17-ID-09

Committee: Infectious Disease

Title: Establishing a Case Definition for Latent TB Infection (TB Infection)

I. Statement of the Problem

CSTE position statement 07-EC-02 recognizes the need to develop an official list of nationally notifiable conditions and a standardized reporting definition for each of these conditions. CSTE position statement 09-ID-65 establishes the definition for Tuberculosis (TB) Disease. As incidence of TB Disease declines in the United States, the focus of efforts to further reduce the burden has shifted to latent TB infection (TB Infection). A standard definition of TB Infection was not established in the 09-ID-65 position statement which deals with TB Disease, nor does a standardized definition exist elsewhere in the United States to facilitate this conversation.

II. Background and Justification

Background

TB is a disease caused by a bacterium called *Mycobacterium tuberculosis.* The active form of tuberculosis (TB Disease) was once the leading cause of death in the United States (US). TB Disease is spread through the air from one person to another when the disease is located in the lungs. People nearby may breathe in these bacteria and become infected.

Not everyone infected with *M. tuberculosis* becomes sick. People who are not sick have what is commonly called Latent TB Infection (TB Infection). People with TB Infection do not feel sick, do not have any symptoms, and cannot spread TB to others. Nevertheless, some people with TB Infection go on to develop TB Disease in the course of their lifetimes. Likelihood of developing TB Disease is variable depending on a number of risk factors.

Consensus in the public health community has recently shifted toward TB elimination efforts. In order to continue to reduce the burden of TB Disease in the US an effort must be made to identify those with TB Infection who are at highest risk for progressing to TB Disease so that they can be treated prophylactically. Many jurisdictions within the US have moved to make TB Infection a reportable condition either universally, or in identified high risk groups in order to facilitate this work. However, their efforts are hindered by a lack of coherence in case definition and approach.

Justification

A case definition for classification of TB Infection is a highly logical first step in the creation of a more complete and nationally understood infrastructure for reporting and sharing information on TB Infection rates and risks for progression to TB Disease. If universal or partial reporting of TB Infection is determined to be necessary, it would be impossible to implement without a standardized case definition.

An increasing number of state and local jurisdictions are moving to adopt reporting mechanisms for TB Infection. A standardized case definition to classify TB Infection cases is required to make data from these jurisdictions comparable, and to facilitate regional and national level assessments about the incidence/prevalence of TB Infection. A standardized case definition will also allow for better estimates of disease burden and modeling of the reservoir, as it will allow reporting from multiple jurisdictions to be used in the estimate.

The populations most affected by TB are often highly mobile and cross border travel is common. A standardized case definition for TB Infection facilitates communication between health departments in different jurisdictions and allows for improved continuity of care.

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

1. Utilize standard sources (e.g. reporting*) for case ascertainment for Latent Tuberculosis Infection (TB Infection). Surveillance for TB Infection should use the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases of TB Infection.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	X	
Laboratory reporting	X	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)	X	
Death certificates		
Hospital discharge or outpatient records	X	
Extracts from electronic medical records	X	
Telephone survey		
School-based survey		
Other _____		

2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for TB Infection but do not add TB Infection to the *Nationally Notifiable Condition List*. If requested by CDC, jurisdictions (e.g. States and Territories) conducting surveillance according to these methods may submit case information to CDC.

IV. Goals of Surveillance

To provide information on the temporal, geographic, and demographic occurrence of TB Infection to facilitate the further prevention and control of TB Disease.

V. Methods for Surveillance: Surveillance for TB Infection should use the recommended sources of data and the extent of coverage listed in Table III.

Surveillance for TB Infection should use the recommended sources of data and the extent of coverage listed in Table III.

VI. Criteria for case identification

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.

In **applicable jurisdictions**, report any person to public health authorities that meets any of the following laboratory criteria:

A positive tuberculin skin test (TST), or

A positive interferon gamma release assay (IGRA)

Guidelines for use of TST or IGRA have been published by the American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention (see reference).

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.

Criterion	TB Infection
Clinical Evidence	
None	
Laboratory Evidence	
Positive TST	S
Positive IGRA	S
Epidemiological Evidence	
None	

Notes:
S = This criterion alone is Sufficient to report a case.
N = All "N" criteria in the same column are Necessary to report a case.
O = At least one of these "O" (One or more) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to report a case.
* A requisition or order for any of the "S" laboratory tests is sufficient to meet the reporting criteria.

C. Disease-specific data elements

Imaging results, regardless of findings (chest radiograph, CT scan)
Microbiologic results
Country of birth
HIV status
Immunosuppressive medications
Known contact to a TB Disease case
TB status at immigration (Class A/B Conditions)
Homelessness
Substance use
Prior known TST or IGRA result
History of incarceration
History of travel to or residence in a country other than the United States, Western Europe or Japan lasting more than 1 month

VII. Case Definition for Case Classification

A. Narrative: Description of criteria to determine how a case should be classified.

Clinical Criteria
Clinical criteria alone are not sufficient to classify a case of TB Infection. Clinical criteria to confirm a suspected case of TB Infection are as follows:

No clinical evidence compatible with TB Disease including:

No signs or symptoms consistent with TB Disease

AND

1) Chest imaging without abnormalities consistent with TB (chest radiograph or CT scan)

OR

2) Abnormal chest imaging that could be consistent with TB Disease with microbiologic testing that is negative for MTB complex AND where TB Disease has been clinically ruled out

Laboratory Criteria

Laboratory/diagnostic criteria alone are not sufficient to confirm a case of TB Infection. Laboratory criteria to identify suspected cases of TB Infection are as follows:

A positive tuberculin skin test (TST) [As defined by the CDC (see reference)]

OR

A positive interferon gamma release assay (IGRA) [As defined by the CDC (see reference)]

Case Classification for TB Infection

Suspected TB Infection

A case that meets one or more of the laboratory criteria

AND

M. tuberculosis complex was not isolated from a clinical specimen, if a specimen was collected

Confirmed TB Infection

A case that meets one of the laboratory criteria for TB Infection

AND

M. tuberculosis complex was not isolated from a clinical specimen, if a specimen was collected

AND

Meets the clinical criteria for TB Infection as listed above

Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance

A new case is an incident TB Infection case that meets the suspected or confirmed case criteria and has not previously been diagnosed or treated for TB Infection OR previously treated for TB Disease.

B. Classification Tables

Table VII-B. Criteria for defining a case of TB Infection.

Criterion	Suspected		Confirmed			
Clinical Evidence						
No signs or symptoms of TB Disease			N	N	N	N
Chest imaging without abnormalities consistent with TB Disease			N		N	
Abnormal chest imaging that could be consistent with TB Disease				N		N
TB Disease clinically ruled out				N		N
Laboratory evidence						
Positive tuberculin skin test	O	O	O	O	O	O
Positive interferon gamma release assay (IGRA)	O	O	O	O	O	O
Specimen not collected for micro-bacteriologic testing	N		N	N		
MTB was not isolated via micro-bacteriologic testing		N			N	N

S = This criterion alone is Sufficient to classify a case.
N = All "N" criteria in the same column are Necessary to classify a case. A number following an "N" indicates that this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion NOT present) is required for the case to meet the classification criteria, list the Absence of criterion as a Necessary component.
O = At least one of these "O" (One or more) criteria in each category (e.g., 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. (These "O" 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 number following an "O" indicates that this criterion is only required for a specific disease/condition subtype.

VIII. Period of Surveillance

Surveillance should be on-going.

IX. Data sharing/release and print criteria

Data are not currently nationally notifiable, and will not be collected at CDC or any other national agency as a result of the propagation of this case definition. Individual jurisdictions where reporting or surveillance of TB Infection is mandated should be governed by their own data sharing and usage agreements.

X. Revision History

There have been no previous position statements specifically on TB Infection.

Position Statement ID	Section of Document	Revision Description
17-ID-09	Table VII-B.	CSTE National Office made minor technical clarifications in Table VII-B to align table with narrative section VII-A.

XI. References

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Council of State and Territorial Epidemiologists (CSTE). Public Health Reporting and National Notification for Tuberculosis. CSTE Position statement 09-ID-65. Available from: http://www.cste.org/resource/resmgr/PS/09-ID-65.pdf

Centers for Disease Control and Prevention (CDC). Latent Tuberculosis Infection: A Guide for Primary Health Care Providers. Available from https://www.cdc.gov/tb/publications/ltbi/diagnosis.htm (Accessed February 2017)

Centers for Disease Control and Prevention (CDC). TB Fact Sheet on Tuberculin Skin Testing Available from: https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm (Accessed February 2017)

Centers for Disease Control and Prevention (CDC). TB Fact Sheet on IGRA Blood Tests for TB infection Available from: https://www.cdc.gov/tb/publications/factsheets/testing/igra.htm (Accessed February 2017)

Lewinsohn DM, Leonard MK, LoBue PA et al. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children. *Clin Inf Dis* 2017: 64 (2): 111-5.

XII. Coordination

Agencies for Response

(1) Centers for Disease Control and Prevention
Brenda Fitzgerald, MD
Director
1600 Clifton Road, NE
Atlanta, GA 30333
Telephone: 404-639-7000
Email: director@cdc.gov

Agencies for Information:

N/A

XIII. Submitting Author:

(1) Andrew Tibbs
Epidemiologist III -Division of Global Populations and Infectious Disease Prevention
Massachusetts Department of Public Health
State Laboratory Institute
305 South Street
Boston, MA 01230
617-983-6893
Andrew.Tibbs@state.ma.us

Co-Author:

(1) ☒Active Member ☐Associate Member
Lynn Sosa
Deputy State Epidemiologist/TB Controller
Connecticut Department of Public Health

410 Capitol Avenue
MS #11 TUB
Hartford, CT 06134
860-509-7723
lynn.sosa@ct.gov

(2) ☒Active Member ☐Associate Member

Shama Desai Ahuja, PhD, MPH
Director, Office of Surveillance and Epidemiology
Bureau of Tuberculosis Control
New York City Department of Health and Mental Hygiene
42-09 28th Street, 21st floor, CN72-B
Long Island City, NY 11101
347.396.7548
sahuja@health.nyc.gov