UNITED STATES DISTRICT COURT	SOUTHERN DISTRICT OF TEXAS
DR. ORLY TAITZ V. JEH JOHNSON, SECRETARY OF DEPARTMENT OF HOMELAND SECURITY, ET AL.	BROWNSVILLE DIVISION CIVIL ACTION NO. B-14-119 **EXHIBIT LIST**
LIST OF: GOVERNMENT EXHIBITS TYPE OF HEARING: INJUNCTION	AUSA: DANIEL D. HU & COLIN KISOR
JUDGE: ANDREW S. HANEN / CLERK: CRISTINA SUSTAETA	REPORTER: BARBARA BARNARD

NO.	DESCRIPTION	OFR	OBJ	ADM	DATE
1.	Memorandum from Secretary of Homeland Security Janet Napolitano, Exercising Prosecutorial Discretion with Respect to Individuals Who Came to the United States as Children (June 15, 2012): http://www.dhs.gov/xlibrary/assets/s1-exercising-prosecutorial-discretion-individuals-who-came-to-us-as-children.pdf				
2.	DR. MIGUEL ESCOBEDO, CV	✓		✓	10-29-14
3.	DHS Occupational Health Advisory – May 1, 2014	✓		✓	10-29-14
4	CDC LETTER TO PHYSICIANS AUGUST 7, 2014	✓		✓	10-29-14
5	ADMINISTRATION FOR CHILDREN AND FAMILIES – LETTER TO TB CONTROLLERS	✓		✓	10-29-14
6.	HHS LETTER TO HEALTH CARE PROVIDERS – GUIDANCE ON CLEARING UAC WITH TB	✓		✓	10-29-14
7.	ACTIVE TB SCREENING ALGORITHM	✓		✓	10-29-14
8.	NEDSS TEXAS REPORTING INSTRUCTIONS AND FORM	✓		✓	10-29-14
9.	CDC GUIDELINES FOR PREVENTING THE TRANSMISSION OF TUBERCULOSIS IN HEALTH CARE SETTINGS - 2005	✓		✓	10-29-14
10.	PRIOR COURT TESTIMONY OF CHIEF OAKS, MR. FIERRO AND MS. BROOKS – 8/27/2014				
11.	CDC TB ELIMINATION SHEET WWW.CDC.GOV/TB/PUBLICATIONS/FACTSHEETS/TESTING/DIAGNOSIS.PDF	✓		✓	10-29-14
12.	CV - Vera F. Dolan	✓		✓	10-29-14
13.	Article	✓		✓	10-29-14
14.	Article	✓		✓	10-29-14
15.	Article	✓		✓	10-29-14

MIGUEL ESCOBEDO, MD., MPH.

CURRICULUM VITAE (Summary)

Education:

- Stanford University School of Medicine, MD
- University of California at Berkeley, MPH
- New Mexico State University, BS Biology

Residency/Fellowship Program:

- Family Practice Residency – Texas Tech Medical School

Current Practice Type and/or Employer:

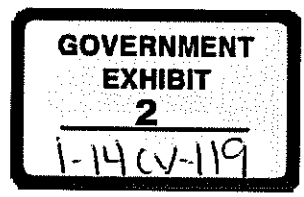
- Medical Officer - Centers for Disease Control and Prevention, US-MX Border Unit, El Paso Quarantine Station

Professional Experience:

- Quarantine Medical Officer – Centers for Disease Control and Prevention
- February 2005 to present
- District Health Officer – New Mexico Department of Health, Dist. III
  January 2003 to October 2003
- Regional Director – Texas Department of Health, Public Health Region 9/10
  January 1996 to January 2003 and October 2003 to February 2005
- Tuberculosis Control Officer – El Paso City-County Health District
  April 1986 to December 1996
- Medical Director, Communicable Diseases Control- El Paso City-County Health District
- Medical Director, Preventive Health Services, El Paso City-County Health District
- Family Medicine Physician, El Paso Centro de Salud Familiar La Fe (Certified Community Health Center)
- Seasonal Agricultural Worker.

Other Pertinent Information:

- WHO consultant, International Health Regulations
- Served on National Advisory Council for TB Elimination - CDC
- Served on Council of Public Health - Texas Medical Association
- Fratis L. Duff M.D. Memorial Award, Texas Health Foundation
- Voting member, Texas Department of Health Institutional Review Board for Human Subjects



Research Interests:

- Border Health Issues
- Quarantine & Traveler's health
- Bi-national Tuberculosis Control

Dr. Escobedo is currently a Medical Health Officer with the Centers for Disease Control Quarantine Station in El Paso. He is past Regional Director for the Texas Department of State Health Services Regions 9/10 and Regional District Health Officer for the New Mexico Department of Health. He served as Tuberculosis and Control Officer and Communicable Diseases Director for El Paso City- County Health District for 10 years. Dr. Escobedo is a graduate of Stanford University School of Medicine and the University of California Berkeley School Of Public Health. He completed a Family Practice Residency Program at Texas Tech El Paso. His research interests include Tuberculosis, Border Health, and Quarantine and Travelers Health. He has authored articles in Public Health Journals.

Homeland Security

Office of Health Affairs

Occupational Health Advisory

May 1, 2014

TO: CBP

SUBJECT: Scabies Outbreak

This document sets forth occupational health and safety guidance for CBP personnel in the handling of subjects presenting with the signs and symptoms of scabies.

Human scabies is caused by an infestation of the skin by the human itch mite (Sarcoptes scabiei var. hominis). The microscopic scabies mite burrows into the upper layer of the skin where it lives and lays its eggs. The scabies mite usually is spread by direct, prolonged, skin-to-skin contact with a person who has scabies. Occasionally transmission occurs from direct skin contact with clothing or bedding from an infected person.

Scabies can spread rapidly under crowded conditions where close body contact is frequent. Institutions such as extended-care facilities, detention centers and prisons are often sites of scabies outbreaks.

The most common symptoms of scabies are intense itching and a skin rash. These symptoms are caused by an allergic reaction to the proteins and feces of the parasite. Severe itching, especially at night, is the earliest and most common symptom of scabies. A pimple-like rash is also common.
Itching and rash may affect much of the body, but is usually limited to these common sites:

- Between the fingers
- Wrist
- Elbow
- Armpit
- Penis
- Nipple
- Waist
- Shoulder blades
- Buttocks

The head, face, neck, palms, and soles are involved in infants and very small children, but usually not adults and older children.

Tiny burrows are sometimes seen on the skin; these are caused by the female scabies mite tunneling just beneath the skin. The burrows appear as tiny raised and crooked grayish-white or skin colored lines on

the skin surface. They are most often found in the webbing between the fingers, in the folds of the skin on the wrist, elbow, or knee.

Complications associated with scabies are usually caused by infection of the sores caused by scratching. A more severe form of scabies, called crusted scabies, may affect certain high-risk groups, including: people with chronic health conditions that weaken the immune system, such as HIV or leukemia; people who are very ill, such as hospitalized individuals or those in nursing facilities.

Infectious Period: When a person is infested with scabies mites the first time, symptoms usually do not appear for up to 2-6 weeks after being infested. Infested person(s) can still spread scabies even if they are not exhibiting symptoms. If a person has had scabies before, symptoms appear much sooner, 1-4 days after exposure.

Scabies mites generally do not survive more than 2 to 3 days away from human skin. Adults and children can return to work or school a day after treatment was started.

Personal protective equipment: Latex or non-latex gloves should be used anytime direct contact will be made with any subjects that are confirmed or suspected of having scabies.

Treatment: The following medications for the treatment of scabies are available only by prescription.

Prescriptions:

A) Permethrin cream 5%; Brand name product: Elimite*
Permethrin is approved by the US Food and Drug Administration (FDA) for the treatment of scabies in persons who are at least 2 months of age. Permethrin is a synthetic pyrethroid similar to naturally occurring pyrethrins which are extracts from the chrysanthemum flower. Permethrin is safe and effective when used as directed. Permethrin kills the scabies mite and eggs. Permethrin is the drug of choice for the treatment of scabies. Two (or more) applications, each about a week apart, may be necessary to eliminate all mites, particularly when treating crusted (Norwegian) scabies. Treatment for confirmed or suspected cases of scabies will be Permethrin 1% lotion. The medication should be applied directly to the skin on all areas of the body except the head. After application, the medication will be left on the skin for 24 hours before being washed off. During application and rinsing contact with the eyes, the inside of the mouth, nose and vagina should be avoided as it will cause irritation. Due to potential complications, treatment for pregnant females is optional. Prescription permethrin, such as Elimite cream, is the most commonly used medicine to treat scabies. Unlike the more toxic lindane, permethrin is considered safe for infants as young as 2 months old. Only permethrin, crotamiton, and sulfur ointment are considered safe for treating children younger than age 2.

B) Crotamiton lotion 10% and Crotamiton cream 10%; Brand name products: Eurax*; Crotan*
Crotamiton is approved by the US Food and Drug Administration (FDA) for the treatment of scabies in adults; it is considered safe when used as directed. Crotamiton is not FDA-approved for use in children. Frequent treatment failure has been reported with crotamiton.

C) Lindane lotion 1%; Brand name products: None available
Lindane is an organochloride. Although FDA-approved for the treatment of scabies, lindane is not recommended as a first-line therapy. Overuse, misuse, or accidentally swallowing lindane can be

toxic to the brain and other parts of the nervous system; its use should be restricted to patients who have failed treatment with or cannot tolerate other medications that pose less risk. Lindane should not be used to treat premature infants, persons with a seizure disorder, women who are pregnant or breast-feeding, persons who have very irritated skin or sores where the lindane will be applied, infants, children, the elderly, and persons who weigh less than 110 pounds.

D) Ivermectin; Brand name product: Stromectol*
Ivermectin is an oral antiparasitic agent approved for the treatment of worm infestations. Evidence suggests that oral ivermectin may be a safe and effective treatment for scabies; however, ivermectin is not FDA-approved for this use. Oral ivermectin has been reported effective in the treatment of crusted scabies; its use should be considered for patients who have failed treatment with or who cannot tolerate FDA-approved topical medications for the treatment of scabies. The dosage of ivermectin is 200 mcg/kg orally. It should be taken on an empty stomach with water. A total of two or more doses at least 7 days apart may be necessary to eliminate a scabies infestation. The safety of ivermectin in children weighing less than 15 kg and in pregnant women has not been established.

E) Persistent nodular scabies may be treated with injections of steroids into the nodules or (rarely) with coal tar products applied to the skin.

For Itching:

Use of the following over-the-counter medicines can help relieve itching from scabies:

A) Oral antihistamines (such as Benadryl). These medicines will not interfere with the diagnosis or treatment of scabies. Don't give antihistamines to your child unless you've checked with the doctor first.
B) Corticosteroid creams (such as hydrocortisone cream). This type of medicine may make the scabies sores look different and make it harder for your doctor to diagnose the problem. Only use this medicine after your doctor has seen and diagnosed your condition.

Most creams or lotions are applied to the entire body from the neck down. On infants, the medicine is also applied to the scalp, face, and neck, taking care to avoid the area around the mouth and eyes. The medicine usually is left on for 8 to 14 hours and then washed off.

Hygiene Guidance:

Immediately after starting treatment for scabies, clean all the affected person's bedding and the clothing that he or she has worn during the past 2 to 3 days (48 to 72 hours). Wash all items in hot water and dry them in a hot dryer. Or dry-clean them.

Any items that cannot be washed or dry-cleaned must be placed in a closed plastic bag for at least 7 days.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

August 7, 2014

Dear Colleagues:

The purposes of this letter are to give you an overview of the tuberculosis (TB) control efforts for unaccompanied children who come into the care and custody of the Department of Health and Human Services after being apprehended by immigration authorities and to let you know about situations when your help might be needed.

When children apprehended by immigration authorities are unaccompanied by a parent or guardian, they are placed in the care and custody of the Department of Health and Human Services (HHS). Typically, HHS then releases children to an appropriate sponsor—usually a parent, relative, or family friend—who can safely and appropriately care for them while their immigration cases proceed. The Administration for Children and Families Office of Refugee Resettlement (ORR) at HHS operates about 100 short-term shelters in 14 states that care for the unaccompanied children until they are released to sponsors.

Most children remain in a shelter for less than 35 days and are released to appropriate sponsors while their immigration cases are processed. Children are not released to a sponsor if they have a medical condition that is a public health threat. When a child is released to a sponsor, the child moves to the community in which the sponsor lives. Although the children are in ORR custody, they are not refugees in the legal sense, and they do not currently qualify for federal refugee benefits.

After admission to a shelter, each child undergoes health examinations, including TB screening that is modeled on the Technical Instructions for Tuberculosis Screening and Treatment for panel physicians developed by the CDC Division of Global Migration and Quarantine. This screening starts with a symptom inventory for all children regardless of age. For children 15–17 years old, the shelter healthcare providers have a choice between (1) chest radiography with further diagnostic tests as needed for radiographic abnormalities or (2) initial testing with either a tuberculin skin test or an interferon-gamma release assay. Children 2–14 years old undergo either a tuberculin skin test or an interferon-gamma release assay, with the skin test preferred for children younger than 5 years old. Children younger than 2 years of age undergo no TB-specific testing unless they are known to have been exposed to contagious TB or have signs or symptoms of TB.

The provisions for health care are different at each shelter. At some shelters, the clinic of the local health department provides services for at least part of the TB screening. Per ORR policy, the medical services offered by a shelter are required to follow local laws about reportable conditions, including suspected or confirmed TB. Through this screening, a small of number of cases of TB have been identified. A local health department has been involved in the initial TB care in each confirmed case that has come to our attention. Children who have TB diagnosed during ORR custody are treated and kept in isolation at the shelter until the TB is non-contagious. When a child being treated for TB who is no longer contagious is released to a sponsor, the TB management is transferred from the local health department in the shelter's community to the health department in the community where the sponsor resides.

If the U.S. TB case definition and the usual counting criteria are met, TB programs should report TB cases among unaccompanied children in their jurisdictions for routine surveillance. The standard data fields that are sent to CDC cannot distinguish the children as unaccompanied.

After a diagnosis of latent *Mycobacterium tuberculosis* infection (LTBI), few children in ORR custody start treatment because the duration of custody is brief. Instead, ORR officials notify the destination state's TB control authority with the child's name, diagnostic findings, and sponsor address (see ORR letter, attached). The personnel at ORR shelters collaborate with state or local public health authorities when initiating contact investigations after TB exposures within shelters. For children who were included in a contact investigation, but not completely examined before release from custody to a sponsor, ORR uses the same type of notification to state officials that includes details about the exposure. Neither ORR nor CDC is asking for disposition results of contacts after referrals to state officials.

We learned of one instance when TB was diagnosed after a child was released from ORR custody, and the local TB control official reported it to officials at ORR. Thanks to these efforts, a contact investigation was initiated for children and ORR shelter workers who were possibly exposed. Should this type of event occur in your jurisdiction, please notify the Director, Division of Refugee Health, ORR, at curi.kim@acf.hhs.gov, and the medical coordinators, at ducsmedical@acf.hhs.gov that TB has been diagnosed in a child who has left ORR custody. To initiate a contact investigation, the officials at ORR need at least the child's name and alien number. If your regulations forbid transmission of personally identifiable information by email, you can schedule a telephone verbal report with ORR officials after you contact them by email. ORR does not plan to provide summary data from contact investigations to CDC or to you; therefore, you might not receive data about contacts for your Aggregate Report for Program Evaluation (ARPE).

The TB Program Consultants in the Field Services and Evaluation Branch, Division of Tuberculosis Elimination, CDC, are temporarily assisting ORR personnel with collecting information about suspected TB cases in unaccompanied children. Because some of the information is at local health departments, the TB Program Consultants might ask for your assistance. This is a short-term project, and we do not expect it to require much of your time.

Thank you for your help. If you have questions about TB control for unaccompanied children in your jurisdiction, please contact the CDC TB Program Consultant (see http://www.cdc.gov/nchhstp/programintegration/MapStateLinks.html) who is assigned to your jurisdiction as the federal cooperative agreement project officer for your TB control program.

Sincerely,

Philip LoBue, MD, FACP, FCCP
Director
Division of Tuberculosis Elimination
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

ADMINISTRATION FOR
CHILDREN & FAMILIES
370 L'Enfant Promenade SW. Washington DC 20447 www.acf.hhs.gov

Dear TB Controller,

Unaccompanied alien children (UAC) are undocumented migrant children who come to the United States without a parent or guardian. Many UAC are apprehended by the Department of Homeland Security (DHS) at the southern border. DHS then transfers UAC to the custody of the Department of Health and Human Services, specifically the Administration for Children and Families' Office of Refugee Resettlement (ORR). Despite being in ORR custody, UAC are *not* legally refugees and do not qualify for refugee benefits. ORR provides UAC with a safe and appropriate environment as well as client-focused care until they are released to a sponsor in the United States or returned to their home country. UAC receive initial medical exams, which include TB screening, upon entering ORR custody.

As most UAC are in short-term custody, if a minor is diagnosed with latent TB infection (LTBI), prophylactic treatment is generally not started. Some UAC with initial negative TB tests who are recent contacts of infectious TB cases may no longer be in ORR custody by the time their second TB tests are due.

This letter is to notify you that ORR has discharged a minor either with LTBI or who has been exposed to infectious TB but has not completed LTBI evaluation. The child will be living in your state. Identifying and clinical information is enclosed.

Thank you.

Sincerely,

Curi Kim, MD, MPH
Director, Division of Refugee Health
Office of Refugee Resettlement

DEPARTMENT OF HEALTH & HUMAN SERVICES

ADMINISTRATION FOR CHILDREN AND FAMILIES
370 L'Enfant Promenade, S.W.
Washington, D.C. 20447

Dear Healthcare Provider,

The Office of Refugee Resettlement/Division of Children Services/Unaccompanied Alien Children (UAC) Program is providing guidance on clearing UAC with suspected or confirmed active tuberculosis (TB) for release from ORR custody and travel. This guidance is consistent with the Centers for Disease Control and Prevention (CDC)'s algorithm for determining when to clear a patient with suspected or confirmed TB for travel on a commercial aircraft.

The algorithm is primarily intended to guide decisions for pulmonary, pleural, or laryngeal TB in persons aged ≥10 years. In general, persons with extrapulmonary TB disease and young children with TB disease are unlikely to pose a public health risk.

A UAC suspected or confirmed to have TB, who does not have or is not at high risk for having multidrug-resistant (MDR) TB, can be cleared for release and travel IF the child is smear negative (3 consecutive negative smears and no subsequent positive smears) AND has been treated for ≥ 1 week with an appropriate regimen AND has been referred to the TB control program of the local health department in the community to which the child will be released. Refer to the charts below:

If cultures or drug susceptibility testing (DST) pending,

AFB Smear + or Cavity on Chest X-ray	TB Culture	**High Risk for MDR**[a]	Current Treatment	Cleared to travel?	Criteria to be cleared for travel
Yes	Unknown	No	N/A	No	1) 3 consecutive negative AFB smears with no subsequent positive smears and 2) Tx for **≥2 weeks** with appropriate regimen
Yes	Unknown	**Yes**	N/A	No	Await DST results and manage accordingly
No	Unknown	No	≥ 1 week	Yes	Not applicable
No	Unknown	No	< 1 week	No	Tx for **≥1 week** with appropriate regimen
No	Unknown	**Yes**	N/A	No	Await DST results and manage accordingly

If NOT MDR TB

AFB Smear+ or Cavity on Chest X-ray	TB Culture	MDR Status	Current Treatment	Cleared to travel?	Criteria to be cleared for travel
Yes	+	No	N/A	No	1) 3 consecutive negative AFB smears with no subsequent positive smears and 2) Tx for **≥2 weeks** with appropriate regimen
No	+	No	≥ 1 week	Yes	Not applicable
No	+	No	< 1 week	No	Tx with appropriate regimen for **≥1 week**

GOVERNMENT EXHIBIT 6
1-14-CV-119

[a] MDR TB is resistant to isoniazid and rifampin. A person is considered high-risk for MDR if (1) a molecular diagnostic test on a respiratory specimen has shown mutations consistent with rifampin resistance, **or** he or she (2) was a known contact of an MDR TB case, **or** (3) has had a prior episode of treatment for TB disease **or** (4) has resided for >1 year in a country from which TB cases reported in the United States occurring in persons born in that country have a high proportion of MDR TB. Based on the U.S. National TB Surveillance System in 2004-2010, these are BELAUS, BHUTAN, DOMINICAN REPUBLIC, ESTONIA, HUNGARY, KAZAKHSTAN, KYRGYZSTAN, LAOS, LATVIA, LITHUANIA, MOLDOVA, MONGOLIA, NEPAL, PERU, RUSSIA, THAILAND, UKRAINE, and SUDAN. This list is updated yearly.

A UAC who the health department is counting and treating as a clinical case of TB disease, even in the absence of respiratory specimens (despite attempts at sputum induction), must be treated for ≥ 1 week with an appropriate regimen before being cleared for release or travel.

A UAC with MDR TB must have two negative cultures obtained after ≥2weeks of treatment (and no subsequent positive cultures) and treatment for ≥4 weeks with an appropriate regimen before being cleared for release or travel.

This algorithm may not apply to all situations and certain exceptions may be made on a case-by-case basis, especially if air travel is not involved. For example, for UAC being released locally, earlier release than indicated by the algorithm may be possible. For unusual or complicated cases, please work with the UAC program provider (shelter, foster care, etc.) to consult the ORR Medical Team.

The key to assuring a favorable medical outcome for the UAC and protecting public health is a smooth transfer of care from the current TB control program to the receiving one. The current TB control program should make the interjurisdictional notification to coordinate care with the receiving TB control program before the minor is released from ORR custody. This should be documented by the UAC program provider.

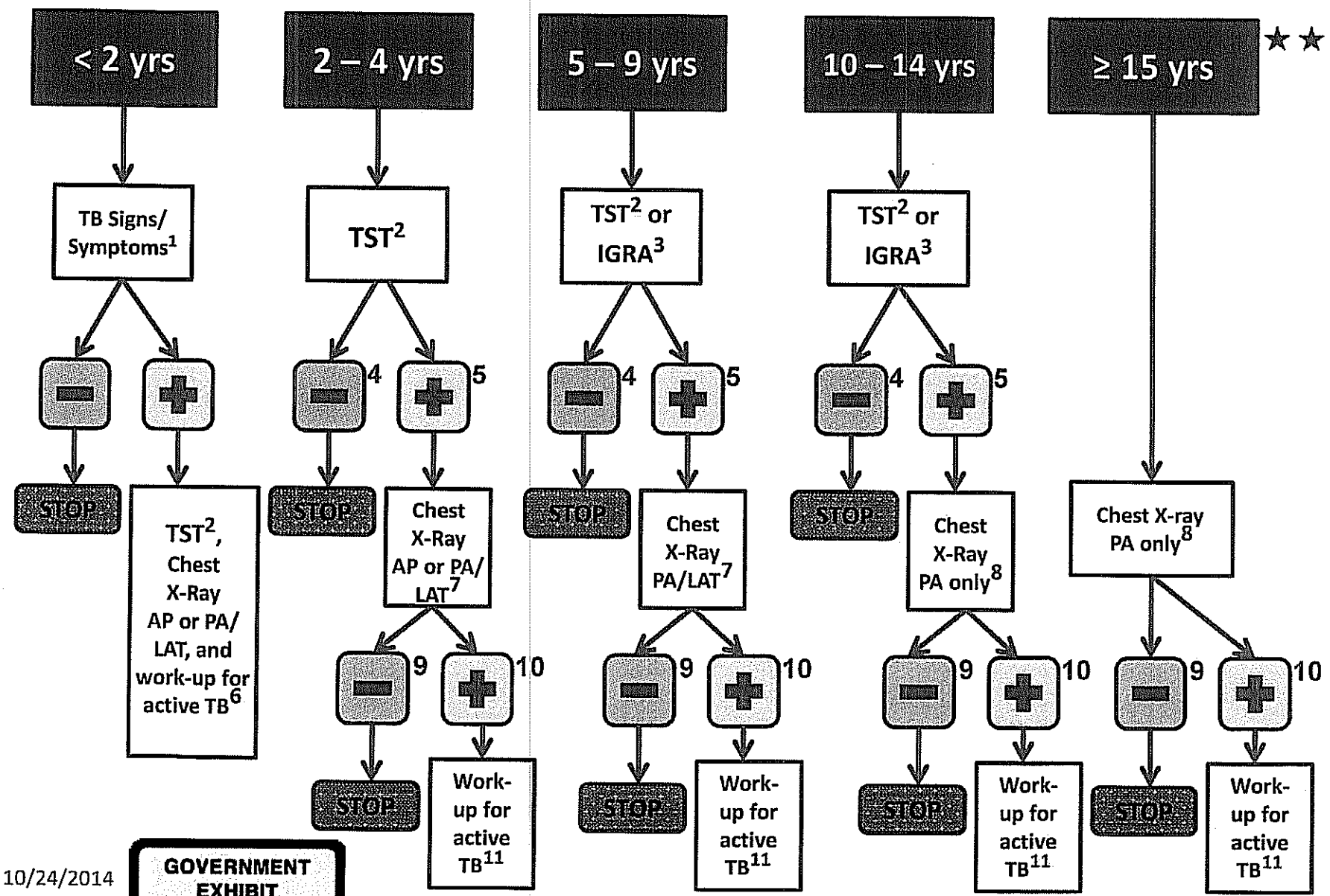
For UAC with suspect or confirmed TB who may be repatriated back to their home country, referral is still indicated. UAC to be repatriated back to Mexico or Central America should be referred to the CureTB program before discharge from ORR custody: http://www.sdcounty.ca.gov/hhsa/programs/phs/cure_tb/ UAC to be repatriated to Central America or any other country should be referred to TBNet before discharge from ORR custody: http://www.migrantclinician.org/services/network/tbnet.html In addition, referrals can also be made to CureTB or TBNet to obtain information about UAC previously diagnosed with TB in their country of origin.

Thank you for taking care of these most vulnerable of children in the U.S.

Sincerely,

Curi Kim, MD, MPH
Medical Officer
Office of Refugee Resettlement
Administration for Children and Families

Active TB Screening Algorithm for UAC in ORR/DCS Care ★



10/24/2014

GOVERNMENT EXHIBIT 7
1-14-cv-119

TB/HIV/STD/ Viral Hepatitis
Epidemiology and Surveillance

Instructions for Reporting Tuberculosis (TB) Identified Among Unaccompanied Alien Children (UAC)
Effective June 6, 2014
Updated: August 29, 2014

The Department of State Health Services (DSHS), TB/HIV/STD/Viral Hepatitis Epidemiology and Surveillance Branch (Branch) is enhancing its reporting mechanism to capture UAC ages 0 – 17 years that are referred to a local health department or health service regional TB program for evaluation for TB effective June 6, 2014.

A simple worksheet with instructions have been sent to all case registries for weekly reporting of UAC identified with TB infection, suspicion of disease or confirmed TB disease.

Reporting UAC Using the Report of Verified Cases of TB (RVCT) Form

1. **Report all TB cases, suspects and infections** identified among UAC to the Branch **within 24 hours of diagnosis using the RVCT form.**

2. Include the name (be specific) of the shelter on the street address section of the RVCT. Branch staff will enter the name of the shelter on Adress1 and the physical address on Adress2.

3. If an unaccompanied minor is evaluated for TB infection or disease after being placed in "sponsored custody", please include on your weekly reporting form. Enter "sponsored custody" in the column, "shelter name".

4. For question # 25, "Primary Reason Evaluated for TB Disease", default to targeted testing.

5. For question #29, "Resident of Long-Term Care Facility", default to yes and enter "type" as residential facility.

6. Send all UAC RVCT reporting forms via PHIN in a separate WinZip file. Clearly indicate that the reporting forms are for reporting UAC.

GOVERNMENT EXHIBIT 8
1-14-CV-119

TEXAS Department of State Health Services

Texas Department of State Health Services
Tuberculosis Symptom Screening Form

Name: _____ DOB: _____

Facility Name: _____

Person completing form: _____ Title _____ Date _____
Print Name

Upon intake, all clients should be screened for symptoms consistent with tuberculosis. Please ask all clients during the intake process if they have any of the symptoms listed below. Persons with symptoms should receive a chest x-ray, regardless of TB skin test or Interferon-Gamma Release Assay (IGRA) test result.

Clients or employees with a documented history of a positive tuberculin skin or IGRAtest result should not be re-tested or receive annual x-rays. In lieu of annual chest x-rays, symptom screening should be performed annually to determine the presence of TB disease. Any person with symptoms should receive a chest x-ray and be evaluated for TB disease.

If a client answers yes to any of the following questions, please document the approximate date each symptom started.

1.	Productive cough for 2 weeks or more	No	Yes	Date _____
2.	Persistent weight loss without dieting	No	Yes	Date _____
3.	Persistent fever above 100 degrees F	No	Yes	Date _____
4.	Night sweats	No	Yes	Date _____
5.	Loss of appetite	No	Yes	Date _____
6.	Swollen glands in neck or elsewhere	No	Yes	Date _____
7.	Coughing up blood (hemoptysis)	No	Yes	Date _____
8.	Shortness of breath	No	Yes	Date _____
9.	Chest pain	No	Yes	Date _____
10.	Headaches, neck stiffness, and/or disorientation or confusion	No	Yes	Date _____

Notes: _____

_____

_____

Chest x-ray referral: Date: _____ Referred to: _____

Sputum collection referral: Date: _____ Referred to: _____

Medical evaluation referral: Date: _____ Referred to: _____

Clients that have symptoms consistent with TB should be placed in isolation under negative air pressure until a diagnosis of tuberculosis can be ruled out. Employees with symptoms consistent with TB should be placed on a work stop precaution until a TB diagnosis is ruled out.

MMWR™

Morbidity and Mortality Weekly Report

Recommendations and Reports December 30, 2005 / Vol. 54 / No. RR-17

Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005

INSIDE: Continuing Education Examination

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

The *MMWR* series of publications is published by the Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30333.

SUGGESTED CITATION
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CONTENTS

Disclosure of Relationship

CDC, our planners, and our content experts wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use.

Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005

Prepared by
Paul A. Jensen, PhD, Lauren A. Lambert, MPH, Michael F. Iademarco, MD, Renee Ridzon, MD
Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention

Summary

In 1994, CDC published the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, 1994. *The guidelines were issued in response to 1) a resurgence of tuberculosis (TB) disease that occurred in the United States in the mid-1980s and early 1990s, 2) the documentation of several high-profile health-care–associated (previously termed "nosocomial") outbreaks related to an increase in the prevalence of TB disease and human immunodeficiency virus (HIV) coinfection, 3) lapses in infection-control practices, 4) delays in the diagnosis and treatment of persons with infectious TB disease, and 5) the appearance and transmission of multidrug-resistant (MDR) TB strains. The 1994 guidelines, which followed statements issued in 1982 and 1990, presented recommendations for TB-infection control based on a risk assessment process that classified health-care facilities according to categories of TB risk, with a corresponding series of administrative, environmental, and respiratory-protection control measures.*

The TB infection-control measures recommended by CDC in 1994 were implemented widely in health-care facilities in the United States. The result has been a decrease in the number of TB outbreaks in health-care settings reported to CDC and a reduction in health-care–associated transmission of Mycobacterium tuberculosis *to patients and health-care workers (HCWs). Concurrent with this success, mobilization of the nation's TB-control programs succeeded in reversing the upsurge in reported cases of TB disease, and case rates have declined in the subsequent 10 years. Findings indicate that although the 2004 TB rate was the lowest recorded in the United States since national reporting began in 1953, the declines in rates for 2003 (2.3%) and 2004 (3.2%) were the smallest since 1993. In addition, TB infection rates greater than the U.S. average continue to be reported in certain racial/ethnic populations. The threat of MDR TB is decreasing, and the transmission of* M. tuberculosis *in health-care settings continues to decrease because of implementation of infection-control measures and reductions in community rates of TB.*

Given the changes in epidemiology and a request by the Advisory Council for the Elimination of Tuberculosis (ACET) for review and update of the 1994 TB infection-control document, CDC has reassessed the TB infection-control guidelines for health-care settings. This report updates TB control recommendations reflecting shifts in the epidemiology of TB, advances in scientific understanding, and changes in health-care practice that have occurred in the United States during the preceding decade. In the context of diminished risk for health-care–associated transmission of M. tuberculosis, *this document places emphasis on actions to maintain momentum and expertise needed to avert another TB resurgence and to eliminate the lingering threat to HCWs, which is mainly from patients or others with unsuspected and undiagnosed infectious TB disease. CDC prepared the current guidelines in consultation with experts in TB, infection control, environmental control, respiratory protection, and occupational health. The new guidelines have been expanded to address a broader concept; health-care–associated settings go beyond the previously defined facilities. The term "health-care setting" includes many types, such as inpatient settings, outpatient settings, TB clinics, settings in correctional facilities in which health care is delivered, settings in which home-based health-care and emergency medical services are provided, and laboratories handling clinical specimens that might contain* M. tuberculosis. *The term "setting" has been chosen over the term "facility," used in the previous guidelines, to broaden the potential places for which these guidelines apply.*

Introduction

Overview

In 1994, CDC published the *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Facilities, 1994* (*1*). The guidelines were issued in response to 1) a resurgence of tuberculosis (TB) disease that occurred in the United States in the mid-1980s and early 1990s, 2) the documentation of multiple high-profile health-care–associated

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(previously "nosocomial") outbreaks related to an increase in the prevalence of TB disease and human immunodeficiency virus (HIV) coinfection, 3) lapses in infection-control practices, 4) delays in the diagnosis and treatment of persons with infectious TB disease (*2,3*), and 5) the appearance and transmission of multidrug-resistant (MDR) TB strains (*4,5*).

The 1994 guidelines, which followed CDC statements issued in 1982 and 1990 (*1,6,7*), presented recommendations for TB infection control based on a risk assessment process. In this process, health-care facilities were classified according to categories of TB risk,with a corresponding series of environmental and respiratory-protection control measures.

The TB infection-control measures recommended by CDC in 1994 were implemented widely in health-care facilities nationwide (*8–15*). As a result, a decrease has occurred in 1) the number of TB outbreaks in health-care settings reported to CDC and 2) health-care–associated transmission of *M. tuberculosis* to patients and health-care workers (HCWs) (*9,16–23*). Concurrent with this success, mobilization of the nation's TB-control programs succeeded in reversing the upsurge in reported cases of TB disease, and case rates have declined in the subsequent 10 years (*4,5*). Findings indicate that although the 2004 TB rate was the lowest recorded in the United States since national reporting began in 1953, the declines in rates for 2003 (2.3%) and 2004 (3.2%) were the lowest since 1993. In addition, TB rates higher than the U.S. average continue to be reported in certain racial/ethnic populations (*24*). The threat of MDR TB is decreasing, and the transmission of *M. tuberculosis* in health-care settings continues to decrease because of implementation of infection-control measures and reductions in community rates of TB (*4,5,25*).

Despite the general decline in TB rates in recent years, a marked geographic variation in TB case rates persists, which means that HCWs in different areas face different risks (*10*). In 2004, case rates varied per 100,000 population: 1.0 in Wyoming, 7.1 in New York, 8.3 in California, and 14.6 in the District of Columbia (*26*). In addition, despite the progress in the United States, the 2004 rate of 4.9 per 100,000 population remained higher than the 2000 goal of 3.5. This goal was established as part of the national strategic plan for TB elimination; the final goal is <1 case per 1,000,000 population by 2010 (*4,5,26*).

Given the changes in epidemiology and a request by the Advisory Council for the Elimination of Tuberculosis (ACET) for review and updating of the 1994 TB infection-control document, CDC has reassessed the TB infection-control guidelines for health-care settings. This report updates TB-control recommendations, reflecting shifts in the epidemiology of TB (*27*), advances in scientific understanding, and changes in health-care practice that have occurred in the United States in the previous decade (*28*). In the context of diminished risk for health-care–associated transmission of *M. tuberculosis*, this report emphasizes actions to maintain momentum and expertise needed to avert another TB resurgence and eliminate the lingering threat to HCWs, which is primarily from patients or other persons with unsuspected and undiagnosed infectious TB disease.

CDC prepared the guidelines in this report in consultation with experts in TB, infection control, environmental control, respiratory protection, and occupational health. This report replaces all previous CDC guidelines for TB infection control in health-care settings (*1,6,7*). Primary references citing evidence-based science are used in this report to support explanatory material and recommendations. Review articles, which include primary references, are used for editorial style and brevity.

The following changes differentiate this report from previous guidelines:

- The risk assessment process includes the assessment of additional aspects of infection control.
- The term "tuberculin skin tests" (TSTs) is used instead of purified protein derivative (PPD).
- The whole-blood interferon gamma release assay (IGRA), QuantiFERON®-TB Gold test (QFT-G) (Cellestis Limited, Carnegie, Victoria, Australia), is a Food and Drug Administration (FDA)–approved in vitro cytokine-based assay for cell-mediated immune reactivity to *M. tuberculosis* and might be used instead of TST in TB screening programs for HCWs. This IGRA is an example of a blood assay for *M. tuberculosis* (BAMT).
- The frequency of TB screening for HCWs has been decreased in various settings, and the criteria for determination of screening frequency have been changed.
- The scope of settings in which the guidelines apply has been broadened to include laboratories and additional outpatient and nontraditional facility-based settings.
- Criteria for serial testing for *M. tuberculosis* infection of HCWs are more clearly defined. In certain settings, this change will decrease the number of HCWs who need serial TB screening.
- These recommendations usually apply to an entire health-care setting rather than areas within a setting.
- New terms, airborne infection precautions (airborne precautions) and airborne infection isolation room (AII room), are introduced.
- Recommendations for annual respirator training, initial respirator fit testing, and periodic respirator fit testing have been added.

- The evidence of the need for respirator fit testing is summarized.
- Information on ultraviolet germicidal irradiation (UVGI) and room-air recirculation units has been expanded.
- Additional information regarding MDR TB and HIV infection has been included.

In accordance with relevant local, state, and federal laws, implementation of all recommendations must safeguard the confidentiality and civil rights of all HCWs and patients who have been infected with *M. tuberculosis* and who develop TB disease.

The 1994 CDC guidelines were aimed primarily at hospital-based facilities, which frequently refer to a physical building or set of buildings. The 2005 guidelines have been expanded to address a broader concept. Setting has been chosen instead of "facility" to expand the scope of potential places for which these guidelines apply (Appendix A). "Setting" is used to describe any relationship (physical or organizational) in which HCWs might share air space with persons with TB disease or in which HCWs might be in contact with clinical specimens. Various setting types might be present in a single facility. Health-care settings include inpatient settings, outpatient settings, and nontraditional facility-based settings.

- Inpatient settings include patient rooms, emergency departments (EDs), intensive care units (ICUs), surgical suites, laboratories, laboratory procedure areas, bronchoscopy suites, sputum induction or inhalation therapy rooms, autopsy suites, and embalming rooms.
- Outpatient settings include TB treatment facilities, medical offices, ambulatory-care settings, dialysis units, and dental-care settings.
- Nontraditional facility-based settings include emergency medical service (EMS), medical settings in correctional facilities (e.g., prisons, jails, and detention centers), home-based health-care and outreach settings, long-term–care settings (e.g., hospices, skilled nursing facilities), and homeless shelters. Other settings in which suspected and confirmed TB patients might be encountered might include cafeterias, general stores, kitchens, laundry areas, maintenance shops, pharmacies, and law enforcement settings.

HCWs Who Should Be Included in a TB Surveillance Program

HCWs refer to all paid and unpaid persons working in health-care settings who have the potential for exposure to *M. tuberculosis* through air space shared with persons with infectious TB disease. Part time, temporary, contract, and full-time HCWs should be included in TB screening programs. All HCWs who have duties that involve face-to-face contact with patients with suspected or confirmed TB disease (including transport staff) should be included in a TB screening program.

The following are HCWs who might be included in a TB screening program:

- Administrators or managers
- Bronchoscopy staff
- Chaplains
- Clerical staff
- Computer programmers
- Construction staff
- Correctional officers
- Craft or repair staff
- Dental staff
- Dietician or dietary staff
- ED staff
- Engineers
- Food service staff
- Health aides
- Health and safety staff
- Housekeeping or custodial staff
- Homeless shelter staff
- Infection-control staff
- ICU staff
- Janitorial staff
- Laboratory staff
- Maintenance staff
- Morgue staff
- Nurses
- Outreach staff
- Pathology laboratory staff
- Patient transport staff, including EMS
- Pediatric staff
- Pharmacists
- Phlebotomists
- Physical and occupational therapists
- Physicians (assistant, attending, fellow, resident, or intern), including
  - — anesthesiologists
  - — pathologists
  - — psychiatrists
  - — psychologists
- Public health educators or teachers
- Public safety staff
- Radiology staff
- Respiratory therapists
- Scientists
- Social workers
- Students (e.g., medical, nursing, technicians, and allied health)

- Technicians (e.g., health, laboratory, radiology, and animal)
- Veterinarians
- Volunteers

In addition, HCWs who perform any of the following activities should also be included in the TB screening program.

- entering patient rooms or treatment rooms whether or not a patient is present;
- participating in aerosol-generating or aerosol-producing procedures (e.g., bronchoscopy, sputum induction, and administration of aerosolized medications) (*29*);
- participating in suspected or confirmed *M. tuberculosis* specimen processing; or
- installing, maintaining, or replacing environmental controls in areas in which persons with TB disease are encountered.

Pathogenesis, Epidemiology, and Transmission of *M. tuberculosis*

M. tuberculosis is carried in airborne particles called droplet nuclei that can be generated when persons who have pulmonary or laryngeal TB disease cough, sneeze, shout, or sing (*30,31*). The particles are approximately 1–5 μm; normal air currents can keep them airborne for prolonged periods and spread them throughout a room or building (*32*). *M. tuberculosis* is usually transmitted only through air, not by surface contact. After the droplet nuclei are in the alveoli, local infection might be established, followed by dissemination to draining lymphatics and hematogenous spread throughout the body (*33*). Infection occurs when a susceptible person inhales droplet nuclei containing *M. tuberculosis*, and the droplet nuclei traverse the mouth or nasal passages, upper respiratory tract, and bronchi to reach the alveoli. Persons with TB pleural effusions might also have concurrent unsuspected pulmonary or laryngeal TB disease.

Usually within 2–12 weeks after initial infection with *M. tuberculosis*, the immune response limits additional multiplication of the tubercle bacilli, and immunologic test results for *M. tuberculosis* infection become positive. However, certain bacilli remain in the body and are viable for multiple years. This condition is referred to as latent tuberculosis infection (LTBI). Persons with LTBI are asymptomatic (they have no symptoms of TB disease) and are not infectious.

In the United States, LTBI has been diagnosed traditionally based on a PPD-based TST result after TB disease has been excluded. In vitro cytokine-based immunoassays for the detection of *M. tuberculosis* infection have been the focus of intense research and development. One such blood assay for *M. tuberculosis* (or BAMT) is an IGRA, the QuantiFERON®-TB test (QFT), and the subsequently developed version, QFT-G. The QFT-G measures cell-mediated immune responses to peptides from two *M. tuberculosis* proteins that are not present in any Bacille Calmette-Guérin (BCG) vaccine strain and that are absent from the majority of nontuberculous mycobacteria (NTM), also known as mycobacteria other than TB (MOTT). QFT-G was approved by FDA in 2005 and is an available option for detecting *M. tuberculosis* infection. CDC recommendations for the United States regarding QFT and QFT-G have been published (*34,35*). Because this field is rapidly evolving, in this report, BAMT will be used generically to refer to the test currently available in the United States.

Additional cytokine-based immunoassays are under development and might be useful in the diagnosis of *M. tuberculosis* infection. Future FDA-licensed products in combination with CDC-issued recommendations might provide additional diagnostic alternatives. The latest CDC recommendations for guidance on diagnostic use of these and related technologies are available at http://www.cdc.gov/nchstp/tb/pubs/mmwrhtml/Maj_guide/Diagnosis.htm.

Typically, approximately 5%–10% of persons who become infected with *M. tuberculosis* and who are not treated for LTBI will develop TB disease during their lifetimes (*1*). The risk for progression of LTBI to TB disease is highest during the first several years after infection (*36–38*).

Persons at Highest Risk for Exposure to and Infection with *M. tuberculosis*

Characteristics of persons exposed to *M. tuberculosis* that might affect the risk for infection are not as well defined. The probability that a person who is exposed to *M. tuberculosis* will become infected depends primarily on the concentration of infectious droplet nuclei in the air and the duration of exposure to a person with infectious TB disease. The closer the proximity and the longer the duration of exposure, the higher the risk is for being infected.

Close contacts are persons who share the same air space in a household or other enclosed environment for a prolonged period (days or weeks, not minutes or hours) with a person with pulmonary TB disease (*39*). A suspect TB patient is a person in whom a diagnosis of TB disease is being considered, whether or not antituberculosis treatment has been started. Persons generally should not remain a suspect TB patient for >3 months (*30,39*).

In addition to close contacts, the following persons are also at higher risk for exposure to and infection with *M. tuberculosis*. Persons listed who are also close contacts should be top priority.

- Foreign-born persons, including children, especially those who have arrived to the United States within 5 years after moving from geographic areas with a high incidence of TB

disease (e.g., Africa, Asia, Eastern Europe, Latin America, and Russia) or who frequently travel to countries with a high prevalence of TB disease.
- Residents and employees of congregate settings that are high risk (e.g., correctional facilities, long-term–care facilities [LTCFs], and homeless shelters).
- HCWs who serve patients who are at high risk.
- HCWs with unprotected exposure to a patient with TB disease before the identification and correct airborne precautions of the patient.
- Certain populations who are medically underserved and who have low income, as defined locally.
- Populations at high risk who are defined locally as having an increased incidence of TB disease.
- Infants, children, and adolescents exposed to adults in high-risk categories.

Persons Whose Condition is at High Risk for Progression From LTBI to TB Disease

The following persons are at high risk for progressing from LTBI to TB disease:
- persons infected with HIV;
- persons infected with *M. tuberculosis* within the previous 2 years;
- infants and children aged <4 years;
- persons with any of the following clinical conditions or other immunocompromising conditions
  - — silicosis,
  - — diabetes mellitus,
  - — chronic renal failure,
  - — certain hematologic disorders (leukemias and lymphomas),
  - — other specific malignancies (e.g., carcinoma of the head, neck, or lung),
  - — body weight ≥10% below ideal body weight,
  - — prolonged corticosteroid use,
  - — other immunosuppressive treatments (including tumor necrosis factor-alpha [TNF-α] antagonists),
  - — organ transplant,
  - — end-stage renal disease (ESRD), and
  - — intestinal bypass or gastrectomy; and
- persons with a history of untreated or inadequately treated TB disease, including persons with chest radiograph findings consistent with previous TB disease.

Persons who use tobacco or alcohol (*40,41*), illegal drugs, including injection drugs and crack cocaine (*42–47*), might also be at increased risk for infection and disease. However, because of multiple other potential risk factors that commonly occur among such persons, use of these substances has been difficult to identify as separate risk factors.

HIV infection is the greatest risk factor for progression from LTBI to TB disease (*22,39,48,49*). Therefore, voluntary HIV counseling, testing, and referral should be routinely offered to all persons at risk for LTBI (*1,50,51*). Health-care settings should be particularly aware of the need for preventing transmission of *M. tuberculosis* in settings in which persons infected with HIV might be encountered or might work (*52*).

All HCWs should be informed regarding the risk for developing TB disease after being infected with *M. tuberculosis* (*1*). However, the rate of TB disease among persons who are HIV-infected and untreated for LTBI in the United States is substantially higher, ranging from 1.7–7.9 TB cases per 100 person-years (*53*). Persons infected with HIV who are already severely immunocompromised and who become newly infected with *M. tuberculosis* have a greater risk for developing TB disease, compared with newly infected persons without HIV infection (*39,53–57*).

The percentage of patients with TB disease who are HIV-infected is decreasing in the United States because of improved infection-control practices and better diagnosis and treatment of both HIV infection and TB. With increased voluntary HIV counseling and testing and the increasing use of treatment for LTBI, TB disease will probably continue to decrease among HIV-infected persons in the United States (*58*). Because the risk for disease is particularly high among HIV-infected persons with *M. tuberculosis* infection, HIV-infected contacts of persons with infectious pulmonary or laryngeal TB disease must be evaluated for *M. tuberculosis* infection, including the exclusion of TB disease, as soon as possible after learning of exposure (*39,49,53*).

Vaccination with BCG probably does not affect the risk for infection after exposure, but it might decrease the risk for progression from infection with *M. tuberculosis* to TB disease, preventing the development of miliary and meningeal disease in infants and young children (*59,60*). Although HIV infection increases the likelihood of progression from LTBI to TB disease (*39,49*), whether HIV infection increases the risk for becoming infected if exposed to *M. tuberculosis* is not known.

Characteristics of a Patient with TB Disease That Increase the Risk for Infectiousness

The following characteristics exist in a patient with TB disease that increases the risk for infectiousness:
- presence of cough;
- cavitation on chest radiograph;
- positive acid-fast bacilli (AFB) sputum smear result;
- respiratory tract disease with involvement of the larynx (substantially infectious);
- respiratory tract disease with involvement of the lung or pleura (exclusively pleural involvement is less infectious);

- failure to cover the mouth and nose when coughing;
- incorrect, lack of, or short duration of antituberculosis treatment; and
- undergoing cough-inducing or aerosol-generating procedures (e.g., bronchoscopy, sputum induction, and administration of aerosolized medications) (*29*).

Environmental Factors That Increase the Risk for Probability of Transmission of *M. tuberculosis*

The probability of the risk for transmission of *M. tuberculosis* is increased as a result of various environmental factors.

- Exposure to TB in small, enclosed spaces.
- Inadequate local or general ventilation that results in insufficient dilution or removal of infectious droplet nuclei.
- Recirculation of air containing infectious droplet nuclei.
- Inadequate cleaning and disinfection of medical equipment.
- Improper procedures for handling specimens.

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

Transmission of *M. tuberculosis* is a risk in health-care settings (*57,61–79*). The magnitude of the risk varies by setting, occupational group, prevalence of TB in the community, patient population, and effectiveness of TB infection-control measures. Health-care–associated transmission of *M. tuberculosis* has been linked to close contact with persons with TB disease during aerosol-generating or aerosol-producing procedures, including bronchoscopy (*29,63,80–82*), endotracheal intubation, suctioning (*66*), other respiratory procedures (*8,9,83–86*), open abscess irrigation (*69,83*), autopsy (*71,72,77*), sputum induction, and aerosol treatments that induce coughing (*87–90*).

Of the reported TB outbreaks in health-care settings, multiple outbreaks involved transmission of MDR TB strains to both patients and HCWs (*56,57,70,87,91–94*). The majority of the patients and certain HCWs were HIV-infected, and progression to TB and MDR TB disease was rapid. Factors contributing to these outbreaks included delayed diagnosis of TB disease, delayed initiation and inadequate airborne precautions, lapses in AII practices and precautions for cough-inducing and aerosol-generating procedures, and lack of adequate respiratory protection. Multiple studies suggest that the decline in health-care–associated transmission observed in specific institutions is associated with the rigorous implementation of infection-control measures (*11,12,18–20,23,95–97*). Because various interventions were implemented simultaneously, the effectiveness of each intervention could not be determined.

After the release of the 1994 CDC infection-control guidelines, increased implementation of recommended infection-control measures occurred and was documented in multiple national surveys (*13,15,98,99*). In a survey of approximately 1,000 hospitals, a TST program was present in nearly all sites, and 70% reported having an AII room (*13*). Other surveys have documented improvement in the proportion of AII rooms meeting CDC criteria and proportion of HCWs using CDC-recommended respiratory protection and receiving serial TST (*15,98*). A survey of New York City hospitals with high caseloads of TB disease indicated 1) a decrease in the time that patients with TB disease spent in EDs before being transferred to a hospital room, 2) an increase in the proportion of patients initially placed in AII rooms, 3) an increase in the proportion of patients started on recommended antituberculosis treatment and reported to the local or state health department, and 4) an increase in the use of recommended respiratory protection and environmental controls (*99*). Reports of increased implementation of recommended TB infection controls combined with decreased reports of outbreaks of TB disease in health-care settings suggest that the recommended controls are effective in reducing and preventing health-care–associated transmission of *M. tuberculosis* (*28*).

Less information is available regarding the implementation of CDC-recommended TB infection-control measures in settings other than hospitals. One study identified major barriers to implementation that contribute to the costs of a TST program in health departments and hospitals, including personnel costs, HCWs' time off from work for TST administration and reading, and training and education of HCWs (*100*). Outbreaks have occurred in outpatient settings (i.e., private physicians' offices and pediatric settings) where the guidelines were not followed (*101–103*). CDC-recommended TB infection-control measures are implemented in correctional facilities, and certain variations might relate to resources, expertise, and oversight (*104–106*).

Fundamentals of TB Infection Control

One of the most critical risks for health-care–associated transmission of *M. tuberculosis* in health-care settings is from patients with unrecognized TB disease who are not promptly handled with appropriate airborne precautions (*56,57,93,104*) or who are moved from an AII room too soon (e.g., patients with unrecognized TB and MDR TB) (*94*). In the United States, the problem of MDR TB, which was amplified by health-care–associated transmission, has been substantially reduced by the use of standardized antituberculosis treatment regimens

in the initial phase of therapy, rapid drug-susceptibility testing, directly observed therapy (DOT), and improved infection-control practices (*1*). DOT is an adherence-enhancing strategy in which an HCW or other specially trained health professional watches a patient swallow each dose of medication and records the dates that the administration was observed. DOT is the standard of care for all patients with TB disease and should be used for all doses during the course of therapy for TB disease and for LTBI whenever feasible.

All health-care settings need a TB infection-control program designed to ensure prompt detection, airborne precautions, and treatment of persons who have suspected or confirmed TB disease (or prompt referral of persons who have suspected TB disease for settings in which persons with TB disease are not expected to be encountered). Such a program is based on a three-level hierarchy of controls, including administrative, environmental, and respiratory protection (*86,107,108*).

Administrative Controls

The first and most important level of TB controls is the use of administrative measures to reduce the risk for exposure to persons who might have TB disease. Administrative controls consist of the following activities:

- assigning responsibility for TB infection control in the setting;
- conducting a TB risk assessment of the setting;
- developing and instituting a written TB infection-control plan to ensure prompt detection, airborne precautions, and treatment of persons who have suspected or confirmed TB disease;
- ensuring the timely availability of recommended laboratory processing, testing, and reporting of results to the ordering physician and infection-control team;
- implementing effective work practices for the management of patients with suspected or confirmed TB disease;
- ensuring proper cleaning and sterilization or disinfection of potentially contaminated equipment (usually endoscopes);
- training and educating HCWs regarding TB, with specific focus on prevention, transmission, and symptoms;
- screening and evaluating HCWs who are at risk for TB disease or who might be exposed to *M. tuberculosis* (i.e., TB screening program);
- applying epidemiologic-based prevention principles, including the use of setting-related infection-control data;
- using appropriate signage advising respiratory hygiene and cough etiquette; and
- coordinating efforts with the local or state health department.

HCWs with TB disease should be allowed to return to work when they 1) have had three negative AFB sputum smear results (*109–112*) collected 8–24 hours apart, with at least one being an early morning specimen because respiratory secretions pool overnight; and 2) have responded to antituberculosis treatment that will probably be effective based on susceptibility results. In addition, HCWs with TB disease should be allowed to return to work when a physician knowledgeable and experienced in managing TB disease determines that HCWs are noninfectious (see Treatment Procedures for LTBI and TB Disease). Consideration should also be given to the type of setting and the potential risk to patients (e.g., general medical office versus HIV clinic) (see Supplements, Estimating the Infectiousness of a TB Patient; Diagnostic Procedures for LTBI and TB Disease; and Treatment Procedures for LTBI and TB Disease).

Environmental Controls

The second level of the hierarchy is the use of environmental controls to prevent the spread and reduce the concentration of infectious droplet nuclei in ambient air.

Primary environmental controls consist of controlling the source of infection by using local exhaust ventilation (e.g., hoods, tents, or booths) and diluting and removing contaminated air by using general ventilation.

Secondary environmental controls consist of controlling the airflow to prevent contamination of air in areas adjacent to the source (AII rooms) and cleaning the air by using high efficiency particulate air (HEPA) filtration or UVGI.

Respiratory-Protection Controls

The first two control levels minimize the number of areas in which exposure to *M. tuberculosis* might occur and, therefore, minimize the number of persons exposed. These control levels also reduce, but do not eliminate, the risk for exposure in the limited areas in which exposure can still occur. Because persons entering these areas might be exposed to *M. tuberculosis*, the third level of the hierarchy is the use of respiratory protective equipment in situations that pose a high risk for exposure. Use of respiratory protection can further reduce risk for exposure of HCWs to infectious droplet nuclei that have been expelled into the air from a patient with infectious TB disease (see Respiratory Protection). The following measures can be taken to reduce the risk for exposure:

- implementing a respiratory-protection program,
- training HCWs on respiratory protection, and
- training patients on respiratory hygiene and cough etiquette procedures.

Relevance to Biologic Terrorism Preparedness

MDR *M. tuberculosis* is classified as a category C agent of biologic terrorism (*113*). Implementation of the TB infection-control guidelines described in this document is essential for preventing and controlling transmission of *M. tuberculosis* in health-care settings. Additional information is at http://www.bt.cdc.gov and http://www.idsociety.org/bt/toc.htm (*114*).

Recommendations for Preventing Transmission of *M. tuberculosis* in Health-Care Settings

TB Infection-Control Program

Every health-care setting should have a TB infection-control plan that is part of an overall infection-control program. The specific details of the TB infection-control program will differ, depending on whether patients with suspected or confirmed TB disease might be encountered in the setting or whether patients with suspected or confirmed TB disease will be transferred to another health-care setting. Administrators making this distinction should obtain medical and epidemiologic consultation from state and local health departments.

TB Infection-Control Program for Settings in Which Patients with Suspected or Confirmed TB Disease Are Expected To Be Encountered

The TB infection-control program should consist of administrative controls, environmental controls, and a respiratory-protection program. Every setting in which services are provided to persons who have suspected or confirmed infectious TB disease, including laboratories and nontraditional facility-based settings, should have a TB infection-control plan. The following steps should be taken to establish a TB infection-control program in these settings:

1. Assign supervisory responsibility for the TB infection-control program to a designated person or group with expertise in LTBI and TB disease, infection control, occupational health, environmental controls, and respiratory protection. Give the supervisor or supervisory body the support and authority to conduct a TB risk assessment, implement and enforce TB infection-control policies, and ensure recommended training and education of HCWs.
   - — Train the persons responsible for implementing and enforcing the TB infection-control program.
   - — Designate one person with a back-up as the TB resource person to whom questions and problems should be addressed, if supervisory responsibility is assigned to a committee.
2. Develop a written TB infection-control plan that outlines a protocol for the prompt recognition and initiation of airborne precautions of persons with suspected or confirmed TB disease, and update it annually.
3. Conduct a problem evaluation (see Problem Evaluation) if a case of suspected or confirmed TB disease is not promptly recognized and appropriate airborne precautions not initiated, or if administrative, environmental, or respiratory-protection controls fail.
4. Perform a contact investigation in collaboration with the local or state health department if health-care–associated transmission of *M. tuberculosis* is suspected (*115*). Implement and monitor corrective action.
5. Collaborate with the local or state health department to develop administrative controls consisting of the risk assessment, the written TB infection-control plan, management of patients with suspected or confirmed TB disease, training and education of HCWs, screening and evaluation of HCWs, problem evaluation, and coordination.
6. Implement and maintain environmental controls, including AII room(s) (see Environmental Controls).
7. Implement a respiratory-protection program.
8. Perform ongoing training and education of HCWs (see Suggested Components of an Initial TB Training and Education Program for HCWs).
9. Create a plan for accepting patients who have suspected or confirmed TB disease if they are transferred from another setting.

TB Infection-Control Program for Settings in Which Patients with Suspected or Confirmed TB Disease Are Not Expected To Be Encountered

Settings in which TB patients might stay before transfer should still have a TB infection-control program in place consisting of administrative, environmental, and respiratory-protection controls. The following steps should be taken to establish a TB infection-control program in these settings:

1. Assign responsibility for the TB infection-control program to appropriate personnel.
2. 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 health-care 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.

3. Conduct a problem evaluation (see Problem Evaluation) if a case of suspected or confirmed TB disease is not promptly recognized, separated from others, and transferred.
4. Perform an investigation in collaboration with the local or state health department if health-care–associated transmission of *M. tuberculosis* is suspected.
5. Collaborate with the local or state health department to develop administrative controls consisting of the risk assessment and the written TB infection-control plan.

TB Risk Assessment

Every health-care setting should conduct initial and ongoing evaluations of the risk for transmission of *M. tuberculosis*, regardless of whether or not patients with suspected or confirmed TB disease are expected to be encountered in the setting. The TB risk assessment determines the types of administrative, environmental, and respiratory-protection controls needed for a setting and serves as an ongoing evaluation tool of the quality of TB infection control and for the identification of needed improvements in infection-control measures. Part of the risk assessment is similar to a program review that is conducted by the local TB-control program (*42*). The TB Risk Assessment Worksheet (Appendix B) can be used as a guide for conducting a risk assessment. This worksheet frequently does not specify values for acceptable performance indicators because of the lack of scientific data.

TB Risk Assessment for Settings in Which Patients with Suspected or Confirmed TB Disease Are Expected To Be Encountered

The initial and ongoing risk assessment for these settings should consist of the following steps:

1. Review the community profile of TB disease in collaboration with the state or local health department.
2. Consult the local or state TB-control program to obtain epidemiologic surveillance data necessary to conduct a TB risk assessment for the health-care setting.
3. Review the number of patients with suspected or confirmed TB disease who have been encountered in the setting during at least the previous 5 years.
4. Determine if persons with unrecognized TB disease have been admitted to or were encountered in the setting during the previous 5 years.
5. Determine which HCWs need to be included in a TB screening program and the frequency of screening (based on risk classification) (Appendix C).
6. Ensure the prompt recognition and evaluation of suspected episodes of health-care–associated transmission of *M. tuberculosis*.
7. Identify areas in the setting with an increased risk for health-care–associated transmission of *M. tuberculosis*, and target them for improved TB infection controls.
8. Assess the number of AII rooms needed for the setting. The risk classification for the setting should help to make this determination, depending on the number of TB patients examined. At least one AII room is needed for settings in which TB patients stay while they are being treated, and additional AII rooms might be needed, depending on the magnitude of patient-days of cases of suspected or confirmed TB disease. Additional AII rooms might be considered if options are limited for transferring patients with suspected or confirmed TB disease to other settings with AII rooms.
9. Determine the types of environmental controls needed other than AII rooms (see TB Airborne Precautions).
10. Determine which HCWs need to be included in the respiratory-protection program.
11. Conduct periodic reassessments (annually, if possible) to ensure
    - proper implementation of the TB infection-control plan,
    - prompt detection and evaluation of suspected TB cases,
    - prompt initiation of airborne precautions of suspected infectious TB cases,
    - recommended medical management of patients with suspected or confirmed TB disease (*31*),
    - functional environmental controls,
    - implementation of the respiratory-protection program, and
    - ongoing HCW training and education regarding TB.
12. Recognize and correct lapses in infection control.

TB Risk Assessment for Settings in Which Patients with Suspected or Confirmed TB Disease Are Not Expected To Be Encountered

The initial and ongoing risk assessment for these settings should consist of the following steps:

1. Review the community profile of TB disease in collaboration with the local or state health department.
2. Consult the local or state TB-control program to obtain epidemiologic surveillance data necessary to conduct a

TB risk assessment for the health-care setting.
3. Determine if persons with unrecognized TB disease were encountered in the setting during the previous 5 years.
4. Determine if any HCWs need to be included in the TB screening program.
5. Determine the types of environmental controls that are currently in place, and determine if any are needed in the setting (Appendices A and D).
6. Document procedures that ensure the prompt recognition and evaluation of suspected episodes of health-care–associated transmission of *M. tuberculosis*.
7. Conduct periodic reassessments (annually, if possible) to ensure 1) proper implementation of the TB infection-control plan; 2) prompt detection and evaluation of suspected TB cases; 3) prompt initiation of airborne precautions of suspected infectious TB cases before transfer; 4) prompt transfer of suspected infectious TB cases; 5) proper functioning of environmental controls, as applicable; and 6) ongoing TB training and education for HCWs.
8. Recognize and correct lapses in infection control.

Use of Risk Classification to Determine Need for TB Screening and Frequency of Screening HCWs

Risk classification should be used as part of the risk assessment to determine the need for a TB screening program for HCWs and the frequency of screening (Appendix C). A risk classification usually should be determined for the entire setting. However, in certain settings (e.g., health-care organizations that encompass multiple sites or types of services), specific areas defined by geography, functional units, patient population, job type, or location within the setting might have separate risk classifications. Examples of assigning risk classifications have been provided (see Risk Classification Examples).

TB Screening Risk Classifications

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

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

The classification of potential ongoing transmission should be temporarily applied to any setting (or group of HCWs) if evidence suggestive of person-to-person (e.g., patient-to-patient, patient-to-HCW, HCW-to-patient, or HCW-to-HCW) transmission of *M. tuberculosis* has occurred in the setting during the preceding year. Evidence of person-to-person transmission of *M. tuberculosis* includes 1) clusters of TST or BAMT conversions, 2) HCW with confirmed TB disease, 3) increased rates of TST or BAMT conversions, 4) unrecognized TB disease in patients or HCWs, or 5) recognition of an identical strain of *M. tuberculosis* in patients or HCWs with TB disease identified by deoxyribonucleic acid (DNA) fingerprinting.

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

TB Screening Procedures for Settings (or HCWs) Classified as Low Risk

- All HCWs should receive baseline TB screening upon hire, using two-step TST or a single BAMT to test for infection with *M. tuberculosis*.
- After baseline testing for infection with *M. tuberculosis*, additional TB screening is not necessary unless an exposure to *M. tuberculosis* occurs.
- HCWs with a baseline positive or newly positive test result for *M. tuberculosis* infection (i.e., TST or BAMT) or documentation of treatment for LTBI or TB disease should receive one chest radiograph result to exclude TB disease (or an interpretable copy within a reasonable time frame, such as 6 months). Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician (*39,116*).

TB Screening Procedures for Settings (or HCWs) Classified as Medium Risk

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

symptoms immediately to the occupational health unit. Treatment for LTBI should be considered in accordance with CDC guidelines (*39*).

TB Screening Procedures for Settings (or HCWs) Classified as Potential Ongoing Transmission

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

Settings Adopting BAMT for Use in TB Screening

Settings that use TST as part of TB screening and want to adopt BAMT can do so directly (without any overlapping TST) or in conjunction with a period of evaluation (e.g., 1 or 2 years) during which time both TST and BAMT are used. Baseline testing for BAMT would be established as a single step test. As with the TST, BAMT results should be recorded in detail. The details should include date of blood draw, result in specific units, and the laboratory interpretation (positive, negative, or indeterminate—and the concentration of cytokine measured, for example, interferon-gamma [IFN-γ]).

Risk Classification Examples

Inpatient Settings with More Than 200 Beds

If less than six TB patients for the preceding year, classify as low risk. If greater than or equal to six TB patients for the preceding year, classify as medium risk.

Inpatient Settings with Less Than 200 Beds

If less than three TB patients for the preceding year, classify as low risk. If greater than or equal to three TB patients for the preceding year, classify as medium risk.

Outpatient, Outreach, and Home-Based Health-Care Settings

If less than three TB patients for the preceding year, classify as low risk. If greater than or equal to three TB patients for the preceding year, classify as medium risk.

Hypothetical Risk Classification Examples

The following hypothetical situations illustrate how assessment data are used to assign a risk classification. The risk classifications are for settings in which patients with suspected or confirmed infectious TB disease are expected to be encountered.

Example A. The setting is a 150-bed hospital located in a small city. During the preceding year, the hospital admitted two patients with a diagnosis of TB disease. One was admitted directly to an AII room, and one stayed on a medical ward for 2 days before being placed in an AII room. A contact investigation of exposed HCWs by hospital infection-control personnel in consultation with the state or local health department did not identify any health-care–associated transmission. Risk classification: low risk.

Example B. The setting is an ambulatory-care site in which a TB clinic is held 2 days per week. During the preceding year, care was delivered to six patients with TB disease and approximately 50 persons with LTBI. No instances of transmission of *M. tuberculosis* were noted. Risk classification: medium risk (because it is a TB clinic).

Example C. The setting is a large publicly funded hospital in a major metropolitan area. The hospital admits an average of 150 patients with TB disease each year, comprising 35% of the city burden. The setting has a strong TB infection-control program (i.e., annually updates infection-control plan, fully implements infection-control plan, and has enough AII rooms [see Environmental Controls]) and an annual conversion rate (for tests for *M. tuberculosis* infection) among HCWs of 0.5%. No evidence of health-care–associated transmission is apparent. The hospital has strong collaborative linkages with the state or local health department. Risk classification: medium risk (with close ongoing surveillance for episodes of transmission from unrecognized cases of TB disease, test conversions for *M. tuberculosis* infection in HCWs as a result of health-care–associated transmission, and specific groups or areas in which a higher risk for health-care–associated transmission exists).

Example D. The setting is an inpatient area of a correctional facility. A proportion of the inmates were born in countries where TB disease is endemic. Two cases of TB disease were diagnosed in inmates during the preceding year. Risk classification: medium risk (Correctional facilities should be classified as at least medium risk).

Example E. A hospital located in a large city admits 35 patients with TB disease per year, uses QFT-G to measure *M. tuberculosis* infection, and has an overall HCW *M. tuberculosis* infection test conversion rate of 1.0%. However, on annual testing, three of the 20 respiratory therapists tested had QFT-G conversions, for a rate of 15%. All of the respiratory therapists who tested positive received medical evaluations,

had TB disease excluded, were diagnosed with LTBI, and were offered and completed a course of treatment for LTBI. None of the respiratory therapists had known exposures to *M. tuberculosis* outside the hospital. The problem evaluation revealed that 1) the respiratory therapists who converted had spent part of their time in the pulmonary function laboratory where induced sputum specimens were collected, and 2) the ventilation in the laboratory was inadequate. Risk classification: potential ongoing transmission for the respiratory therapists (because of evidence of health-care–associated transmission). The rest of the setting was classified as medium risk. To address the problem, booths were installed for sputum induction. On subsequent testing for *M. tuberculosis* infection, no conversions were noted at the repeat testing 3 months later, and the respiratory therapists were then reclassified back to medium risk.

Example F. The setting is an ambulatory-care center associated with a large health maintenance organization (HMO). The patient volume is high, and the HMO is located in the inner city where TB rates are the highest in the state. During the preceding year, one patient who was known to have TB disease was evaluated at the center. The person was recognized as a TB patient on his first visit and was promptly triaged to an ED with an AII room capacity. While in the ambulatory-care center, the patient was held in an area separate from HCWs and other patients and instructed to wear a surgical or procedure mask, if possible. QFT-G was used for infection-control surveillance purposes, and a contact investigation was conducted among exposed staff, and no QFT-G conversions were noted. Risk classification: low risk.

Example G. The setting is a clinic for the care of persons infected with HIV. The clinic serves a large metropolitan area and a patient population of 2,000. The clinic has an AII room and a TB infection-control program. All patients are screened for TB disease upon enrollment, and airborne precautions are promptly initiated for anyone with respiratory complaints while the patient is being evaluated. During the preceding year, seven patients who were encountered in the clinic were subsequently determined to have TB disease. All patients were promptly put into an AII room, and no contact investigations were performed. The local health department was promptly notified in all cases. Annual TST has determined a conversion rate of 0.3%, which is low compared with the rate of the hospital with which the clinic is associated. Risk classification: medium risk (because persons infected with HIV might be encountered).

Example H. A home health-care agency employs 125 workers, many of whom perform duties, including nursing, physical therapy, and basic home care. The agency did not care for any patients with suspected or confirmed TB disease during the preceding year. Approximately 30% of the agency's workers are foreign-born, many of whom have immigrated within the previous 5 years. At baseline two-step testing, four had a positive initial TST result, and two had a positive second-step TST result. All except one of these workers was foreign-born. Upon further screening, none were determined to have TB disease. The home health-care agency is based in a major metropolitan area and delivers care to a community where the majority of persons are poor and medically underserved and TB case rates are higher than the community as a whole. Risk classification: low risk (because HCWs might be from populations at higher risk for LTBI and subsequent progression to TB disease because of foreign birth and recent immigration or HIV-infected clients might be overrepresented, medium risk could be considered).

Screening HCWs Who Transfer to Other Health-Care Settings

All HCWs should receive baseline TB screening, even in settings considered to be low risk. Infection-control plans should address HCWs who transfer from one health-care setting to another and consider that the transferring HCWs might be at an equivalent or higher risk for exposure in different settings. Infection-control plans might need to be customized to balance the assessed risks and the efficacy of the plan based on consideration of various logistical factors. Guidance is provided based on different scenarios.

Because some institutions might adopt BAMT for the purposes of testing for *M. tuberculosis* infection, infection-control programs might be confronted with interpreting historic and current TST and BAMT results when HCWs transfer to a different setting. On a case-by-case basis, expert medical opinion might be needed to interpret results and refer patients with discordant BAMT and TST baseline results. Therefore, infection-control programs should keep all records when documenting previous test results. For example, an infection-control program using a BAMT strategy should request and keep historic TST results of a HCW transferring from a previous setting. Even if the HCW is transferring from a setting that used BAMT to a setting that uses BAMT, historic TST results might be needed when in the future the HCW transfers to a setting that uses TST. Similarly, historic BAMT results might be needed when the HCW transfers from a setting that used TST to a setting that uses BAMT.

HCWs transferring from low-risk to low-risk settings. After a baseline result for infection with *M. tuberculosis* is established and documented, serial testing for *M. tuberculosis* infection is not necessary.

HCWs transferring from low-risk to medium-risk settings. After a baseline result for infection with *M. tuberculosis* is established and documented, annual TB screening (including

a symptom screen and TST or BAMT for persons with previously negative test results) should be performed.

HCWs transferring from low- or medium-risk settings to settings with a temporary classification of potential ongoing transmission. After a baseline result for infection with *M. tuberculosis* is established, a decision should be made regarding follow-up screening on an individual basis. If transmission seems to be ongoing, consider including the HCW in the screenings every 8–10 weeks until a determination has been made that ongoing transmission has ceased. When the setting is reclassified back to medium-risk, annual TB screening should be resumed.

Calculation and Use of Conversion Rates for *M. tuberculosis* Infection

The *M. tuberculosis* infection conversion rate is the percentage of HCWs whose test result for *M. tuberculosis* infection has converted within a specified period. Timely detection of *M. tuberculosis* infection in HCWs not only facilitates treatment for LTBI, but also can indicate the need for a source case investigation and a revision of the risk assessment for the setting. Conversion in test results for *M. tuberculosis*, regardless of the testing method used, is usually interpreted as presumptive evidence of new *M. tuberculosis* infection, and recent infections are associated with an increased risk for progression to TB disease.

For administrative purposes, a TST conversion is ≥10 mm increase in the size of the TST induration during a 2-year period in 1) an HCW with a documented negative (<10 mm) baseline two-step TST result or 2) a person who is not an HCW with a negative (<10 mm) TST result within 2 years.

In settings conducting serial testing for *M. tuberculosis* infection (medium-risk settings), use the following steps to estimate the risk for test conversion in HCWs.

- Calculate a conversion rate by dividing the number of conversions among 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 (see Use of Conversion Test Data for *M. tuberculosis* Infection To Identify Lapses in Infection Control).
- Identify areas or groups in the setting with a potentially high risk for *M. tuberculosis* transmission by comparing conversion rates in HCWs with potential exposure to patients with TB disease to conversion rates in HCWs for whom health-care–associated exposure to *M. tuberculosis* is not probable.

Use of Conversion Test Data for *M. tuberculosis* Infection To Identify Lapses in Infection Control

- Conversion rates above the baseline level (which will be different in each setting) should instigate an investigation to evaluate the likelihood of health-care–associated transmission. When testing for *M. tuberculosis* infection, if conversions are determined to be the result of well-documented community exposure or probable false-positive test results, then the risk classification of the setting does not need to be adjusted.
- For settings that no longer perform serial testing for *M. tuberculosis* infection among HCWs, reassessment of the risk for the setting is essential to ensure that the infection-control program is effective. The setting should have ongoing communication with the local or state health department regarding incidence and epidemiology of TB in the population served and should ensure that timely contact investigations are performed for HCWs or patients with unprotected exposure to a person with TB disease.

Example Calculation of Conversion Rates

Medical Center A is classified as medium risk and uses TST for annual screening. At the end of 2004, a total of 10,051 persons were designated as HCWs. Of these, 9,246 had negative baseline test results for *M. tuberculosis* infection. Of the HCWs tested, 10 experienced an increase in TST result by ≥10 mm. The overall setting conversion rate for 2004 is 0.11%. If five of the 10 HCWs whose test results converted were among the 100 HCWs employed in the ICU of Hospital X (in Medical Center A), then the ICU setting-specific conversion rate for 2004 is 5%.

Evaluation of HCWs for LTBI should include information from a serial testing program, but this information must be interpreted as only one part of a full assessment. TST or BAMT conversion criteria for administrative (surveillance) purposes are not applicable for medical evaluation of HCWs for the diagnosis of LTBI (see Supplement, Surveillance and Detection of *M. tuberculosis* Infections in Health-Care Workers [HCWs]).

Evaluation of TB Infection-Control Procedures and Identification of Problems

Annual evaluations of the TB infection-control plan are needed to ensure the proper implementation of the plan and to recognize and correct lapses in infection control. Previous hospital admissions and outpatient visits of patients with TB disease should be noted before the onset of TB symptoms. Medical records of a sample of patients with suspected and confirmed TB disease who were treated or examined at the setting should be

reviewed to identify possible problems in TB infection control. The review should be based on the factors listed on the TB Risk Assessment Worksheet (Appendix B).

- Time interval from suspicion of TB until initiation of airborne precautions and antituberculosis treatment to:
  - suspicion of TB disease and patient triage to proper AII room or referral center for settings that do not provide care for patients with suspected or confirmed TB disease;
  - admission until TB disease was suspected;
  - admission until medical evaluation for TB disease was performed;
  - admission until specimens for AFB smears and polymerase chain reaction (PCR)–based nucleic acid amplification (NAA) tests for *M. tuberculosis* were ordered;
  - admission until specimens for mycobacterial culture were ordered;
  - ordering of AFB smears, NAA tests, and mycobacterial culture until specimens were collected;
  - collection of specimens until performance and AFB smear results were reported;
  - collection of specimens until performance and culture results were reported;
  - collection of specimens until species identification was reported;
  - collection of specimens until drug-susceptibility test results were reported;
  - admission until airborne precautions were initiated; and
  - admission until antituberculosis treatment was initiated.
- Duration of airborne precautions.
- Measurement of meeting criteria for discontinuing airborne precautions. Certain patients might be correctly discharged from an AII room to home.
- Patient history of previous admission.
- Adequacy of antituberculosis treatment regimens.
- Adequacy of procedures for collection of follow-up sputum specimens.
- Adequacy of discharge planning.
- Number of visits to outpatient setting from the start of symptoms until TB disease was suspected (for outpatient settings).

Work practices related to airborne precautions should be observed to determine if employers are enforcing all practices, if HCWs are adhering to infection-control policies, and if patient adherence to airborne precautions is being enforced. Data from the case reviews and observations in the annual risk assessment should be used to determine the need to modify 1) protocols for identifying and initiating prompt airborne precautions for patients with suspected or confirmed infectious TB disease, 2) protocols for patient management, 3) laboratory procedures, or 4) TB training and education programs for HCWs.

Environmental Assessment

- Data from the most recent environmental evaluation should be reviewed to determine if recommended environmental controls are in place (see Suggested Components of an Initial TB Training and Education Program for HCWs).
- Environmental control maintenance procedures and logs should be reviewed to determine if maintenance is conducted properly and regularly.
- Environmental control design specifications should be compared with guidelines from the American Institute of Architects (AIA) and other ventilation guidelines (*117,118*) (see Risk Classification Examples) and the installed system performance.
- Environmental data should be used to assist building managers and engineers in evaluating the performance of the installed system.
- The number and types of aerosol-generating or aerosol-producing procedures (e.g., specimen processing and manipulation, bronchoscopy, sputum induction, and administration of aerosolized medications) performed in the setting should be assessed.
- The number of AII rooms should be suitable for the setting based on AIA Guidelines and the setting risk assessment. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has adapted the AIA guidelines when accrediting facilities (*118*).

Suggested Components of an Initial TB Training and Education Program for HCWs

The following are suggested components of an initial TB training and education program:

1. Clinical Information

- Basic concepts of *M. tuberculosis* transmission, pathogenesis, and diagnosis, including the difference between LTBI and TB disease and the possibility of reinfection after previous infection with *M. tuberculosis* or TB disease.
- Symptoms and signs of TB disease and the importance of a high index of suspicion for patients or HCWs with these symptoms.
- Indications for initiation of airborne precautions of inpatients with suspected or confirmed TB disease.
- Policies and indications for discontinuing airborne precautions.

- Principles of treatment for LTBI and for TB disease (indications, use, effectiveness, and potential adverse effects).

2. Epidemiology of TB

- Epidemiology of TB in the local community, the United States, and worldwide.
- Risk factors for TB disease.

3. Infection-Control Practices to Prevent and Detect *M. tuberculosis* Transmission in Health-Care Settings

- Overview of the TB infection-control program.
- Potential for occupational exposure to infectious TB disease in health-care settings.
- Principles and practices of infection control to reduce the risk for transmission of *M. tuberculosis*, including the hierarchy of TB infection-control measures, written policies and procedures, monitoring, and control measures for HCWs at increased risk for exposure to *M. tuberculosis*.
- Rationale for infection-control measures and documentation evaluating the effect of these measures in reducing occupational TB risk exposure and *M. tuberculosis* transmission.
- Reasons for testing for *M. tuberculosis* infection, importance of a positive test result for *M. tuberculosis* infection, importance of participation in a TB screening program, and importance of retaining documentation of previous test result for *M. tuberculosis* infection, chest radiograph results, and treatment for LTBI and TB disease.
- Efficacy and safety of BCG vaccination and principles of screening for *M. tuberculosis* infection and interpretation in BCG recipients.
- Procedures for investigating an *M. tuberculosis* infection test conversion or TB disease occurring in the workplace.
- Joint responsibility of HCWs and employers to ensure prompt medical evaluation after *M. tuberculosis* test conversion or development of symptoms or signs of TB disease in HCWs.
- Role of HCW in preventing transmission of *M. tuberculosis*.
- Responsibility of HCWs to promptly report a diagnosis of TB disease to the setting's administration and infection-control program.
- Responsibility of clinicians and the infection-control program to report to the state or local health department a suspected case of TB disease in a patient (including autopsy findings) or HCW.
- Responsibilities and policies of the setting, the local health department, and the state health department to ensure confidentiality for HCWs with TB disease or LTBI.
- Responsibility of the setting to inform EMS staff who transported a patient with suspected or confirmed TB disease.
- Responsibilities and policies of the setting to ensure that an HCW with TB disease is noninfectious before returning to duty.
- Importance of completing therapy for LTBI or TB disease to protect the HCW's health and to reduce the risk to others.
- Proper implementation and monitoring of environmental controls (see Environmental Controls).
- Training for safe collection, management, and disposal of clinical specimens.
- Required Occupational Safety and Health Administration (OSHA) record keeping on HCW test conversions for *M. tuberculosis* infection.
- Record-keeping and surveillance of TB cases among patients in the setting.
- Proper use of (see Respiratory Protection) and the need to inform the infection-control program of factors that might affect the efficacy of respiratory protection as required by OSHA.
- Success of adherence to infection-control practices in decreasing the risk for transmission of *M. tuberculosis* in health-care settings.

4. TB and Immunocompromising Conditions

- Relationship between infection with *M. tuberculosis* and medical conditions and treatments that can lead to impaired immunity.
- Available tests and counseling and referrals for persons with HIV infection, diabetes, and other immunocompromising conditions associated with an increased risk for progression to TB disease.
- Procedures for informing employee health or infection-control personnel of medical conditions associated with immunosuppression.
- Policies on voluntary work reassignment options for immunocompromised HCWs.
- Applicable confidentiality safeguards of the health-care setting, locality, and state.

5. TB and Public Health

- Role of the local and state health department's TB-control program in screening for LTBI and TB disease, providing treatment, conducting contact investigations and outbreak investigations, and providing education, counseling, and responses to public inquiries.
- Roles of CDC and of OSHA.

- Availability of information, advice, and counseling from community sources, including universities, local experts, and hotlines.
- Responsibility of the setting's clinicians and infection-control program to promptly report to the state or local health department a case of suspected TB disease or a cluster of TST or BAMT conversions.
- Responsibility of the setting's clinicians and infection-control program to promptly report to the state or local health department a person with suspected or confirmed TB disease who leaves the setting against medical advice.

Managing Patients Who Have Suspected or Confirmed TB Disease: General Recommendations

The primary TB risk to HCWs is the undiagnosed or unsuspected patient with infectious TB disease. A high index of suspicion for TB disease and rapid implementation of precautions are essential to prevent and interrupt transmission. Specific precautions will vary depending on the setting.

Prompt Triage

Within health-care settings, protocols should be implemented and enforced to promptly identify, separate from others, and either transfer or manage persons who have suspected or confirmed infectious TB disease. When patients' medical histories are taken, all patients should be routinely asked about 1) a history of TB exposure, infection, or disease; 2) symptoms or signs of TB disease; and 3) medical conditions that increase their risk for TB disease (see Supplements, Diagnostic Procedures for LTBI and TB Disease; and Treatment Procedures for LTBI and TB Disease). The medical evaluation should include an interview conducted in the patient's primary language, with the assistance of a qualified medical interpreter, if necessary. HCWs who are the first point of contact should be trained to ask questions that will facilitate detection of persons who have suspected or confirmed infectious TB disease. For assistance with language interpretation, contact the local and state health department. Interpretation resources are also available (*119*) at http://www.atanet.org; http://www. languageline.com; and http://www.ncihc.org.

A diagnosis of respiratory TB disease should be considered for any patient with symptoms or signs of infection in the lung, pleura, or airways (including larynx), including coughing for ≥3 weeks, loss of appetite, unexplained weight loss, night sweats, bloody sputum or hemoptysis, hoarseness, fever, fatigue, or chest pain. The index of suspicion for TB disease will vary by geographic area and will depend on the population served by the setting. The index of suspicion should be substantially high for geographic areas and groups of patients characterized by high TB incidence (*26*).

Special steps should be taken in settings other than TB clinics. Patients with symptoms suggestive of undiagnosed or inadequately treated TB disease should be promptly referred so that they can receive a medical evaluation. These patients should not be kept in the setting any longer than required to arrange a referral or transfer to an AII room. While in the setting, symptomatic patients should wear a surgical or procedure mask, if possible, and should be instructed to observe strict respiratory hygiene and cough etiquette procedures (see Glossary) (*120–122*).

Immunocompromised persons, including those who are HIV-infected, with infectious TB disease should be physically separated from other persons to protect both themselves and others. To avoid exposing HIV-infected or otherwise severely immunocompromised persons to *M. tuberculosis*, consider location and scheduling issues to avoid exposure.

TB Airborne Precautions

Within health-care settings, TB airborne precautions should be initiated for any patient who has symptoms or signs of TB disease, or who has documented infectious TB disease and has not completed antituberculosis treatment. For patients placed in AII rooms because of suspected infectious TB disease of the lungs, airway, or larynx, airborne precautions may be discontinued when infectious TB disease is considered unlikely and either 1) another diagnosis is made that explains the clinical syndrome or 2) the patient has three consecutive, negative AFB sputum smear results (*109–112,123*). Each of the three sputum specimens should be collected in 8–24-hour intervals (*124*), and at least one specimen should be an early morning specimen because respiratory secretions pool overnight. Generally, this method will allow patients with negative sputum smear results to be released from airborne precautions in 2 days.

The classification of the risk assessment of the health-care setting is used to determine how many AII rooms each setting needs, depending on the number of TB patients examined. At least one AII room is needed for settings in which TB patients stay while they are being treated, and additional AII rooms might be needed depending on the magnitude of patient-days of persons with suspected or confirmed TB disease (*118*). Additional rooms might be considered if options are limited for transferring patients with suspected or confirmed TB disease to other settings with AII rooms. For example, for a hospital with 120 beds, a minimum of one AII room is needed, possibly more, depending on how many TB patients are examined in 1 year.

TB Airborne Precautions for Settings in Which Patients with Suspected or Confirmed TB Disease Are Expected To Be Encountered

Settings that plan to evaluate and manage patients with TB disease should have at least one AII room or enclosure that meets AII requirements (see Environmental Controls; and Supplement, Environmental Controls). These settings should develop written policies that specify 1) indications for airborne precautions, 2) persons authorized to initiate and discontinue airborne precautions, 3) specific airborne precautions, 4) AII room-monitoring procedures, 5) procedures for managing patients who do not adhere to airborne precautions, and 6) criteria for discontinuing airborne precautions.

A high index of suspicion should be maintained for TB disease. If a patient has suspected or confirmed TB disease, airborne precautions should be promptly initiated. Persons with suspected or confirmed TB disease who are inpatients should remain in AII rooms until they are determined to be noninfectious and have demonstrated a clinical response to a standard multidrug antituberculosis treatment regimen or until an alternative diagnosis is made. If the alternative diagnosis cannot be clearly established, even with three negative sputum smear results, empiric treatment of TB disease should strongly be considered (see Supplement, Estimating the Infectiousness of a TB Patient). Outpatients with suspected or confirmed infectious TB disease should remain in AII rooms until they are transferred or until their visit is complete.

TB Airborne Precautions for Settings in Which Patients with Suspected or Confirmed TB Disease Are Not Expected To Be Encountered

Settings in which patients with suspected or confirmed TB disease are not expected to be encountered do not need an AII room or a respiratory-protection program for the prevention of transmission of *M. tuberculosis*. However, follow these steps in these settings.

A written protocol should be developed for referring patients with suspected or confirmed TB disease to a collaborating referral setting in which the patient can be evaluated and managed properly. The referral setting should provide documentation of intent to collaborate. The protocol should be reviewed routinely and revised as needed.

Patients with suspected or confirmed TB disease should be placed in an AII room, if available, or in a room that meets the requirements for an AII room, or in a separate room with the door closed, apart from other patients and not in an open waiting area. Adequate time should elapse to ensure removal of *M. tuberculosis*–contaminated room air before allowing entry by staff or another patient (Tables 1 and 2).

If an AII room is not available, persons with suspected or confirmed infectious TB disease should wear a surgical or procedure mask, if possible. Patients should be instructed to keep the mask on and to change the mask if it becomes wet. If patients cannot tolerate a mask, they should observe strict respiratory hygiene and cough etiquette procedures.

AII Room Practices

AII rooms should be single-patient rooms in which environmental factors and entry of visitors and HCWs are controlled to minimize the transmission of *M. tuberculosis*. All HCWs who enter an AII room should wear at least N95 disposable respirators (see Respiratory Protection). Visitors may be offered respiratory protection (i.e., N95) and should be instructed by HCWs on the use of the respirator before entering an AII room. AII rooms have specific requirements for controlled ventilation, negative pressure, and air filtration (*118*) (see Environmental Controls). Each inpatient AII room should have a private bathroom.

Settings with AII Rooms

Health-care personnel settings with AII rooms should

- keep doors to AII rooms closed except when patients, HCWs, or others must enter or exit the room (*118*);
- maintain enough AII rooms to provide airborne precautions of all patients who have suspected or confirmed TB disease. Estimate the number of AII rooms needed based on the results of the risk assessment for the setting;
- monitor and record direction of airflow (i.e., negative pressure) in the room on a daily basis, while the room is being used for TB airborne precautions. Record results in an electronic or readily retrievable document;
- consider grouping AII rooms in one part of the health-care setting to limit costs, reduce the possibility of transmitting *M. tuberculosis* to other patients, facilitate the care of TB patients, and facilitate the installation and maintenance of optimal environmental controls (particularly ventilation). Depending on the architecture and the environmental control systems of a particular setting, AII rooms might be grouped either horizontally (e.g., a wing of a facility) or vertically (e.g., the last few rooms of separate floors of a facility);
- perform diagnostic and treatment procedures (e.g., sputum collection and inhalation therapy) in an AII room.
- ensure patient adherence to airborne precautions. In their primary language, with the assistance of a qualified medical interpreter, if necessary, educate patients (and family and visitors) who are placed in an AII room about *M. tuberculosis* transmission and the reasons for airborne precautions. For assistance with language interpretation,

contact the local and state health department. Interpretation resources are available (*119*) at http://www.atanet.org; http://www.languageline.com; and http://www.ncihc.org. Facilitate patient adherence by using incentives (e.g., provide telephones, televisions, or radios in AII rooms; and grant special dietary requests) and other measures. Address problems that could interfere with adherence (e.g., management of withdrawal from addictive substances, including tobacco); and

- ensure that patients with suspected or confirmed infectious TB disease who must be transported to another area of the setting or to another setting for a medically essential procedure bypass the waiting area and wear a surgical or procedure mask, if possible. Drivers, HCWs, and other staff who are transporting persons with suspected or confirmed infectious TB disease might consider wearing an N95 respirator. Schedule procedures on patients with TB disease when a minimum number of HCWs and other patients are present and as the last procedure of the day to maximize the time available for removal of airborne contamination (Tables 1 and 2).

Diagnostic Procedures

Diagnostic procedures should be performed in settings with appropriate infection-control capabilities. The following recommendations should be applied for diagnosing TB disease and for evaluating patients for potential infectiousness.

Clinical Diagnosis

A complete medical history should be obtained, including symptoms of TB disease, previous TB disease and treatment, previous history of infection with *M. tuberculosis*, and previous treatment of LTBI or exposure to persons with TB disease. A physical examination should be performed, including chest radiograph, microscopic examination, culture, and, when indicated, NAA testing of sputum (*39,53,125,126*). If possible, sputum induction with aerosol inhalation is preferred, particularly when the patient cannot produce sputum. Gastric aspiration might be necessary for those patients, particularly children, who cannot produce sputum, even with aerosol inhalation (*127–130*). Bronchoscopy might be needed for specimen collection, especially if sputum specimens have been nondiagnostic and doubt exists as to the diagnosis (*90,111,127,128,131–134*).

All patients with suspected or confirmed infectious TB disease should be placed under airborne precautions until they have been determined to be noninfectious (see Supplement, Estimating the Infectiousness of a TB Patient). Adult and adolescent patients who might be infectious include persons who are coughing; have cavitation on chest radiograph; have positive AFB sputum smear results; have respiratory tract disease with involvement of the lung, pleura or airways, including larynx, who fail to cover the mouth and nose when coughing; are not on antituberculosis treatment or are on incorrect antituberculosis treatment; or are undergoing cough-inducing or aerosol-generating procedures (e.g., sputum induction, bronchoscopy, and airway suction) (*30,135*).

Persons diagnosed with extrapulmonary TB disease should be evaluated for the presence of concurrent pulmonary TB disease. An additional concern in infection control with children relates to adult household members and visitors who might be the source case (*136*). Pediatric patients, including adolescents, who might be infectious include those who have extensive pulmonary or laryngeal involvement, prolonged cough, positive sputum AFB smears results, cavitary TB on chest radiograph (as is typically observed in immunocompetent adults with TB disease), or those for whom cough-inducing or aerosol-generating procedures are performed (*136,137*).

Although children are uncommonly infectious, pediatric patients should be evaluated for infectiousness by using the same criteria as for adults (i.e., on the basis of pulmonary or laryngeal involvement). Patients with suspected or confirmed TB disease should be immediately reported to the local public health authorities so that arrangements can be made for tracking their treatment to completion, preferably through a case management system, so that DOT can be arranged and standard procedures for identifying and evaluating TB contacts can be initiated. Coordinate efforts with the local or state health department to arrange treatment and long-term follow-up and evaluation of contacts.

Laboratory Diagnosis

To produce the highest quality laboratory results, laboratories performing mycobacteriologic tests should be skilled in both the laboratory and the administrative aspects of specimen processing. Laboratories should use or have prompt access to the most rapid methods available: 1) fluorescent microscopy and concentration for AFB smears; 2) rapid NAA testing for direct detection of *M. tuberculosis* in patient specimens (*125*); 3) solid and rapid broth culture methods for isolation of mycobacteria; 4) nucleic acid probes or high pressure liquid chromatography (HPLC) for species identification; and 5) rapid broth culture methods for drug susceptibility testing. Laboratories should incorporate other more rapid or sensitive tests as they become available, practical, and affordable (see Supplement, Diagnostic Procedures for LTBI and TB Disease) (*138,139*).

In accordance with local and state laws and regulations, a system should be in place to ensure that laboratories report any positive results from any specimens to clinicians within 24 hours of receipt of the specimen (*139,140*). Certain settings

perform AFB smears on-site for rapid results (and results should be reported to clinicians within 24 hours) and then send specimens or cultures to a referral laboratory for identification and drug-susceptibility testing. This referral practice can speed the receipt of smear results but delay culture identification and drug-susceptibility results. Settings that cannot provide the full range of mycobacteriologic testing services should contract with their referral laboratories to ensure rapid results while maintaining proficiency for on-site testing. In addition, referral laboratories should be instructed to store isolates in case additional testing is necessary.

All drug susceptibility results on *M. tuberculosis* isolates should be reported to the local or state health department as soon as these results are available. Laboratories that rarely receive specimens for mycobacteriologic analysis should refer specimens to a laboratory that performs these tests routinely. The reference laboratory should provide rapid testing and reporting. Out-of-state reference laboratories should provide all results to the local or state health department from which the specimen originated.

Special Considerations for Persons Who Are at High Risk for TB Disease or in Whom TB Disease Might Be Difficult to Diagnose

The probability of TB disease is higher among patients who 1) previously had TB disease or were exposed to *M. tuberculosis*, 2) belong to a group at high risk for TB disease or, 3) have a positive TST or BAMT result. TB disease is strongly suggested if the diagnostic evaluation reveals symptoms or signs of TB disease, a chest radiograph consistent with TB disease, or AFB in sputum or from any other specimen. TB disease can occur simultaneously in immunocompromised persons who have pulmonary infections caused by other organisms (e.g., *Pneumocystis jaroveci* [formerly *P. carinii*] and *M. avium* complex) and should be considered in the diagnostic evaluation of all such patients with symptoms or signs of TB disease (*53*).

TB disease can be difficult to diagnose in persons who have HIV infection (*49*) (or other conditions associated with severe suppression of cell mediated immunity) because of nonclassical or normal radiographic presentation or the simultaneous occurrence of other pulmonary infections (e.g., *P. jaroveci* or *M. avium* complex) (*2*). Patients who are HIV-infected are also at greater risk for having extrapulmonary TB (*2*). The difficulty in diagnosing TB disease in HIV-infected can be compounded by the possible lower sensitivity and specificity of sputum smear results for detecting AFB (*53,141*) and the overgrowth of cultures with *M. avium* complex in specimens from patients infected with both *M. tuberculosis* and *M. avium* complex. The TST in patients with advanced HIV infection is unreliable and cannot be used in clinical decision making (*35,53,142*).

For immunocompromised patients who have respiratory symptoms or signs that are attributed initially to infections or conditions other than TB disease, conduct an evaluation for coexisting TB disease. If the patient does not respond to recommended treatment for the presumed cause of the pulmonary abnormalities, repeat the evaluation (see Supplement, Diagnostic Procedures for LTBI and TB Disease). In certain settings in which immunocompromised patients and patients with TB disease are examined, implementing airborne precautions might be prudent for all persons at high risk. These persons include those infected with HIV who have an abnormal chest radiograph or respiratory symptoms, symptomatic foreign-born persons who have immigrated within the previous 5 years from TB-endemic countries, and persons with pulmonary infiltrates on chest radiograph, or symptoms or signs of TB disease.

Initiation of Treatment

For patients who have confirmed TB disease or who are considered highly probable to have TB disease, promptly start antituberculosis treatment in accordance with current guidelines (see Supplements, Diagnostic Procedures for LTBI and TB Disease; and Treatment Procedures for LTBI and TB Disease) (*31*). In accordance with local and state regulations, local health departments should be notified of all cases of suspected TB.

DOT is the standard of care for all patients with TB disease and should be used for all doses during the course of therapy for treatment of TB disease. All inpatient medication should be administered by DOT and reported to the state or local health department. Rates of relapse and development of drug-resistance are decreased when DOT is used (*143–145*). All patients on intermittent (i.e., once or twice per week) treatment for TB disease or LTBI should receive DOT. Settings should collaborate with the local or state health department on decisions concerning inpatient DOT and arrangements for outpatient DOT (*31*).

Managing Patients Who Have Suspected or Confirmed TB Disease: Considerations for Special Circumstances and Settings

The recommendations for preventing transmission of *M. tuberculosis* are applicable to all health-care settings, including those that have been described (Appendix A). These settings should each have independent risk assessments if they are

stand-alone settings, or each setting should have a detailed section written as part of the risk assessment for the overall setting.

Minimum Requirements

The specific precautions for the settings included in this section vary, depending on the setting.

Inpatient Settings

Emergency Departments (EDs)

The symptoms of TB disease are usually symptoms for which patients might seek treatment in EDs. Because TB symptoms are common and nonspecific, infectious TB disease could be encountered in these settings. The use of ED-based TB screening has not been demonstrated to be consistently effective (*146*).

The amount of time patients with suspected or confirmed infectious TB disease spend in EDs and urgent-care settings should be minimized. Patients with suspected or confirmed infectious TB disease should be promptly identified, evaluated, and separated from other patients. Ideally, such patients should be placed in an AII room. When an AII room is not available, use a room with effective general ventilation, and use air cleaning technologies (e.g., a portable HEPA filtration system), if available, or transfer the patient to a setting or area with recommended infection-control capacity. Facility engineering personnel with expertise in heating, ventilation, and air conditioning (HVAC) and air handlers have evaluated how this option is applied to ensure no over pressurization of return air or unwanted deviations exists in design of air flow in the zone.

EDs with a high volume of patients with suspected or confirmed TB disease should have at least one AII room (see TB Risk Assessment). Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase equivalent air changes per hour (ACH) in waiting areas (Table 1). HCWs entering an AII room or any room with a patient with infectious TB disease should wear at least an N95 disposable respirator. After a patient with suspected or confirmed TB disease exits a room, allow adequate time to elapse to ensure removal of *M. tuberculosis*-contaminated room air before allowing entry by staff or another patient (Tables 1 and 2).

Before a patient leaves an AII room, perform an assessment of 1) the patient's need to discontinue airborne precautions, 2) the risk for transmission and the patient's ability to observe strict respiratory hygiene, and 3) cough etiquette procedures. Patients with suspected or confirmed infectious TB who are outside an AII room should wear a surgical or procedure mask, if possible. Patients who cannot tolerate masks because of medical conditions should observe strict respiratory hygiene and cough etiquette procedures.

TABLE 1. Air changes per hour (ACH) and time required for removal efficiencies of 99% and 99.9% of airborne contaminants*

	Minutes required for removal efficiency†	
ACH	99%	99.9%
2	138	207
4	69	104
6	46	69
12	23	35
15	18	28
20	14	21
50	6	8
400	<1	1

*This table can be used to estimate the time necessary to clear the air of airborne *Mycobacterium tuberculosis* after the source patient leaves the area or when aerosol-producing procedures are complete.
†Time in minutes to reduce the airborne concentration by 99% or 99.9%.

Intensive Care Units (ICUs)

Patients with infectious TB disease might become sick enough to require admission to an ICU. Place ICU patients with suspected or confirmed infectious TB disease in an AII room, if possible. ICUs with a high volume of patients with suspected or confirmed TB disease should have at least one AII room (Appendix B). Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase equivalent ACH in waiting areas (see Environmental Controls).

HCWs entering an AII room or any room with a patient with infectious TB disease should wear at least an N95 disposable respirator. To help reduce the risk for contaminating a ventilator or discharging *M. tuberculosis* into the ambient air when mechanically ventilating (i.e., with a ventilator or manual resuscitator) a patient with suspected or confirmed TB disease, place a bacterial filter on the patient's endotracheal tube (or at the expiratory side of the breathing circuit of a ventilator) (*147–151*). In selecting a bacterial filter, give preference to models specified by the manufacturer to filter particles 0.3 μm in size in both the unloaded and loaded states with a filter efficiency of ≥95% (i.e., filter penetration of <5%) at the maximum design flow rates of the ventilator for the service life of the filter, as specified by the manufacturer.

Surgical Suites

Surgical suites require special infection-control considerations for preventing transmission of *M. tuberculosis*. Normally, the direction of airflow should be from the operating room (OR) to the hallway (positive pressure) to minimize contamination of the surgical field. Certain hospitals have procedure rooms with reversible airflow or pressure, whereas others have positive-pressure rooms with a negative pressure anteroom. Surgical staff, particularly those close to the surgical field, should use respiratory protection (e.g., a valveless N95

disposable respirator) to protect themselves and the patient undergoing surgery.

When possible, postpone non-urgent surgical procedures on patients with suspected or confirmed TB disease until the patient is determined to be noninfectious or determined to not have TB disease. When surgery cannot be postponed, procedures should be performed in a surgical suite with recommended ventilation controls. Procedures should be scheduled for patients with suspected or confirmed TB disease when a minimum number of HCWs and other patients are present in the surgical suite, and at the end of the day to maximize the time available for removal of airborne contamination (Tables 1 and 2).

If a surgical suite or an OR has an anteroom, the anteroom should be either 1) positive pressure compared with both the corridor and the suite or OR (with filtered supply air) or 2) negative pressure compared with both the corridor and the suite or OR. In the usual design in which an OR has no anteroom, keep the doors to the OR closed, and minimize traffic into and out of the room and in the corridor. Using additional air-cleaning technologies (e.g., UVGI) should be considered to increase the equivalent ACH. Air-cleaning systems can be placed in the room or in surrounding areas to minimize contamination of the surroundings after the procedure (*114*) (see Environmental Controls).

Ventilation in the OR should be designed to provide a sterile environment in the surgical field while preventing contaminated air from flowing to other areas in the health-care setting. Personnel steps should be taken to reduce the risk for contaminating ventilator or anesthesia equipment or discharging tubercle bacilli into the ambient air when operating on a patient with suspected or confirmed TB disease (*152*). A bacterial filter should be placed on the patient's endotracheal tube (or at the expiratory side of the breathing circuit of a ventilator or anesthesia machine, if used) (*147–151*). When selecting a bacterial filter, give preference to models specified by the manufacturer to filter particles 0.3 μm in size in both the unloaded and loaded states with a filter efficiency of ≥95% (i.e., filter penetration of <5%) at the maximum design flow rates of the ventilator for the service life of the filter, as specified by the manufacturer.

When surgical procedures (or other procedures that require a sterile field) are performed on patients with suspected or confirmed infectious TB, respiratory protection should be worn by HCWs to protect the sterile field from the respiratory secretions of HCWs and to protect HCWs from the infectious droplet nuclei generated from the patient. When selecting respiratory protection, do not use valved or positive-pressure respirators, because they do not protect the sterile field. A respirator with a valveless filtering facepiece (e.g., N95 disposable respirator) should be used.

Postoperative recovery of a patient with suspected or confirmed TB disease should be in an AII room in any location where the patient is recovering (*118*). If an AII or comparable room is not available for surgery or postoperative recovery, air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Environmental Controls); however, the infection-control committee should be involved in the selection and placement of these supplemental controls.

Laboratories

Staff who work in laboratories that handle clinical specimens encounter risks not typically present in other areas of a health-care setting (*153–155*). Laboratories that handle TB specimens include 1) pass-through facilities that forward specimens to reference laboratories for analysis; 2) diagnostic laboratories that process specimens and perform acid-fast staining and primary culture for *M. tuberculosis*; and 3) facilities that perform extensive identification, subtyping, and susceptibility studies.

Procedures involving the manipulation of specimens or cultures containing *M. tuberculosis* introduce additional substantial risks that must be addressed in an effective TB infection-control program. Personnel who work with mycobacteriology specimens should be thoroughly trained in methods that minimize the production of aerosols and undergo periodic competency testing to include direct observation of their work practices. Risks for transmission of *M. tuberculosis* in laboratories include aerosol formation during any specimen or isolate manipulation and percutaneous inoculation from accidental exposures. Biosafety recommendations for laboratories performing diagnostic testing for TB have been published (*74,75,138,156,157*).

In laboratories affiliated with a health-care setting (e.g., a hospital) and in free-standing laboratories, the laboratory director, in collaboration with the infection-control staff for the setting, and in consultation with the state TB laboratory, should develop a risk-based infection-control plan for the laboratory that minimizes the risk for exposure to *M. tuberculosis*. Consider factors including 1) incidence of TB disease (including drug-resistant TB) in the community and in patients served by settings that submit specimens to the laboratory, 2) design of the laboratory, 3) level of TB diagnostic service offered, 4) number of specimens processed, and 5) whether or not aerosol-generating or aerosol-producing procedures are performed and the frequency at which they are performed. Referral laboratories should store isolates in case additional testing is necessary.

Biosafety level (BSL)-2 practices and procedures, containment equipment, and facilities are required for nonaerosol-producing manipulations of clinical specimens (e.g., preparing direct smears for acid-fast staining when done in conjunction with training and periodic checking of competency) (*138*). All specimens suspected of containing *M. tuberculosis* (including specimens processed for other microorganisms) should be handled in a Class I or II biological safety cabinet (BSC) (*158,159*). Conduct all aerosol-generating activities (e.g., inoculating culture media, setting up biochemical and antimicrobic susceptibility tests, opening centrifuge cups, and performing sonication) in a Class I or II BSC (*158*).

For laboratories that are considered at least medium risk (Appendix C), conduct testing for *M. tuberculosis* infection at least annually among laboratorians who perform TB diagnostics or manipulate specimens from which *M. tuberculosis* is commonly isolated (e.g., sputum, lower respiratory secretions, or tissues) (Appendix D). More frequent testing for *M. tuberculosis* is recommended in the event of a documented conversion among laboratory staff or a laboratory accident that poses a risk for exposure to *M. tuberculosis* (e.g., malfunction of a centrifuge leading to aerosolization of a sample).

Based on the risk assessment for the laboratory, employees should use personal protective equipment (including respiratory protection) recommended by local regulations for each activity. For activities that have a low risk for generating aerosols, standard personal protective equipment consists of protective laboratory coats, gowns, or smocks designed specifically for use in the laboratory. Protective garments should be left in the laboratory before going to nonlaboratory areas.

For all laboratory procedures, disposable gloves should be worn. Gloves should be disposed of when work is completed, the gloves are overtly contaminated, or the integrity of the glove is compromised. Local or state regulations should determine procedures for the disposal of gloves. Face protection (e.g., goggles, full-facepiece respirator, face shield, or other splatter guard) should also be used when manipulating specimens inside or outside a BSC. Use respiratory protection when performing procedures that can result in aerosolization outside a BSC. The minimum level of respiratory protection is an N95 filtering facepiece respirator. Laboratory workers who use respiratory protection should be provided with the same training on respirator use and care and the same fit testing as other HCWs.

After documented laboratory accidents, conduct an investigation of exposed laboratory workers. Laboratories in which specimens for mycobacteriologic studies (e.g., AFB smears and cultures) are processed should follow the AIA and CDC/National Institute of Health guidelines (*118,159*) (see Environmental Controls). BSL-3 practices, containment equipment, and facilities are recommended for the propagation and manipulation of cultures of *M. tuberculosis* complex (including *M. bovis*) and for animal studies in which primates that are experimentally or naturally infected with *M. tuberculosis* or *M. bovis* are used. Animal studies in which guinea pigs or mice are used can be conducted at animal BSL-2. Aerosol infection methods are recommended to be conducted at BSL-3 (*159*).

Bronchoscopy Suites

Because bronchoscopy is a cough-inducing procedure that might be performed on patients with suspected or confirmed TB disease, bronchoscopy suites require special attention (*29,81,160,161*). Bronchoscopy can result in the transmission of *M. tuberculosis* either through the airborne route (*29,63,81,86,162*) or a contaminated bronchoscope (*80,82,163–170*). Closed and effectively filtered ventilatory circuitry and minimizing opening of such circuitry in intubated and mechanically ventilated patients might minimize exposure (see Intensive Care Units) (*149*).

If possible, avoid bronchoscopy on patients with suspected or confirmed TB disease or postpone the procedure until the patient is determined to be noninfectious, by confirmation of the three negative AFB sputum smear results (*109–112*). When collection of spontaneous sputum specimen is not adequate or possible, sputum induction has been demonstrated to be equivalent to bronchoscopy for obtaining specimens for culture (*110*). Bronchoscopy might have the advantage of confirmation of the diagnosis with histologic specimens, collection of additional specimens, including post bronchoscopy sputum that might increase the diagnostic yield, and the opportunity to confirm an alternate diagnosis. If the diagnosis of TB disease is suspected, consideration should be given to empiric antituberculosis treatment.

A physical examination should be performed, and a chest radiograph, microscopic examination, culture, and NAA testing of sputum or other relevant specimens should also be obtained, including gastric aspirates (*125*), as indicated (*53,126,131,130*). Because 15%–20% of patients with TB disease have negative TST results, a negative TST result is of limited value in the evaluation of the patient with suspected TB disease, particularly in patients from high TB incidence groups in whom TST positive rates exceed 30% (*31*).

Whenever feasible, perform bronchoscopy in a room that meets the ventilation requirements for an AII room (same as the AIA guidelines parameters for bronchoscopy rooms) (see Environmental Controls). Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase equivalent ACH.

If sputum specimens must be obtained and the patient cannot produce sputum, consider sputum induction before bronchoscopy (*111*). In a patient who is intubated and mechanically ventilated, minimize the opening of circuitry. At least N95 respirators should be worn by HCWs while present during a bronchoscopy procedure on a patient with suspected or confirmed infectious TB disease. Because of the increased risk for *M. tuberculosis* transmission during the performance of bronchoscopy procedures on patients with TB disease, consider using a higher level of respiratory protection than an N95 disposable respirator (e.g., an elastomeric full-facepiece respirator or a powered air-purifying respirator [PAPR] [*29*]) (see Respiratory Protection).

After bronchoscopy is performed on a patient with suspected or confirmed infectious TB disease, allow adequate time to elapse to ensure removal of *M. tuberculosis*–contaminated room air before performing another procedure in the same room (Tables 1 and 2). During the period after bronchoscopy when the patient is still coughing, collect at least one sputum for AFB to increase the yield of the procedure. Patients with suspected or confirmed TB disease who are undergoing bronchoscopy should be kept in an AII room until coughing subsides.

Sputum Induction and Inhalation Therapy Rooms

Sputum induction and inhalation therapy induces coughing, which increases the potential for transmission of *M. tuberculosis* (*87,88,90*). Therefore, appropriate precautions should be taken when working with patients with suspected or confirmed TB disease. Sputum induction procedures for persons with suspected or confirmed TB disease should be considered after determination that self-produced sputum collection is inadequate and that the AFB smear result on other specimens collected is negative. HCWs who order or perform sputum induction or inhalation therapy in an environment without proper controls for the purpose of diagnosing conditions other than TB disease should assess the patient's risk for TB disease.

Cough-inducing or aerosol-generating procedures in patients with diagnosed TB should be conducted only after an assessment of infectiousness has been considered for each patient and should be conducted in an environment with proper controls. Sputum induction should be performed by using local exhaust ventilation (e.g., booths with special ventilation) or alternatively in a room that meets or exceeds the requirements of an AII room (see Environmental Controls) (*90*). At least an N95 disposable respirator should be worn by HCWs performing sputum inductions or inhalation therapy on a patient with suspected or confirmed infectious TB disease. Based on the risk assessment, consideration should be given to using a higher level of respiratory protection (e.g., an elastomeric full-facepiece respirator or a PAPR) (see Respiratory Protection) (*90*).

After sputum induction or inhalation therapy is performed on a patient with suspected or confirmed infectious TB disease, allow adequate time to elapse to ensure removal of *M. tuberculosis*–contaminated room air before performing another procedure in the same room (Tables 1 and 2). Patients with suspected or confirmed TB disease who are undergoing sputum induction or inhalation therapy should be kept in an AII room until coughing subsides.

Autopsy Suites

Autopsies performed on bodies with suspected or confirmed TB disease can pose a high risk for transmission of *M. tuberculosis*, particularly during the performance of aerosol-generating procedures (e.g., median sternotomy). Persons who handle bodies might be at risk for transmission of *M. tuberculosis* (*77,78,171–177*). Because certain procedures performed as part of an autopsy might generate infectious aerosols, special airborne precautions are required.

Autopsies should not be performed on bodies with suspected or confirmed TB disease without adequate protection for those performing the autopsy procedures. Settings in which autopsies are performed should meet or exceed the requirements of an AII room, if possible (see Environmental Controls), and the drawing in the American Conference of Governmental Industrial Hygienists® (ACGIH) Industrial Ventilation Manual VS-99-07 (*178*). Air should be exhausted to the outside of the building. Air-cleaning technologies (e.g., HEPA filtration or UVGI) can be used to increase the number of equivalent ACH (see Environmental Controls).

As an added administrative measure, when performing autopsies on bodies with suspected or confirmed TB disease, coordination between attending physicians and pathologists is needed to ensure proper infection control and specimen collection. The use of local exhaust ventilation should be considered to reduce exposures to infectious aerosols (e.g., when using a saw, including Striker saw). For HCWs performing an autopsy on a body with suspected or confirmed TB disease, at least N95 disposable respirators should be worn (see Respiratory Protection). Based on the risk assessment, consider using a higher level of respiratory protection than an N95 disposable respirator (e.g., an elastomeric full-facepiece respirator or a PAPR) (see Respiratory Protection).

After an autopsy is performed on a body with suspected or confirmed TB disease, allow adequate time to elapse to ensure removal of *M. tuberculosis*–contaminated room air before performing another procedure in the same room (Tables 1 and 2). If time delay is not feasible, the autopsy staff should continue to wear respirators while they are in the room.

Embalming Rooms

Tissue or organ removal in an embalming room performed on bodies with suspected or confirmed TB disease can pose a high risk for transmission of *M. tuberculosis*, particularly during the performance of aerosol-generating procedures. Persons who handle corpses might be at risk for transmission of *M. tuberculosis* (*77,78,171–176*). Because certain procedures performed as part of embalming might generate infectious aerosols, special airborne precautions are required.

Embalming involving tissue or organ removal should not be performed on bodies with suspected or confirmed TB disease without adequate protection for the persons performing the procedures. Settings in which these procedures are performed should meet or exceed the requirements of an AII room, if possible (see Environmental Controls), and the drawing in the ACGIH Industrial Ventilation Manual VS-99-07 (*178*). Air should be exhausted to the outside of the building. Air-cleaning technologies (e.g., HEPA filtration or UVGI) can be used to increase the number of equivalent ACH (see Environmental Controls). The use of local exhaust ventilation should be considered to reduce exposures to infectious aerosols (e.g., when using a saw, including Striker saw) and vapors from embalming fluids.

When HCWs remove tissues or organs from a body with suspected or confirmed TB disease, at least N95 disposable respirators should be worn (see Respiratory Protection). Based on the risk assessment, consider using a higher level of respiratory protection than an N95 disposable respirator (e.g., an elastomeric full-facepiece respirator or a PAPR) (see Respiratory Protection).

After tissue or organ removal is performed on a body with suspected or confirmed TB disease, allow adequate time to elapse to ensure removal of *M. tuberculosis*–contaminated room air before performing another procedure in the same room (see Environmental Controls). If time delay is not feasible, the staff should continue to wear respirators while in the room.

Outpatient Settings

Outpatient settings might include TB treatment facilities, dental-care settings, medical offices, ambulatory-care settings, and dialysis units. Environmental controls should be implemented based on the types of activities that are performed in the setting.

TB Treatment Facilities

TB treatment facilities might include TB clinics, infectious disease clinics, or pulmonary clinics. TB clinics and other settings in which patients with TB disease and LTBI are examined on a regular basis require special attention. The same principles of triage used in EDs and ambulatory-care settings (see Minimum Requirements) should be applied to TB treatment facilities. These principles include prompt identification, evaluation, and airborne precautions of patients with suspected or confirmed infectious TB disease.

All TB clinic staff, including outreach workers, should be screened for *M. tuberculosis* infection (Appendix C). Patients with suspected or confirmed infectious TB disease should be physically separated from all patients, but especially from those with HIV infection and other immunocompromising conditions that increase the likelihood of development of TB disease if infected. Immunosuppressed patients with suspected or confirmed infectious TB disease need to be physically separated from others to protect both the patient and others. Appointments should be scheduled to avoid exposing HIV-infected or otherwise severely immunocompromised persons to *M. tuberculosis*. Certain times of the day should be designated for appointments for patients with infectious TB disease or treat them in areas in which immunocompromised persons are not treated.

Persons with suspected or confirmed infectious TB disease should be promptly placed in an AII room to minimize exposure in the waiting room and other areas of the clinic, and they should be instructed to observe strict respiratory hygiene and cough etiquette procedures. Clinics that provide care for patients with suspected or confirmed infectious TB disease should have at least one AII room. The need for additional AII rooms should be based on the risk assessment for the setting.

All cough-inducing and aerosol-generating procedures should be performed using environmental controls (e.g., in a booth or an AII room) (see Environmental Controls). Patients should be left in the booth or AII room until coughing subsides. Another patient or HCW should not be allowed to enter the booth or AII room until sufficient time has elapsed for adequate removal of *M. tuberculosis*-contaminated air (see Environmental Controls). A respiratory-protection program should be implemented for all HCWs who work in the TB clinic and who enter AII rooms, visit areas in which persons with suspected or confirmed TB disease are located, or transport patients with suspected or confirmed TB disease in vehicles. When persons with suspected or confirmed infectious TB disease are in the TB clinic and not in an AII room, they should wear a surgical or procedure mask, if possible.

Medical Offices and Ambulatory-Care Settings

The symptoms of TB disease are usually symptoms for which patients might seek treatment in a medical office. Therefore, infectious TB disease could possibly be encountered in certain medical offices and ambulatory-care settings.

Because of the potential for *M. tuberculosis* transmission in medical offices and ambulatory-care settings, follow the general