita un método para prevenir el embarazo, venga a la clínica o vaya a su doctor. Usted siempre puede recibir condones en la clínica.

INSTRUCCIONES PARA LA MEDICINA RIF: Tome la medicina RIF a la misma hora, cada día. Si se le olvida una dosis, no tome la dosis mas tarde. Tome solamente una dosis de la medicina cada día.

Cada mes, usted necesita venir a la clínica. La enfermera le va a pesar y hacerle preguntas sobre los síntomas para averiguar si usted tiene problemas con la medicina RIF. Ella hará una cita para la próxima evaluación y para rellenar la medicina RIF. Si usted no puede venir a la clínica para su cita, la enfermera puede hacer arreglos para ir a su casa para hacer la evaluación y rellenar la medicina.

Si usted tiene preguntas o problemas, favor de llamar a la clínica y pida hablar con

SAMPLE

_____COUNTY HEALTH DEPARTMENT
TUBERCULOSIS CONTROL PROGRAM

PREVENTIVE TREATMENT FOR TUBERCULOSIS INFECTION
Rifampin

Your positive tuberculosis (TB) skin test shows that you are infected with TB germs. You are not contagious, and cannot pass the germ to anyone else.

After reviewing your health history and chest x-ray, the doctor has recommended that you take preventive treatment for the positive skin test. This treatment will reduce the risk of becoming ill with TB in the future.

In order to destroy TB germs, a strong medication must be used on a regular basis for a long period of time. One of the medications used for preventive treatment is called rifampin, or RIF, and it is taken for four months. Adverse reactions to RIF include;

- Abdominal pain
- Dark urine
- Loss of appetite
- Nausea
- Rash/itching
- Tiredness
- Vomiting
- Yellow skin and/or eyes
- Easy bleeding
- Aching joints
- Dizziness
- Easy bruising

Most people do not experience these symptoms, but if you do, you should call the clinic and speak with a nurse.

The side effects listed below are **minor** problems. If you have any of these side effects, you can continue taking your medicine:

- Rifampin can turn urine, saliva, or tears orange. The doctor or nurse may advise you not to wear soft contact lenses because they may get stained.
- Rifampin can make you more sensitive to the sun. This means you should use a good sunscreen and cover exposed areas so you don't burn. If you are going to be out in the sun, use sunblock.
- Rifampin also makes birth control pills and implants less effective. Women who take rifampin should use another form of birth control.
- If you are taking rifampin as well as methadone (used to treat drug addiction), you may have withdrawal symptoms. Your doctor or nurse may want to adjust your methadone dosage.

It is important to monitor the health of the liver prior to, and during the time you are taking RIF. For adults, blood is drawn before starting RIF, and if they develop symptoms of side effects to the medication. Children under age 15 years have blood drawn only if they develop symptoms of side effects to the medication.

During the time you are taking RIF you should avoid drinking alcohol, especially on a daily basis. The intake of alcohol may inhibit the absorption of RIF. It will also increase your risk of having side effects from the medication.

It is important for women of childbearing age <u>not to become pregnant</u> during the time they are taking RIF. If you need a method of birth control, you should see you health care provider, or contact the Yavapai County Health Department Reproductive Health clinic for an appointment. Condoms are available at all times from our clinic.

If you see a doctor or dentist for any reason while you are taking RIF, give them the name of the medication and explain that you are taking it for “prevention of active tuberculosis.”

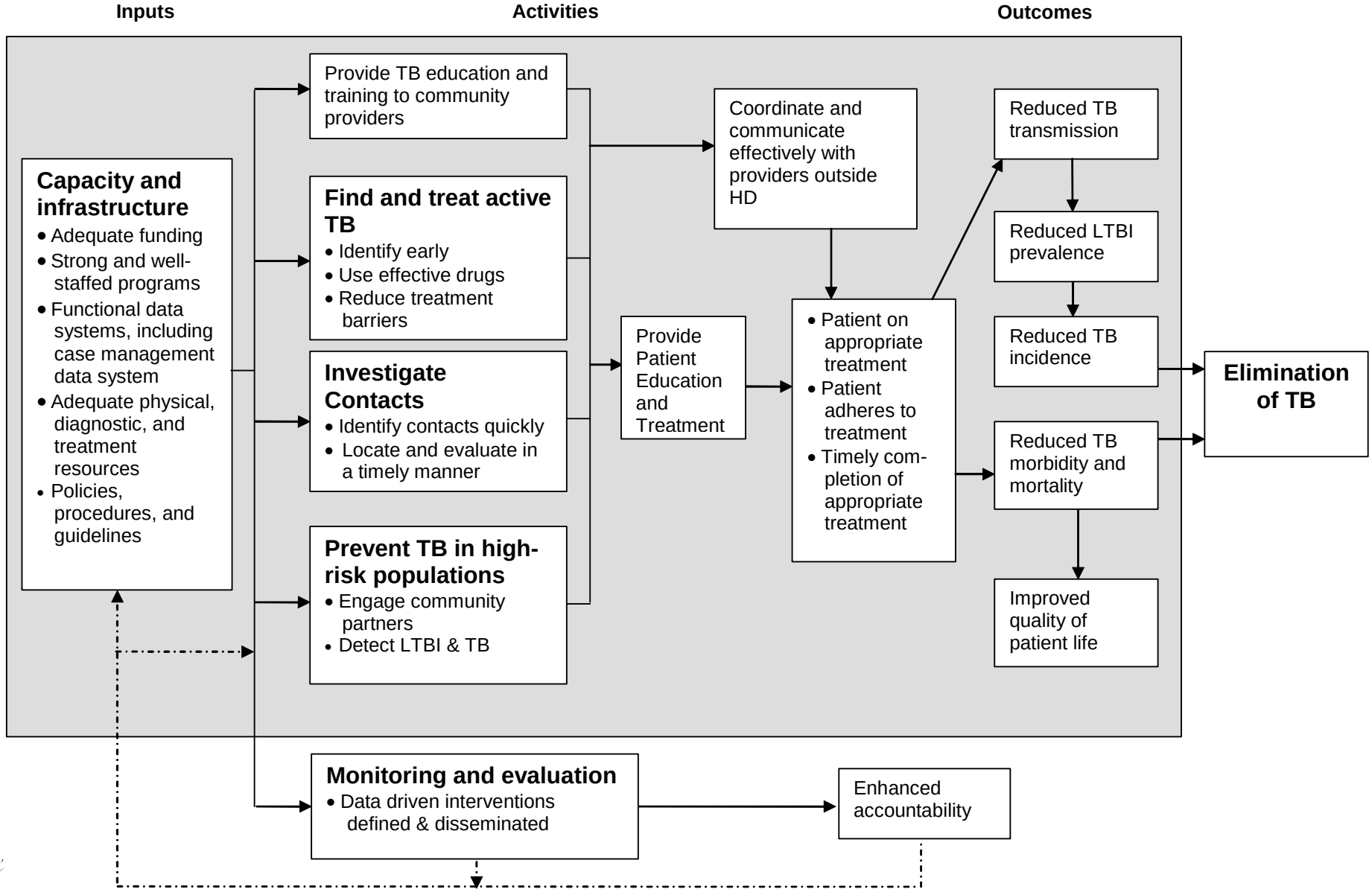
INSTRUCTIONS: Take your RIF at the same time every day. If you forget a dose, <u>DO NOT TAKE AN EXTRA DOSE</u>.

The nurse will make an appointment for your next evaluation and medication refill at the time of each visit. You will be weighed and questioned about possible signs of medication side effects at each visit. If you are unable to come to the clinic for your appointments the nurse will arrange to come to your home or another clinic location for your evaluations and refills.

If you have questions or problems, call

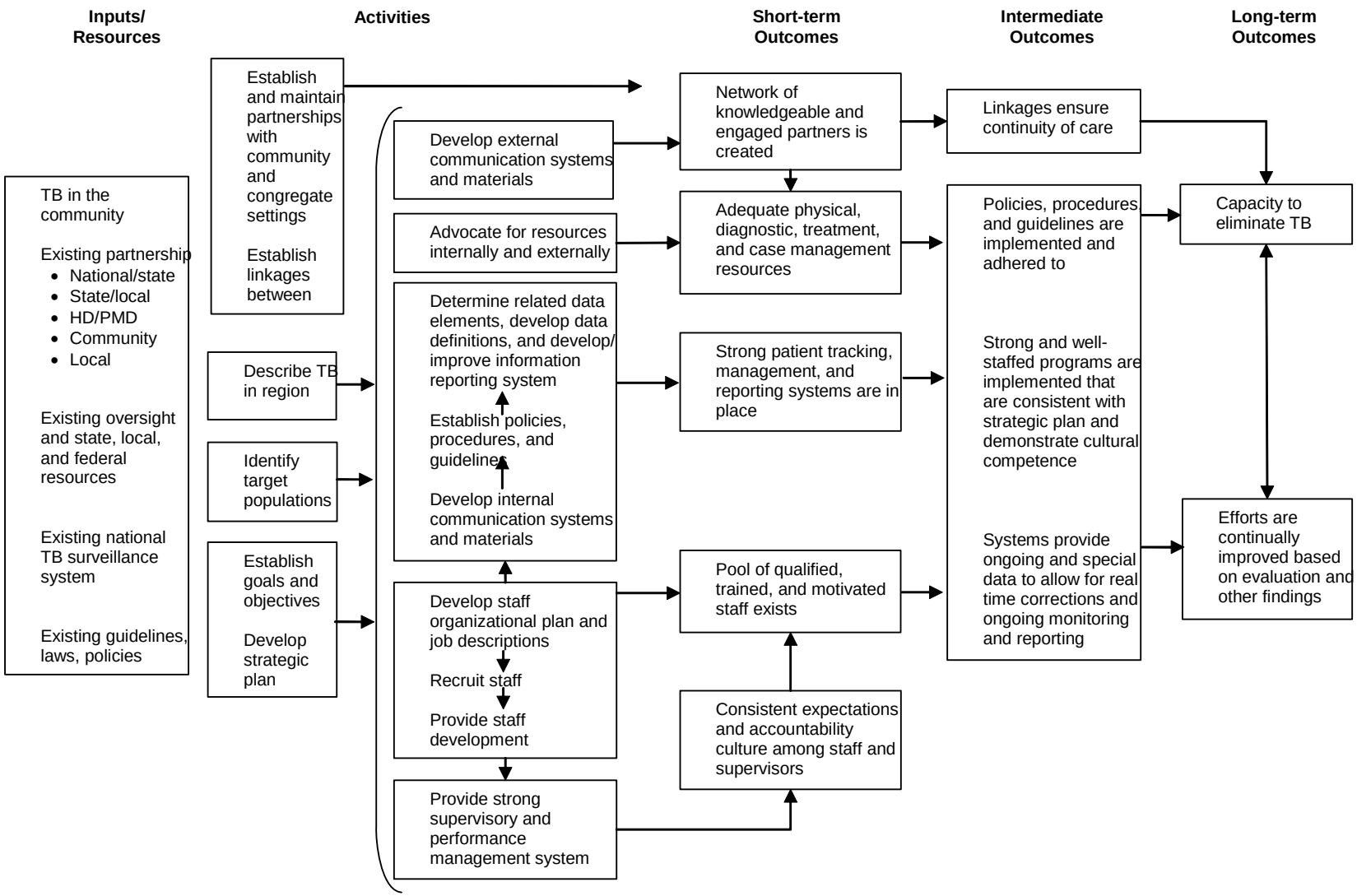
Meta-model for TB Elimination

Goal: Eliminate TB in the United States.



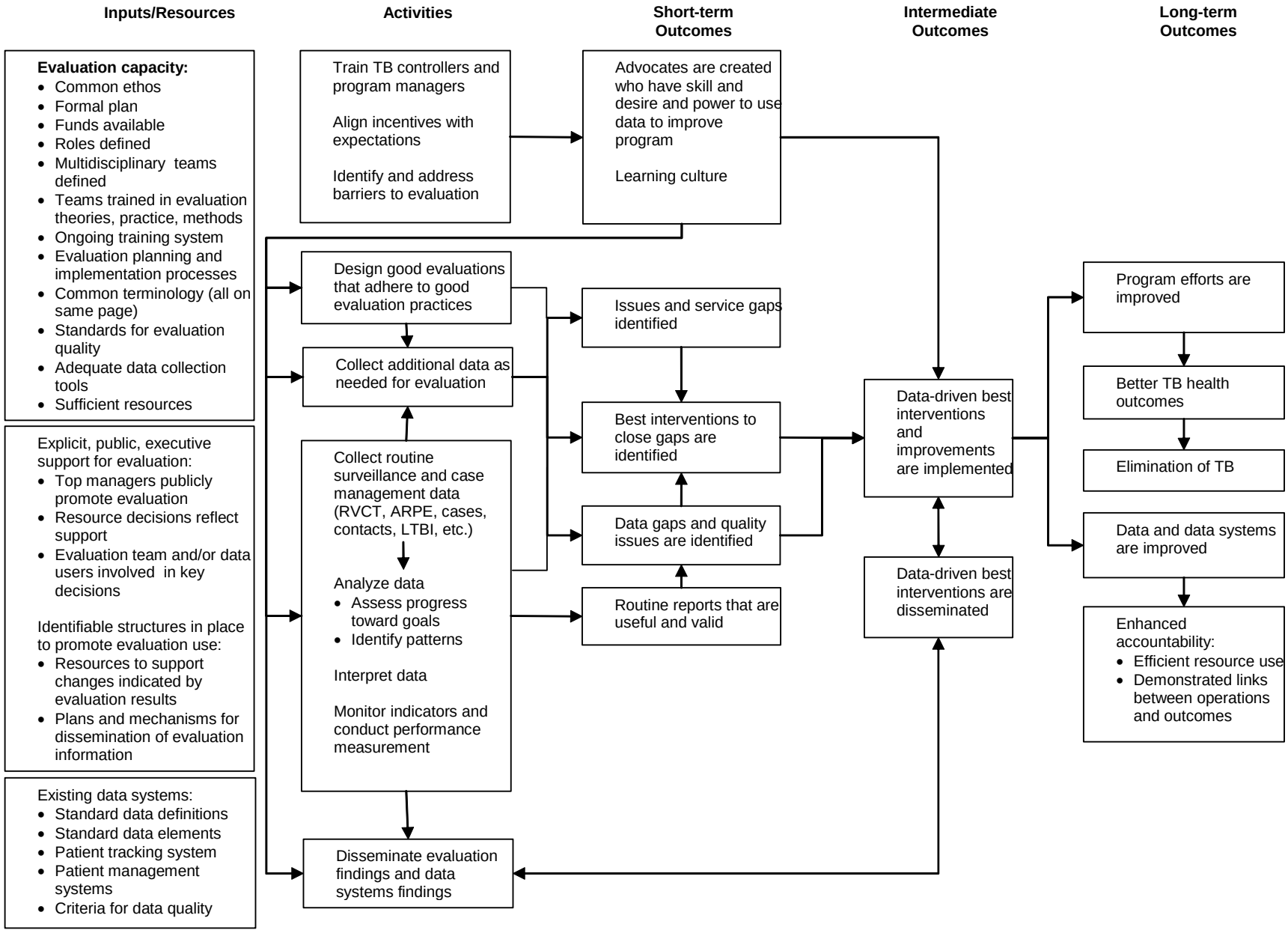
Capacity and Infrastructure to Eliminate TB

Goal: Develop capacity and infrastructure, which are essential inputs/resources in the other models.



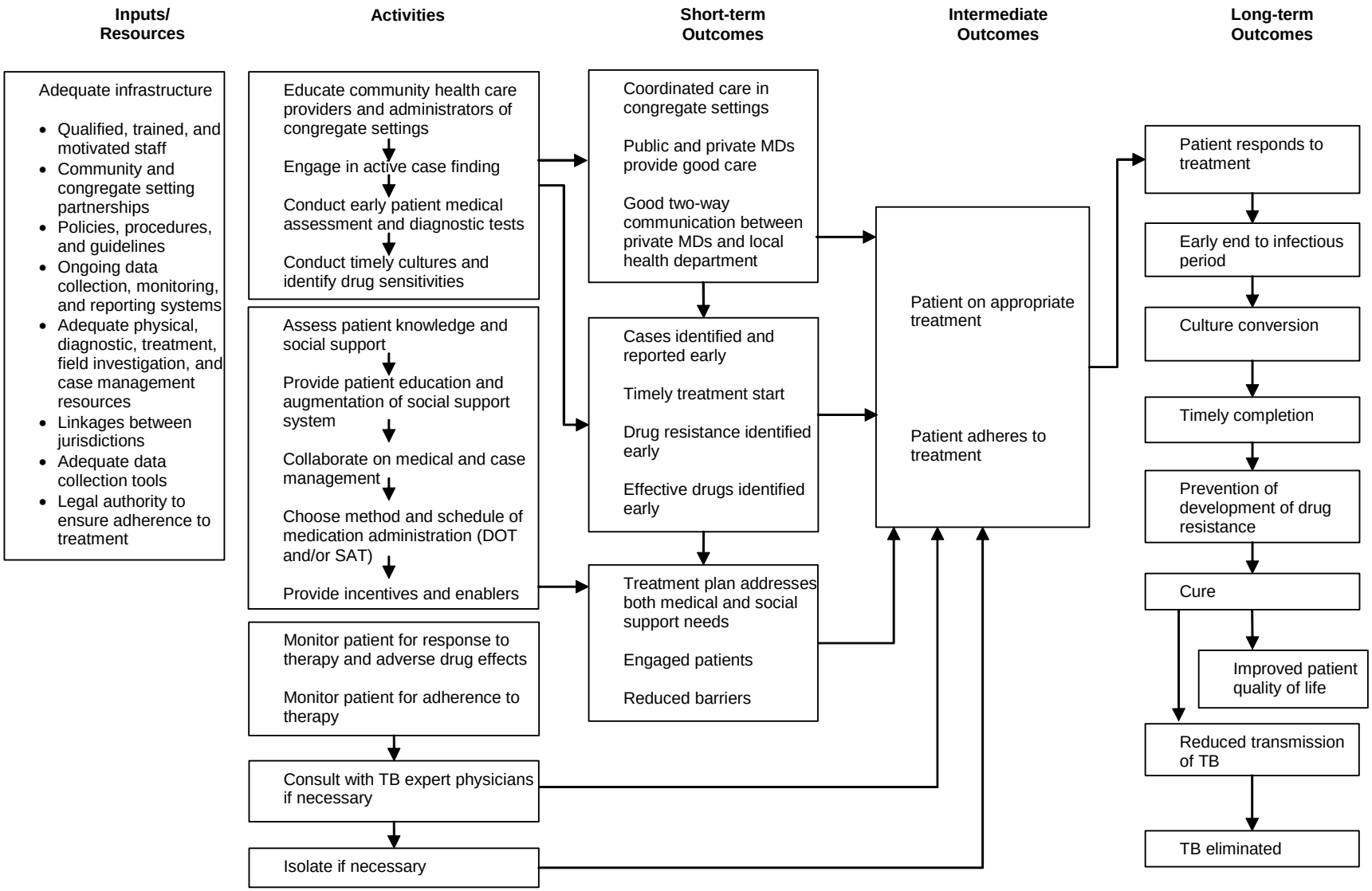
Evaluation Capacity

Goal: Programs at every level conduct ongoing monitoring and timely evaluation to improve patient and public health outcomes.
Develop and maintain appropriate comprehensive data systems and IT infrastructure (with linked data systems).
Make better use of data.



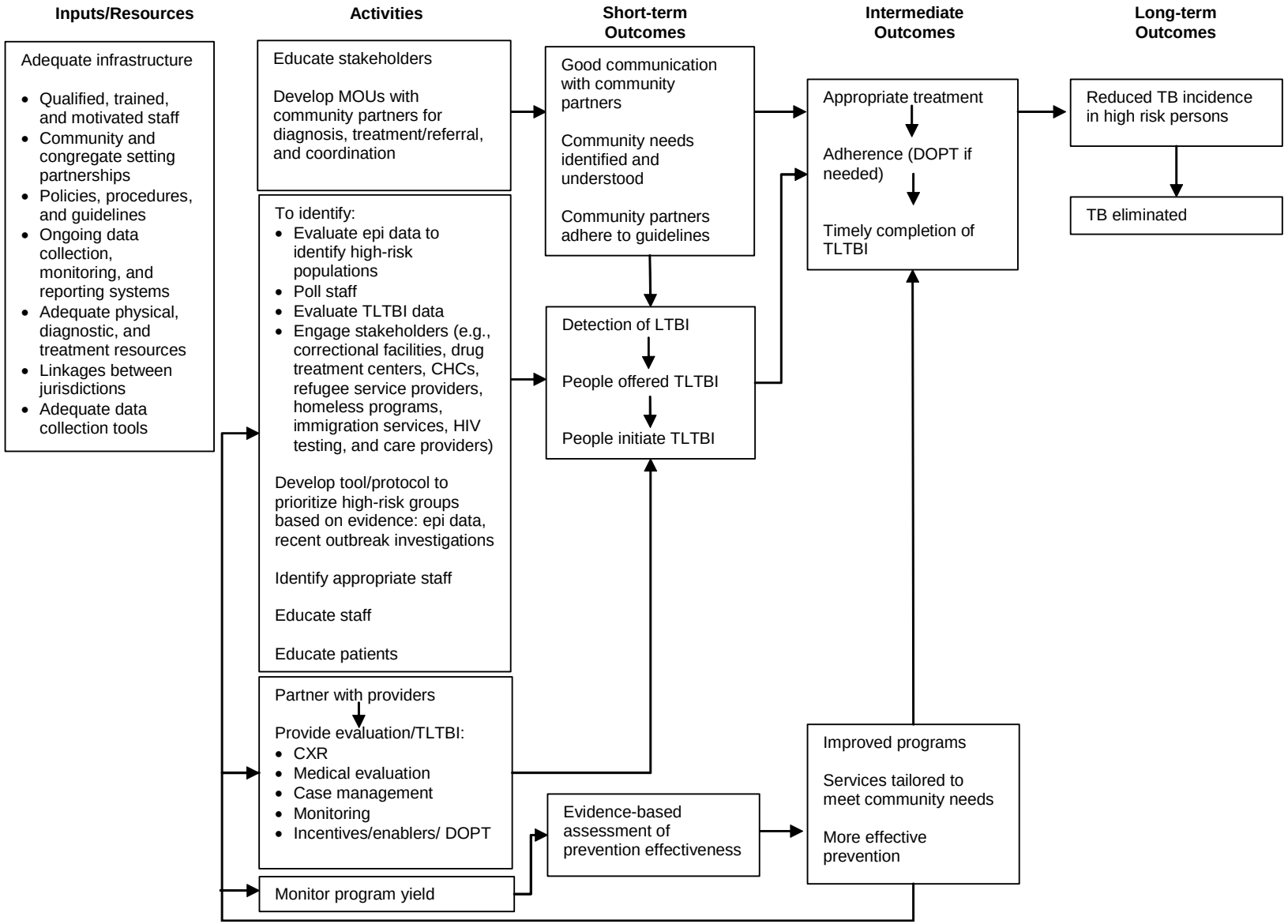
Timely Completion of Appropriate Treatment

Goal: Timely identification and treatment of people with active TB.



Prevent TB in High Risk

Goal: Prevent TB among high-risk populations through targeted testing and treatment.



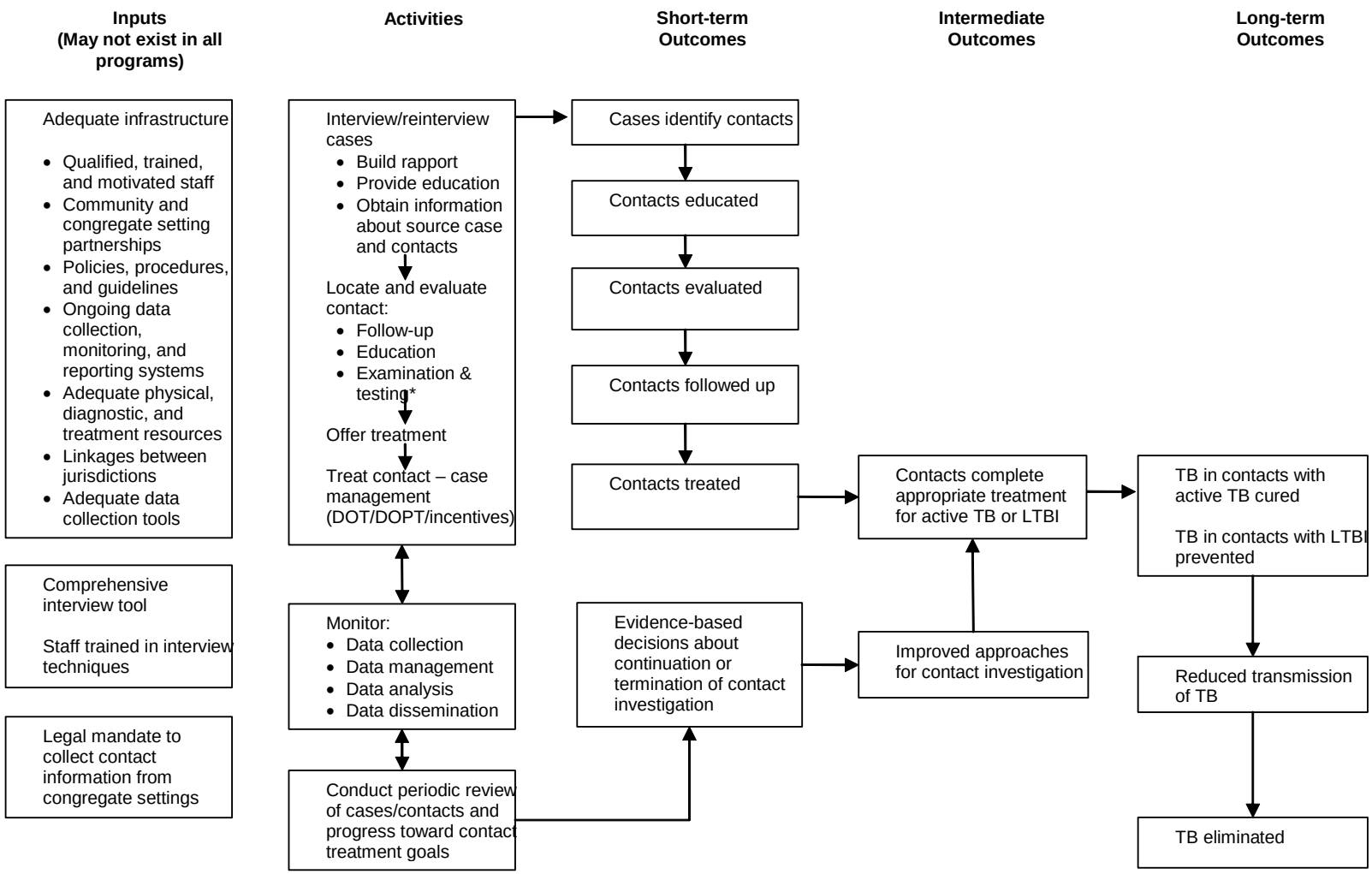
Strategies: Identify and prioritize high risk persons; targeted testing and treatment for LTBI; develop partnerships with providers treating high risk groups

Note: Infection control is another strategy for preventing TB that will be addressed in another model

Notes: LTBI = latent TB infection; TLTBI = treatment for LTBI; DOPT = directly observed preventive therapy; CXR = chest X-ray; MOU = memorandum of understanding; CHC = community health center

Contact Investigation

Goal: Prevent TB by finding and screening contacts and active TB cases to identify and treat cases of TB and LTBI.



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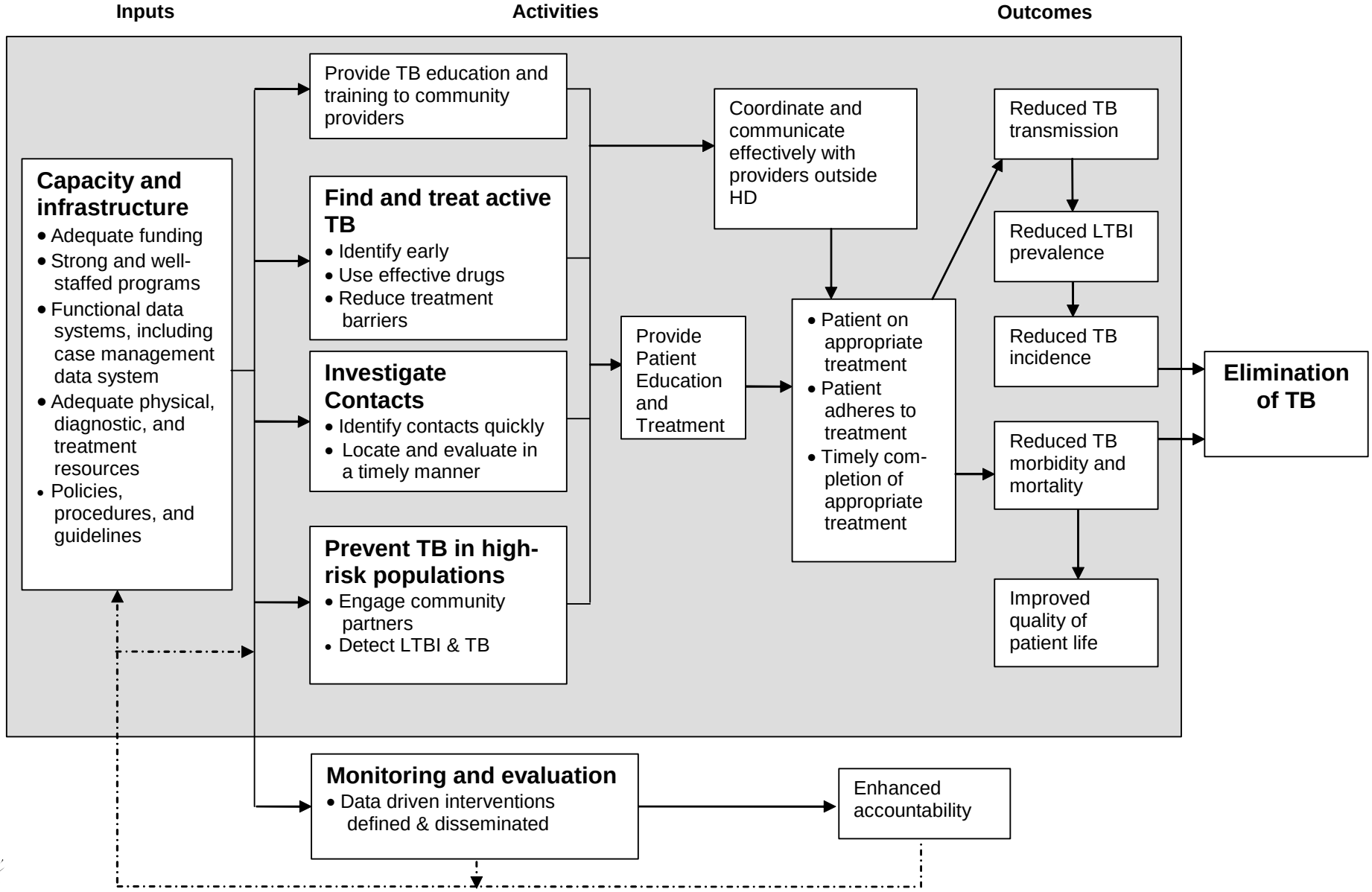

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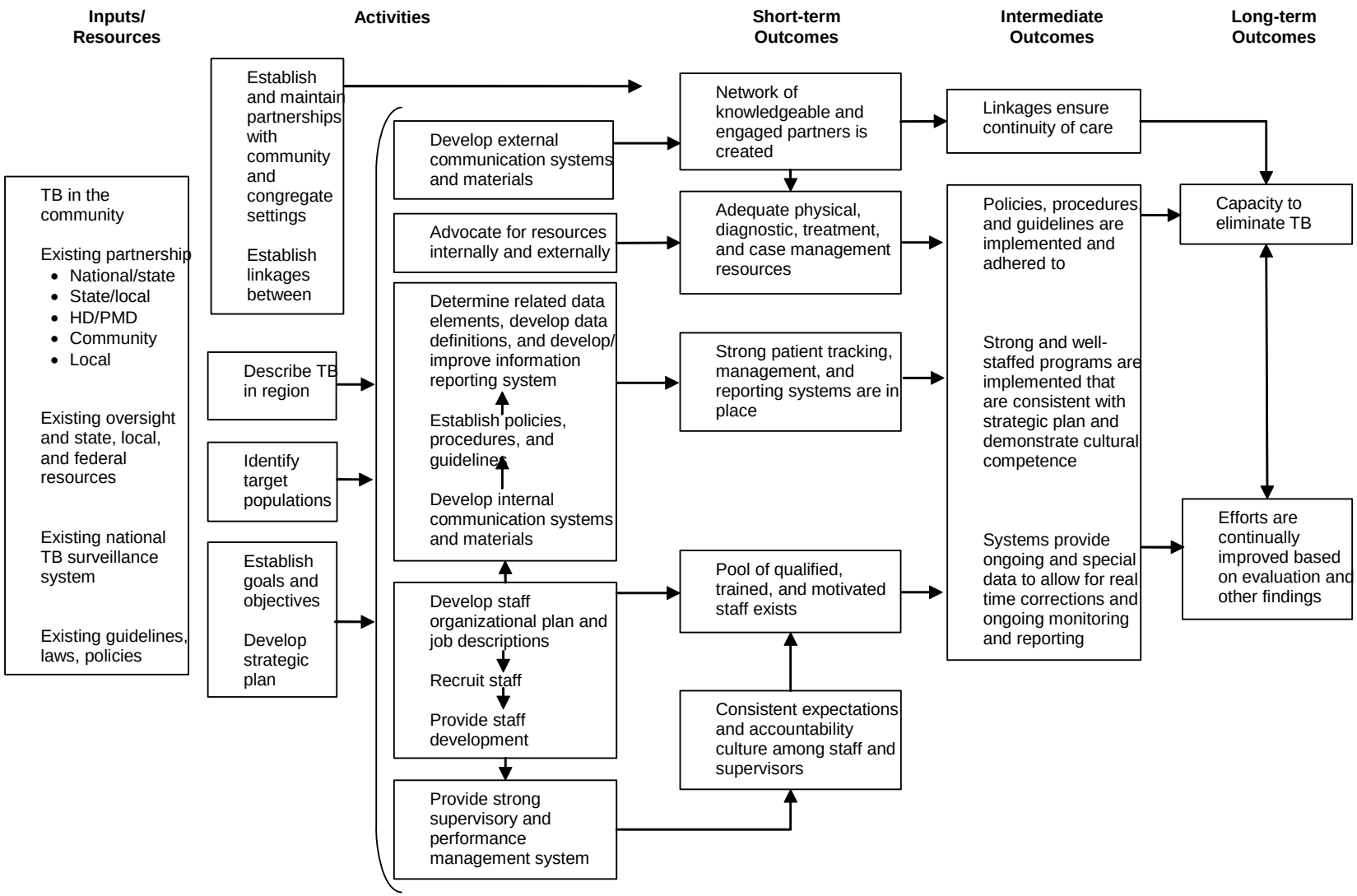

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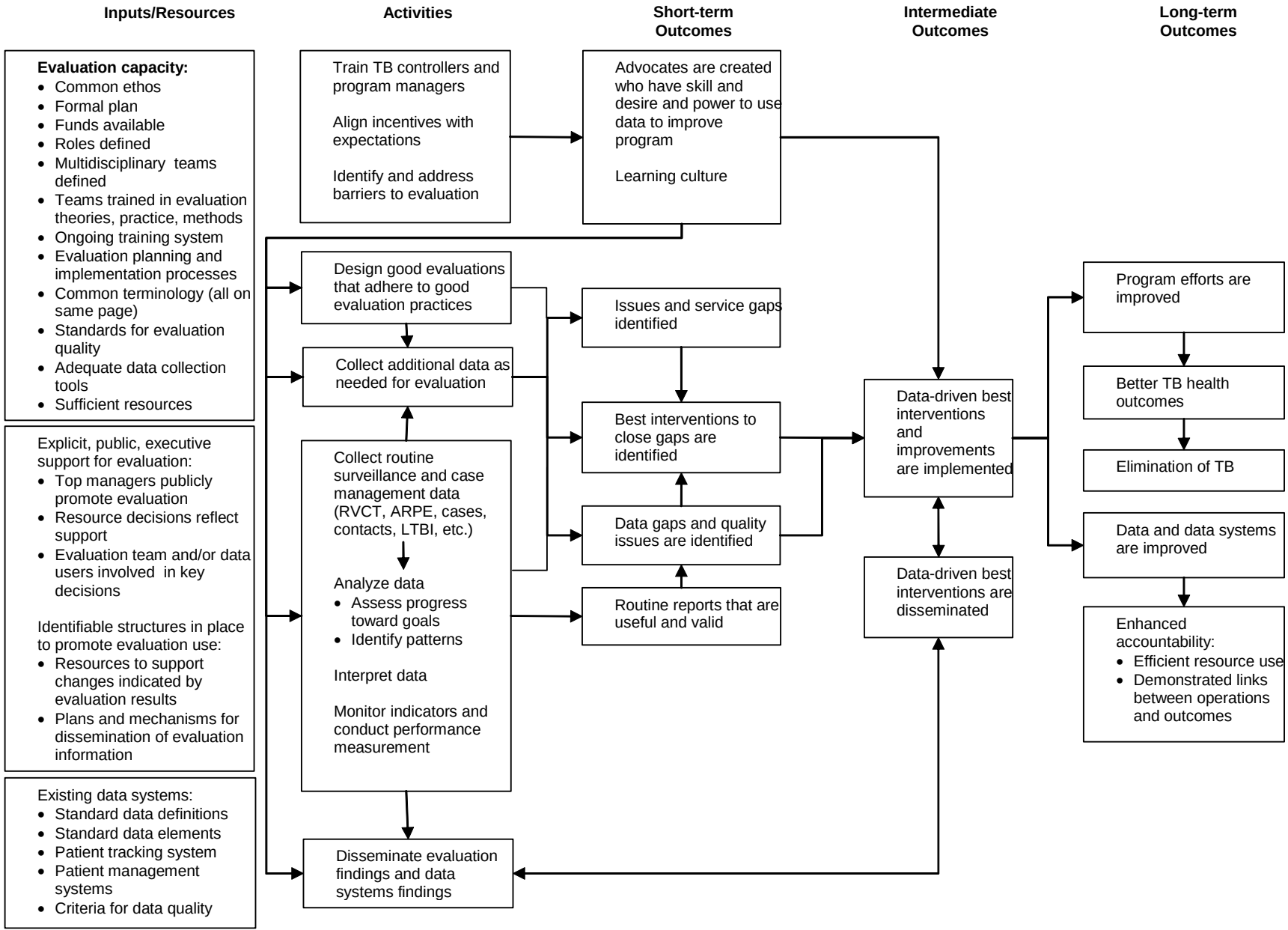

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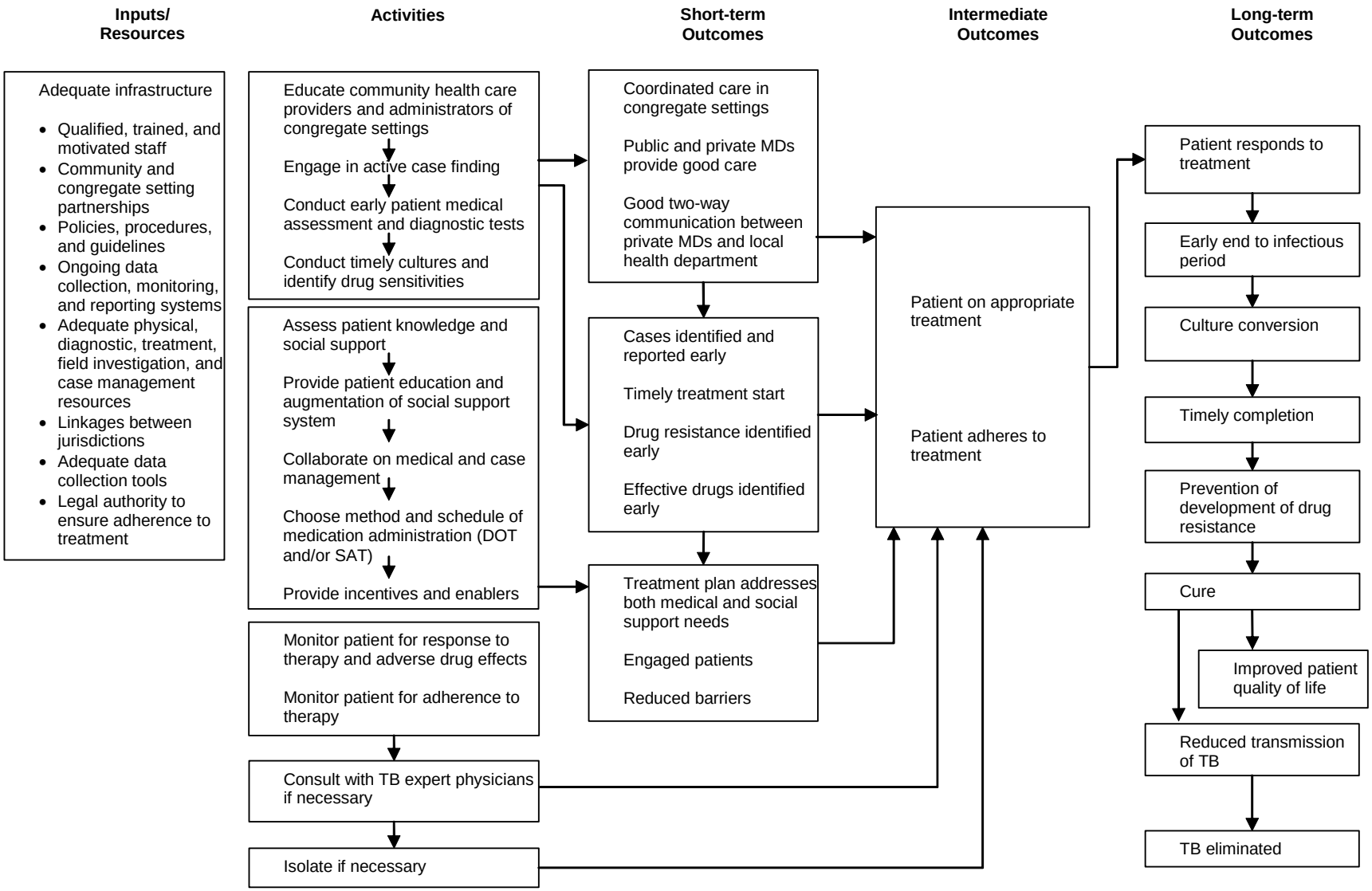

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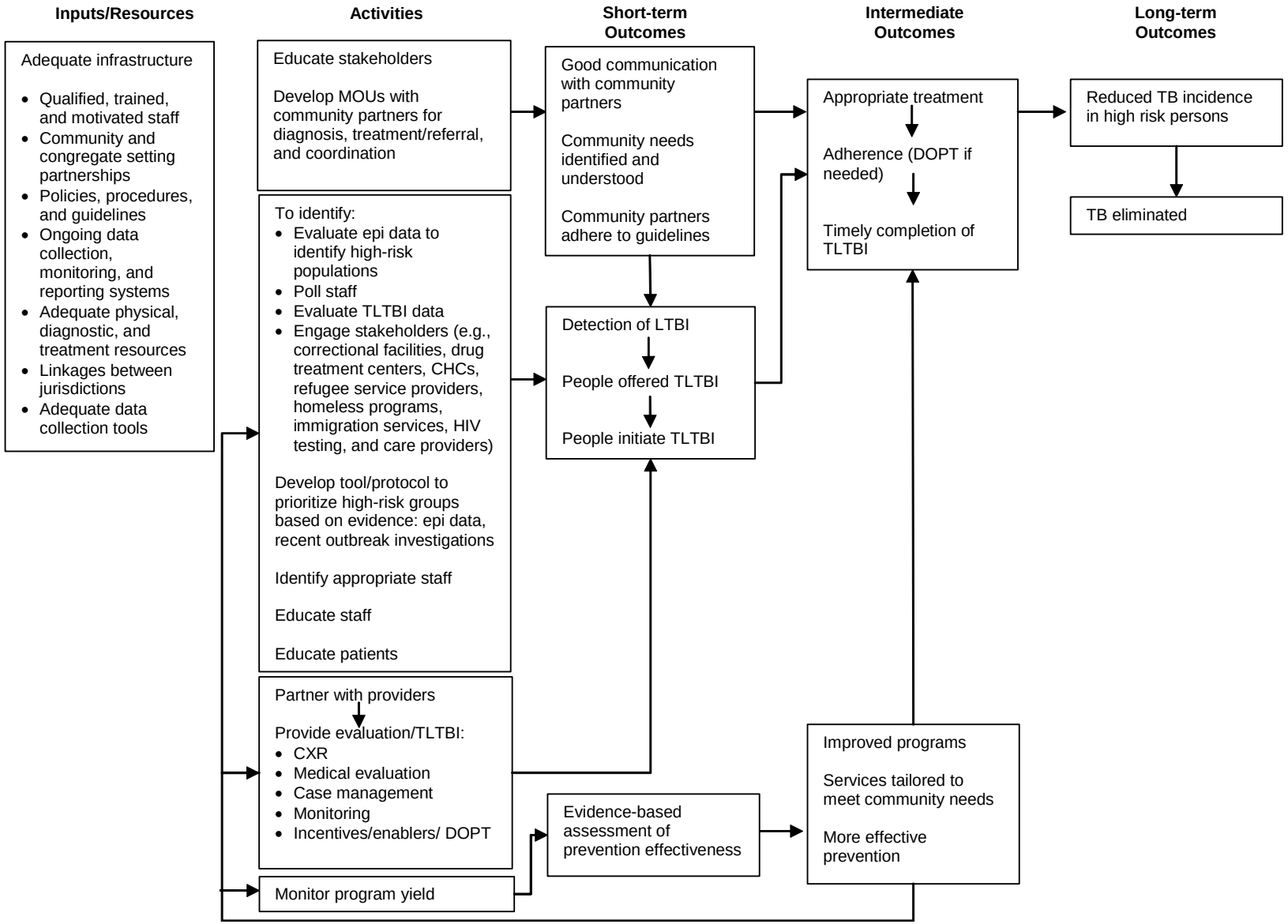

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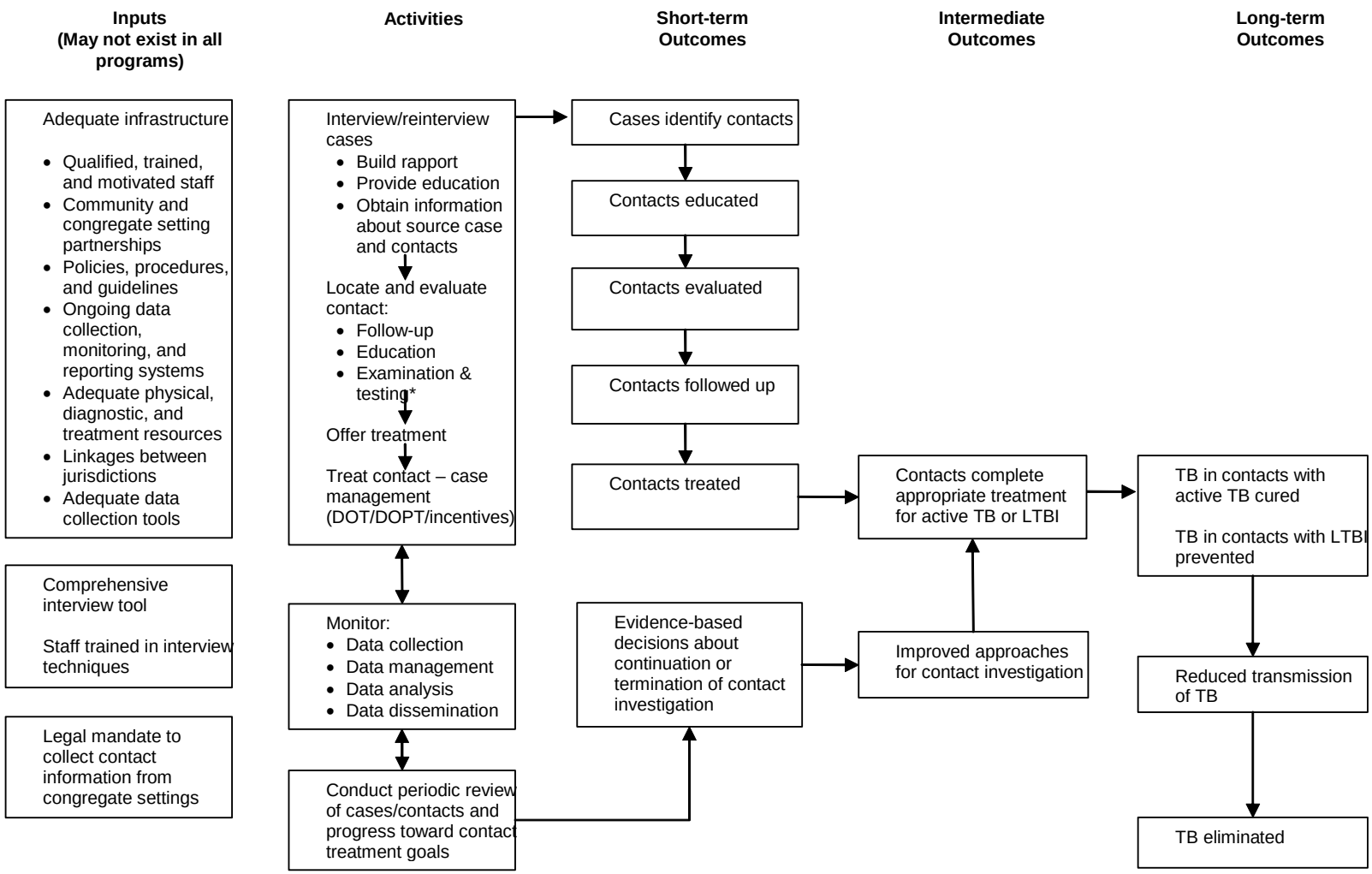

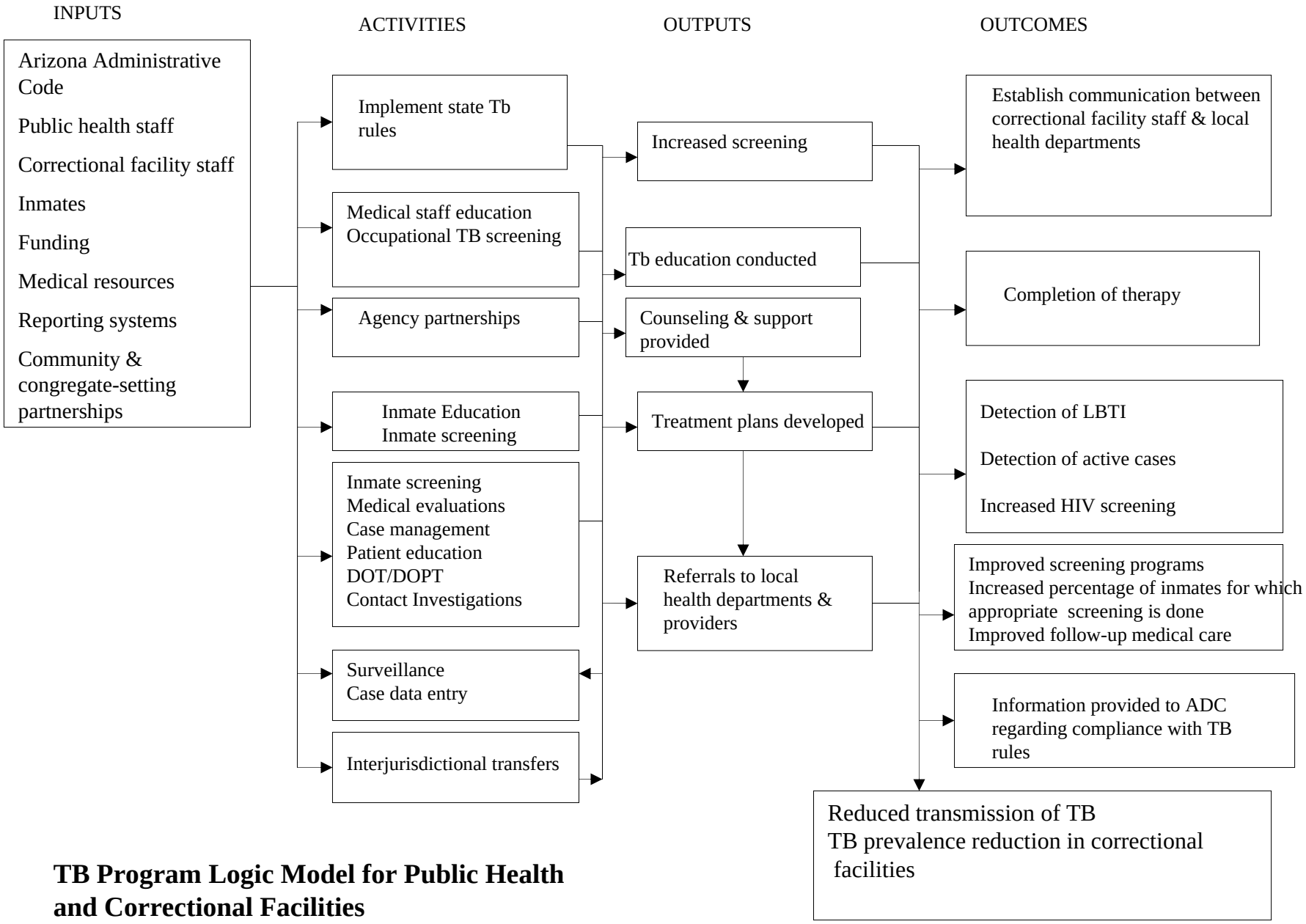

TB Program Logic Model for Public Health and Correctional Facilities

Tuberculosis Logic Model

I. Capacity and Infrastructure to Eliminate TB

Inputs/Resources	Activities	Outcomes
Burden of TB in the community	Establish and maintain partnerships with community resources	<u>Short-term Outcomes</u>
	Establish linkages with existing partners	Network of knowledgeable and engaged partners is created
Existing partnerships: County Health Departments Border Health Navajo Nation Phoenix Indian Health Services Correctional Facilities	Describe Burden of TB in community	Adequate physical, diagnostic, treatment and case management resources
	Identify target populations	Strong patient tracking, management, and reporting systems are in place
Existing oversight and state, local, and federal resources	Establish goals and objectives	Pool of qualified, trained and motivated staff exists
	Develop strategic plan	Consistent expectations and accountability culture among staff and supervisors
Existing TB surveillance system	Develop external communication systems and materials	
	Advocate for resources internally and externally	<u>Mid-term Outcomes</u>
Existing guidelines, laws and policies	Determine related data elements, develop data definitions, and develop/improve information reporting system	Linkages ensure continuity of care
	Establish policies, procedures, and guidelines	Policies, and guidelines are implemented and adhered to
	Develop internal communication systems and materials	Strong and well-staffed programs are implemented that are consistent with strategic plan and demonstrate cultural competence
	Develop staff organizational plan and job descriptions	Systems provide ongoing and special data to allow for real time connections and ongoing monitoring and reporting
	Recruit staff	
	Provide staff development	<u>Long-term Outcomes</u>
	Provide strong supervisory and performance management system	Capacity to eliminate TB
		Efforts are continually improved based on evaluation and other findings

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), 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, IFN-γ release assays (IGRA). In the United States, the currently available test is QuantiFERON®-TB Gold test (QFT-G).

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 two 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 two 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 two-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 two to four weeks for mycobacteria to grow (two to four 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 *µ*m 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-fact bacilli (AFB) sputum smear results, the infectious period begins three months before the collection date of the first positive smear result or the symptom onset date (whichever is earlier) and 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 one month before the symptom onset date and ends when the patient is placed into AII (whichever was earlier).

interferon-γ release assay (IGRA): A type of an *ex vivo* test that detects cell-mediated immune response to this cytokine. In the U.S., QuantiFERON®-TB Gold test (QFT-G) is a currently available IGRA.

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 names 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 six 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, two or more contacts are identified as having TB disease, regardless of their assigned priority, (i.e., high-, medium-, or low-priority).
- 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).
- A genotype cluster leads to discovery of one or more verified transmission links which were missed during a contact investigation within the prior two 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 one 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 two to three weeks.

purified protein derivative (PPD) tuberculin: A material used in diagnostic tests for *M. tuberculosis* infection. In the U.S., 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 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 one day. In 2005, QFT was replaced by QFT-G, which has greater specificity because of antigen selection. QFT-G appears to be capable of distinguishing between the sensitization caused by *M. tuberculosis* infection and that caused by bacille Calmette-Guérin vaccination.

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 two 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 two 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 three 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 one to three 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.