Surveillance

CONTENTS

Introduction

Purpose

Use this section to do the following:

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

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

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

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

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

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

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

Surveillance in TB Control Activities

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

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

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

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

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

For more information on surveillance in contact investigations, see the Contact Investigation section.

Targeted testing: Review and interpretation of surveillance data inform targeted testing policies and strategies. Targeted testing is intended to identify persons other than TB contacts who have an increased risk for acquiring TB and to offer such persons diagnostic testing for *M. tuberculosis* infection and treatment, if indicated, in order to prevent subsequent progression to TB disease. Targeted testing and treatment of TBI are best accomplished through cost-effective programs aimed at patients and populations identified on the basis of local surveillance data as being at increased risk for TB.[8]

For more information on surveillance and targeted testing, see the Targeted Testing section.

Treatment of TBI: Surveillance of persons with TBI does not routinely occur in the United States. However, the CDC is developing a national surveillance system to record adverse events leading to the hospitalization or death of a person under treatment for TBI. Healthcare providers are encouraged to report such events to ODH by calling 1-614-466-2381. Surveillance of these events will provide data to evaluate the safety of treatment regimens recommended in current guidelines.[9]

For more information on surveillance and targeted testing, see the Targeted Testing section. For more information on updated TBI treatment recommendations, see the CDC's "Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection—United States, 2003" (*MMWR* 2003;52[31];735–739) at this link: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5231a4.htm and see the CDC's "Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent *Mycobacterium tuberculosis* Infection" (*MMWR 2011*; 60[48];1650-1653) at this link: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=mm6048a3_w

Policy

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

For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the Introduction 1.18

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

Laws and Rules

Ohio laws and rules on tuberculosis are located in the Ohio Revised Code 339.71 thru 339.89 and the Ohio Administrative Code.

Ohio Revised Code
339.74 TB record bureau
339.79 Reporting case of TB that is resistant to one or more drugs
339.80 Investigations
339.81 Confidential information
3707.04 Quarantine regulations
3701.56 Enforcement of quarantine
3701.34 Health Commissioner authority (quarantine)
3701.13 Powers of Health Department (quarantine)

Ohio Administrative Code
Reporting & Isolation Requirements
3701-3-01 Reportable disease definitions
3701-3-02 Reportable diseases
3701-3-03 Reportable disease notification
3701-3-04 Lab reporting
3701-3-05 Time of report
3701-3-06 Reporting to ODH
3701-3-08 Release of medical records
3701-3-13 Isolation requirement
3701-15-1 Definitions
3701-15-2 Acceptable Tuberculosis program
3701-15-3 Tuberculosis standards for the purposes of section 3701.14 of the Revised Code

See http://codes.ohio.gov/

Contact the Ohio Department of Health TB Program at (614) 466-2381 for assistance with interpreting state laws and rules regarding TB control.

Tuberculosis Classification System

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

Table 1: TUBERCULOSIS CLASSIFICATION SYSTEM[10]

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

Source: Adapted from: CDC. Classification system. In: Chapter 2: transmission and pathogenesis. *Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]. Updated November 2001.

Reporting Tuberculosis

Detecting and reporting suspected cases of tuberculosis (TB) is the key step in stopping transmission of *Mycobacterium tuberculosis* because it leads to prompt initiation of effective multiple-drug treatment, which rapidly reduces infectiousness. The Centers for Disease Control and Prevention (CDC) claim that delays in reporting cases of pulmonary TB are one of the major challenges to successful control of TB.[11] As one of the strategies to achieve the goal of reduction of TB morbidity and mortality, the CDC recommends immediate reporting of a suspected or confirmed case of TB to the jurisdictional health agency.[12] By Ohio law and regulation, a case of TB disease must be reported to the local public health agency.

When reporting TB, keep the following definitions in mind:

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

Table 2: CASE DEFINITIONS[17]

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

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

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

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

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

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

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

Prompt reporting (prior to culture confirmation) allows the state and local public health agency to do the following quickly:

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

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

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

- Epidemiologic investigation, including identification and examination of contacts
- Expert Medical Consultation
- Laboratory services; The *M. tuberculosis* isolate should be sent to the state laboratory so genotyping can be performed when needed. [22]

3701-3-03 Reportable Disease Notification

(A) A health care provider with knowledge of a case or suspect case of a disease which is required by law to be reported, including all class "A", class "B", and class "C" categories of disease designated as reportable under rule 3701-3-02 of the Administrative Code, shall submit a case report in the manner set forth in rule 3701-3-05 of the Administrative Code and by the director in the Ohio infectious disease control manual.

(1) A health care provider may submit electronic reports in the manner approved by the director in the Ohio infectious disease control manual.

(2) Unless otherwise demonstrated, a health care provider who submits electronic reports in the manner approved by the director shall be presumed compliant with section 3701.23 of the Revised Code and rules 3701-3-02, 3701-3-04, and 3701-3-05 of the Administrative Code.

(B) Reports of cases and suspect cases shall include, but not limited to, the following:

(1) Case or suspect case information: name, diagnosis or suspected diagnosis, date of birth, sex, telephone number, and street address including city, state, and zip code.

(2) Health care provider information: name, telephone number, and street address including city, state, and zip code.

(3) Supplementary information as needed to complete official surveillance forms provided or set forth by the director in the Ohio infectious disease control manual.

(C) Any individual having knowledge of a person suffering from a disease suspected of being communicable is authorized to report to public health authorities all known facts relating to the case or incident.

Replaces: 3701-3-03
Effective: 02/01/2011
R.C. 119.032 review dates: 02/01/2016

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

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

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

Table 3: WHEN TO REPORT TUBERCULOSIS

What Condition/ Test Result	Who Reports	When to Report	How to Report
Confirmed or suspected cases of tuberculosis (TB) disease Confirmation by laboratory tests is not required. This includes pulmonary and extrapulmonary cases.	▪ Physicians ▪ Other healthcare providers ▪ Hospitals ▪ Other similar private or public institutions ▪ Anyone providing treatment to the confirmed or suspected case Note: The attending physician or other healthcare provider must report even if the laboratory is also reporting the test results.	Report by the close of the next business day after the case or suspected case presents and/or a positive laboratory result to the county TB control unit where the patient resides. If patient residence is unknown, report to the county TB control unit in which the reporting health care provider or laboratory is located.	Telephone Check local directory for TB control unit hours of operation and telephone number. Fax Check local directory for TB control unit hours of operation and fax number.
Sputum smears positive for acid-fast bacilli (AFB) Cultures growing AFB or cultures that are demonstrated positive for *Mycobacterium tuberculosis* complex* Nucleic acid amplification tests/DNA probes positive for *M. tuberculosis* complex	All laboratories that perform TB testing In-state laboratories that send specimens for out-of-state testing Note: The laboratory must report even if the attending physician or other healthcare provider is also reporting.	Report by the close of the next business day Note: If specimens or isolates are sent to the state public health laboratory within 2 days after specimen collection or identification of *M. tuberculosis,* then the requirement to report results are fulfilled.	

* Note: This includes both the preliminary report of cultures growing AFB without confirmation of *M. tuberculosis* complex and the final report of cultures that are demonstrated to be positive for *M. tuberculosis* complex.

Use the Ohio Confidential Reportable Disease form (HEA 3334, rev. 1/09) Positive Laboratory Findings for Reportable Disease form (HEA 3333, rev. 8/05). County TB control units should report via the Ohio Disease Reporting System (ODRS) or telephone.

For the local TB control units, all information on the Report of Verified Case of Tuberculosis (RVCT; CDC 72.9A, revised 9/08) is required to be reported in ODRS for all cases and suspected cases.

All the information on the Follow-up Report – 1 (CDC 72.9B, revised 9/08) is required to be reported in ODRS for all culture-positive cases to report the results of drug susceptibility testing. All the information on the Follow-up Report – 2 (CDC 72.9C, revised 9/08) is required to be reported in ODRS for all cases and suspected cases to report when and why treatment stopped or to report that a suspected case does not have TB.

Healthcare Providers

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

Reporting Healthcare Provider

- Name
- Address
- Phone number
- Date of report

Patient Information

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

Demographic and Social Information

- Date of birth
- Sex
- Race/ethnic origin
- Country of birth/date of arrival in the United States
- Drug and alcohol use

Demographic and Social Information

- Homeless within past year?
- Diagnosed in a correctional facility or long-term care facility?
- Primary occupation

Medical Information

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

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

Local public health agencies are required to complete and submit the reports listed in Table 4 to the Ohio Department of Health TB program:

Table 4: REQUIRED REPORTS

Report Title	When Due
Report of Verified Case of Tuberculosis	By close of next business day
Initial Drug Susceptibility Report (Follow-up 1)	When results are available
Case Completion Report (Follow-up 2)	When patient completes treatment for active TB disease or when a suspect is determined not to have TB

To download forms for the above required reports, go to section three of the Infectious Disease Reporting Manual (IDCM). The IDCM can be downloaded from Ohio Department of Health at http://www.odh.ohio.gov/healthResources/infectiousDiseaseManual.aspx

The Report of Verified Case of Tuberculosis (RVCT) forms are designed to collect information on cases of TB. Data obtained from RVCT forms are entered into the Ohio Disease Reporting System (ODRS) by the local TB control unit and the ODH TB Program, and then transferred electronically to the CDC. While a case of TB is required to be reported to the CDC only if active disease is verified and the case is to be part of the annual morbidity count, the CDC encourages the use of the RVCT forms and ODRS for the collection of data on suspected cases of TB.

Computerized Tuberculosis Registry

To carry out mandatory community public health responsibilities, the state TB control program maintains a computerized record system (case registry) with up-to-date information on all current clinically active and suspected TB cases in the community.[23] The TB case registry should ensure that laboratory data, including all initial diagnostic tests, are promptly reported, if applicable, to the healthcare provider and local and state TB control programs. Follow-up tests, including data on sputum culture conversion and drug susceptibility testing of clinical isolates, should also be promptly reported so any needed modifications in management can be made. Aggregate program data should be analyzed, interpreted, and made available to the healthcare community and to community groups and organizations with specific interests in public health. Providing this information supports education and advocacy and facilitates collaboration in the planning process.

To ensure appropriate follow-up of all TB patients and persons suspected of having TB, the following registry information is updated by the local TB control unit and/or the ODH TB Program on a continuing basis:[24]

- Acid-fast bacilli smear results
- Culture results
- Drug susceptibility/genotyping results
- Clinical status
- Chest radiograph results
- Drug treatment regimen changes
- Doses of medications being administered
- Directly observed therapy status/compliance

Document Retention

The Ohio TB Program does not maintain medical records.

Radiographs and medical records are NOT stored by the state. Radiographs and medical records are held by the healthcare provider or radiology office where the radiographs were obtained. Case management health information and other TB records should be maintained at the local public health agency according to current applicable record retention rules and regulations.

Genotyping

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

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

The diversity of strains provides a means to identify instances of recent transmission of tuberculosis (TB) as well as the chains of transmission that occur among persons with TB. This diversity also helps to elucidate the patterns and dynamics of TB transmission. When a person with TB improves but then becomes ill again, this diversity can differentiate reactivation with the same strain of *M. tuberculosis* from reinfection with a different strain. Genotyping can also be used to identify false-positive cultures.

Advances in DNA analytic methods have made it possible for TB programs to obtain rapid and reliable genotyping results. These advances include the following:

- The determination of the complete DNA sequence of *M. tuberculosis* in 1998
- The development of IS6110-based restriction fragment length polymorphism (RFLP) genotyping, which provided a discriminatory typing method and led to a standardized system for genotyping *M. tuberculosis* isolates

Two new methods, spoligotyping and mycobacterial interspersed repetitive units (MIRU) analysis, are based on polymerase chain reaction (PCR) and provide much more rapid results than RFLP analysis. The addition of genotype information to the pool of information generated by surveillance data and data collected through epidemiologic investigation allow confirmation of suspected transmission. A potential outbreak should be suspected whenever there is more than one case of TB whose isolate has the same genotype (genotype cluster). Further investigation that includes review of surveillance data, chart review, and reinterview of TB cases may refute or confirm the epidemiologic connection between more than one TB case. In some instances, a genotype cluster reflects a false-positive culture that may be a result of laboratory cross-contamination. Routine review of genotyping data, along with epidemiologic, clinical, and laboratory data, may identify patients who are wrongly classified as TB patients and should be further investigated

For more information on genotyping, see the National Tuberculosis Controllers Association/Centers for Disease Control and Prevention Advisory Group on Tuberculosis Genotyping's *Guide to the Application of Genotyping to Tuberculosis Prevention and Control* (2004) at this hyperlink:

http://www.cdc.gov/tb/programs/genotyping/images/TBGenotypingGuide_June2004.pdf.

All positive *M. tuberculosis* cultures should be sent to the Ohio department of Health Laboratory for referral to the appropriate national genotyping laboratory. For information on how to request genotyping tests, see the Laboratory Services section.

For technical support and guidance on the application of genotyping, please call the Ohio TB Program at (614) 466-2381.

Dissemination and Evaluation

Dissemination

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

Evaluation

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

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

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