09-ID-10

Committee: Infectious

Title: National Surveillance for Anthrax

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:

Anthrax meets the definition of a nationally and **immediately** notifiable condition—as specified in CSTE position statement 08-EC-02—for the following reason(s):

- The condition is included on the list of Category A possible bioterrorism agents and toxins.
- A majority of state and territorial jurisdictions—or jurisdictions comprising a majority of the US population—have laws or regulations requiring **immediate** reporting of the condition to public health authorities; the Centers for Disease Control and Prevention (CDC) requests **immediate** notification of the condition; and the CDC has condition-specific policies and practices concerning its response to, and use of, notifications.
- If the source of the infection is not recognized or is recognized as one of BT or potential mass exposure, or if the case or cases involve serious illness of naturally-occurring anthrax such as with systemic involvement where medical countermeasures available through CDC may be requested for therapy, the CDC requests **immediate (extremely urgent)** notification. If the source of infection can be attributed to a naturally-occurring or occupation exposure and the case or cases are responding to current medical management the CDC requests **immediate (urgent)** notification for confirmed and probable cases.

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

CSTE requests that CDC adopt these standardized reporting and case classification definitions for anthrax to facilitate more timely, complete, and standardized local and national surveillance of this condition.

IV. Goals of Surveillance:

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

V. Methods for Surveillance:

Surveillance for anthrax should use the sources of data and the extent of coverage listed in Table V below.

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

	Extent of 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. 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 illness to public health authorities that meets any of the following criteria:

I. A person with clinically compatible illness (one or more from Table VI-B Clinical presentation) and one of the following:

- Culture and identification of *B. anthracis* from clinical specimens
- Demonstration of *B. anthracis* antigens in tissues by immunohistochemical staining using both *B. anthracis* cell wall and capsule monoclonal antibodies
- Evidence of a four-fold rise in antibodies to protective antigen between acute and convalescent sera or a fourfold change in antibodies to protective antigen in paired convalescent sera using quantitative anti-PA IgG ELISA testing
- Evidence of *B. anthracis* DNA (for example, by polymerase chain reaction) in clinical specimens collected from a normally sterile site (such as blood or CSF) or lesion of other affected tissue (skin, pulmonary, reticuloendothelial, or gastrointestinal)
- Positive result on testing of clinical serum specimens using the Quick ELISA Anthrax-PA kit
- Detection of Lethal Factor (LF) in clinical serum specimens by LF mass spectrometry
- Positive result on testing of culture from clinical specimens with the RedLine Alert test

II. A person with clinically compatible illness (one or more from Table VI-B Clinical presentation) AND any of the epidemiologic linkages:

- exposure to the same environment, animal, or objects as persons who have laboratory-confirmed anthrax
- consumption of the same food as persons who have laboratory-confirmed anthrax

III. A person whose healthcare record contains a diagnosis of anthrax.

IV. A person whose death certificate lists anthrax as a cause of death or a significant condition contributing to death.

Other recommended surveillance procedures

- All cases of anthrax should be reported.
- Reporting should be ongoing and routine.
- Reporting should be immediate.

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**		
	I	II	III/IV
Clinical Evidence			
Painless skin lesion developing over 2 to 6 days from a papular through a vesicular stage into a depressed black eschar with surrounding edema	O1	O1	
Fever (any)	O1,2,3,4,5	O1,2,3,4,5	
Malaise	O1,3,4	O1,3,4	
Lymphadenopathy	O1	O1	
Prodrome resembling a viral respiratory illness	O2	O2	
Hypoxia	O2	O2	
Dyspnea	O2	O2	
Acute respiratory distress	O2	O2	
Cyanosis	O2	O2	
Shock	O2,3,4	O2,3,4	
Radiological evidence of mediastinal widening	O2	O2	
Radiological evidence of pleural effusion	O2	O2	
Severe abdominal pain and tenderness	O3	O3	
Nausea	O3	O3	
Vomiting	O3	O3	
Hematemesis	O3	O3	
Bloody diarrhea	O3	O3	
Anorexia	O3	O3	
Abdominal swelling	O3	O3	
Signs of septicemia	O1,2,3,4,5	O1,2,3,4,5	
Painless mucosal lesion in the oral cavity	O4	O4	
Painless mucosal lesion in the oropharynx	O4	O4	
Cervical adenopathy	O4	O4	
Cervical edema	O4	O4	

Pharyngitis	O4	O4	
Convulsions	O5	O5	
Coma	O5	O5	
Meningeal signs	O5	O5	
Healthcare record contains a diagnosis of anthrax			S1,2,3,4,5
Death certificate lists anthrax as a cause of death or a significant condition contributing to death			S1,2,3,4,5
Laboratory Evidence			
Culture and identification of *B. anthracis* from clinical specimens	O1,2,3,4,5		
Demonstration of *B. anthracis* antigens in tissues by immunohistochemical staining using both *B. anthracis* cell wall and capsule monoclonal antibodies	O1,2,3,4,5		
Evidence of a four-fold rise in antibodies to protective antigen between acute and convalescent sera or a fourfold change in antibodies to protective antigen in paired convalescent sera using quantitative anti-PA IgG ELISA testing	O1,2,3,4,5		
Evidence of *B. anthracis* DNA (for example, by polymerase chain reaction) in clinical specimens collected from a normally sterile site (such as blood or CSF) or lesion of other affected tissue (skin, pulmonary, reticuloendothelial, or gastrointestinal)	O1,2,3,4,5		
Positive result on testing of clinical serum specimens using the Quick ELISA Anthrax-PA kit	O1,2,3,4,5		
Detection of Lethal Factor (LF) in clinical serum specimens by LF mass spectrometry	O1,2,3,4,5		
Positive result on testing of culture from clinical specimens with the RedLine Alert test	O1,2,3,4,5		
Epidemiologic Evidence			
Exposure to the same environment, animal, or Objects as persons who have laboratory-confirmed anthrax		O1,2,3,4,5	
Consumption of the same food as persons who have laboratory-confirmed anthrax		O1,3,4	

S = This criterion alone is Sufficient 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 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.)
1 = Cutaneous anthrax
2 = Inhalation anthrax
3 = Gastrointestinal anthrax
4 = Oropharyngeal anthrax
5 = Meningeal anthrax

C. Disease Specific Data Elements:

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

Environmental risk factors
Epidemiological linkage to a documented anthrax environmental exposure
Contact with animal or animal products
• Animal
• Exposure type
• Current location
• Exposure date
Handled suspicious mail
Exposed to suspicious powder
Hunting
Contact with raw/undercooked meat
Travel in the month prior to symptom onset
• Date of travel
• Location of travel
Occupational risk factors
Occupation
• Mail Handler
Working in a clinical or microbiological laboratory processing samples that could potentially contain anthrax
Contact with animal hides

Contact with raw/undercooked meat (e.g. slaughterhouse workers, butchers)
Contact with livestock (e.g. ranchers, veterinarians)
Contact with wool or goat hair

VII. Case Definition for Case Classification

A. Narrative description of criteria to determine whether a case should be classified as confirmed, probable (presumptive), or suspected (possible).

Clinical description

An acute illness, or post-mortem examination, characterized into several distinct clinical forms, including:

Cutaneous anthrax: A painless skin lesion developing over 2 to 6 days from a papular through a vesicular stage into a depressed black eschar with surrounding edema. Fever, malaise and lymphadenopathy may accompany the lesion.

Inhalation anthrax: A prodrome resembling a viral respiratory illness, followed by hypoxia, dyspnea or acute respiratory distress with resulting cyanosis and shock. Radiological evidence of mediastinal widening or pleural effusion is common.

Gastrointestinal anthrax: Severe abdominal pain and tenderness, nausea, vomiting, hematemesis, bloody diarrhea, anorexia, fever, abdominal swelling and septicemia.

Oropharyngeal anthrax: A painless mucosal lesion in the oral cavity or oropharynx, with cervical adenopathy, edema, pharyngitis, fever, and possibly septicemia.

Meningeal anthrax: Fever, convulsions, coma, or meningeal signs. Signs of another form will likely be evident as this syndrome is usually secondary to the above syndromes.

Case classification

Suspect:
An illness suggestive of one of the known anthrax clinical forms. No definitive, presumptive, or suggestive laboratory evidence of *B. anthracis*, or epidemiologic evidence relating it to anthrax.

Probable:
A clinically compatible illness that does not meet the confirmed case definition, but with one of the following:

- Epidemiological link to a documented anthrax environmental exposure;
- Evidence of *B. anthracis* DNA (for example, by LRN-validated polymerase chain reaction) in clinical specimens collected from a normally sterile site (such as blood or CSF) or lesion of other affected tissue (skin, pulmonary, reticuloendothelial, or gastrointestinal);
- Positive result on testing of clinical serum specimens using the Quick ELISA Anthrax-PA kit;
- Detection of Lethal Factor (LF) in clinical serum specimens by LF mass spectrometry
- Positive result on testing of culture from clinical specimens with the RedLine Alert test.

Confirmed:
A clinically compatible illness with one of the following:

- Culture and identification of *B. anthracis* from clinical specimens by the Laboratory Response Network (LRN);
- Demonstration of *B. anthracis* antigens in tissues by immunohistochemical staining using both *B. anthracis* cell wall and capsule monoclonal antibodies;
- Evidence of a four-fold rise in antibodies to protective antigen between acute and convalescent sera or a fourfold change in antibodies to protective antigen in paired convalescent sera using Centers for Disease Control and Prevention (CDC) quantitative anti-PA IgG ELISA testing;
- Documented anthrax environmental exposure AND evidence of *B. anthracis* DNA (for example, by LRN-validated polymerase chain reaction) in clinical specimens collected from a normally sterile site (such as blood or CSF) or lesion of other affected tissue (skin, pulmonary, reticuloendothelial, or gastrointestinal).

B. Classification Table:

Table VII-B lists the criteria that must be met for a case to be classified as confirmed, probable (presumptive), or suspected (possible).

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

	Case Definition			
Criterion	**Confirmed**	**Probable**		**Suspect**
Clinical Evidence				
Painless skin lesion developing over 2 to 6 days from a papular through a vesicular stage into a depressed black eschar with surrounding edema	O1	O1	O1	O1
Fever (any)	O1,2,3,4,5	O1,2,3,4,5	O1,2,3,4,5	O1,2,3,4,5
Malaise	O1,3,4	O1,3,4	O1,3,4	O1
Lymphadenopathy	O1	O1	O1	O1
Prodrome resembling a viral respiratory illness	O2	O2	O2	O2
Hypoxia	O2	O2	O2	O2
Dyspnea	O2	O2	O2	O2
Acute respiratory distress	O2	O2	O2	O2
Cyanosis	O2	O2	O2	O2
Shock	O2,3,4	O2,3,4	O2,3,4	O2,3,4

Radiological evidence of mediastinal widening	O2	O2	O2	O2
Radiological evidence of pleural effusion	O2	O2	O2	O2
Severe abdominal pain and tenderness	O3	O3	O3	O3
Nausea	O3	O3	O3	O3
Vomiting	O3	O3	O3	O3
Hematemesis	O3	O3	O3	O3
Bloody diarrhea	O3	O3	O3	O3
Anorexia	O3	O3	O3	O3
Abdominal swelling	O3	O3	O3	O3
Signs of septicemia	O1,2,3,4,5	O1,2,3,4,5	O1,2,3,4,5	O1,2,3,4,5
Painless mucosal lesion in the oral cavity	O4	O4	O4	O4
Painless mucosal lesion in the oropharynx	O4	O4	O4	O4
Cervical adenopathy	O4	O4	O4	O4
Cervical edema	O4	O4	O4	O4
Pharyngitis	O4	O4	O4	O4
Convulsions	O5	O5	O5	O5
Coma	O5	O5	O5	O5
Meningeal signs	O5	O5	O5	O5
Laboratory Evidence				
Culture and identification of *B. anthracis* from clinical specimens	O1,2,3,4,5			A1,2,3,4,5
Demonstration of *B. anthracis* antigens in tissues by immunohistochemical staining using both *B. anthracis* cell wall and capsule monoclonal antibodies	O1,2,3,4,5			A1,2,3,4,5
Evidence of a four-fold rise in antibodies to protective antigen between acute and convalescent sera or a fourfold change in antibodies to	O1,2,3,4,5			A1,2,3,4,5

protective antigen in paired convalescent sera using quantitative anti-PA IgG ELISA testing				
Evidence of *B. anthracis* DNA (for example, by polymerase chain reaction) in clinical specimens collected from a normally sterile site (such as blood or CSF) or lesion of other affected tissue (skin, pulmonary, reticuloendothelial, or gastrointestinal)			O1,2,3,4,5	A1,2,3,4,5
Positive result on testing of clinical serum specimens using the Quick ELISA Anthrax-PA kit			O1,2,3,4,5	A1,2,3,4,5
Detection of Lethal Factor (LF) in clinical serum specimens by LF mass spectrometry			O1,2,3,4,5	A1,2,3,4,5
Positive result on testing of culture from clinical specimens with the RedLine Alert test			O1,2,3,4,5	A1,2,3,4,5
Epidemiologic Evidence				
Epidemiologically linked to a documented anthrax environmental exposure		O1,2,3,4,5		A1,2,3,4,5

A = This criterion must be absent (i.e., NOT present) for the case to meet the classification criteria.
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.
1 = Cutaneous anthrax
2 = Inhalation anthrax
3 = Gastrointestinal anthrax
4 = Oropharyngeal anthrax
5 = Meningeal anthrax

VIII. Period of Surveillance

Surveillance should be ongoing.

IX. Data sharing/release and print criteria:

- Notification to CDC of all probable and confirmed cases of anthrax is recommended.

- Anthrax, caused by *Bacillus anthracis* (*B. anthracis*), is a naturally occurring disease in the United States and in many parts of the world, and is also one of the most likely biological agents to be used as a bioterrorism weapon. Case notification to the national level provides CDC, the lead agency for the national public health response to biological terrorism, the ability to conduct national real-time surveillance for a potential bioterrorism release or outbreak of *B. anthracis* which would require immediate and coordinated public health, medical, and law enforcement response at the local, state and national levels, as well as rapid deployment of federal response personnel and resources.
- Cumulative and aggregate case data as they are reported to CDC will be monitored to allow for detection of changing trends in cases by CDC subject matter experts and epidemiologists in the Division of Bioterrorism, Preparedness and Response (DBPR) and the Bacterial Zoonoses Branch (BZB) in the Division of Foodborne, Bacterial, and Mycotic Diseases (DFBMD).
- Annual case data on anthrax is summarized in the yearly Summary of Notifiable Diseases. In the event of an increased number of cases of either natural or bioterrorism-related origin the CDC will relay information to the states and territories on an increased, situation-dependent frequency.
- State-specific compiled data is published in the annual MMWR Surveillance Summaries. All cases are verified by CDC epidemiologists or with the state (s) reporting before publication. Due to the very low frequency of occurrence of cases of anthrax in the United States, additional case information will usually be published in the form of individual case or investigation summaries in the MMWR or manuscripts in peer-reviewed journals. The frequency of release of additional publication of this data will be dependent on any change in status from the current epidemiologic situation in the US.
- Summary de-identified case data is reported nationally in the annual MMWR Surveillance Summary report for all confirmed cases. In the event of a suspected biotoerrorism event, or an event where cases may appear in multiple states, CDC will coordinate the sharing of necessary data between the affected or potentially affected state and territorial health departments. In circumstances where there is a potential for an international health impact, data from these notifications may be sent to the Pan American Health Organization (PAHO), the World Organization of Animal Health (OIE), or the World Health Organization (WHO) via the International Health Regulations (IHR) mechanism.

X. References:

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