09-ID-65

Committee: Infectious

Title: Public Health Reporting and National Notification for Tuberculosis

I. Statement of the Problem

CSTE position statement 07-EC-02 recognized the need to develop an official list of nationally notifiable conditions and a standardized reporting definition for each condition on the official list. The position statement also specified that each definition had to comply with American Health Information Community recommended standards to support "automated case reporting from electronic health records or other clinical care information systems." In July 2008, CSTE identified sixty-eight conditions warranting inclusion on the official list, each of which now requires a standardized reporting definition.

II. Background and Justification

Background[1]

Tuberculosis is a disease caused by bacteria called *Mycobacterium tuberculosis*. The bacteria usually attack the lungs, but tuberculosis can affect any part of the body, including the kidneys, spine, and brain. If not treated properly, tuberculosis can be fatal. Tuberculosis was once the leading cause of death in the United States. Tuberculosis is spread through the air from one person to another. Bacteria become airborne when a person with active tuberculosis of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected.

Not everyone infected with *Mycobacterium tuberculosis* becomes sick. People who are not sick have what is called latent tuberculosis infection. People who have latent tuberculosis infection do not feel sick, do not have any symptoms, and cannot spread tuberculosis to others. Nevertheless, some people with latent tuberculosis infection go on to develop active tuberculosis.

Justification

Tuberculosis meets the following criteria for a nationally and **standard** notifiable condition, as specified in CSTE position statement 08-EC-02:

- A majority of state and territorial jurisdictions—or jurisdictions comprising a majority of the US population—have laws or regulations requiring **standard** reporting of tuberculosis to public health authorities
- CDC requests **standard** notification of tuberculosis to federal authorities
- CDC has condition-specific policies and practices concerning the agency's response to, and use of, notifications.

[1] Much of the material in the background is directly quoted from the CDC's Tuberculosis Website. See the References for further information on this source.

III. Statement of the desired action(s) to be taken

CSTE requests that CDC adopt this standardized reporting definition for tuberculosis to facilitate more timely, complete, and standardized local and national reporting of this condition.

IV. Goals of Surveillance

To provide information on the temporal, geographic, and demographic occurrence of tuberculosis to facilitate its prevention and control.

V. Methods for Surveillance

Surveillance for tuberculosis should use the sources of data and the extent of coverage listed in table V.

Table V. Recommended sources of data and extent of coverage for ascertaining cases of tuberculosis.

	Coverage	
Source of data for case ascertainment	Population-wide	Sentinel sites
clinician reporting	x	
laboratory reporting	x	
reporting by other entities (e.g., hospitals, veterinarians, pharmacies)	x	
death certificates	x	
hospital discharge or outpatient records	x	
extracts from electronic medical records	x	
telephone survey		
school-based survey		
other _____		

VI. Criteria for Reporting

Reporting refers to the process of healthcare providers or institutions (e.g., clinicians, clinical laboratories, hospitals) submitting basic information to governmental public health agencies about cases of illness that meet certain reporting requirements or criteria. Cases of illness may also be ascertained by the secondary analysis of administrative health data or clinical data. The purpose of this section is to provide those criteria that should be used to determine whether a specific illness should be reported.

A. Narrative description of criteria to determine whether a case should be reported to public health authorities

Report any person to public health authorities that meets *all* of the following criteria:

- positive tuberculin skin test or positive interferon gamma release assay for *M. tuberculosi*s
- signs and symptoms compatible with tuberculosis (e.g., abnormal chest radiograph, abnormal chest computerized tomography scan or other chest imaging study, or clinical evidence of current disease)
- receiving treatment with two or more antituberculosis medications
- completed diagnostic evaluation for tuberculosis

Report any person to public health authorities that meets *any* of the following laboratory criteria:

- isolation of *M. tuberculosis* complex from a clinical specimen*
- demonstration of *M. tuberculosis* complex from a clinical specimen by nucleic acid amplification test**
- demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated

* Use of rapid identification techniques for *M. tuberculosi*s (e.g., DNA probes and mycolic acids high-pressure liquid chromatography performed on a culture from a clinical specimen) are acceptable under this criterion.
** Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species for clinical purposes. A culture isolate of *M. tuberculosis* complex is required for complete drug susceptibility testing and also genotyping. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert, or a test produced and validated in accordance with applicable FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations.

Report any person to public health authorities that meets *any* of the following criteria:

- the person's healthcare record contains a diagnosis of current, active tuberculosis disease
- the person's death certificate lists tuberculosis as a cause of death or a significant condition contributing to death

Other recommended reporting procedures

- All cases of tuberculosis should be reported.
- Reporting should be on-going and routine.
- Frequency of reporting should follow the state health department's routine schedule.

- A case should not be counted twice within any consecutive 12-month period. However, a case in which the patient had previously had verified disease should be reported again if the patient was discharged from treatment. A case should also be reported again if the patient was lost to supervision for greater than 12 months and disease can be verified again.

B. Table of criteria to determine whether a case should be reported to public health authorities

Table VI-B. Table of criteria to determine whether a case should be reported to public health authorities. Requirements for reporting are established under State and Territorial laws and/or regulations and may differ from jurisdiction to jurisdiction. These criteria are suggested as a standard approach to identifying cases of this condition for purposes of reporting, but reporting should follow State and Territorial law/regulation if any conflicts occur between these criteria and those laws/regulations.

Criterion	**Reporting**	
Clinical Evidence		
Abnormal chest radiograph consistent with tuberculosis†		O
Abnormal chest computerized tomography scan or other chest imaging study consistent with tuberculosis		O
Clinical evidence of current disease		O
Treatment with two or more antituberculosis medications		N
Completed clinical evaluation with a diagnosis of current, active tuberculosis		N
Healthcare record contains a diagnosis of current, active tuberculosis disease	S	
Death certificate lists tuberculosis as a cause of death or a significant condition contributing to death	S	
Laboratory Evidence		
Positive tuberculin skin test		O
Positive interferon gamma release assay for *M. tuberculosis*		O
Isolation of *M. tuberculosis* from a culture of a clinical specimen*	S	
Demonstration of *M. tuberculosis* using a DNA probe on a culture from a clinical specimen	S	
Demonstration of *M. tuberculosis* mycolic acids using high-pressure liquid chromatography on a culture from a clinical specimen	S	
Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test**	S	
Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated	S	

Notes:
† "A patchy or nodular infiltrate in the apical or subapical posterior areas of the upper lobes or the superior segment of a lower lobe is highly suspicious for early chronic tuberculosis, especially if bilateral or associated with cavity formation." (Fitzgerald and Haas, 2005)
S = This criterion alone is Sufficient to identify a case for reporting.
N = All "N" criteria in the same column are Necessary to identify a case for reporting.
O = At least one of these "O" (Optional) criteria in each category (i.e., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to identify a case for reporting. (These optional criteria are alternatives, which means that a single column will have either no O criteria or multiple O criteria; no column should have only one O.)
† "A patchy or nodular infiltrate in the apical or subapical posterior areas of the upper lobes or the superior segment of a lower lobe is highly suspicious for early chronic tuberculosis, especially if bilateral or associated with cavity formation." (Fitzgerald and Haas, 2005)

C. Disease Specific Data Elements:

Disease-specific data elements to be included in the initial report are listed below.

Country of origin
Time arrived in the US
Occupation
Clinical Information
Major body site of TB
Status of patient at diagnosis
Signs and symptoms
Cough
Date treatment started
Name of medication
Test method -Skin test
Collection date
Test result
Name of test
Test result
Specimen collection date
Source of specimen
Epidemiological Information
Environmental risk factors
Location of probable exposure
Medical risk factors
Occupational risk factors
Sociobehavioral risk factors

VII. Case Definition for Case Classification

A. Narrative description of criteria to determine whether a case should be classified as confirmed.

Clinical description

A chronic bacterial infection caused by *Mycobacterium tuberculosis*, usually characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs may be involved.

Clinical case definition

A case that meets **all** of the following criteria:

- A positive tuberculin skin test or positive interferon gamma release assay 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,** or
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated.

Case classification

Confirmed: a case that meets the clinical case definition or is laboratory confirmed

Comment

A case should not be counted twice within any consecutive 12-month period. However, a case in which the patient had previously had verified TB disease should be reported and counted again if more than 12 months have elapsed since the patient completed therapy. A case should also be reported and counted again if the patient was lost to supervision for greater than 12 months and TB disease can be verified again. Mycobacterial diseases other than those caused by *M. tuberculosis* complex should not be counted in tuberculosis morbidity statistics unless there is concurrent tuberculosis.

*Use of rapid identification techniques for *M. tuberculosis* (e.g., DNA probes and mycolic acids high-pressure liquid chromatography performed on a culture from a clinical specimen) are acceptable under this criterion.
** Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species for clinical purposes. A culture isolate of *M. tuberculosis* complex is required for complete drug susceptibility testing and also genotyping. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert, or a test produced and validated in accordance with applicable FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations.

B. Table of criteria to determine whether a case should be reported to public health authorities

Table VII-B. Table of criteria to determine whether a case is classified.

	Case Definition	
Criterion	**Confirmed**	
Clinical Evidence		
Abnormal chest radiograph consistent with tuberculosis†		O
Abnormal chest computerized tomography scan or other chest imaging study consistent with tuberculosis		O
Clinical evidence of current disease		O
Treatment with two or more antituberculosis medications		N
Completed clinical evaluation with a diagnosis of current, active tuberculosis		N
Laboratory Evidence		
Positive tuberculin skin test		O
Positive interferon gamma release assay for *M. tuberculosis*		O
Isolation of *M. tuberculosis* from a culture of a clinical specimen*	S	
Demonstration of *M. tuberculosis* using a DNA probe on a culture from a clinical specimen	S	
Demonstration of *M. tuberculosis* mycolic acids using high-pressure liquid chromatography on a culture from a clinical specimen	S	
Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test**	S	
Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained	S	

Notes:
S = This criterion alone is Sufficient to classify a case.
N = All "N" criteria in the same column are Necessary to classify a case.
O = At least one of these "O" (Optional) criteria in each category (i.e., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to classify a case.
† "A patchy or nodular infiltrate in the apical or subapical posterior areas of the upper lobes or the superior segment of a lower lobe is highly suspicious for early chronic tuberculosis, especially if bilateral or associated with cavity formation." (Fitzgerald and Haas, 2005)

VIII. Period of Surveillance

Surveillance should be on-going.

IX. Data sharing/release and print criteria

Notification to CDC of confirmed cases of TB is recommended.

- Data are analyzed to monitor TB trends, evaluate program success, and assist in focusing resources to eliminate TB. Annual summaries of surveillance data are used to monitor national TB trends by demographic and risk conditions. These annual reports are published as a report for the agency. CDC periodically conducts special analyses for publication in peer-reviewed scientific journals to describe and interpret national TB surveillance data. Surveillance data are also used in DTBE materials for training and education of health care providers, the general public, and the media.

- Aggregate data are published yearly in the MMWR and in the annual CDC surveillance report, "Reported Tuberculosis in the United States." Annual reports are disseminated to health department TB control officers, pulmonary and infectious disease experts, and others concerned with TB control. The annual surveillance report and accompanying summary slide set are posted each year on the DTBE web site: http://www.cdc.gov/tb/surv/default.htm.

- Limited aggregate data are published annually in the MMWR in March for World TB Day. State-specific compiled data are published annually in the surveillance report in November. In addition, public use aggregate data are available through the Online Tuberculosis Information System (OTIS): http://www.cdc.gov/tb/surv/default.htm. OTIS provides data on verified cases of TB reported to CDC by state health departments, the District of Columbia and Puerto Rico. The data on OTIS are released for public use in accordance with the Assurance and do not identify patients directly, nor do they contain information that can identify patients indirectly. Any effort to determine the identity of any reported cases, or to use the information for any purpose other than statistical reporting and analysis, is a violation of the Assurance.

- To document TB in the Americas, CDC reports aggregate national data on verified TB cases to PAHO annually for inclusion in a yearly WHO surveillance report. No personal identifying or state-specific information is re-released to PAHO or WHO.

X. References

"Updated guidelines for the use of nucleic acid amplification tests in the diagnosis of tuberculosis." MMWR 58(01)

"Guidelines for using the Quantiferon-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States." MMWR 54(RR15)

Centers for Disease Control and Prevention (CDC). Tuberculosis case definition for public health surveillance (Revised March 17, 2009). Available at CSTE tuberculosis forum: http://www.cste.org/dnn/PositionStatementDiscussion/tabid/277/aff/108/aft/243/afv/topic/Default.aspx [log-in at http://www.cste.org/dnn/PositionStatementDiscussion/tabid/277/Default.aspx] Accessed March 20, 2009.

Centers for Disease Control and Prevention (CDC). Recommendations for reporting and counting tuberculosis cases. (Revised March 17, 2009) Available at CSTE tuberculosis forum: http://www.cste.org/dnn/PositionStatementDiscussion/tabid/277/aff/108/aft/243/afv/topic/Default.aspx [log-in at http://www.cste.org/dnn/PositionStatementDiscussion/tabid/277/Default.aspx] Accessed March 20, 2009.

Centers for Disease Control and Prevention [Internet]. Division of Tuberculosis Elimination (DTBE). Atlanta: CDC. Available from: http://www.cdc.gov/tb/default.htm Last updated: 2008 Aug 4. Accessed: 2008 Aug 26.

Council of State and Territorial Epidemiologists (CSTE). CSTE official list of nationally notifiable conditions. CSTE position statement 07-EC-02. Atlanta: CSTE; June 2007. Available from: http://www.cste.org.

Council of State and Territorial Epidemiologists (CSTE). Criteria for inclusion of conditions on CSTE nationally notifiable condition list and for categorization as immediately or routinely notifiable. CSTE position statement 08-EC-02. Atlanta: CSTE; June 2008. Available from: http://www.cste.org.

Council of State and Territorial Epidemiologists (CSTE). Data Release Guidelines of the Council of State & Territorial Epidemiologists for the National Public Health System. Atlanta: CSTE; June 1996.

Council of State and Territorial Epidemiologists, Centers for Disease Control and Prevention. CDC-CSTE Intergovernmental Data Release Guidelines Working Group (DRGWG) Report: CDC-ATSDR Data Release Guidelines and Procedures for Re-release of State-Provided Data.

Atlanta: CSTE; 2005. Available from: http://www.cste.org/pdffiles/2005/drgwgreport.pdf or http://www.cdc.gov/od/foia/policies/drgwg.pdf.

Fitzgerald D, Haas DW. Chapter 248 – *Mycobacterium tuberculosis*. In: Mandell GL, Bennett JE, Dolin R, editors. Principles and Practice of Infectious Diseases, 6th edition. Philadelphia: Churchill Livingstone; 2005.
Heymann DL, editor. Control of communicable diseases manual. 18th edition. Washington: American Public Health Association; 2004.

XI. Coordination:

Agencies for Response:

(1) Thomas R Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta GA 30333
(404) 639-7000
txf2@cdc.gov

XII. Submitting Author:

(1) Jose T. Montero, MD
Director and State Epidemiologist
New Hampshire Department of Health
29 Hazen Dr
Concord, NH 03301
(603) 271-5325
jmontero@dhhs.state.nh.us

Co-Authors:

(1) Associate Member
Harry F. Hull, Medical Epidemiologist
HF Hull & Associates, LLC
1140 St. Dennis Court
Saint Paul, MN 55116
(651) 695-8114
hullhf@msn.com

(2) Associate Member
Cecil Lynch, Medical Informaticist
OntoReason
7292 Shady Woods Circle
Midvale, UT 84047
(916) 412.5504
clynch@ontoreason.com

(3) Associate Member
R. Gibson Parrish, Medical Epidemiologist
P.O. Box 197
480 Bayley Hazen Road
Peacham, VT 05862
(802) 592-3357
gib.parrish@gmail.com