

# Surveillance

---

## CONTENTS

<b>Introduction.....</b>	<b>2.2</b>
Purpose.....	2.2
Policy .....	2.5
Laws and rules.....	2.5
<b>Reporting Tuberculosis .....</b>	<b>2.6</b>
Reporting suspected or confirmed cases of tuberculosis to the local public health agency.....	2.8
Required reports from local public health agencies to the Montana Tuberculosis Program .....	2.10
<b>Data Collection Forms .....</b>	<b>2.11</b>
<b>Genotyping.....</b>	<b>2.12</b>
<b>References .....</b>	<b>2.14</b>

---

# Introduction

## Purpose

Use this section to

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

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

1. determine TB patterns and trends of the disease;
2. identify sentinel events, such as potential outbreaks, recent transmission, multidrug resistance, and deaths;
3. identify high-risk populations and settings;
4. establish priorities for control and prevention activities; and
5. strategically plan use of limited resources.<sup>1</sup>

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

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

In addition to providing the epidemiologic profile of TB in a given jurisdiction, state and local surveillance are essential to national TB surveillance.<sup>2</sup> 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.<sup>3</sup>

Reporting of new cases is essential for surveillance purposes.<sup>4</sup>

## 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.<sup>5</sup>



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.<sup>6</sup> Genotyping data should routinely be reviewed because genotype clusters also may indicate an outbreak. Prompt identification of potential outbreaks and rapid responses are necessary to limit further TB transmission. When an outbreak is identified, short-term investigation activities should follow the same principles as those for the epidemiologic part of the contact investigation (i.e., defining the infectious period, settings, risk groups, mode of transmission, contact identification, and follow-up). However, long-term activities require continued active surveillance.



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

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



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

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



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

**Treatment of LTBI:** Surveillance of persons with LTBI does not routinely occur in the United States. However, the CDC is developing a national surveillance system to record adverse events leading to the hospitalization or death of a person under treatment for LTBI. Healthcare providers are encouraged to report such events to the CDC's Division of Tuberculosis Elimination by calling 1-404-639-8401. Surveillance of these events will provide data to evaluate the safety of treatment regimens recommended in current guidelines.<sup>9</sup>



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

## Policy

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



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



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

## Laws and Rules

Montana laws and rules on tuberculosis (TB) are located in the Montana Code Annotated (MCA) and the Administrative Rules of Montana (ARM).



In the MCA, see Chapter 17 (Tuberculosis Control) in Title 50 (Health and Safety) found in Part 1-Tuberculosis Control.



In the ARM, see Subchapter 10 (Tuberculosis Control) in 37.114.1001–37.114.1016 found at [this link](#).

Contact the Montana TB Program at 406-444-0273 for assistance with interpreting Montana laws and rules regarding TB control.



---

## Reporting Tuberculosis

Detecting and reporting suspected cases of tuberculosis (TB) is the key step in stopping transmission of *Mycobacterium tuberculosis* because it leads to prompt initiation of effective multiple-drug treatment, which rapidly reduces infectiousness. The Centers for Disease Control and Prevention (CDC) reports that delays in reporting cases of pulmonary TB are one of the major challenges to successful control of TB.<sup>10</sup> 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.<sup>11</sup> Also, by Montana law and regulation, a case of TB disease in the United States must be reported to the local public health agency.

When reporting TB, keep the following definitions in mind:

- **Case:** An episode of TB disease in a person meeting the laboratory or clinical criteria for TB, as defined in the document “Case Definitions for Infectious Conditions Under Public Health Surveillance.”<sup>12</sup> These criteria are listed below in Table 1.<sup>13</sup>
- **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.<sup>14</sup>
- **Confirmed:** A case that meets the clinical case definition or is laboratory confirmed, as described below in Table 1.<sup>15</sup>

TABLE 1: CASE DEFINITIONS<sup>16</sup>

Clinical Case Definition	Laboratory Criteria for Diagnosis
<p>A case that meets all of the following criteria:</p> <ul style="list-style-type: none"> <li>▪ A positive tuberculin skin test</li> <li>▪ 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)</li> <li>▪ Treatment with 2 or more antituberculosis medications</li> <li>▪ Completed diagnostic evaluation</li> </ul>	<p>A case is laboratory confirmed when it meets one of the following criteria:</p> <ul style="list-style-type: none"> <li>▪ Isolation of <i>Mycobacterium tuberculosis</i> from a clinical specimen*</li> <li>▪ Demonstration of <i>M. tuberculosis</i> from a clinical specimen by nucleic acid amplification (NAA) test†</li> <li>▪ Demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained</li> </ul>
<p>* Use of rapid identification techniques for <i>M. tuberculosis</i> (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.</p> <p>† 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.</p>	

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

Suspect pulmonary TB and initiate a diagnostic investigation when the historic features, signs, symptoms, and radiographic findings of TB are evident among adults. TB should be suspected in any patient who has a persistent cough for over two to three weeks, or other indicative signs and symptoms.<sup>17</sup>



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.<sup>18</sup>

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<sup>19</sup>

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.<sup>20</sup>

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

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

TABLE 2: WHEN TO REPORT TUBERCULOSIS

What Condition/ Test Result	Who Reports	When to Report	How to Report
<p><b>Confirmed or suspected cases of tuberculosis (TB) disease</b></p> <p>Confirmation by laboratory tests is not required.</p> <p>This includes pulmonary and extrapulmonary cases.</p>	<p>Anyone who knows or suspects that a case or suspected case of TB exists, including but not limited to physician, dentist, nurse, medical examiner, other healthcare practitioner, administrator of healthcare facility, public or private school administrator, city health officer, or laboratory staff person</p>	<p>Immediately</p>	<p>Call the local public health agency.</p> <hr/>

## **Healthcare Providers**

Healthcare providers should report the following information on suspect or confirmed cases of TB and any other information related to case management requested by the local public health agency and/or the Montana TB Program.

1. Name and age of the case
2. Whether or not the case is suspected or confirmed
3. Name and address of the case's physician
4. Name of the reporter or other person the department can contact for pertinent information about the case

## **Laboratories**

Laboratories should report the same information as healthcare providers.

# Required Reports from Local Public Health Agencies to the Montana Tuberculosis Program

Local public health agencies are required to complete and submit the reports listed in Table 3 to the Montana TB Program manager at the Montana Department of Public Health and Human Services TB Program.

Transmit these reports by fax to the attention of the Montana TB Program manager at 406-444-0272.

TABLE 3: REQUIRED REPORTS

Report Title	When Due
"Confirmed/Suspected Report of TB Disease"	Within 7 days of receipt of confirmed/suspect case notification by the local public health agency
"TB Case Monthly Report"	Monthly
"TB Contact Investigation Report"	<p>At these milestones during a contact investigation of exposure to pulmonary TB:</p> <ul style="list-style-type: none"> <li>▪ Upon completion of initial tuberculin skin testing of contacts</li> <li>▪ Upon completion of retests of contacts</li> <li>▪ Upon contacts' completion of therapy for latent tuberculosis infection</li> </ul> <p>For recommended time frames of tasks in contact investigations, refer to the "Time Frames for Contact Investigation" topic in the Contact Investigation section.</p>



Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273.

# Data Collection Forms

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

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

Chart of a Patient on Treatment for Tuberculosis Disease	
<p><b>Tuberculosis (TB) Disease Treatment/Case Management</b></p> <ul style="list-style-type: none"> <li>▪ "Confirmed/Suspected Report of TB Disease"</li> <li>▪ "TB Case Monthly Report"</li> <li>▪ "TB Diagnostic Referral Form"</li> <li>▪ "Treatment Plan"</li> <li>▪ "Directly Observed Therapy Agreement"</li> <li>▪ "Home Isolation Agreement"</li> <li>▪ "TB Home Evaluation"</li> <li>▪ "Bacteriology Data Sheet"</li> <li>▪ "Biochemistry Data Sheet"</li> </ul>	<ul style="list-style-type: none"> <li>▪ "Treatment of Active TB Education Form"</li> <li>▪ "Monthly TB Patient Assessment"</li> <li>▪ "Directly Observed Therapy Form 1 - Treatment Record"</li> <li>▪ "Directly Observed Therapy Form 2 - Side Effects and Adverse Reactions"</li> </ul> <p><b>Transfer Notifications</b></p> <ul style="list-style-type: none"> <li>▪ "Interjurisdictional Tuberculosis Notification"</li> <li>▪ "Interjurisdictional TB Notification Follow-Up"</li> </ul>
Chart of a Patient on Treatment for Latent Tuberculosis Infection	
<p><b>Latent Tuberculosis Infection (LTBI) Treatment</b></p> <ul style="list-style-type: none"> <li>▪ "LTBI Medicine Enrollment Form: State Provided Medicine Application"</li> <li>▪ "Treatment of LTBI Education Form"</li> <li>▪ "Monthly LTBI Patient Assessment"</li> <li>▪ "Biochemistry Data Sheet"</li> </ul>	<p><b>If on Directly Observed Therapy</b></p> <ul style="list-style-type: none"> <li>▪ "Directly Observed Therapy Agreement"</li> <li>▪ "Directly Observed Therapy Form 1 - Treatment Record"</li> <li>▪ "Directly Observed Therapy Form 2 - Side Effects and Adverse Reactions"</li> </ul> <p><b>Transfer Notifications</b></p> <ul style="list-style-type: none"> <li>▪ "Interjurisdictional Tuberculosis Notification"</li> <li>▪ "Interjurisdictional TB Notification Follow-Up"</li> </ul>
File for a Contact Investigation	
<ul style="list-style-type: none"> <li>▪ "TB Contact Investigation Report"</li> <li>▪ "TB Contact Investigation Summary"</li> </ul>	



Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273.

---

# 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 strain 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
- The development of two new methods, spoligotyping and mycobacterial interspersed repetitive units (MIRU) analysis, which are based on polymerase chain reaction (PCR) and provide much more rapid results than RFLP analysis<sup>21</sup>

The addition of genotype information to the pool of information generated by surveillance data and data collected through epidemiologic investigation allow confirmation of suspected transmission. A potential outbreak should be suspected whenever there is more than one case of TB whose isolate has the same genotype (genotype cluster). Further investigation that includes review of surveillance data, chart review, and reinterview of TB cases may refute or confirm the epidemiologic connection between more than one TB case. In some instances, a genotype cluster reflects a false-positive culture that may be a result of laboratory cross-contamination. Routine review of genotyping data, along with epidemiologic, clinical, and laboratory data, may identify patients who are wrongly classified as TB patients and should be further investigated.

The Montana TB Program reviews genotyping data to check for any matches. Upon identification of a match, the Montana TB Program manager telephones the local public health agency managing the case to discuss what further steps should be taken.



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).



All *M. tuberculosis* cultures originating at the Montana Public Health Laboratory are automatically submitted to a national genotyping laboratory for genotyping analysis. All other laboratories, including out-of-state labs, must submit *M. tuberculosis* cultures to the Montana Public Health Laboratory for genotyping, as well as for confirmation and susceptibility testing, per Montana Administrative Rule 37.114.1016.

---

# References

---

- <sup>1</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):10.
- <sup>2</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):10.
- <sup>3</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):10.
- <sup>4</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):15.
- <sup>5</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):5.
- <sup>6</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):39.
- <sup>7</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):39.
- <sup>8</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):15.
- <sup>9</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):42.
- <sup>10</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):3.
- <sup>11</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):15.
- <sup>12</sup> CDC. Case definitions for infectious conditions under public health surveillance. *MMWR* 1997;46(No. RR-10):40–41. <sup>13</sup> CDC. *Reported Tuberculosis in the United States, 2004*. Atlanta, GA: US Department of Health and Human Services, CDC; September 2005. Appendix B, Section V.
- <sup>14</sup> CDC. *Reported Tuberculosis in the United States, 2004*. Atlanta, GA: US Department of Health and Human Services, CDC; September 2005. Appendix B, Section V.
- <sup>15</sup> CDC. Case definitions for infectious conditions under public health surveillance. *MMWR* 1997;46(No. RR-10):40–41. <sup>16</sup> CDC. Case definitions for infectious conditions under public health surveillance. *MMWR* 1997;46(No. RR-10):40–41. <sup>17</sup> ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):33.
- <sup>18</sup> ATS, CDC, IDSA. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med* 2000;161:1392.
- <sup>19</sup> County of Los Angeles Tuberculosis Control Program. *Tuberculosis Control Program Manual: 2003 Edition* [County of Los Angeles Public Health Web site]. 2003;8–6. Accessed February 7, 2007.
- <sup>20</sup> County of Los Angeles Tuberculosis Control Program. *Tuberculosis Control Program Manual: 2003 Edition* [County of Los Angeles Public Health Web site]. 2003;8–7. Accessed February 7, 2007.
- <sup>21</sup> National Tuberculosis Controllers Association/Centers for Disease Control and Prevention (CDC) Advisory Group on Tuberculosis Genotyping's *Guide to the Application of Genotyping to Tuberculosis Prevention and Control* [Division of Tuberculosis Elimination Web site]. Accessed February 7, 2007.