

Electronic Disease Notification



EDN Tuberculosis Follow-up Guide

This guidance document is intended for EDN users who use the TB follow-up module in EDN. The guide is designed to train EDN users on worksheet follow-up reporting and worksheet completion.

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This document was prepared by

The tuberculosis follow-up worksheet guidance manual was prepared by the following branches within the Centers for Disease Control and Prevention's Division of Tuberculosis Elimination and Division of Global Migration and Quarantine

Division of Global Migration and Quarantine

Immigrant, Refugee, and Migrant Health Branch

Kendra Cuffe, MPH
Deborah Lee, MPH
Rossanne Philen, MD, MS CAPT USPHS
Meghan Weems, MPH
Jenna Kirschenman, MPH, MSW
Shameer Poonja, MPH
Drew Posey, MD, MPH
Mary Naughton, MD, MPH

Division of Tuberculosis Elimination

Surveillance, Epidemiology, and Outbreak Investigations Branch

Thomas Navin, MD
Roque Miramontes, MPH
Kai Young, MPH

Field Services and Evaluation Branch

Victor Balaban, PhD
Awal Khan, PhD
Alstead Forbes
Mark Miner

National TB Controllers Association (NTCA), EDN Workgroup Members, 2009-2011

Phil Lowenthal, MPH	Sam Householder, MPH
Marge Higgins, LSW	Maura McGarty, RN, BSN
Adam Palmer, MPH	Deborah Sod, RN, MPH
Jose Zabala, MHSA	Carol J. Pozsik
Marisa Ramos, PhD	Susan Dicker, RN, MS, MPH
Michael Arbise	Jason Cummins, MPH
Eric Cleghorn	Lorna Will, RN, MA
Kim Do	Kate Penrose, MS
Maureen Murphy, RN, MSN	Blain Mamo, MPH

Information Sources

The appendices at the end of this guide were compiled from the websites of various agencies. Listed below are the sources for the material presented.

Appendix A: Frequently Asked Questions, Technical Instructions

Agency: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Global Migration and Quarantine

Source: <http://www.cdc.gov/immigrantrefugeehealth/exams/ti/panel/tuberculosis-panel-technical-instructions-faq.html>

Date Accessed: July 15, 2011

Appendix B: 1991 vs. 2007 Tuberculosis Technical Instructions

Agency: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Global Migration and Quarantine

Source: <http://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/tuberculosis-guidelines.html>

Date Accessed: July 15, 2011

Appendix D: TB Follow-up Worksheet Glossary

Agency: Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of Tuberculosis Elimination

Source: <http://www.cdc.gov/tb/programs/rvct/ParticipantManual.pdf>, pg. 225

Date Accessed: July 01, 2011

Appendix E: National TB Program Objectives and Performance Targets for 2015

Agency: Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of Tuberculosis Elimination

Source: <http://www.cdc.gov/tb/programs/Evaluation/Indicators/default.htm>

Date Accessed: July 15, 2011

Appendix F: Domestic TB Screening Guidelines

Agency: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Global Migration and Quarantine

Source: <http://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/tuberculosis-guidelines.html>

Date Accessed: July 15, 2011

Appendix G: Privacy Act System Notice 09-20-0103

Agency: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Global Migration and Quarantine

Source: <http://www.cdc.gov/SORNnotice/09-20-0103.htm>

Date Accessed: September 1, 2011

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Introduction to Electronic Disease Notification, Tuberculosis Follow-up Module

Background

The Electronic Disease Notification (EDN) system is a web-based notification system that notifies U.S. health departments of aliens arriving with conditions of public health significance including tuberculosis (TB). EDN manages demographic and health information received from several overseas partners which includes the International Organization for Migration (IOM). EDN disseminates this information to U.S. health departments which can be accessed directly through the EDN website. It is highly recommended that aliens classified overseas with class B TB conditions have domestic medical follow-up evaluations for TB. The primary purpose of domestic TB follow-up is to reduce the risk of TB disease or the possibility of new transmission in the U.S. The TB follow-up module of EDN functions to collect domestic TB follow-up evaluation outcome data from U.S. health departments. Once an evaluation has been completed, U.S. health departments report evaluation and treatment outcomes to CDC.

The Electronic Disease Notification (EDN) is a case-based surveillance system--an organized infrastructure that enables ongoing, systematic collection, management, analysis, interpretation, and dissemination of health-related data. EDN is fully operational and implemented. The system began collecting data on U.S.-bound aliens in 2006.

The objectives of the TB follow-up module of the EDN system are to

- Provide an electronic system to record Department of State (DS) form information and additional supporting documentation
- Electronically notify U.S. health departments of newly arriving refugees and immigrants with TB conditions
- Provide U.S. health departments access to recorded DS form information and all scanned overseas DS forms
- Provide U.S. health departments with an electronic system to record and evaluate the outcome of domestic follow-up
- Inform U.S. health departments of domestic subsequent migration

The purposes of TB follow-up data collection are to

- Monitor and track foreign born persons arriving to the U.S. from overseas with TB class conditions
- Track the progress of U.S. TB control programs towards achieving the National TB Program Objectives and Performance Targets for 2015 through the National TB Indicators Project
- Provide one method of evaluating the efficacy and efficiency of overseas TB diagnosis, treatment, and prevention activities (e.g., '91 and '07 TB Technical Instructions) and panel physician performance
- Conduct analyses approved by NCEZID, DGMQ, IRMHB through "Protocol to Maintain Data Security and Confidentiality for the Electronic Disease Notification System"

Important note: State and local health departments are not required to obtain approval for analyses using their jurisdictional data.

Tuberculosis Follow-up Worksheet

The worksheet is designed to serve as a data collection tool for TB follow-up evaluation outcomes. Each reporting health department should generate one follow-up worksheet per notification and send the worksheet to appropriate parties through either U.S. mail or fax.

Impact of Tuberculosis Follow-up Surveillance Data

Information collected on the worksheet provides essential disease surveillance data for domestic TB control programs. Data will be vital for measuring the efficiency and effectiveness of global TB prevention activities. The TB follow-up worksheet content will be discussed in the guide.

Quality Assurance

Assuring data completeness and quality is strongly encouraged for all TB follow-up reporting. Each reporting jurisdiction is expected to implement measures for reviewing and updating incomplete or incorrect data. These activities should include ensuring that TB follow-up outcome data are collected and entered into EDN accurately.

Although health departments share TB follow-up outcome data with CDC, the responsibility and authority for TB follow-up reporting rests with the health department. States vary in the structure and organization of their surveillance systems, and often in the completeness or quality assurance of their case reporting. As with any reportable disease, the completeness of TB reporting reflects how actively health departments solicit case report information.

Data Entry and Security

Data collected from the TB follow-up worksheet are entered in the software system designated by jurisdictions and then transmitted electronically to CDC through EDN.

Data security is the responsibility of the reporting state or local health department.

Access to TB follow-up worksheets and EDN should be restricted to individuals authorized to perform TB follow-up related duties for aliens. Hard copies should be stored and secured in a locked area. Approved access to any database containing TB follow-up outcome data should be controlled through the use of a local user identification (user ID) and password. All other electronic surveillance files should also be protected with passwords known only to designated surveillance staff.

Patient Confidentiality

The TB follow-up worksheet provides personally identifiable information to U.S. health departments for locating alien arrivals with TB class conditions. Due to the highly confidential nature of TB follow-up data, CDC implements several measures to protect patient privacy that include:

Authorized users: Only authorized users directly involved with TB follow-up examinations for U.S. bound aliens at the state, local or federal level can have access to domestic TB follow-up data. Authorized users at the

federal level include EDN staff, information technology staff, and other partners directly involved in TB follow-up. Authorized users at the state and local level will only have access to records belonging to their jurisdiction.

A database security package is implemented on CDC's mainframe computer to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of the Centers for Disease Control and Prevention (CDC), or its contractors, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.

Secure Network: EDN is accessible only through the secured data network (SDN) connection. SDN is a secure data transfer service offered by CDC. SDN has a highly sophisticated firewall system in place to protect personally identifiable information and provide a high level of data integrity. The server is physically located at the National Center for Health Statistics and is protected under both a Windows firewall system security feature and the CDC firewall. The SDN monitors EDN system 24 hours a day, seven days a week for data redundancy features and disaster recovery features.

Digital Certificates: A digital certificate is required for all EDN users to gain access to the EDN website on the SDN server. The digital certificate must be installed on the user's work computer to provide assurances of their identity every time they log on. Each digital certificate must be renewed on an annual basis. To gain access to EDN, an authorized user must select a challenge phrase. Challenge phrases will be routinely updated.

CDC has provided an Assurance of Confidentiality for the TB follow-up module of EDN. Information on the TB follow-up worksheets that would permit identification of any individual will be held in confidence and will not be released without the consent of the individual, in accordance with section 306 and 308 (d) of the Public Health Services Act (42 U.S.C. 242k and 242m).

Privacy Act

Please see Appendix G entitled *Privacy Act System Notice 09-20-0103* for information regarding the Privacy Act as it applies to EDN.

This section of the TB follow-up guide provides an overview of the TB follow-up worksheet and variable descriptions and purposes.

A. Demographic Information			TB Follow-Up Worksheet		Version 2.0 10/30/2007			
A1. Name (Last, First, Middle)		A2. Alien Number:		A3. Visa Type:		A4. Initial U.S. Entry Date:		
A5. Age:	A6. Gender:	A7. DOB:	A8. TB Class:		A9. Class Condition:			
A10. Country of Examination:			A11. Country of Birth:					
A12. Data Entry Q-Station:		A13. Officer in Charge:		A14. Q-Station Phone:				
A15a. Address:			A16a. Sponsor Agency Name:					
A15b. Phone:			A16b. Sponsor Agency Phone:					
A15c. Other:			A16c. Sponsor Agency Address:					
B. Jurisdictional Information								
B1. Destination State:		B2. Jurisdiction:		B3. Jurisdiction Phone #:				
C. U.S. Evaluation								
C1. Date of Initial U.S. Medical Evaluation:								
C2a. TST Placed:		☐ Yes	☐ No	☐ Unknown				
C2b. TST Placement Date:				C2c. History of Previous Positive TST ☐				
C2d. TST mm:								
C2d. TST Interpretation:		☐ Positive	☐ Negative	☐ Unknown				
C3a. Quantiferon (QFT) Test:		☐ Yes	☐ No	☐ Unknown				
C3b. QFT Collection Date:								
C3c. QFT Result:		☐ Positive	☐ Negative	☐ Indeterminate	☐ Unknown			
U.S. Review of Overseas CXR			Domestic CXR		Comparison			
C4. Overseas CXR Available?			C7. U.S. CXR Done? ☐ Yes ☐ No ☐ Not Verifiable		C11. U.S. CXR Comparison to Overseas CXR:			
☐ Yes ☐ No ☐ Not Verifiable			C8. Date of U.S. CXR		☐ Stable			
C5. U.S. Interpretation of Overseas CXR:			C9. Interpretation of U.S. CXR:		☐ Worsening			
☐ Normal ☐ Abnormal ☐ Poor Quality ☐ Unknown			☐ Normal ☐ Abnormal ☐ Unknown		☐ Improving			
C6. Overseas CXR Abnormal Findings:			C10. U.S. CXR Abnormal Findings:		☐ Unknown			
☐ Abnormal, not TB ☐ Cavity ☐ Fibrosis			☐ Abnormal, not TB ☐ Cavity ☐ Fibrosis					
☐ Infiltrate ☐ Granuloma(s) ☐ Adenopathy			☐ Infiltrate ☐ Granuloma(s) ☐ Adenopathy					
☐ Other (Specify)			☐ Other (Specify)					
C12. U.S. Microscopy/Bacteriology			☐ Specimen not collected in U.S.					
#	Spec Source	Date	AFB Smear Result		Culture Result		Drug Resistance (DR)	
1			☐ Not Done	☐ Positive	☐ Not Done	☐ NTM	☐ Not Done	☐ Mono-RIF
			☐ Negative	☐ Unknown	☐ Negative	☐ Contaminated	☐ No DR	☐ MDR-TB
			☐ Negative	☐ Unknown	☐ MTB Complex	☐ Unknown	☐ Mono-INH	☐ Other DR
2			☐ Not Done	☐ Positive	☐ Not Done	☐ NTM	☐ Not Done	☐ Mono-RIF
			☐ Negative	☐ Unknown	☐ Negative	☐ Contaminated	☐ No DR	☐ MDR-TB
			☐ Negative	☐ Unknown	☐ MTB Complex	☐ Unknown	☐ Mono-INH	☐ Other DR
3			☐ Not Done	☐ Positive	☐ Not Done	☐ NTM	☐ Not Done	☐ Mono-RIF
			☐ Negative	☐ Unknown	☐ Negative	☐ Contaminated	☐ No DR	☐ MDR-TB
			☐ Negative	☐ Unknown	☐ MTB Complex	☐ Unknown	☐ Mono-INH	☐ Other DR

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TB Follow-up Worksheet Overview

Overview

The TB follow-up worksheet includes the seven sections:

1. Section A - Demographic Information
2. Section B - Jurisdictional Information
3. Section C - U.S. Evaluation
 - Tuberculin Skin Test (TST) result section
 - QuantiFERON® result section
 - U.S. Review of Overseas Chest X-ray
 - Domestic CXR
 - Comparison
 - U.S. Microscopy/Bacteriology
 - U.S. Review of Overseas Treatment
4. Section D - Evaluation Disposition
5. Section E - U.S. Treatment
6. Section F - Comments
7. Section G - Screen Site Information

Worksheet Completion End-Points

The TB follow-up worksheet should be completed until an evaluation end-point has been reached. These end-points are recorded in Section D-Evaluation Disposition on the worksheet. Evaluation end points are explained below. End-points are discussed in greater detail on **page 30**.

- 1. Evaluation has been completed and treatment recommendation has been made.**
- 2. Evaluation was initiated but not completed because the patient**
 - a. Moved within U.S.
 - b. Was lost to follow-up
 - c. Returned to county of origin
 - d. Refused evaluation
 - e. Died
 - f. Other
- 3. Evaluation was not initiated because the patient**
 - a. Could not be located
 - b. Moved within U.S.
 - c. Was lost to follow-up
 - d. Returned to country of origin
 - e. Refused evaluation
 - f. Died
 - g. Unknown
 - h. Other

Domestic TB Follow-up Evaluation Goals

Domestic follow-up examination results should be performed in a timely manner. Evaluation goals are discussed in further detail below.

1. Initial medical evaluation should occur within **30 days** of arrival. This initial evaluation often includes a U.S. review of pre-departure medical information and previous treatment, TST or IGRA, domestic CXR, and sputum collection, if indicated.
2. The domestic TB follow-up evaluation should be completed within **90 days** of arrival. This includes comparison of pre-departure and U.S. exam results, results of U.S. Microscopy/Bacteriology, and determination of a disposition.
3. If treatment is recommended for TB disease or LTBI, the treatment start and end dates should be documented in the U.S. Treatment section. Since treatment for TB can take up to nine months on average, the treatment end date should be reported within **one year** of the treatment start date.

Section	Evaluation Goal (<i>within x days of U.S. arrival</i>)
Section C. - U.S. Evaluation	-
Initial U.S. Medical Evaluation (C1. – C3.)	30 days
U.S. Review of Overseas CXR (C4. – C6.)	30 days
Domestic CXR (C7. – C10.)	30 days
Comparison (C11.)	30 days
U.S. Microscopy/Bacteriology (C12.)	<12 weeks
U.S. Review of Overseas Treatment (C13. – C16)	30 days
Section D. - Evaluation Disposition	-
Disposition (D1. – D2.)	90 days
Diagnosis (D3. – D4.)	90 days
Section E. – U .S. Treatment	-
U.S. Treatment Initiated (E1. – E2.)	90 days
U.S. Treatment Completed (E3. – E4.)	<9 months

Reporting

Follow-up examination outcomes should be reported in a timely manner. As soon as results become available, information should be entered into EDN within **five** business days for accurate and speedy reporting.

Worksheet Variable Descriptions and Explanations

The following contains detailed descriptions of each data item located on the TB follow-up worksheet.

Section A: Demographic Information

Section A. Introduction

Section A of the tuberculosis follow-up worksheet contains alien demographic information. This section should have been **pre-populated by the EDN system**. In the event that section A is left blank, enter the following manually: Name, Alien Number (Alien #), and Date of Birth (DOB). This information will be sufficient for EDN purposes. If this form is used by a provider to complete the evaluation, manually completing all the fields in section A may be advantageous.

Alien contact information is located in this section. Additional contact information may have been recorded on the individuals scanned documents by a U.S. quarantine station official.

A. Demographic Information				
A1. Name (Last, First, Middle)		A2. Alien Number:	A3. Visa Type:	A4. Initial U.S. Entry Date:
A5. Age:	A6. Gender:	A7. DOB:	A8. TB Class:	A9. Class Condition:
A10. Country of Examination:			A11. Country of Birth	
A12. Data Entry Q-Station		A13. Officer in Charge		A14. Q-Station Phone:
A15a. Address: A15b. Phone: A15c. Other:			A16a. Sponsor Agency Name: A16b. Sponsor Agency Phone: A16c. Sponsor Agency Address	

Purpose(s): Case Management. Health departments are able to use the available demographic and contact information to locate the new arrival and arrange for the domestic TB evaluation.

	Description	Comment
Name (Last, First, Middle)	Complete name of immigrant or refugee.	
Alien Number	Unique identification number.	
Visa Type	Visa classification of alien as determined by the Department of State. Visa types are explained in Table 2.	I Immigrant P Parolee K1 Fiancé V1 Temporary Spouse or Minor Child R Refugee A Asylee
Initial Entry Date	The date the immigrant or refugee arrived to the U.S., as documented by CDC Quarantine Station or U.S. Bureau of Citizenship.	
Age	Age at the time of U.S. arrival.	This is system calculated by the date of birth and A4 .
Gender-Male, Female (e.g., m, f)	Alien's gender.	
DOB (mm/dd/yyyy)	Alien date of Birth.	

	Description (continued)	Comment (continued)
TB Class	TB Classification as determined by overseas panel physician.	Class A, Class B1, Class B2, Class B3, or B-other.
Class Condition	Indicates that the alien has a reportable condition for which follow-up in the United States is strongly advised. A class condition will fall either in the Class A or Class B category. Class conditions are listed on page 16 .	Without a waiver, applicants for legal permanent residence status in the United States are considered inadmissible if they are found to have one or more of the following health-related conditions listed on page 16 .
Country of Examination	The country in which the alien was examined by a panel physician.	List of country abbreviations is located in Appendix C.
Country of Birth	The birth country of the alien.	List of country abbreviations is located in appendix C.
Data Entry Q-Station	Port where the alien arrived into the U.S. as documented by CDC Quarantine Station Officer in Charge (OIC) for identified port of arrival.	
Officer in Charge	Name of Quarantine OIC who documented the aliens arrival into the U.S. and is in charge of daily activities at the station.	
Q-Station Phone	Phone number of OIC .	
Address, Phone, Other	Other contact information for the quarantine station.	
Sponsor Agency Name, Address, Phone	Sponsor agency contact information.	Refugees often have a sponsoring agency. Immigrants do not.

Table 1. Visa Explanations

Immigrant	An immigrant is a foreign-born person in the United States with permanent resident status.
Asylee and Parolee	An asylee is a foreign-born person in the United States who is unable or unwilling to return to his or her country of nationality because of persecution or a well-founded fear of persecution. An asylee meets the same criteria as those for a refugee; the only difference is the person's location at the time of application –the potential asylee is in the United States or applying for admission at a port of entry, and the potential refugee is outside the United States. A parolee is a foreign-born person allowed to enter the United States for urgent humanitarian reasons or because entry is determined to be of significant public benefit.
Fiancé/Family	The V visa (in the nonimmigrant category) allows the spouse or child of a U.S. legal permanent resident to live and work in the United States. The K visa (in the nonimmigrant category) allows the fiancé of a U.S. citizen to enter the United States for a specific period and specifically for the purpose of marriage.
Refugee	A refugee is a foreign-born person who is in a country other than his or her country of nationality and who is unable or unwilling to return to that country because of persecution or a well-founded fear of persecution.

Table 2. EDN Class Conditions

Class A (From past medical history and physical exam worksheets: DS-2053, DS-2054)

Class A arrivals are uncommon. When a Class A condition is identified during the pre-departure exam, the individual is restricted from travel until the condition is treated or in remission. Once treatment is completed, they are reclassified as a Class B. In unusual circumstances, someone with a Class A condition may be granted a waiver to travel as long as testing indicates they are not contagious and will not expose others while traveling. The expectation is that Class A arrivals seek medical care within 1 week of arrival in the U.S.

- Infectious tuberculosis
- Syphilis, untreated
- Chancroid, untreated
- Gonorrhea, untreated
- Granuloma inguinale, untreated
- Lymphogranuloma venereum, untreated
- Hansen's disease, untreated multibacillary
- Addiction or abuse of specific substance
- Any physical or mental disorder (including other substance-related disorder) with harmful behavior or history of such behavior likely to recur

** HIV was removed from this list in January 2010*

Class B (From past medical history and physical exam worksheets: DS-2053, DS-2054)

Class B conditions are not inadmissible, but represent a significant departure from normal health

- Syphilis (with residual defect) treated within the last year
- Current pregnancy
- Any physical or mental disorder (excluding addiction or abuse of specific substance but including other substance-related disorder) without harmful behavior or history of such behavior unlikely to recur
- Hansen's Disease, treated multibacillary
- Hansen's Disease, paucibacillary
- Sustained, full remission of addiction or abuse of specific substances
- Non-infectious pulmonary tuberculosis
- Non-infectious extrapulmonary tuberculosis
- Latent tuberculosis infection evaluation
- Tuberculosis Contact Evaluation
- Class B Other

Section B: Jurisdictional Information

Section B. Introduction

Section B of the tuberculosis follow-up worksheet contains information indicating the assigned U.S. jurisdiction for the alien. U.S. jurisdiction assignment is based on the immigrant or refugee's self-reported U.S. address. This section is pre-populated by EDN.

Jurisdictional Information	
B1. Destination State:	B2. Jurisdiction: Jurisdiction Phone:

Purpose(s): Notifies U.S. health department of incoming immigrant or refugee with a TB class condition. Provides jurisdiction contact information for local clinicians who provide U.S. medical evaluations for immigrants and refugees with TB class conditions.

	Description	Comment
Destination State	Alien destination state.	
Jurisdiction	Health department responsible for alien U.S. medical evaluation.	

Section C: U.S. Evaluation

Section C. Introduction

The U.S. Evaluation section should be completed by a local health professional in your jurisdiction. U.S. evaluation should be initiated within **30 days** of the alien's arrival date. Data should be reported to CDC in a timely manner.

C. U.S. Evaluation			
C1. Date of Initial U.S. Medical Evaluation: __/__/____			
C2a. TST Placed: ☐ Yes ☐ No C2b. TST Placement Date: __/__/____ C2c. TST mm: _____ C2d. TST Interpretation: ☐ Positive ☐ Negative ☐ Indeterminate ☐ Unknown C2e. History of Previous Positive TST ☐			
C3a. QuantiFERON (QFT) Test: ☐ Yes ☐ No ☐ Unknown C3b. QFT Collection Date: __/__/____ C3c. QFT Result: ☐ Positive ☐ Negative ☐ Indeterminate ☐ Unknown			
U.S. Review of Overseas CXR		Domestic CXR	
C4. Overseas CXR Available ☐ Yes ☐ No ☐ Not Verifiable		C7. U.S. CXR Done? ☐ Yes ☐ No ☐ Not Verifiable C8. Date of U.S. CXR: __/__/____	
C5. U.S. Interpretation of Overseas CXR: ☐ Normal ☐ Abnormal ☐ Poor Quality ☐ Unknown		C9. Interpretation of U.S. CXR: ☐ Normal ☐ Abnormal ☐ Unknown	
C6. Overseas CXR Abnormal Findings: ☐ Abnormal ☐ Cavity ☐ Fibrosis ☐ Infiltrate ☐ Granuloma(ta) ☐ Adenopathy ☐ Other (Specify)		C10. U.S. CXR Abnormal Findings: ☐ Not Applicable ☐ Abnormal ☐ Cavity ☐ Fibrosis ☐ Infiltrate ☐ Granuloma(ta) ☐ Adenopathy ☐ Other (Specify)	
C11. U.S. CZR Comparison to Overseas CXR: ☐ Stable ☐ Worsening ☐ Improving ☐ Unknown			
C12. U.S. Microscopy/Bacteriology ☐ Specimen not collected in the U.S.			
#	Spec Source	Date	AFB Smear Result
1			☐ Not Done ☐ Positive ☐ Negative ☐ Unknown
2			☐ Not Done ☐ Positive ☐ Negative ☐ Unknown
3			☐ Not Done ☐ Positive ☐ Negative ☐ Unknown
Culture Result			
☐ Not Done ☐ NTM ☐ Negative ☐ Contaminated ☐ MTB Complex ☐ Unknown			
Drug Resistance			
☐ Not Done ☐ Mono-Rif ☐ No DR ☐ MDR-TB ☐ Mono-INH ☐ Other DR			
U.S. Review of Overseas Treatment			
C12: Overseas Treatment Recommended by Panel Physician ☐ Yes ☐ No ☐ Unknown		C13: U.S. Review of TB Disease Overseas Treatment: ☐ Yes ☐ No ☐ Unknown If Yes, ☐ Patient-Reported ☐ Panel Physician-Documented ☐ Both	
		C14: Arrived on Treatment ☐ Yes ☐ No ☐ Unknown	C15: Completed Treatment Overseas ☐ Yes ☐ No ☐ Unknown
C16: Overseas Treatment Concerns ☐ Yes ☐ No			

C1. Date of Initial U.S. Medical Evaluation

C1. Date of Initial U.S. Medical Evaluation: __/__/____

Primary Purpose(s): TB program performance measurement indicator. Data are used to determine *if* and *when* the individual first received a diagnostic for tuberculosis and whether the evaluation was initiated within 30 days of U.S. arrival.

	Description	Comment
Date of Initiate U.S. Medical Evaluation (mm/dd/yyyy)	Month, day and year when the medical evaluation for alien was initiated by a U.S. medical provider resulting in initial diagnostic tests or medical assessment.	Does <u>not</u> mean when the health department first contacted the immigrant or refugee.

C2. Tuberculin Skin Test (TST)

C2a. TST Placed:	☐ Yes	☐ No
C2b. TST Placement Date:	__/__/__	
C2c. TST mm:	_____	
C2d. TST Interpretation:	☐ Positive	☐ Negative ☐ Indeterminate ☐ Unknown
C2e. History of Previous Positive TST	☐	

Purpose(s): Case management, surveillance, and TB program performance measurement indicator. This result helps guide clinicians in diagnosing TB infection and is a factor in determining whether the patient's disease meets the public health definition of TB. The TST result is collected for surveillance, TB program performance evaluation, and other analytic purposes.

	Description	Comment
TST Placed - Yes, No	Indicates whether a tuberculin skin test was administered.	
TST Placement Date – Month, Day, Year (e.g., 01/01/2010)	Date that the tuberculin skin test (TST) performed U.S.	Refers to the date the TST was placed , not read.
TST mm	The U.S. TST measurement in approximate millimeters of induration.	
TST Interpretation – Positive, Negative, Indeterminate, Unknown	Interpretation of TST reaction per CDC guidelines.	
History of Previous Positive TST	Medical history of a positive TST result.	Can be confirmed with information from the DS forms and/or by the patient's verbal history.

C3. QuantiFERON® (QFT)

C3a. QuantiFERON® (QFT) Test:	☐ Yes	☐ No	☐ Unknown
C3b. QFT Collection Date:	__/__/__		
C3c. QFT Result:	☐ Positive	☐ Negative	☐ Indeterminate ☐ Unknown

Purpose(s): Case management, surveillance, and TB program performance measurement. This result helps guide clinicians in diagnosing TB infection and is a factor in determining whether the patient's disease meets the public health definition of TB. QFT result is collected for surveillance, TB program performance evaluation, and other analytic purposes.

	Description	Comment
QFT Test – Yes, No	Indicates whether a QFT test performed in the U.S.	If a different brand was used, please indicate the results in this section <u>AND</u> indicate the brand used in the comments section, section F.
QFT Collection Date – Month, Day, Year (e.g., 01/01/2010)	Date QFT was performed in the U.S.	
QFT Result – Positive, Negative, Indeterminate, Unknown	Result of QFT.	If a different brand was used and the a result option is not available (i.e. invalid), please indicate the brand <u>AND</u> the result in the comments section, section F.

C4.-C6. U.S Review of Overseas CXR

U.S. Review of Overseas CXR
C4. Overseas CXR Available ☐ Yes ☐ No ☐ Not Verifiable
C5. U.S. Interpretation of Overseas CXR: ☐ Normal ☐ Abnormal ☐ Poor Quality ☐ Unknown
C6. Overseas CXR Abnormal Findings: ☐ Abnormal ☐ Cavity ☐ Fibrosis ☐ Infiltrate ☐ Granuloma(ta) ☐ Adenopathy ☐ Other (Specify)

Purpose: Performance measurement. Information collected is used to evaluate the accuracy of overseas CXR interpretations made by panel physicians only when an overseas CXR is available for U.S. review. It is also used to compared compare the result U.S. CXR with the overseas CXR to see whether the condition is stable, worsening, or improving.

	Description	Comment
Overseas CXR Available – Yes, No, Unknown, Not Verifiable	Overseas chest X-ray, if physically available.	Please verify that the chest X-ray has both the name and date of birth of the individual. If this is not documented on the X-ray, please indicate “not verifiable.”
U.S. Interpretation of Overseas CXR – Normal, Abnormal, Poor Quality, Unknown	The U.S. clinician’s interpretation of the chest X-ray that was taken overseas by the panel physician.	If no CXR is physically available then indicate “unknown.” Please do not transcribe what was reported on the overseas medical evaluation to complete this section.
Overseas CXR Abnormal Findings – Abnormal, Cavity, Fibrosis, Infiltrate, Granuloma(ta), Adenopathy, Other (Specify)	The U.S clinician’s interpretation of abnormalities found on the overseas CXR. If a U.S. physician interprets the overseas CXR as abnormal, indicate type of abnormality(-ies) reported. Check all that apply.	If no CXR is available, leave this section blank. Please specify other found abnormalities such as miliary in the comments section. Do not transcribe what was reported on the overseas medical evaluation to complete this section.

Domestic CXR
C7. U.S. CXR Done? ☐ Yes ☐ No ☐ Not Verifiable
C8. Date of U.S. CXR: __/__/____
C9. Interpretation of U.S. CXR: ☐ Normal ☐ Abnormal ☐ Unknown
C10. U.S. CXR Abnormal Findings: ☐ Not Applicable ☐ Abnormal ☐ Cavity ☐ Fibrosis ☐ Infiltrate ☐ Granuloma(ta) ☐ Adenopathy ☐ Other (Specify)

Purpose(s): Case management, surveillance, and performance measurement. This information helps guide clinicians in diagnosing TB infection and is a factor in determining whether the patient’s disease meets the public health definition of TB. Information collected will be used to assess a TB program’s performance in initiating and completing medical evaluation.

	Description	Comment
U.S. CXR Done? - Yes, No, Unknown, Not Verifiable	Indicate if CXR was done during U.S. medical evaluation.	A chest X-ray is considered to be “not verifiable” if the name and date of birth is not located on the X-ray film.
Date of U.S. CXR (mm/dd/yyyy)	Date the chest X-ray was taken in the U.S.	If no chest X-ray was taken in the U.S. then leave blank.
U.S. Interpretation U.S. CXR - Normal, Abnormal, Poor Quality, Unknown	Interpretation of the chest X-ray that was taken in the U.S.	The interpretation is considered “unknown” if the CXR or result is not available.
U.S. CXR Abnormal Findings - Abnormal, Cavity, Fibrosis, Infiltrate, Granuloma(ta), Adenopathy, Other (Specify)	Indicate the abnormality (-ies) found in the CXR. Check all that apply.	If chest X-ray was not taken in the U.S. then leave blank. Please specify other found abnormalities such as miliary in the comments section.

C11. Comparison

Comparison
C11. U.S. CXR Comparison to Overseas CXR: ☐ Stable ☐ Worsening ☐ Improving ☐ Unknown

Purpose(s): Management and surveillance. This result helps clinicians see whether a patient's condition is improving or worsening. Data collected will be used for surveillance of the incidence TB disease progression in this population.

	Description	Comment
U.S. CXR Comparison to Overseas CXR Stable, Worsening, Improving, Unknown	Comparison of Overseas chest X-ray findings with U.S. chest X-ray findings.	The section should be completed only if an overseas CXR is physically available and verifiable (the name and date of birth are on the CXR).

C12. U.S. Microscopy/Bacteriology

U.S. Microscopy ☐ Specimen not collected in U.S.							
#	Spec Source	Date	AFB Smear Result	Culture Result	Drug Resistance (DR)		
		__/__/__	☐ Not Done ☐ Positive ☐ Negative ☐ Unknown	☐ Not Done ☐ NTM ☐ Negative ☐ Contaminated ☐ MTB Complex ☐ Unknown	☐ Not Done ☐ Mono-RIF ☐ No DR ☐ MDR-TB ☐ Mono-INH ☐ Other DR		
		__/__/__	☐ Not Done ☐ Positive ☐ Negative ☐ Unknown	☐ Not Done ☐ NTM ☐ Negative ☐ Contaminated ☐ MTB Complex ☐ Unknown	☐ Not Done ☐ Mono-RIF ☐ No DR ☐ MDR-TB ☐ Mono-INH ☐ Other DR		
		__/__/__	☐ Not Done ☐ Positive ☐ Negative ☐ Unknown	☐ Not Done ☐ NTM ☐ Negative ☐ Contaminated ☐ MTB Complex ☐ Unknown	☐ Not Done ☐ Mono-RIF ☐ No DR ☐ MDR-TB ☐ Mono-INH ☐ Other DR		

Purpose(s): Case management and surveillance. Data will be used to assess the incidence of new cases of MDR-TB for pulmonary tuberculosis in this population. These results help guide clinicians in determining the appropriate treatment for those diagnosed with latent TB infection (LTBI) or TB disease.

	Description	Comment
Specimen not collected in U.S.	Specimen was not collected in the U.S.	
Spec Source	Sputum includes spontaneous and induced sputum. Sputum or pulmonary secretions obtained by bronchoscopy procedures or gastric aspiration should also be included. Do NOT include tracheal suction.	Examples of specimen sources include the following: sputum and bronchial washing.
Date (mm/dd/yyyy)	Date of specimen collection.	
AFB Smear Result Not Done, Positive, Negative, Unknown	AFB smear result.	
Culture Result Not Done, NTM, Negative, Contaminated, MTB Complex, Unknown	Sputum culture result.	Not Done Culture not performed
		NTM Non-tuberculosis mycobacteria
		Negative Results were negative for growth of mycobacterium
		Contaminated Sputum culture test for acid-fast bacillus is known to have been contaminated

	Description (continued)	Comment (continued)	
Culture Result (continued) Not Done, NTM, Negative, Contaminated, MTB Complex, Unknown	Sputum culture result. (continued)	MTB	Culture results are positive for growth of mycobacterium tuberculosis complex (<i>M. tuberculosis</i> , <i>M. bovis</i> , <i>M. africanum</i>)
		Unknown	If it NOT known if a sputum smear was performed, or the results are NOT known for a reason other than pending results (e.g., result was lost or no other specimens can be obtained).
Drug Resistance (DR) Not Done, Mono-Rif, No DR, MDR-TB, Mono-INH, Other DR	Indicates the result of drug resistance testing.	Mono-Rif	Any specimen cultures resistant only to Rifampin. Specimen cultures resistant to Rifampin and another drug (except Isoniazid) would be noted under “Other Resistance)
		No DR	Pan susceptible
		MDR-TB	Multiple drug resistant tuberculosis
		Mono-INH	Any specimen cultures resistant only to Isoniazid (regardless of concentration level of resistance). Specimen cultures resistant to Isoniazid and another drug (except Rifampin) would be noted under ‘Other Resistance’
		Other DR	Resistance to drugs or drug combination not listed above. Please record the resistant pattern in Section F: Comments

C13. – C17. U.S. Review of Overseas Treatment

U.S. Review of Overseas Treatment			
C13: Overseas Treatment Recommended by Panel Physician ☐ Yes ☐ No ☐ Unknown	C14: U.S. Review of TB Disease Overseas Treatment: ☐ Yes ☐ No ☐ Unknown If Yes, ☐ Patient-Reported ☐ Panel Physician-Documented ☐ Both	C15: Arrived on Treatment ☐ Yes ☐ No ☐ Unknown	C16: Completed Treatment Overseas ☐ Yes ☐ No ☐ Unknown
C17: Overseas Treatment Concerns		☐ Yes	☐ No

Purpose(s): Case management, evaluation of panel physician, clinical, and surveillance. The results provide clinicians with a method of evaluating a patient's overseas treatment. Provides one method of evaluating overseas panel physician performance. Provides a method of determining what type of TB follow-up is needed.

	Description	Comment
Overseas Treatment Recommended by Panel Physician	Indicates whether a treatment recommendation was made by an overseas panel physician.	Indicate "Yes" if treatment recommendation is documented on the DS forms/medical packet. Indicate "No" if treatment recommendation is NOT documented on the DS forms/medical packet. Indicate "Unknown" if it is NOT known if this information is documented
U.S. Review of TB Disease	Indicates whether overseas treatment was reviewed by U.S. clinician. Also determines whether treatment was documented by the panel physician on DS forms, was patient reported, or was reported by both.	If no overseas treatment was recommended or documented, you may skip C14-C17 and proceed to section D.
Arrived on Treatment	Indicates if the patient arrived on treatment from overseas.	
Completed Treatment Overseas	Indicates whether treatment was completed overseas.	
Overseas Treatment Concerns	Indicates whether the U.S. clinician has concerns regarding the treatment regime prescribed by the overseas panel physician.	If there are concerns, the U.S. clinician should indicate comments in section F.

Section D: Disposition

Section D: Introduction

This section collects information on when an evaluation end-point has been reached. The end points are indicated in D2. (i.e., Completed Evaluation, Initiated Evaluation/Not Completed, Did Not Initiate Evaluation). Once an evaluation end-point has been reached and a treatment recommendation has been made, the evaluation is considered to be completed. The objective is to reach a determination or disposition within 90 days of the individual's arrival date. Once a disposition is reached, (if treatment is initiated or not) this data should be obtained by the appropriate jurisdiction and reported back to EDN in a timely manner.

D. Disposition		
D1. Disposition Date: __/__/____		
D2. Evaluation Disposition:		
☐ Completed Evaluation	☐ Initiated Evaluation/Not Completed	☐ Did Not Initiate Evaluation
☐ Treatment Recommended ☐ No Treatment Recommended	☐ Moved within U.S. ☐ Lost to Follow-up ☐ Returned to Country of Origin ☐ Refused Evaluation ☐ Died ☐ Other, specify	☐ Not Located ☐ Moved within U.S. ☐ Lost to Follow-Up ☐ Returned to Country of Origin ☐ Refused Evaluation ☐ Died ☐ Unknown ☐ Other, specify
D3. Diagnosis ☐ Class 0 – no TB exposure, not infected ☐ Class 1 – TB exposure, no evidence of infection ☐ Class 2 – TB infection, no disease ☐ Class 3 – TB, active disease ☐ Pulmonary ☐ Extra-pulmonary ☐ Both Sites ☐ Class 4 – TB, inactive disease		
D4. ☐ RVCT Reported		D5. RVCT#:

D1.-D2. Disposition Date and Evaluation Disposition

D1. Disposition Date: __/__/____		
D2. Evaluation Disposition:		
☐ Completed Evaluation	☐ Initiated Evaluation/Not Completed	☐ Did Not Initiate Evaluation
☐ Treatment Recommended ☐ No Treatment Recommended	☐ Moved within U.S. ☐ Lost to Follow-up ☐ Returned to Country of Origin ☐ Refused Evaluation ☐ Died ☐ Other, specify	☐ Not Located ☐ Moved within U.S. ☐ Lost to Follow-Up ☐ Returned to Country of Origin ☐ Refused Evaluation ☐ Died ☐ Unknown ☐ Other, specify

Purpose(s): Case management, TB program performance measurement indicator, surveillance. Determines whether an evaluation end-point has been appropriately reached for case management and performance measurement. Provides information of the number of immigrant and refugees who are recommended treatment for either LTBI or TB disease for surveillance.

	Description	Comment
Disposition Date	Date in which an evaluation end point has been reached.	
Evaluation Disposition Completed Evaluation: Treatment Recommended, No Treatment Recommended Initiated Evaluation/Not Completed: Moved within U.S., Lost to Follow-up, Returned to Country of Origin, Refused Evaluation, Died, Other, specify Did Not Initiate Evaluation: Not located, Moved within U.S., Lost to Follow-up, Returned to Country of Origin, Refused Evaluation, Died, Unknown, Other, specify	Please see descriptions and comments on page 30 .	

		Description	Comments
Evaluation End Points	Completed Evaluation	The domestic evaluation has been completed and has led to a final diagnosis.	
	Treatment Recommended	Treatment is recommended by clinician.	If treatment is recommended, Section E. (U.S. treatment) should be completed.
	No Treatment Recommended	Treatment is not recommended by the clinician.	If treatment is not recommended, Section E. (U.S. treatment) should not be completed.

		Description	Comments
Evaluation End Points	Initiated Evaluation/Not Completed	The alien was located, and evaluation was initiated, but the evaluation was not completed because	
	Moved within U.S.	the alien moved to another jurisdiction before completed the evaluation.	Initial jurisdiction can provide locating information for the new jurisdiction.
	Lost to Follow-up	the alien failed to return to complete the evaluation.	Initial jurisdiction CANNOT provide locating information.
	Returned to Country of Origin	it is known the alien returned to their country of origin prior to completion of the evaluation.	
	Refused Evaluation	alien refused to complete evaluation.	
	Died	alien died prior to completing the U.S. evaluation .	
	Other, specify	reasons other than those stated previously did not allow for the evaluation to be completed.	Specify the reason for “Not Completed”, in the form’s comments section (Section F.).

		Description	Comments
Evaluation End-Points	Did Not Initiate Evaluation	Evaluation was not initiated.	
	Not Located	alien could not be located.	
	Moved within U.S.	alien was located, an evaluation was NOT initiated because I/R moved to another jurisdiction before initiating the evaluation.	Initial jurisdiction is able to provide locating information for the new jurisdiction.
	Lost to Follow-Up	alien was located but an evaluation was NOT initiated.	Initial jurisdiction cannot provide locating information.
	Returned to Country of Origin	alien was located but an evaluation was NOT initiated and it is known the I/R returned to their country of origin, prior to initiation of the evaluation.	
	Refused Evaluation	alien was located but an evaluation was NOT initiated because of I/R refusal.	
	Died	alien was located but an evaluation was NOT initiated due to death.	
	Unknown	unknown reasons.	
	Other, specify	alien was located but an evaluation was NOT initiated due to other reasons.	Other reasons should be specified in the comments section.

D3. Diagnosis

The diagnosis section of the worksheet collects information on the patient's domestic TB diagnosis.

- D3. Diagnosis**
- ☐ Class 0 – no TB exposure, not infected
 - ☐ Class 1 – TB exposure, no evidence of infection
 - ☐ Class 2 – TB infection, no disease
 - ☐ Class 3 – TB, active disease
 - ☐ Pulmonary ☐ Extra-pulmonary ☐ Both Sites
 - ☐ Class 4 – TB, inactive disease

Purpose(s): Management and surveillance. Data is used track TB diagnoses.

Classification of Persons Exposed to and/or Infected with M. tuberculosis	Description	Comments
Class 0	No TB Exposure	- Negative reaction to tuberculin skin test or IGRA - No history of exposure
Class 1: TB exposure, no evidence of infection	Exposure to TB but not latent TB infection	- Negative reaction to tuberculin skin test or IGRA - No evidence of infection. - History of exposure to tuberculosis but negative reaction to the tuberculin skin test
Class 2: TB infection, no disease	Latent TB Infection (LTBI)	- Positive reaction to the tuberculin skin test - Negative microscopy/bacteriology results - No clinical or radiographic evidence of tuberculosis
Class 3: TB, active disease	Active TB disease	- Clinically active tuberculosis - Person must have clinical and/or radiologic evidence of tuberculosis - Established most definitively by isolation of M. tuberculosis - In absence for a positive culture for M. tuberculosis, persons in this class must have a positive reaction to the tuberculin test - Class 3 is further defined as pulmonary, extra-pulmonary, both sites on the follow-up form.

Classification of Persons Exposed to and/or Infected with <i>M. tuberculosis</i>	Description <i>(continued)</i>	Comments <i>(continued)</i>
Class 4: Tuberculosis, inactive disease	Old, healed, inactive TB disease	• History of previous episode(s) of tuberculosis or abnormal stable radiographic findings • Positive reaction to tuberculin skin test • Negative microscopy/bacteriology • No clinical and/or radiographic evidence of current disease

Source:

<http://wonder.cdc.gov/wonder/prevguid/p0000425/p0000425.asp#head007000000000000>

Note:

The Class 5 TB Suspect category is intentionally left out of EDN TB follow-up reporting. The goal is to capture the complete follow-up: diagnostic, disposition, treatment. Allowing for Class 5 TB suspect as an end-point would not allow CDC to collect information on alien treatment.

Section E: U.S. Treatment

Section E. Introduction

Section E. collects information on domestic TB treatment. Section E. should only be filled out if treatment was recommended for an individual with a Class 2, 3, or 4 classifications.

U.S. Treatment	
E1: U.S. Treatment Initiated: ____/____/____ ☐ No Treatment ☐ Active Disease ☐ LTBI ☐ Unknown	E2: U.S. Treatment Start Date: _____ E3. U.S. Treatment Completed ☐ Yes ☐ No E4. U.S. Treatment End Date: ____/____/____

Purpose(s): TB program performance measurement indicator and surveillance. Determines the initiation and completion rates of treatment for those diagnosed with LTBI and TB disease for both surveillance and program performance monitoring.

	Description	Comment
U.S. Treatment Initiated	Indicates whether treatment was initiated in the U.S.	If patient refused treatment, indicate “no treatment.
U.S. Treatment Start Date (mm/dd/yyyy)	Date U.S. treatment was initiated.	If “no treatment” was indicated in E1, leave the rest of section E. blank.
U.S. Treatment Completed	Indicates whether U.S. treatment was <u>completed</u> .	
U.S. Treatment End Date	Indicates the date where U.S. treatment was ended regardless of treatment completion.	If treatment was not completed, please indicate the end date in the comments section.

Section F: Comments

Section F. Introduction

Section F is the comments section of the TB follow-up worksheet. Please include any important medical or patient outcome information or clarifications that could not be captured in other sections of the worksheet here.

F. Comments

Purpose(s): Section contains all items that needed to be specified on the worksheet.

	Description	Comment
Comments	Comments section.	Use this section to specify which brand of IGRA was used, and to add any other comments you deem important.

Section G: Screen Site Information

Section G. Introduction

Section G contains information about where the immigrant or refugee was evaluated. EDN does not collect the physician's signature.

G. Screen Site Information:

Provider's Name:

Clinic Name:

Telephone Number:

Physician's Signature:

Date (mm/dd/yyyy):

Purpose(s): Information collected in this section provides health departments a means to contact the health care providers for additional or missing information

	Description	Comment
Providers Name	The name of the provider who performed U.S. medical evaluation.	
Clinic Name	The name of the clinic the patient was evaluated.	
Telephone Number	Clinic phone number.	
Physicians Signature	The physician's signature.	This is not required for EDN data entry.
Date (mm/dd/yyyy)	The date this worksheet was completed.	

Appendix A: Frequently Asked Questions, Technical Instructions

2007 Tuberculosis Technical Instructions Frequently Asked Questions (FAQ)

Please visit the following website in order to see up to date FAQ's regarding 2007 Technical Instructions.
<http://www.cdc.gov/immigrantrefugeehealth/exams/ti/panel/tuberculosis-panel-technical-instructions-faq.html>

What are the tuberculosis (TB) Technical Instructions?

HHS/CDC regulations require that all aliens coming to the United States be screened for tuberculosis (TB). CDC's Division of Global Migration and Quarantine (DGMQ) develops requirements for TB testing and treatment of immigrants and refugees that are called Technical Instructions.

Why are there different sets of TB Technical Instructions?

The TB Technical Instructions developed in 1991 were based on the best screening tests and treatment known at that time. The TB Technical Instructions were updated in 2007 to use newer, more precise tests to reduce the chance of bringing TB into the United States and improve the health of aliens through earlier diagnosis and updated methods of treatment.

How are the 2007 TB Technical Instructions being implemented?

CDC is working to apply the 2007 TB Technical Instructions to all countries and implements them according to a number of factors. The order of implementation is based on a country's number of immigrants coming to the United States, the number of refugees resettling to the United States, the health care resources in the country, the rates of TB in the country, and the rate of TB in immigrant groups in the United States.

How do the 1991 TB Technical Instructions screen for TB?

The 1991 TB Technical Instructions call for a chest X-ray and, if the chest radiograph suggests active TB, three sputum samples (i.e., a small amount of mucus from deep in the lungs) to determine if immigrants or refugees have TB. The sputum sample is looked at by a lab to see if TB bacteria are present.

What was updated in the 2007 TB Technical Instructions?

CDC updated the TB guidelines in 2007 to make testing more precise by requiring cultures for immigrant applicants thought to have TB. A culture test involves putting a sputum sample (i.e., a small amount of mucus from deep in the lungs) in a petri dish to see if TB bacteria grow. Drug susceptibility testing (DST) on positive TB cultures was added to see which drugs would be likely to kill the type of TB found. Another update is the addition of directly observed therapy (DOT). Treatment must be completed before arrival in the United States and medical staff must observe patients in person as they swallow each dose of TB medication.

How do the 2007 TB Technical Instructions affect the TB evaluation in children?

To help detect TB in children, the 2007 TB Technical Instructions require that children aged 2 through 14 years undergo a test for cell-mediated immunity (TB skin test or interferon gamma release assay) if they are medically screened in countries where the TB rate is 20 cases or more per 100,000 population. If the skin test is positive, a chest X-ray is required. If the chest X-ray suggests TB, three cultures and three sputum smears are required.

For a sputum smear, a small amount of mucus is collected from deep in the lungs (sputum), smeared on a slide, and viewed under a microscope to look for TB bacteria. A culture involves putting a sputum sample (i.e., a small amount of mucus from deep in the lungs) in a petri dish to see if TB bacteria grows.

Do the requirements of the TB Technical Instructions apply to children from other countries who are being adopted by U.S. citizens?

Yes. The TB Technical Instructions apply to immigrant medical screening. Children from other countries who are being adopted by U.S. citizens are applying for U.S. entry as immigrants. They, therefore, must undergo the required immigrant TB examination, according to CDC's Technical Instructions.

How has CDC revised the tuberculosis (TB) Technical Instructions for children aged 10 and younger?

Now children aged 10 and younger with a positive TB skin test can travel as long as other TB tests do not suggest that they are likely to spread the disease to others.

All immigrants and refugees applying for a U.S. immigrant visa must complete a medical exam. This exam includes screening for TB. If an applicant has a positive TB skin test, a chest X-ray is performed. If the chest radiograph suggest TB, three sputum samples are taken to do further testing. Sputum samples are used in smear and culture tests, which are very useful in detecting TB. Although, smear tests can be done quickly, they are less accurate than cultures. Cultures take 6-8 weeks before results are final.

Immigrant applicants over age 10 cannot travel to the United States until these culture results are ready. But, for children age 10 and younger, the process is now slightly different. Typically, young children are not infectious (able to spread TB). However, even in young children, if certain factors are present care should be taken to decrease the risk of spreading TB to others. Therefore, children age 10 and younger must wait until culture results are ready if they have any of the following:

- Positive sputum smears
- A chest X-ray that shows
 - One or more cavities, or
 - Widespread TB disease in the lungs (especially in the upper area of the lungs)
- A forceful and productive cough
- Contact with a person who has multidrug-resistant tuberculosis (MDR TB) who could have spread TB at the time of contact

Sometimes children cannot provide sputum samples. In these cases, a special procedure is done to collect fluid from the stomach for smear and culture tests. This procedure is known as gastric aspiration. Children age 10 and younger who have positive smears after this procedure can still travel to the United States before cultures are ready.

Why do these instructions only apply only to children age 10 and younger?

It is rare that children age 10 and younger can spread TB to others. Children over age 10 are more likely to have TB that can be easily spread to others.

Since children age 10 and younger are less likely to spread TB to others, they do not pose a major public health risk. Thus, CDC will now allow immigrant applicants in this young age group to travel to the United States after sputum has been collected, if they do not show signs that they are infectious (or, that they can spread TB to others).

What does the term “cavities” refer to in the Technical Instructions?

Cavities are hollow spaces within the lungs that may contain TB bacteria. They can be seen on a chest radiograph and are often found in people with severe TB disease. These people are typically very infectious (meaning that they are able to spread TB to others).

If an immigrant applicant age 10 or younger is found to have cavities in the lungs, he or she is likely infectious. Thus, the child must wait for the medical screening to be complete before the immigration process can be completed. This includes waiting for sputum culture results, which take 6-8 weeks.

How does CDC know if a child age 10 and younger has a “forceful and productive cough?”

During the medical exam, a panel physician will check a patient’s health in a number of ways. If a patient is coughing, a panel physician will determine if that cough is forceful and productive. Children who have a forceful or productive cough are better able to spread TB to others through their coughing. Patients who have a positive skin test, a chest radiograph that shows signs of TB, and a cough that is forceful and productive may have more severe TB disease. Thus, any immigrant applicant with these signs and symptoms must wait until cultures are complete before traveling to the United States or receiving a U.S. immigrant visa. The culture process takes 6-8 weeks.

If the results from cultures are positive before a child (age 10 and younger) leaves for the United States, can the child still leave?

If cultures come back positive before a child leaves for the United States, the child needs to begin TB treatment in the country of origin. However, a waiver can be filed through the U.S. consulate for a child with positive cultures. If the waiver request is granted by the U.S. Department of Homeland Security, the child may be able to travel to the United States before treatment is finished. For more information on the waiver process, please see: DHS Waiver Information. <http://www.uscis.gov/portal/site/uscis/menuitem>

What countries are using the 2007 Technical Instructions?

As of August 2011, a list of countries using the 2007 Technical Instructions is indicated on **page 39**. To view the latest updated list of countries please visit the following website:

<http://www.cdc.gov/immigrantrefugeehealth/exams/ti/panel/tuberculosis-implemementation.html>

Country	Population	Start date
Bangladesh	All applicants	June 15, 2011
Botswana	All applicants	March 3, 2008
Cambodia	All applicants	February 1, 2010
China	All applicants	July 1, 2009
Dominican Republic	All applicants	February 2, 2009
Egypt	All applicants	November 15, 2009
Ethiopia	Refugees (Eritreans)	March 10, 2009
	All applicants	April 1, 2009
Ghana	All applicants	October 1, 2010
Guatemala	All applicants	May 2, 2011
Haiti	All applicants	September 26, 2009
Hong Kong SAR	All applicants	November 3, 2008
India	All applicants	October 1, 2010
Japan	All applicants	June 1, 2009
Jordan	All applicants	April 5, 2009
Kenya	Refugees (includes Ethiopians, Somalis, and Sudanese)	January 1, 2008
	All applicants	April 1, 2009
Lesotho	All applicants	March 3, 2008
Macau SAR	All applicants	November 3, 2008
Malaysia	Refugees (Burmese)	January 1, 2009
Mexico	All applicants	October 1, 2007
Mozambique	All applicants	March 3, 2008
Namibia	All applicants	March 3, 2008
Nepal	Refugees (Bhutanese)	December 13, 2007
	All applicants	August 2, 2010
Nigeria	All applicants	October 1, 2010
Philippines	All applicants	October 1, 2007
South Africa	All applicants	March 3, 2008
South Korea	All applicants	May 2, 2011
Swaziland	All applicants	March 3, 2008
Taiwan	All applicants	April 1, 2009

Source

CDC,. "2007 Tuberculosis Technical Instructions Frequently Asked Questions." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 19 Jan 2010. Web. 15 Jun 2011. <<http://www.cdc.gov/immigrantrefugeehealth/exams/ti/panel/tuberculosis-panel-technical-instructions-faq.html>>.

Appendix B: 1991 vs. 2007 Tuberculosis Technical Instructions

CDC's Division of Global Migration and Quarantine (DGMQ) has regulatory authority to establish the requirements for tuberculosis control among applicants for U.S. immigrants. These requirements are called technical instructions. The table below summarizes the differences between the 1991 and 2007 TB technical instructions. This table is available online through the Division of Global Migration and Quarantine website. <http://www.cdc.gov/ncezid/dgmq/>

Category	1991	2007
CXR	Persons ≥ 15 years: PA; < 15 years: in specific circumstances Front and lateral views in children	Required for all applicants ≥ 15 years. Applicants < 15 years undergo CXR if they have a TST ≥ 10 mm or a positive IFRA (when required based on estimated TB incidence rate in country of origin) or have signs and symptoms suggestive of TB, or HIV infection. Frontal and lateral views in children < 10 years of age.
TST or IGRA	TST: not routine, used infrequently in specific circumstances; IGRA: not used	All applicants 2-14 years of age living in countries with a WHO-estimated incidence rate of ≥ 20 per 100,000. All applicants who are contacts of a known TB case.
Tuberculosis (TB) laboratory screening	Persons ≥ 15 years with CXR and/or symptoms suggestive of active disease: AFB smears x 3, or Children < 15 years of age who are contacts, have history of TB disease, or signs or symptoms: AFB smears x 3	Persons with TB symptoms, abnormal physical examination, or CXR suggestive of TB disease, or who are HIV positive: • Sputum for AFB smears x 3 and for TB cultures x 3, & • Drug susceptibility testing (DST) on positive cultures (for persons who cannot produce sputum: specimen collection by other means such as induced sputum or gastric aspirates).
Initial patient management prior to laboratory results	Not applicable	Consider treatment for other lower respiratory infection (no fluoroquinolones) if applicable.
Management of persons with positive TST or IGRA	Not applicable	Applicants 2-14 years of age or contacts who have a TST ≥ 10 mm or a positive IGRA, but who otherwise have a negative evaluation for TB, will be classified for U.S. follow-up as Class 2 B2 TB, LTBI Evaluation, with TST results and treatment status documented.
TB treatment and management	TB treatment outdated, and minimal guidance for drug-resistant TB	Treating physicians should follow ATS/CDC/IDSA guidelines. Directly observed therapy (DOT) should be implemented for treatment of pulmonary and extrapulmonary TB. For drug-resistant patients, refer also to written guidance from the Francis J. Curry National Tuberculosis Center and California Department of Health Services, 2005: Drug-Resistant Tuberculosis: A Survival Guide for Clinicians; MDR TB expert consultations and CDC consultations recommended. Treatment of drug-resistant and MDR TB should be done by or in close consultation with experts in the management of such cases and in coordination with the Division of Global Migration and Quarantine (DGMQ). Identification of applicants with MDR TB should be reported to DGMQ.
Sources of TB drugs	Source not specified	Quality-assured drugs: WHO Global Drug Facility for first-line drugs and International Dispensary Association and WHO Green Light Committee for second-line drugs.

Category	1991	2007
Laboratory monitoring during TB treatment	No monitoring after AFB smear becomes negative	Drug susceptible, drug resistant (but no MDR) TB: two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture once a month during therapy until cultures are negative for 2 consecutive months. MDR TB: two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture once a month during therapy. No drug-susceptibility testing results (culture negative): one sputum specimen should be collected and submitted for AFB microscopy
Laboratory monitoring after TB treatment	Not applicable	All applicants are to have two sputum specimens collected and submitted for AFB microscopy and mycobacteria culture at the end of therapy. Applicants may not be cleared unless results are negative.
Management of known TB contact	Not applicable	All contacts should receive a TST or IGRA. If the TST is ≥ 5mm or IGRA is positive, the contact should be further evaluated with medical history, physical examination, and CXR. If the contact is not started on LTBI therapy, he or she should receive an evaluation with medical history, physical examination, and CXR every 3 months until departure. If the TST is <5 mm, or the IGRA is negative, and the contact is not placed on prophylaxis, the TST or IFRA should be repeated every 3 months until ≥ 8 weeks after contact ends, the index case has negative sputums smears for 3 consecutive months, or TST become ≥ 5 mm or IGRA becomes positive. Children <4 years of age and applicants with impaired immunity who are contacts of a known TB case (that is not isoniazid resistant) and who have a negative evaluation for TB disease, should begin directly observed preventive therapy (DOPT) regardless of TST or IGRA results. Preventive therapy may be discontinued if TST is <5mm or IFRA is negative 8 weeks after conclusion of exposure to the infectious case. Contacts cleared for travel should receive a Class B3 TB, Contact Evaluation classification.
Validity of TB screening examination	12 months if normal; 6 months if Class A condition of Class B1 or B2 TB condition	6 months if no TB classification or only Class B2 TB or Class B3 TB. 3 months if Class B1 TB, Pulmonary or Class B1 TB, Extrapulmonary
Pre-departure clearance examination	Not applicable	Additions screening immediately prior to departure (pre-departure evaluation) may be required in the event of an outbreak of TB disease or in the setting of extremely elevated rates of TB disease. CDC will inform panel physicians and Consulates when this additional screening is required. When required, pre-departure screening would occur within 3 weeks of departure for all applications with findings suggestive of TB disease on medical history, physical examination, or CXR but with negative sputum smears and negative cultures. Pre-departure screening would consist of medical history, physical exam, CXR, and at least 3 sputum smears for AFB microscopy (cultures not required).

Category	1991	2007
Information transfer to CDC and state and local public health departments	Paper: DS medical forms travel with refugees and immigrants and are processed at port of entry and CDC headquarters	Paper: DS medical forms and additional information on TB treatment travel with applicants and are processed at port of entry and CDC headquarters. Electronic data transfer of DS medical forms, including TB screening, diagnosis and treatment, when available. Class A and B1 cases reported to U.S. Embassy upon detection. Panel physician are required to make 3 copies of all DS forms for all refugees and for immigrants with Class A conditions or any Class B TB condition.

Appendix C: Country Codes

Birth Country	Country Name	Region
AC	ANTIGUA AND BARBUDA	Caribbean
AF	AFGHANISTAN	Near East
AG	ALGERIA	North Africa
AJ	AZERBAIJAN	USSR/Former Soviet Union
AL	ALBANIA	Eastern Europe
AM	ARMENIA	USSR/Former Soviet Union
AN	ANDORRA	Western Europe
AO	ANGOLA	Southern Africa
AQ	AMERICAN SAMOA	Pacific
AR	ARGENTINA	South America
AS	AUSTRALIA	Austral Asia
AT	ASHMORE AND CARTIER ISL	Pacific
AU	AUSTRIA	Western Europe
AV	ANGUILLA	Caribbean
AY	ANTARCTICA	Pacific
BA	BAHRAIN	Middle East
BB	BARBADOS	Caribbean
BC	BOTSWANA	Southern Africa
BD	BERMUDA	North America
BE	BELGIUM	Western Europe
BF	BAHAMAS, THE	Caribbean
BG	BANGLADESH	Central Asia
BH	BELIZE	Central America
BK	BOSNIA AND HERCEGOVINA	Eastern Europe
BL	BOLIVIA	South America
BM	BURMA, MYANMAR	East Asia
BN	BENIN	West Africa
BO	BELARUS	USSR/Former Soviet Union
BP	SOLOMON ISLANDS	Pacific
BQ	NAVASSA ISLAND	Caribbean
BR	BRAZIL	South America
BS	BASSAS DA INDIA	Southern Africa
BT	BHUTAN	Central Asia
BU	BULGARIA	Eastern Europe
BV	BOUVET ISLAND	Southern Africa
BX	BRUNEI	East Asia
BY	BURUNDI	Central Africa
CA	CANADA	North America
CB	CAMBODIA	East Asia
CD	CHAD	Central Africa
CE	SRI LANKA	Central Asia
CF	CONGO	Central Africa
CG	DEMOCRATIC REPUBLIC OF THE CONGO	Central Africa

CH	CHINA	East Asia
CI	CHILE	South America
CJ	CAYMAN ISLANDS	Caribbean
CK	COCOS (KEELING) ISLANDS	Pacific
CM	CAMEROON	Central Africa
CN	COMOROS	Southern Africa
CO	COLOMBIA	South America
CQ	NORTHERN MARIANA ISLANDS	Pacific
CR	CORAL SEA ISLANDS	Pacific
CS	COSTA RICA	Central America
CT	CENTRAL AFRICAN REPUBLIC	Central Africa
CU	CUBA	Caribbean
CV	CAPE VERDE	West Africa
CW	COOK ISLANDS	Pacific
CY	CYPRUS	Middle East
CZ	CZECHOSLOVAKIA (OLD)	Eastern Europe
DA	DENMARK	Western Europe
DJ	DJIBOUTI	East Africa
DO	DOMINICA	Caribbean
DQ	JARVIS ISLAND	Pacific
DR	DOMINICAN REPUBLIC	Caribbean
EC	ECUADOR	South America
EG	EGYPT	North Africa
EI	IRELAND	Western Europe
EK	EQUATORIAL GUINEA	Central Africa
EN	ESTONIA	USSR/Former Soviet Union
ER	ERITREA	East Africa
ES	EL SALVADOR	Central America
ET	ETHIOPIA	East Africa
EU	EUROPA ISLAND	Southern Africa
EZ	CZECH REPUBLIC	Eastern Europe
FG	FRENCH GUIANA	South America
FI	FINLAND	Western Europe
FJ	FIJI	Pacific
FK	FALKLAND (IS MALVINAS)	South America
FM	FED STATES MICRONESIA	Pacific
FO	FAROE ISLANDS	Western Europe
FP	FRENCH POLYNESIA	Pacific
FQ	BAKER ISLAND	Pacific
FR	FRANCE	Western Europe
FS	SOUTHERN OCEAN & ANTARCTIC LANDS	East Asia
GA	GAMBIA, THE	West Africa
GB	GABON	Central Africa
GG	GEORGIA	USSR/Former Soviet Union
GH	GHANA	West Africa
GI	GIBRALTAR	Western Europe
GJ	GRENADA	Caribbean
GK	GUERNSEY	Western Europe
GL	GREENLAND	Western Europe

GM	GERMANY	Western Europe
GO	GLORIOSO ISLANDS	Southern Africa
GP	GUADELOUPE	Caribbean
GQ	GUAM	Pacific
GR	GREECE	Eastern Europe
GT	GUATEMALA	Central America
GV	GUINEA	West Africa
GY	GUYANA	South America
GZ	GAZA STRIP	Middle East
HA	HAITI	Caribbean
HK	HONG KONG	East Asia
HM	HEARD ISLAND & MCDONALD ISLANDS	South Africa
HO	HONDURAS	Central America
HQ	HOWLAND ISLAND	Pacific
HR	CROATIA	Eastern Europe
HU	HUNGARY	Eastern Europe
IC	ICELAND	Western Europe
ID	INDONESIA	East Asia
IM	MAN, ISLE OF	Western Europe
IN	INDIA	Central Asia
IO	BRITISH INDIAN OCEAN TERRITORY	Southern Africa
IP	CLIPPERTON ISLAND	Latin America
IR	IRAN	Near Asia
IS	ISRAEL	Middle East
IT	ITALY	Western Europe
IV	IVORY COAST	West Africa
IZ	IRAQ	Middle East
JA	JAPAN	East Asia
JE	JERSEY	Western Europe
JM	JAMAICA	Caribbean
JN	JAN MAYEN	Western Europe
JO	JORDAN	Middle East
JQ	JOHNSTON ATOLL	Pacific
JS	JERUSALEM	Middle East
JU	JUAN DE NOVA ISLAND	Southern Africa
KE	KENYA	East Africa
KG	KYRGYZSTAN	USSR/Former Soviet Union
KN	KOREA, DEMOCRATIC PEOPLE'S REPUBLIC	East Asia
KQ	KINGMAN REEF	Pacific
KR	KIRIBATI	Pacific
KS	KOREA, REPUBLIC OF	East Asia
KT	CHRISTMAS ISLAND	Pacific
KU	KUWAIT	Middle East
KZ	KAZAKHSTAN	USSR/Former Soviet Union
LA	LAOS	East Asia
LE	LEBANON	Middle East
LG	LATVIA	USSR/Former Soviet Union
LH	LITHUANIA	USSR/Former Soviet Union

LI	LIBERIA	West Africa
LO	SLOVAK REPUBLIC	Eastern Europe
LQ	PALMYRA ATOLL	Pacific
LS	LIECHTENSTEIN	Western Europe
LT	LESOTHO	Southern Africa
LU	LUXEMBOURG	Western Europe
LY	LIBYA	North Africa
MA	MADAGASCAR	South Africa
MB	MARTINIQUE	Caribbean
MC	MACAU	East Asia
MD	MOLDOVA	USSR/Former Soviet Union
MF	MAYOTTE	Southern Africa
MG	MONGOLIA	Central Asia
MH	MONTERRAT	Caribbean
MI	MALAWI	Central Africa
MK	MACEDONIA	Eastern Europe
ML	MALI	West Africa
MN	MONACO	Western Europe
MO	MOROCCO	North Africa
MP	MAURITIUS	Southern Africa
MQ	MIDWAY ISLAND	Pacific
MR	MAURITANIA	West Africa
MT	MALTA	Western Europe
MU	OMAN	Middle East
MV	MALDIVES	Central Asia
MW	MONTENEGRO	Eastern Europe
MX	MEXICO	Central America
MY	MALAYSIA	East Asia
MZ	MOZAMBIQUE	Southern Africa
NC	NEW CALEDONIA	Australasia
NE	NIUE	Pacific
NF	NORFOLK ISLAND	Pacific
NG	NIGER	West Africa
NH	VANUATU	Pacific
NI	NIGERIA	West Africa
NL	NETHERLANDS	Western Europe
NO	NORWAY	Western Europe
NP	NEPAL	Central Asia
NR	NAURU	Pacific
NS	SURINAME	South America
NT	NETHERLANDS ANTILLES	Caribbean
NU	NICARAGUA	Central America
NZ	NEW ZEALAND	Australasia
PA	PARAGUAY	South America
PC	PITCAIRN ISLANDS	Pacific
PE	PERU	South America
PF	PARACEL ISLANDS	East Asia
PG	SPRATLY ISLANDS	East Asia
PK	PAKISTAN	Near Asia

PL	POLAND	Eastern Europe
PM	PANAMA	Central America
PO	PORTUGAL	Western Europe
PP	PAPUA NEW GUINEA	Australasia Asia
PS	TRUST TERR OF PACIFIC	Pacific
PT	PORTUGUESE TIMOR	Pacific
PU	GUINEA-BISSAU	West Africa
QA	QATAR	Middle East
RE	REUNION	South Africa
RM	MARSHALL ISLANDS	Pacific
RO	ROMANIA	Eastern Europe
RP	PHILIPPINES	Pacific
RQ	PUERTO RICO	Caribbean
RS	RUSSIA	USSR/Former Soviet Union
RW	RWANDA	Central Africa
SA	SAUDI ARABIA	Middle East
SB	ST. PIERRE AND MIQUELON	North America
SC	ST. KITTS AND NEVIS	Caribbean
SE	SEYCHELLES	Southern Africa
SF	SOUTH AFRICA	Southern Africa
SG	SENEGAL	West Africa
SH	ST. HELENA	Southern Africa
SI	SLOVENIA	Eastern Europe
SL	SIERRA LEONE	West Africa
SM	SAN MARINO	Western Europe
SN	SINGAPORE	East Asia
SO	SOMALIA	East Africa
SP	SPAIN	Western Europe
SR	SERBIA	Eastern Europe
ST	ST LUCIA	Caribbean
SU	SUDAN	North Africa
SV	SVALBARD	Western Europe
SW	SWEDEN	Western Europe
SX	S. GEORGIA/S.SANDWICH ISLANDS	Latin America
SY	SYRIA	Middle East
SZ	SWITZERLAND	Western Europe
TC	UNITED ARAB EMIRATES	Middle East
TD	TRINIDAD AND TOBAGO	Caribbean
TE	TROMELIN ISLAND	Southern Africa
TH	THAILAND	East Asia
TI	TAJIKISTAN	USSR/Former Soviet Union
TK	TURKS AND CAICOS ISLANDS	Caribbean
TL	TOKELAU	Pacific
TN	TONGA	Pacific
TO	TOGO	West Africa
TP	SAO TOME AND PRINCIPE	Central Africa
TS	TUNISIA	North Africa
TU	TURKEY	Near Asia
TV	TUVALU	Pacific

TW	TAIWAN	East Asia
TX	TURKMENISTAN	USSR/Former Soviet Union
TZ	TANZANIA, UNITED REPUBLIC OF	East Africa
UG	UGANDA	Central Africa
UK	UNITED KINGDOM	Western Europe
UM	U.S. MINOR OUTLYING ISLANDS	Pacific
UP	UKRAINE	USSR/Former Soviet Union
UR	U.S.S.R. (OLD)	USSR/Former Soviet Union
UV	BURKINA FASO	West Africa
UY	URUGUAY	South America
UZ	UZBEKISTAN	Eastern Europe
VC	ST. VINCENT/GRENADINES	Caribbean
VE	VENEZUELA	South America
VI	BRITISH VIRGIN ISLANDS	Caribbean
VM	VIETNAM	East Asia
VQ	VIRGIN ISLANDS	Caribbean
VT	VATICAN CITY	Western Europe
WA	NAMIBIA	Southern Africa
WE	WEST BANK	Middle East
WF	WALLIS AND FUTUNA	Pacific
WI	WESTERN SAHARA	North Africa
WQ	WAKE ISLAND	Pacific
WS	WESTERN SAMOA	Pacific
WZ	SWAZILAND	Southern Africa
YM	YEMEN	Middle East
YU	YUGOSLAVIA (OLD)	Eastern Europe
ZA	ZAMBIA	Southern Africa
ZI	ZIMBABWE	Southern Africa
ZZ	UNKNOWN	Uncertain
US	USA	North America
MM	BURMA	East Asia

Appendix D: TB Worksheet Glossary

Term	Definition
Acid-fast bacilli (AFB)	Microorganisms that, when stained, retain color even after they have been washed in an acid solution; may be detected under a microscope in a stained smear
Active TB disease	An illness caused by bacteria called <i>Mycobacterium tuberculosis</i> , in which tuberculosis (TB) bacteria are multiplying and attacking parts of the body, most commonly the lungs. A person with active TB disease is capable of spreading the disease to others if the TB bacteria are active in the lungs or throat. The symptoms of active TB include weakness, weight loss, fever, no appetite, chills, and sweating at night. Other symptoms may include a bad cough, pain in the chest, and coughing up blood.
Case management	A system in which a specific health department employee is assigned primary responsibility for a patient, must conduct a systematic regular review of the patient's progress, and must address any barriers to the patient's adherence to treatment.
Cavity	A hollow space within the lung, visible on a chest X-ray or CT scan
Clinical evaluation	An evaluation done to find out whether a patient has symptoms of TB disease or is responding to treatment; also done to check for adverse reaction to TB medications
Clinician	A physician, physician's assistant, or nurse
Country of birth	The country where a person was born
Culture	To grow organisms on media (substances containing nutrients) so that they or the product of this process can be identified
Diagnostic evaluation	An evaluation used to diagnose TB disease; includes a medical history, a chest X-ray, the collection of specimens for bacteriologic examination, and possibly a tuberculin skin test or an interferon-gamma release assay such as the QuantiFERON®-TB Gold Test
Drug resistance drug susceptibility test.	A laboratory method for finding drug resistance in microorganisms
Drug-resistant TB	TB caused by organisms that are able to grow in the presence of particular drug; TB that is resistant to at least one first-line antituberculosis drug
Ethambutol (EMB)	A drug used to treat TB disease; may cause vision problems. Ethambutol should be used cautiously in children who are too young to be monitored for changes in their vision.

Extrapulmonary TB	TB disease that occurs in places other than the lungs, such as the lymph nodes, the pleura, the brain, the kidneys, or the bones; most types of extrapulmonary TB are not infectious
Interferon-gamma (IFN- γ)	Protein that is normally produced by the body in response to infection
Interferon-gamma release assay	A type of blood test that measures a person's immune reactivity to <i>M. tuberculosis</i> by measuring release of IFN- γ . In the U.S., QuantiFERON [®] -TB Gold, QuantiFERON [®] -TB Gold In-Tube, and T-SPOT [®] are examples of this kind of test.
Isoniazid (INH)	A drug that is used for treating LTBI and one of the drugs used to treat TB disease; although relatively safe, it may cause hepatitis and other severe adverse reaction in some patients
Latent TB infection (LTBI)	Refers to the condition when a person is infected with tubercle bacilli, but TB disease has not developed. Persons with LTBI do not have TB disease symptoms and they cannot spread TB germs to others. Persons with LTBI usually have a positive result to the Mantoux tuberculin skin test or an interferon-gamma release assay.
LTBI treatment	Medication that is given to people who have latent TB infection to prevent them from developing TB disease
Mantoux Tuberculin skin test (TST)	A method of testing for TB infection; a needle and syringe are used to inject 0.1 mL of 5 tuberculin units of liquid tuberculin between the layers of the skin (intradermally), usually on the forearm; the reaction to this test, a palpable swollen area (induration), is measured 48 to 72 hours after the injection and is interpreted as positive or negative depending on the size of the reaction and the patient's risk factors for TB
Multidrug-resistant TB (MDR TB)	Resistant to at least the drugs isoniazid and rifampin, MDR TB is more difficult to treat than drug-susceptible TB
<i>Mycobacterium tuberculosis</i>	One of the organisms that causes TB in humans, and sometimes called the tubercle bacillus; belongs to a group of bacteria called mycobacteria
<i>Mycobacterium tuberculosis</i> complex	A group of closely related mycobacteria that can cause active TB (e.g., <i>M. tuberculosis</i> , <i>M. bovis</i> , and <i>M. africanum</i>). Most TB in the United States is caused by <i>M. tuberculosis</i> .
Pulmonary TB	TB disease that occurs in the lungs, typically causing a cough and an abnormal chest X-ray. Pulmonary TB is usually infectious if untreated. Most TB cases reported in the United States are pulmonary TB.
Rifampin	A drug used to treat TB disease; also used for LTBI

	treatment. Rifampin has several possible side effects (for example, hepatitis, turning body fluids orange, and drug interactions).
Report of Verified Case of Tuberculosis (RVCT)	The national tuberculosis (TB) surveillance data reporting form. All jurisdictions report these data to CDC on each newly reported case of TB. The results are used for determining the TB morbidity case rates for the United States, U.S. territories, U.S. island areas and U.S. outlying areas.
Smear	A specimen that has been smeared onto a glass slide, stained, washing in an acid solution, and then placed under the microscope for examination; used to detect acid-fast bacilli in a specimen
Specimen	A sample collected from a person for testing
Sputum	Phlegm from deep in the lungs, collected in a sterile container for processing and examination
Susceptibility	An organism's ability to be killed by a particular drug

Appendix E: National TB Program Objectives and Performance Targets for 2015

The table below summarizes the National TB Program Objective and Performance Targets for 2015. Areas that directly involve the EDN TB follow-up module are highlighted in green.

Objective Categories	Objectives and Performance Targets
1. Completion of Treatment	For patients with newly diagnosed TB for whom 12 months or less of treatment is indicated, increase the proportion of patients who complete treatment within 12 months to 93.0%.
2. TB Case Rates - U.S.-born Persons - Foreign-born Persons - U.S.-born Non-Hispanic Blacks - Children Younger than 5 Years of Age	Decrease the TB case rate in U.S.-born persons to fewer than 0.7 cases per 100,000. * Increase the average yearly decline in TB case rate in U.S.-born persons to at least 11.0%. Decrease the TB case rate for foreign-born persons to less than 14.0 cases per 100,000. * Increase the average yearly decline in TB case rate in foreign-born persons to at least 4.0%. Decrease the TB case rate in U.S.-born non-Hispanic blacks to less than 1.3 cases per 100,000. Decrease the TB case rate for children younger than 5 years of age to less than 0.4 cases per 100,000.
3. Contact Investigation - Contact Elicitation - Evaluation - Treatment Initiation - Treatment Completion	Increase the proportion of TB patients with positive acid-fast bacillus (AFB) sputum-smear results who have contacts elicited to 100.0%. Increase the proportion of contacts to sputum AFB smear-positive TB patients who are evaluated for infection and disease to 93.0%. Increase the proportion of contacts to sputum AFB smear-positive TB patients with newly diagnosed latent TB infection (LTBI) who start treatment to 88.0%. For contacts to sputum AFB smear-positive TB patients who start treatment for newly diagnosed LTBI, increase the proportion who complete treatment to 79.0%.
4. Laboratory Reporting - Turnaround Time - Drug-susceptibility Result	Increase the proportion of culture-positive or nucleic acid amplification (NAA) test-positive TB cases with a pleural or respiratory site of disease that have the identification of <i>M. tuberculosis</i> complex reported by laboratory within N days from the date the initial diagnostic pleural or respiratory specimen was collected to n%. Increase the proportion of culture-positive TB cases with initial drug-susceptibility results reported to 100.0%.

5. Treatment Initiation	Increase the proportion of TB patients with positive AFB sputum-smear results who initiate treatment within 7 days of specimen collection to n%.
6. Sputum Culture Conversion	Increase the proportion of TB patients with positive sputum culture results who have documented conversion to sputum culture-negative within 60 days of treatment initiation to 61.5%.
7. Data Reporting • RVCT • ARPEs • EDN	Increase the completeness of each core Report of Verified Case of Tuberculosis (RVCT) data item reported to CDC, as described in the TB Cooperative Agreement announcement, to 99.2%. Increase the completeness of each core Aggregated Reports of Program Evaluation (ARPEs) data items reported to CDC, as described in the TB Cooperative Agreement announcement, to 100.0%. Increase the completeness of each core Electronic Disease Notification (EDN) system data item reported to CDC, as described in the TB Cooperative Agreements announcement, to n%.
8. Recommended Initial Therapy	Increase the proportion of patients who are started on the recommended initial 4-drug regimen when suspected of having TB disease to 93.4%.
9. Universal Genotyping	Increase the proportion of culture-confirmed TB cases with a genotyping result reported to 94.0%.
10. Known HIV Status	Increase the proportion of TB cases with positive or negative HIV test result reported to 88.7%.
11. Evaluation of Immigrants and Refugees • Evaluation Initiation • Evaluation Completion • Treatment Initiation • Treatment Completion	For immigrants and refugees with abnormal chest X-rays read overseas as consistent with TB, increase the proportion who initiate medical evaluation within 30 days of arrival to n%. For immigrants and refugees with abnormal chest X-rays read overseas as consistent with TB, increase the proportion who complete medical evaluation within 90 days of arrival to n%. For immigrants and refugees with abnormal chest X-rays read overseas as consistent with TB and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S., increase the proportion who start treatment to n%. For immigrants and refugees with abnormal chest X-rays read overseas as consistent with TB, and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S. and started on treatment, increase the proportion who complete LTBI treatment to n%.
12. Sputum-culture Reported	Increase the proportion of TB cases with a pleural or respiratory site of disease in patients ages 12 years or older that have a sputum-culture result reported to 95.7%.
13. Program Evaluation	Increase program evaluation activities by monitoring program progress and tracking evaluation status of cooperative agreement recipients.

• Evaluation Focal Point	Increase the percent of cooperative agreement recipients that have an evaluation focal point
14. Human Resource Development Plan	Increase the percent of cooperative agreement recipients who submit a program-specific human resource development plan (HRD), as outlined in the TB Cooperative Agreement announcement, to 100.0%. Increase the percent of cooperative agreement recipients who submit a yearly update of progress-to-date on HRD activities to 100.0%.
15. Training Focal Point	Increase the percent of cooperative agreement recipients that have a TB training focal point.

Appendix F: Domestic TB Screening Guidelines

Guidelines for Screening for Tuberculosis Infection and Disease during the Domestic Medical Examination for Newly Arrived Refugees

Background

Tuberculosis (TB) rates in the United States have continued to decline, reaching their lowest point on record in 2007 (1). Although TB is decreasing overall in the United States, there is a disproportional increase in TB in foreign-born individuals. For example, in 2007, the TB rate among foreign-born persons in the United States was 9.7 times that of U.S.-born persons (1). In cities that are home to many newly arriving immigrants and refugees, rates of TB can be well above the national average. Additionally, the prevalence of drug-resistant TB and extrapulmonary disease is higher among foreign-born persons, making the diagnosis and management of these cases both challenging and essential for effective prevention and control of TB among newly arriving refugees (2). The rate of TB disease appears to remain high for many years after immigration, making it essential that clinicians identify and treat latent tuberculosis infection (LTBI) prior to the development of TB disease. In addition, because of the high rate of reactivation, healthcare providers who serve immigrants and refugees should maintain a high index of suspicion, regardless of the results of medical examinations performed overseas (3).

This document provides an overview of the overseas medical screening process for refugees relocating to the United States, and outlines guidelines for clinicians evaluating refugees for TB during the medical examination for new arrivals. This document does not replace existing guidelines but is meant to highlight specific needs in refugees and should augment and be used in conjunction with existing guidelines from national authorities (ATS/CDC/IDSA) and state TB control programs.

Overview of Overseas Pre-departure Tuberculosis Screening for Refugees

Prior to departure for the United States, all refugees receive an overseas medical examination. This examination is to identify individuals with conditions that, by law, necessitate exclusion from, or treatment before departure for, the United States. CDC stipulates the content of this examination through Technical Instructions (TIs) issued to panel physicians and organizations that perform the medical screening examinations. The TB TIs issued in 1991 were revised in 2007 (4). The TB TIs are being implemented in priority countries on a rolling basis, as determined by factors such as refugee volume and burden of tuberculosis disease. Current requirements for specific countries, date of implementation for each country, and a comparison of the 1991 and 2007 TIs are listed in Appendix B. Updates can be found at: <http://www.cdc.gov/immigrantrefugeehealth/exams/ti/panel/tuberculosis-panel-technical-instructions.html>.

Panel physicians provide information on screening and treatment results. This information accompanies the refugee and should be available to the evaluating provider in the United States. In addition, the information is provided through the Electronic Disease Notification (EDN) system to individual state health departments. If the evaluating provider in the United States is not receiving this information, the state refugee health program should be contacted for guidance. This information should always include screening information, as well as any diagnostic procedures and treatment rendered, including such data as:

- Pre-resettlement medical screening evaluations.
- Pre-departure screening evaluations (screening performed within 3 weeks of departure, which includes a medical examination, chest radiograph, and three sputum smears for culture and AFB). These requirements are applied when CDC determines that the risk of importation of tuberculosis is great enough to warrant these efforts for specific populations. As such, they are not applied to all refugees.
 - Pre-departure tuberculosis classifications [Appendix. B]
 - Testing for TB infection documentation
 - Tuberculin skin test documentation (including name of product, expiration date, amount administered, and type of product used, such as 5TU PPD-S or 2TU of RT 23)
 - OR
 - IGRA test documentation, if used.
 - Chest radiograph findings, when performed for screening
- Pre-departure treatment information
 - Directly observed therapy (DOT) regimen received, including doses of all medications, start and completion dates, and periods of interruption.
- Chest radiograph findings before, during, and after treatment.
- Laboratory results
 - Sputum smear AFB microscopy results obtained before, during, and after treatment.
 - Cultures for mycobacteria obtained before, during, and after treatment, including any that were contaminated.
 - Drug susceptibility test results performed on any positive culture.
- Clinical course, including such information as clinical improvement or lack of improvement during and after treatment.

Domestic Refugee Screening for Tuberculosis

The primary goal of the domestic refugee medical screening evaluation for TB is to identify individuals with latent TB infection (LTBI) or TB disease, to facilitate timely treatment and control. Individuals with LTBI or disease, and contacts of known cases of disease should be treated according to U.S. standards of care (www.cdc.gov/nchstp/tb/pubs/mmwrhtml/Maj_guide/Treatment.htm). Cases of confirmed or suspected TB disease must be reported to appropriate authorities (i.e., state or local health department) for monitoring and further public health intervention, such as contact investigation. Some areas may also require reporting of individuals with latent TB infection.

Medical History and Physical Examination of Refugees for Tuberculosis During the Domestic Medical Screening Evaluation

Tuberculosis disease should infrequently be encountered during the domestic refugee medical screening evaluation but, when identified, it may represent primary pulmonary or extrapulmonary disease (Appendix A). Patients with TB disease may be minimally symptomatic, particularly those with extrapulmonary disease. In fact, some individuals with tuberculosis disease, particularly children, may be asymptomatic. Others may deny symptoms due to cultural issues, fears, or other concerns.

Symptoms of pulmonary tuberculosis are often indolent and include malaise, weight loss, night sweats, cough, pleuritic chest pain, fever, and hemoptysis. Symptoms of extrapulmonary disease generally reflect the organ involved (e.g., abdominal pain with gastrointestinal TB). Although extrapulmonary TB can be found in virtually any organ of the body, statistically, lymphadenopathy is the most commonly identified extrapulmonary manifestation. Symptoms may also be nonspecific, such as failure to thrive in children.

All pre-departure medical records for the refugee should be closely reviewed. A thorough medical history must be obtained. In addition to current signs or symptoms of disease (e.g., weight loss, night sweats, fever, cough), specific information may be helpful in identifying a person at higher risk of tuberculosis disease or latent tuberculosis infection:

- Previous history of TB
- Illness suggestive of TB (e.g., cough >3 weeks, dyspnea, weight loss, fever, night sweats or hemoptysis)
- Prior treatment suggestive of TB treatment
- Prior diagnostic evaluation suggestive of TB
- Family or household contact with a person who currently has or had TB disease, treatment, or diagnostic evaluation suggestive of TB

In addition, in children, a history of recurrent pneumonias, failure to thrive, or recurrent or persistent fevers should increase the provider's index of suspicion. Providers should keep in mind that children experience higher rates of extrapulmonary TB disease, including meningitis, and disease of the middle ear and mastoid, lymph nodes, bones, joints, and skin.

The physical examination should include height, weight, temperature, respiratory rate, blood pressure, thorough pulmonary examination, and inspection and palpation of all major palpable lymph node beds (see history and physical examination guidance document: www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/guidelines-history-physical.html). In addition, a careful skin examination is important, as it may reveal cutaneous disease, scars from scrofula or bacille Calmette-Guérin (BCG) vaccination, or hints of prior chest surgery that may alert the clinician.

Testing Newly Arrived Refugees for Tuberculosis Infection and Disease

Screening Tests

Screening can be performed by using one of two modalities: the Mantoux tuberculin skin test (TST) or an interferon-gamma release assay (IGRA) for *Mycobacterium tuberculosis* (Figure 1). Currently, the QuantiFERON®-TB Gold In-tube Test (QFT-G) and T-Spot are two approved IGRAs in the United States. Either the TST or an IGRA should be performed during the domestic refugee medical screening examination, unless overseas testing results are available. There is no reason to repeat a TST if a documented previous positive TST result is available. The TST should be repeated if no documentation of a result (in mm induration) is available; however, if the refugee reports a history of a previous severe reaction to a TST (e.g. blistering, ulceration), repeating the TST is contraindicated.

Skin Testing

Interpreting the results of the TST depends on the patient's risk factors (Table 1). In otherwise healthy refugees from areas of the world where TB is common, >10-mm induration is considered positive. A cutoff of >5-mm induration is considered positive in persons with HIV infection, those with recent close contact with a known case of infectious TB, persons with fibrotic changes in chest radiogram consistent with prior TB, persons with organ transplants, and other immuno-suppressed persons. Many refugees from TB-endemic areas will have been vaccinated against TB with BCG vaccine. Although previous BCG may influence the results of the TST, especially in infants, a history of vaccination with BCG should not influence interpretation of the TST. The clinician must provide a thorough explanation to the patient of the reasons for not considering the BCG in the interpretation of the test. A positive result by TST demands further evaluation to exclude TB disease (Figure 1).

TST testing can be performed in all persons, including children and pregnant women. False-negative results may be more frequent in young children and in persons with a compromised immune system. False negatives also

may occur more commonly in persons at high-risk for TB (a high pre-test probability). A TST should be administered and read by a trained health-care provider. For additional information about performing a TST, visit <http://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm>.

IGRA

The interferon-gamma release assays (IGRAs) utilize *M. tuberculosis* complex-specific antigens to stimulate patient T- lymphocytes. Importantly, IGRAs do not cross react with antigens related to the *M. tuberculosis* BCG. Sensitized cells, in someone previously exposed to *M. tuberculosis*, will produce the cytokine interferon (IFN)- γ . The QFT-Gold test and third-generation QFT Gold in-tube test (Cellestis, Victoria, Australia) are based on the quantification of IFN- γ produced by T-lymphocytes in whole blood stimulated by *M. tuberculosis* complex-specific antigens (e.g. ESAT-6, CFP-10 and TB7.7). The T-Spot TB Test (Oxford Immunotec, Marlborough, MA) measures the number of T-lymphocytes producing IFN- γ when stimulated by *M. tuberculosis* complex-specific antigens. IGRAs are being increasingly used by physicians and health departments for evaluation of tuberculosis infection. Clinicians should perform and interpret these tests as recommended in national guidelines (5). It should be noted that these tests are currently not recommended in those <5 years of age (5). A positive result by an IGRA (indicating infection with the TB mycobacterium) demands further evaluation to exclude TB disease (Figure 2).

Diagnostic Evaluation

Chest Radiography: A chest radiograph should be performed for all refugees with a positive TST or IGRA test, either prior to immigration or on domestic refugee medical screening; a previous history of tuberculosis disease, including those with a Class A or B TB designation from an overseas examination; or symptoms consistent with TB disease, regardless of TST or IGRA results. A negative TST and/or IGRA does not eliminate TB disease from the differential diagnosis of a symptomatic patient. Pregnant women with a positive TST or IGRA should have a shielded chest radiograph. If the pregnant woman is asymptomatic and in the first trimester of pregnancy, the chest radiograph may be postponed until the second trimester. A posterior-anterior (PA) radiogram should be performed. In addition to the PA, a lateral radiograph is recommended in young children less than 11 years of age, since one of the most common findings is hilar adenopathy, which is poorly visualized on a PA film.

Specimen collection and mycobacterial culture: In the event that a refugee is symptomatic and/or has chest radiogram findings or physical findings (such as lymphadenopathy) suggestive of TB disease, attempts should be made to collect specimens for acid-fast smear (AFB) and mycobacterial culture. If pulmonary disease is suspected, three sputum samples should be collected at least 8-24 hours apart, with at least one being an early morning specimen. In addition, current CDC guidelines recommend nucleic acid amplification testing be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities (6). Sputa should be induced in persons unable to expectorate spontaneously. Specimens should be collected in either a well-ventilated area or a sputum collection booth or room with negative pressure. Collection of early morning specimens is preferred because of the overnight accumulation of secretions. Sputum should be collected under direct observation. This is to ensure that the patient is being properly coached and is giving a good coughing effort, as well as to ensure that uncooperative patients are producing their own sputum for examination. Children are often unable to expectorate voluntarily, so gastric aspirates or hypertonic saline-induced sputum may need to be obtained in lieu of a standard sputum sample. Children frequently must be hospitalized to collect adequate samples. Since diagnosis and management of children can be very challenging, consultation with an experienced and knowledgeable expert in pediatric TB is encouraged.

In the setting of suspected extrapulmonary disease, consideration should be given to obtaining one or more specimens of body fluid or tissue of the suspected site of disease if this can be done with an acceptable risk of complications. In general if there are multiple options for obtaining a specimen, the least invasive method should be used first (e.g., obtaining urine before performing a renal biopsy). Because of the increased risk for drug-resistant TB among many refugees, strong efforts should be made to obtain adequate specimens for AFB culture, so that drug-

susceptibility testing may be performed. At least one culture-positive specimen from each patient should have conventional drug-susceptibility testing. Rapid drug-susceptibility testing of positive culture isolates can be obtained from CDC after consultation with the state health department and may be particularly useful in some circumstances (e.g., suspect MDR, or history of previous treatment). In addition, some state health department laboratories offer rapid drug-susceptibility testing of direct specimens from patients who are at high risk for drug resistance.

Summary of Diagnostic Classifications

Diagnosis is based on the results of the clinical evaluation, chest radiograph, screening tests, and overseas exam. All refugees will meet one of the following categories.

Latent TB Infection, No Disease

Asymptomatic refugee with a positive TST or QFT-G and a negative chest radiograph and physical examination. Refugee should be offered treatment for LTBI if not previously treated for TB disease or LTBI and no contraindications to LTBI treatment. CDC guidelines for LTBI treatment and monitoring should be followed (7).

TB, Not Clinically Active:

- **Old, healed, not previously treated TB**

Asymptomatic refugee with a chest radiograph that indicates old, healed, no TB disease (stable chest radiogram) and no history of having received previous TB treatment. Refugee should be offered treatment for LTBI as above.

- **Old, healed, previously treated TB**

A refugee with no current clinical symptoms who has a chest radiograph that has findings consistent with old/healed TB who has a documented history of receiving treatment for TB in accordance with current ATS/IDSA/CDC guidelines. No treatment needed.

Suspect or Confirmed TB disease

Screening results indicate suspected or confirmed TB disease. The results may include a combination of a positive TST or QFT-G, abnormal chest radiograph or CT scan, pathology findings consistent with TB disease (e.g., caseating granuloma), signs and symptoms consistent with either pulmonary or extrapulmonary disease, and sputum or tissue smear positive for AFB or a culture positive for *M. tuberculosis*. Immediate follow-up is needed for definitive diagnosis and treatment. All suspect or confirmed cases (pulmonary or extrapulmonary) should be reported to the local health authorities within 24 hours of determination so that appropriate public health measures can be implemented. Cases of suspect TB disease should be reported promptly—do not wait for culture confirmation to report suspected TB disease. When pulmonary or laryngeal TB is suspected, the patient should be isolated in an appropriate setting to prevent spread of infection until his or her infectious potential is evaluated.

Overview of Treatment

All treatment should be administered in accordance with the ATS/CDC/IDSA guidelines for treatment of TB: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>.

Latent Tuberculosis Infection (LTBI)

Standard treatment for latent TB consists of oral isoniazid (INH) for 9 months for all ages. If INH is contraindicated alternative regimens are available at <http://www.cdc.gov/tb/publications/LTBI/treatment.htm>. When the patient is using INH, unless he or she has underlying medical conditions that increase his or her risk of liver problems, there is no need to check baseline liver function tests (LFTs). However, baseline laboratory testing in patients whose initial evaluation suggests a liver disorder is indicated. Baseline hepatic measurements include serum aspartate aminotransferase (serum glutamic oxaloacetic transaminase) (AST [SGOT]) or alanine aminotransferase (serum glutamic pyruvic transaminase) (AST [SGPT]) and bilirubin. Baseline testing is also indicated for patients with HIV infection, pregnant women, and women in the immediate postpartum period (i.e., within 3 months of delivery), persons with chronic liver disease (e.g. hepatitis B or C, alcoholic hepatitis, or cirrhosis), persons who use alcohol regularly, and persons at risk for chronic liver disease. For patients who do need liver testing, treatment should be discontinued if a) liver function tests rise to 3 times the upper limit of normal if there are signs and symptoms of hepatitis, or b) if LFTs rise to 5 times the upper limit of normal if asymptomatic. DOT may be prudent for children less than 5 years of age who are close contacts of persons with TB disease. For dosing and monitoring guidelines, please see the national LTBI treatment guidelines at www.cdc.gov/mmwr/PDF/rr/rr4906.pdf and for special considerations see www.cdc.gov/tb/publications/LTBI/treatment.htm.

Tuberculosis Disease

National treatment guidelines state that a provider who is treating a patient with TB disease is assuming a public health function that includes not only prescribing an appropriate regimen but also ensuring adherence to the regimen until treatment is completed. TB disease should be treated in consultation with the public health department and a medical expert in the treatment of TB. All patients with TB disease should receive therapy under DOT.

References

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6. Centers for Disease Control and Prevention (CDC). Updated guidelines for the use of nucleic acid amplification tests in the diagnosis of tuberculosis. *MMWR Morb Mortal Wkly Rep* 2009;58(1):7-10.
7. Targeted tuberculin testing and treatment of latent tuberculosis infection. American Thoracic Society. *MMWR Recomm Rep* 2000;49(RR-6):1-51.

Table 1. TST Testing Interpretation Guidelines for Refugees

Induration of ≥ 5 mm is considered positive in

- Refugees with HIV
- Refugees known to have been recently in close contact with someone with infectious TB
- Refugees with changes on chest X-ray consistent with prior TB
- Refugees with organ transplants and other immunosuppressed patients

Induration of ≥ 10 mm is considered positive in

- All other refugees

Sources of Additional Information: Additional information regarding screening of refugees for tuberculosis and other infectious diseases can be obtained by visiting the CDC website at <http://www.cdc.gov/nceid/dgmq/> or at the WHO website at <http://www.who.int/tb/surveillanceworkshop/>

Summary of Primary Pulmonary and Reactivation Tuberculosis

Primary pulmonary tuberculosis: Adults with primary pulmonary TB classically present with fever, extensive pulmonary infiltrates, and hypoxia. This presentation should be uncommon during the domestic refugee medical screening examination, since the overseas medical examination should prevent those with TB disease from traveling. However, children and immunocompromised hosts may not have these classic symptoms or radiograph findings of TB. Therefore, special attention should be paid when evaluating these populations. Children, in particular, may have very subtle findings on chest radiogram and may be asymptomatic despite having TB disease. They may also present with such symptoms as malaise, failure to thrive or weight loss, or a history of recurrent pneumonias.

Reactivation TB (post-primary tuberculosis): Reactivation of tuberculosis is the clinical scenario most likely to be encountered during a refugee screening exam. Reactivation of disease often manifests years after initial infection and may either be pulmonary or extrapulmonary. Progression from TB infection to disease is more likely to occur in older persons or those with comorbid conditions, including malnutrition, immunocompromised states (HIV, malignancy, diabetes mellitus, immunosuppressant medications), substance abuse and in those who smoke tobacco. Other factors common in refugees that may increase the risk of reactivation include stress (e.g., stress of immigration) and vitamin D deficiency.

Glossary of Abbreviations

ATS American Thoracic Society
BCG bacille Calmette-Guérin
CDC Centers for Disease Control and Prevention, United States
CXR Chest radiograph
DGMQ Division of Global Migration and Quarantine
DOT Directly observed therapy
DTBE Division of Tuberculosis Elimination
FDA U.S. Food and Drug Administration
EDN Electronic disease notification
HIV Human immunodeficiency virus

IDSA Infectious Diseases Society of America
IGRA Interferon-gamma release assays
LTBI Latent tuberculosis infection
MDR TB Multidrug-resistant tuberculosis
PPD Purified protein derivative
TB Tuberculosis
TI Technical instructions
TU Tuberculin units
TST Tuberculin skin test
QFT QuantiFERON® test
WHO World Health Organization

Appendix G: Privacy Act System Notice 09-20-0103

System name: Alien Tuberculosis Follow-up Program. HHS/CDC/NCEZID.

Security classification: None.

System location: Office of the Director, Division of Global Migration and Quarantine, National Center for Emerging and Zoonotic Infectious Diseases, Corporate Square, Bldg. 10, Rm. 1209, Centers for Disease Control and Prevention.

Categories of individuals covered by the system: Immigrant and refugee aliens with tuberculosis.

Categories of records in the system: Medical history.

Authority for maintenance of the system: Public Health Service Act, Section 325, “Examination of Aliens” (42 U.S.C. 252); and the Immigration and Nationality Act, Section 212(g), “Application for Waiver of Grounds of Inadmissibility” (8 U.S.C. 1182(g)).

Purpose(s): To provide a record system for the surveillance and periodic medical evaluation of immigrant aliens with tuberculosis.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Disclosure may be made to state health departments, city health departments or the courts, private physicians, or other healthcare facilities that will provide medical care for the immigrant alien.

Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

In the event of litigation where the defendant is: (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Department of Justice has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual’s mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

Records may be disclosed by CDC in connection with public health activities to the Social Security Administration for sources of locating information to accomplish the research or program purposes for which the records were collected.

CDC is authorized to share information on aliens with the Social Security Administration to determine eligibility for benefits, pursuant to Section 1631 (e) of the Social Security Act as amended by Public Law 103-296, or as otherwise provided for in the Social Security Act.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage: Card files and computer tapes/disks and printouts.

Retrievability: Records are retrieved by name, Alien Registration Number, and by year of birth.

Safeguards:

1. Authorized Users: A database security package is implemented on CDC's mainframe computer to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of the Centers for Disease Control and Prevention (CDC), or its contractors, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.
2. Physical Safeguards: Access to the CDC Clifton Road facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric keypad) system. Access to the data entry area is also controlled by a cardkey system. The hard copy records are kept in locked cabinets in locked rooms. The local fire department is located nearby. The computer room is protected by an automatic sprinkler system, automatic sensors (e.g., water, heat, smoke, etc.) are installed, and portable fire extinguishers are located throughout the computer room. The system is backed up on a nightly basis with copies of the files stored off site in a secure fireproof safe. The 24-hour guard service in buildings provides personnel screening of visitors. Electronic anti-intrusion devices are in effect at the Federal Records Center.
3. Procedural Safeguards: Protection for computerized records both on the mainframe and the CIO Local Area Network (LAN) includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and Vault Management System for secure off-site storage is available for backup tapes. To avoid inadvertent data disclosure, "degaussing" is performed to ensure that all data are removed from Privacy Act computer tapes and/or other magnetic media. Additional safeguards may be built into the program by the system analyst as warranted by the sensitivity of the data. CDC and contractor employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts, and the CDC Project Director, contract officers and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.
4. Implementation Guidelines: The safeguards outlined above are developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual; and Part 6, "Automated Information System Security," of the HHS Information Resources Management Manual. FRC safeguards are in compliance with GSA Federal Property Management Regulations, Subchapter B-- Archives and Records. Data maintained in CDC Atlanta's Processing Center are in compliance with OMB Circular A-130, Appendix III. Security is provided for information collection, processing, transmission, storage, and dissemination in general support systems and major applications. The CIO LAN currently operates under Novell Netware v 4.11 and is in compliance with "CDC & ATSDR Security Standards for Novell File Servers."

Retention and disposal: Card files are maintained in agency for two years. Destroyed by paper recycling process after 2 years. Computer file maintained 4 years at CDC. Records destroyed by erasing tape after 4 years.

System manager(s) and address: Director, Division of Quarantine, National Center for Infectious Diseases, Prevention Services, Corporate Square, Bldg. 10, Rm. 1207, MS E03, Centers for Disease Control and Prevention.

Notification procedure: An individual may learn if a record exists about himself or herself by contacting the system manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either: (1) submit a notarized request to verify their identity; or (2) certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a \$5,000 fine.

An individual who requests notification of or access to medical records shall, at the time the request is made, designate in writing a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child by means of a birth certificate or court order, as well as verify that he or she is who he or she claims to be.

The following information must be provided when requesting notification: (1) full name; (2) the approximate date and place of the study, if known; and (3) nature of the questionnaire or study in which the requester participated.

Record access procedures: Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An accounting of disclosures that have been made on the record, if any, may be requested.

Contesting record procedures: Contact the official at the address specified under System Manager above, reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

Record source categories: Information obtained from alien's visa medical documents at port of entry by Quarantine Inspectors.

Systems exempted from certain provisions of the act: None.