

## XIII. DATA COLLECTION

### MODULE OUTLINE

1. Standards of Public Health Practice
  2. Reporting
    - a. Reporting Suspected or Confirmed Cases of TB
    - b. Tennessee Department of Health Reportable Diseases and Events Laboratory Reporting Guide
  3. Suspected and Confirmed TB Cases
    - a. Tuberculosis Case Definition for Public Health Surveillance
  4. Surveillance System and the Report of a Verified Case of Tuberculosis (RVCT)
  5. Aggregate Reports for Program Evaluation (ARPE)
    - a. ARPE Submission and Timeframes
  6. Genotyping
    - a. Definition and Uses
    - b. Performing Genotyping
    - c. Reporting Genotyping Results
    - d. Cluster Investigation
    - e. Additional Genotyping Resources
  7. National TB Indicators Project (NTIP)
    - a. Additional NTIP Resources
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### **1. STANDARDS OF PUBLIC HEALTH PRACTICE**

- XIII-1. TBI case data are entered into the state surveillance system.
- XIII-2. Suspected and confirmed TB case data are entered into the state surveillance system.
- XIII-3. A Report of a Verified Case of Tuberculosis (RVCT) is completed and included in the medical record for each confirmed case of TB.
- XIII-4. An Aggregate Report for Program Evaluation (ARPE) is completed accurately and submitted to the TTBEF Central Office (C.O.) annually.

### **2. REPORTING**

#### Reporting Suspected and Confirmed Cases of TB:

*Source:* Chapter 1200-14-01-.02 of the Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation.

(1) All healthcare providers and other persons knowing of or suspecting a case, culture, or specimen of a reportable disease or event shall report that occurrence to the Department of Health in the time and manner set forth by the Commissioner in the List.

(2) The Commissioner shall re-evaluate, update, and post the List at least annually and from time to time as appropriate. The Commissioner shall post the annual update on or before

November 15<sup>th</sup> of each year and this new List shall become effective starting January 1<sup>st</sup> of the following year. If the Commissioner posts an updated List more frequently than on an annual basis, then the updated List will become effective on the date stated in the List. The List shall be available online at the Department of Health’s website and in print.

- (a) If any attending physician or other person knows or has good reason to suspect that a person having tuberculosis is behaving so as to expose other persons to infection, or is about to so conduct themselves, the attending physician or other person shall notify the state, district, municipal or county health office of the name and address of the diseased person and the essential facts in the case.

Reference:

1. Tennessee Code Annotated §68-9-201

Tennessee Department of Health Reportable Diseases and Events Laboratory Reporting Guide *Mycobacterium tuberculosis* complex (*M. tuberculosis*, *M. bovis*, *M. africanum*, *M. canetti*, *M. microti*, *caprae*, *pinnipedii*, and *mungi*) is a Category 1B event which requires immediate telephonic notification (next business day), followed by a written report using the PH-1600 (Refer to Appendix R) within 1 week.

<http://health.state.tn.us/ReportableDiseases/Common/ReportableDiseasesList.pdf>

<http://health.state.tn.us/ReportableDiseases/Default.aspx>

<http://health.state.tn.us/ReportableDiseases/Common/PH-1600.pdf>

### **3. SUSPECTED AND CONFIRMED TB CASES**

#### **Tuberculosis Case Definition for Public Health Surveillance**

“Suspect” Case of TB—a patient that:

- Is suspected by a clinician of having active TB disease; and
- Is undergoing a medical evaluation by a clinician that includes at least the following elements:
  - Complete medical history
  - Physical examination by the clinician
  - Chest radiography (including for individuals with suspected extrapulmonary TB disease)
  - Appropriate diagnostic tests for TB disease; and
- Is started on an appropriate multi-drug regimen for TB disease, even if final diagnostic data (e.g., sputum, bronchial wash, or biopsy culture results) are pending.

“Clinical Case” of TB—a case that meets **all** of the following criteria:

- A positive tuberculin skin test (TST) result or positive interferon gamma release assay (IGRA) for *M. tuberculosis*

- Other signs and symptoms compatible with tuberculosis (TB) (e.g., abnormal chest radiograph, abnormal chest computerized tomography scan or other chest imaging study, or clinical evidence of current disease)
- Treatment with two or more anti-TB medications
- A completed diagnostic evaluation

#### Laboratory Criteria for Diagnosis

- Isolation of *M. tuberculosis* complex from a clinical specimen **or**
- Demonstration of *M. tuberculosis* complex from a clinical specimen by nucleic acid amplification test (NAAT) **or**
- Demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained, or is falsely negative or contaminated.

#### Reference:

1. CDC. Report of Verified Case of Tuberculosis: Self-Study Modules. 2009.  
<http://www.cdc.gov/tb/programs/rvct/InstructionManual.pdf>

#### **4. SURVEILLANCE SYSTEM AND THE REPORT OF A VERIFIED CASE OF TUBERCULOSIS (RVCT)**

The Report of Verified Case of Tuberculosis (RVCT) (**Refer to Appendix S**) is the national TB surveillance reporting form.

- Consider initiating a RVCT upon being notified of a suspected case of TB.
- An RVCT must be completed for every confirmed case of TB.
- Instructions for completing the RVCT can be found at  
<http://www.cdc.gov/TB/programs/rvct/InstructionManual.pdf>  
The RVCT can be found at: <http://www.cdc.gov/TB/programs/rvct/RVCT-form.pdf>
- An RVCT is completed and included in the medical record for each confirmed case of TB (**Standard of Public Health Practice XIII-3**).

TBI case data are entered into the state surveillance system (**Standard of Public Health Practice XIII-1**). Suspected and confirmed TB case data are entered into the state surveillance system (**Standard of Public Health Practice XIII-2**).

- Regional TB programs will identify surveillance system users and complete the necessary paperwork to provide users access to the surveillance system
- Data will be entered into the surveillance system within the timeframes outlined in **Table XIII-1**.
- When the case status of a patient changes from “Suspect” to “Confirmed” notifications to TTBE Central Office (C.O.) should be created within five (5) business days from the status changing to confirmed.
- Specific information of the TB surveillance system can be found at:  
[http://health.state.tn.us/ReportableDiseases/Common/NBS\\_User\\_Guide.pdf](http://health.state.tn.us/ReportableDiseases/Common/NBS_User_Guide.pdf)

**Table XIII-1: Timeframe for Data Entry Into State Surveillance System**

Timeframe	Required Data Entry Variables
Within five (5) business days of receiving notification	<ul style="list-style-type: none"> <li>• Patient name</li> <li>• Patient address</li> </ul>
	<ul style="list-style-type: none"> <li>• Date of birth</li> <li>• Date reported</li> </ul>
	<ul style="list-style-type: none"> <li>• Sex at birth</li> <li>• Previous diagnosis of TB</li> </ul>
	<ul style="list-style-type: none"> <li>• Race</li> <li>• Ethnicity</li> </ul>
	<ul style="list-style-type: none"> <li>• Country of birth</li> <li>• Month/year arrived in U.S.</li> </ul>
	<ul style="list-style-type: none"> <li>• Pediatric information</li> <li>• Status at TB diagnosis</li> </ul>
	<ul style="list-style-type: none"> <li>• Site of TB disease</li> <li>• Primary reason evaluated</li> </ul>
Within one (1) to two (2) weeks after notification	<ul style="list-style-type: none"> <li>• TST or IGRA</li> <li>• Initial chest X-ray</li> </ul>
	<ul style="list-style-type: none"> <li>• Initial CT</li> <li>• Additional TB risk factors</li> </ul>
	<ul style="list-style-type: none"> <li>• Occupation</li> <li>• Date treatment started</li> </ul>
	<ul style="list-style-type: none"> <li>• Treatment regimen</li> <li>• HIV status</li> </ul>
	<ul style="list-style-type: none"> <li>• Resident of a corr. facility</li> <li>• Resident of long-term care</li> </ul>
	<ul style="list-style-type: none"> <li>• Non-injecting drug use</li> <li>• Injecting drug use</li> </ul>
	<ul style="list-style-type: none"> <li>• Alcohol use</li> <li>• Smear results</li> </ul>
Within eight (8) weeks after notification	<ul style="list-style-type: none"> <li>• Disposition of patient.</li> </ul>
Within four (4) weeks of culture confirmation (if obtained)	<ul style="list-style-type: none"> <li>• Complete “Follow-up 1” form</li> </ul>
Within one (1) week after last dose of medication was administered	<ul style="list-style-type: none"> <li>• Complete “Follow-up 2” form</li> </ul>

**5. AGGREGATE REPORTS FOR PROGRAM EVALUATION (ARPE)**

The ARPEs collect outcomes of contact investigations around TB cases that are (1) AFB sputum smear-positive, (2) AFB sputum smear-negative/culture-positive, and (3) other (clinical, other positive culture, provider-verified, etc.) (Refer to Appendix L). The ARPE can be accessed online at: [http://www.cdc.gov/tb/publications/PDF/ARPEs\\_manualsm1.pdf](http://www.cdc.gov/tb/publications/PDF/ARPEs_manualsm1.pdf) (Refer to Appendix 1 on hyperlinked document)

ARPE Submission and Timeframes

Prior to submission, a TTBE C.O. epidemiologist will send a cohort list to each region along with the appropriate number of ARPE forms. An ARPE is completed accurately and submitted to the TTBE C.O. annually (Standard of Public Health Practice XIII-4). The TTBE C.O. will collate these data and submit the outcomes to the Centers for Disease Control and Prevention (CDC) Division of Tuberculosis Elimination (DTBE) via the National TB Indicators Project (NTIP) website.

Guidance on definition of ARPE variables and instructions for completing the ARPE form can be found at:

[http://www.cdc.gov/tb/publications/PDF/ARPEs\\_manual.pdf](http://www.cdc.gov/tb/publications/PDF/ARPEs_manual.pdf)

## 6. GENOTYPING

### Definition and Uses

TB genotyping is a laboratory-based approach used to analyze the genetic material of *Mycobacterium tuberculosis*. Genotyping, in combination with epidemiologic data, helps identify persons with TB disease that are involved in the same chain of recent transmission.

Below are several applications of genotyping for the TB program:

- Discover unsuspected transmission relationships between TB patients
  - Identify unknown or unusual transmission settings, such as bars or clubs, instead of traditional settings like the home or workplace
  - Uncover inter-jurisdictional transmission
- Establish criteria for outbreak-related case definitions
- Identify additional persons with TB disease involved in an outbreak
- Determine completeness of contact investigations
- Detect laboratory cross-contamination
- Distinguish recent infection from activation of an old infection

### Performing Genotyping

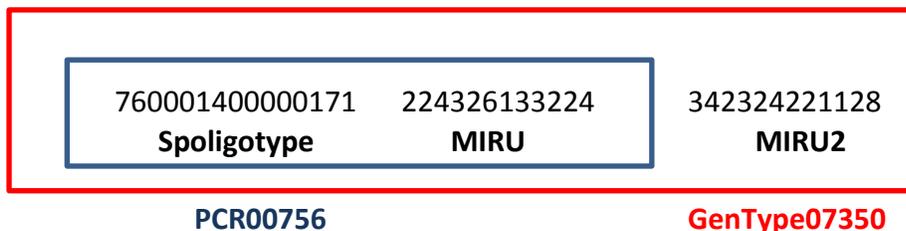
Genotyping can only be performed on isolates that are culture-positive for *M. tuberculosis*. Therefore, patients who are clinical or provider-verified cases will not have a genotyping result available. Isolates are sent from the Tennessee Department of Health, Division of Laboratory Services to a CDC-contracted genotyping laboratory.

### Reporting Genotyping Results

Three (3) genotyping methods are available:

- Spoligotyping (Spoligotype)
- Mycobacterial interspersed repetitive unit (MIRU) analysis
- IS6110-based restriction fragment length polymorphism (RFLP) analysis

Spoligotyping produces results in a standardized 15-digit code (e.g., 777777777760771). MIRU analysis may result in a 12-loci report or a 24-loci report (referred to as “MIRU” and “MIRU2” results, respectively). Unique numbers are assigned to clusters specifying each spoligotype and MIRU pattern. This unique number is a “PCR Type”. When MIRU2 results are added to the spoligotype and MIRU numbers, the combination pattern is called a “GenType.”



Once genotype testing is completed, the spoligotype, MIRU and MIRU2 results are uploaded into the TB Genotyping Information Management System (TB GIMS) by the CDC-contracted genotyping lab. These data are then available to TTBE C.O. epidemiologists who link them to specific patient surveillance information (either in TB GIMS, in the state surveillance system, or in both). Genotyping data are then made available to regional TB program staff for further investigation of epidemiologic links and cluster investigations.

### Cluster Investigation

The TTBE C.O. staff monitors genotype clusters, and as genotype results become available and, in consultation with DTBE, identify “clusters of concern.” TTBE C.O. will notify and facilitate discussions with regional TB program staff regarding clusters of concern and on what further investigation is needed. Clusters will then be prioritized for further investigation based on:

- Cluster characteristics,
- Size of the cluster and how recently cases were added to the cluster, and
- Resources available to thoroughly investigate the cluster.

Characteristics of higher priority clusters include:

- Pediatric cases
- Homelessness
- HIV-positive
- Alcohol and drug abuse
- Drug-resistance
- Cases localized to one county or zip code

Best practices for cluster investigations can be found at:

[http://www.cdc.gov/tb/publications/factsheets/statistics/Genotyping\\_BestPractices.pdf](http://www.cdc.gov/tb/publications/factsheets/statistics/Genotyping_BestPractices.pdf)

### Additional Genotyping Resources:

<http://www.cdc.gov/tb/publications/factsheets/statistics/genotyping.pdf>

<http://www.cdc.gov/tb/programs/genotyping/GenotypingReport.pdf>

[http://www.cdc.gov/tb/programs/genotyping/images/TBGenotypingGuide\\_June2004.pdf](http://www.cdc.gov/tb/programs/genotyping/images/TBGenotypingGuide_June2004.pdf)

<http://www.cdc.gov/tb/programs/genotyping/tbgims/default.htm>

<http://www.cdc.gov/tb/publications/factsheets/statistics/gims.htm>

## **7. NATIONAL TB INDICATORS PROJECT (NTIP)**

NTIP is a monitoring system for tracking the progress of U.S. TB control programs toward achieving the National TB Program Objectives. NTIP focuses on the 15 objective categories listed in **Table XIII-2**.

**Table XIII-2: National TB Indicators Project (NTIP) Objectives and Performance Targets**

Objective Categories		Objectives and Performance Targets for 2015
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	
	<ul style="list-style-type: none"> <li>U.S.-born persons</li> </ul>	Decrease the TB case rate in U.S.-born persons to less than 0.7 cases per 100,000. <ul style="list-style-type: none"> <li>Increase the average yearly decline in TB case rate in U.S.-born persons to at least 11.0%.</li> </ul>
	<ul style="list-style-type: none"> <li>Foreign-born persons</li> </ul>	Decrease the TB case rate for foreign-born persons to less than 14.0 cases per 100,000. <ul style="list-style-type: none"> <li>Increase the average yearly decline in TB case rate in foreign-born persons to at least 4.0%.</li> </ul>
	<ul style="list-style-type: none"> <li>U.S.-born, non-Hispanic blacks</li> </ul>	Decrease the TB case rate in U.S.-born, non-Hispanic blacks to less than 1.3 cases per 100,000.
	<ul style="list-style-type: none"> <li>Children younger than five (5) years of age</li> </ul>	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	
	<ul style="list-style-type: none"> <li>Contact elicitation</li> </ul>	Increase the proportion of TB patients with positive acid-fast (AFB) sputum-smear results who have contacts elicited to 100.0%.
	<ul style="list-style-type: none"> <li>Evaluation</li> </ul>	Increase the proportion of contacts to sputum AFB smear-positive TB patients who are evaluated for infection and disease to 93.0%.
	<ul style="list-style-type: none"> <li>Treatment initiation</li> </ul>	Increase the proportion of contacts to sputum AFB smear-positive TB patients with newly diagnosed latent TB infection (TBI) who start treatment to 88.0%.
	<ul style="list-style-type: none"> <li>Treatment completion</li> </ul>	For contacts to sputum AFB smear-positive TB patients who have started treatment for newly diagnosed TBI, increase the proportion who complete treatment to 79.0%.

Objective Categories		Objectives and Performance Targets
4	Laboratory Reporting	
	<ul style="list-style-type: none"> <li>• Turnaround time</li> </ul>	Increase the proportion of culture-positive or nucleic acid amplification test-positive TB cases with a pleural or respiratory site of disease that have the identification of <i>M. tuberculosis</i> reported by laboratory within 25 days from the date of the initial diagnostic pleural or respiratory specimen was collected to 82.7%.
	<ul style="list-style-type: none"> <li>• Drug-susceptibility result</li> </ul>	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 95.2%.
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	
	<ul style="list-style-type: none"> <li>• RVCT</li> </ul>	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%.
	<ul style="list-style-type: none"> <li>• ARPEs</li> </ul>	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%.
<ul style="list-style-type: none"> <li>• EDN</li> </ul>	Increase the completeness of each core Electronic Disease Notification (EDN) system data item reported to CDC, as described in the TB Cooperative Agreement announcement, to n%.	
8	Recommended Initial Therapy	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 TB culture-confirmed TB cases with a genotyping result reported to 94.0%.
10	Known HIV Status	Increase the proportion of TB cases with a positive or negative HIV test result reported to 88.7%.

Objective Categories		Objectives and Performance Targets
11	Evaluation of Immigrants and Refugees	
	<ul style="list-style-type: none"> <li>Evaluation initiation</li> </ul>	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 notification to 64.8%.
	<ul style="list-style-type: none"> <li>Evaluation completion</li> </ul>	For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who complete medical evaluation within 90 of notification to 62.0%.
	<ul style="list-style-type: none"> <li>Treatment initiation</li> </ul>	For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB and who are diagnosed with latent TB infection during evaluation in the U.S., increase the proportion who start treatment to 87.3%.
	<ul style="list-style-type: none"> <li>Treatment completion</li> </ul>	For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who complete latent TB infection treatment to 75.7%.
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	
	<ul style="list-style-type: none"> <li>Evaluation focal point (applicable to state programs only)</li> </ul>	<p>Increase program evaluation activities by monitoring program progress and tracking evaluation status of cooperative agreement recipients.</p> <p>Increase the percentage of cooperative agreement recipients that have an evaluation focal point.</p>
14	Human Resources Development Plan (applicable to state programs only)	<p>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%</p> <p>Increase the percent of cooperative agreement recipients who submit a yearly update of progress-to-date on HRD activities to 100.0%.</p>
15	Training Focal Point (applicable to state programs only)	Increase the percent of cooperative agreement recipients that have a TB training focal point.

Additional NTIP Resources

<http://www.cdc.gov/tb/publications/factsheets/statistics/NTIP.htm>

<http://www.cdc.gov/tb/publications/factsheets/statistics/NTIPFAQs.htm>

Reference:

1. CDC. <http://www.cdc.gov/tb/programs/Evaluation/Indicators/ProgramObjectives.pdf>