09-ID-29

Committee: Infectious

Title: National Surveillance for Botulism

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:

Botulism meets the definition of a nationally and **immediately** and **standard** 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 and standard** reporting of the condition to public health authorities
- The Centers for Disease Control and Prevention (CDC) requests **immediate and standard** notification of the condition.
- The CDC has condition-specific policies and practices concerning its response to, and use of, notifications

- **Immediate notification, Extremely Urgent** (CDC official will return the call to the State/Territory within 1 hour of the DEOC receiving the call): Any case of human botulism that meets one or more of the following criteria:
    - Cases of foodborne botulism, except those that are endemic to Alaska
    - Cases of botulism suspected to result from an intentional release of botulinum toxin
    - Cases involved in clusters or outbreaks of infant botulism
    - Cases that are of unknown etiology or do not otherwise meet criteria for standard notification

- **Standard notification**: Cases of human botulism that meet one of the following classifications, and do not meet one or more criteria for immediate notification:
    - Sporadic cases or clusters of wound botulism
    - Sporadic cases of infant botulism

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

CSTE requests that CDC adopt this standardized reporting definition for botulism 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 botulism to facilitate its prevention and control.

V. Methods for Surveillance:

Surveillance for botulism 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 botulism

	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 by humans and machines to determine whether a specific illness should be reported.[1]

A. Narrative description of criteria to be used by humans 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:

- A person for whom a diagnostic test specific for botulism has been ordered (see table 2a).
- A person for whom anti-toxin specific for botulism has been ordered (see table 2a).
- A person with *at least one* of the clinical presentations in table 2a AND who has ingested the same food as persons who have laboratory-confirmed botulism.
- A person with at least one of the clinical presentations in table 2 AND at least one of the historical findings in table 2a.
- A person whose healthcare record contains a diagnosis of botulism.
- A person whose death certificate lists botulism as a cause of death or a significant condition contributing to death.

Other recommended surveillance procedures

- All cases of botulism should be reported.
- Reporting should be on-going and routine.
- Reporting should be immediate.

[1] "Human-based" criteria (described below under "A. Narrative") can be applied by medical care providers and laboratory staff based on clinical judgment and clinical diagnosis. Machine-based criteria (described below under "B. Table") can be applied using computerized algorithms that operate in electronic health record systems, including computerized records of laboratory test orders and laboratory test results.

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

Table VI-B. Proposed Table of criteria to determine whether a case should be reported to public health authorities. Note: The following criteria are proposed for evaluation before general implementation. For purposes of currently implementing reporting the narrative description in VI-A, should be used.

Criterion	Reporting		
Historical findings			
history of a fresh, contaminated wound during the two weeks before onset of symptoms			O
ingestion of home-canned food within the 48 hours before onset of symptoms			O
Clinical presentations			
illness of variable severity			
diplopia (double vision)		O	O
blurred vision		O	O
bulbar weakness		O	O
impaired respiration		O	O
progressive weakness		O	O
progressive symmetric paralysis		O	O
healthcare record contains a diagnosis of botulism	S		
death certificate lists botulism as a cause of death or a significant condition contributing to death	S		
Laboratory findings			
detection of botulinum toxin in serum	S*		
detection of botulinum toxin in stool	S*		
detection of botulinum toxin in patient's food	S*		
isolation of *Clostridium botulinum* from stool	S*		
isolation of *Clostridium botulinum* from wound	S*		
Epidemiologic linkages			
ingestion of the same food as persons who have laboratory-confirmed botulism		N	

Special criteria				
age < 1 year				
request for anti-toxin specific for botulinum toxin	S*			

S = This criterion alone is sufficient to report a case.
N = All "N" criteria in the same column—in conjunction with at least one of the "O" criteria in each category (e.g., clinical presentation and laboratory findings) in the same column—are required to report a case. A number following an "N" indicates that this criterion is only required for a specific clinical presentation (see below).
O = At least one of these "O" criteria in each category (e.g., clinical presentation and laboratory findings) in the same column—in conjunction with all other "N" criteria in the same column—is required to report a case. A number following an "O" indicates that this criterion is only required for a specific clinical presentation (see below).
* A requisition or order for any of the "S" or "N" laboratory tests is sufficient to meet the reporting criteria.
1 = Foodborne botulism
2 = Infant botulism
3 = Wound botulism
4 = Other botulism

C. Disease Specific Data Elements:

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

See "CDC Botulism Antitoxin Release and Reaction Report" [Form 1 (version 1/15/2002)] and "Suspected Botulism Clinical Outcome Report" [Form 2 (version 1/15/2002)] for extended data elements.

VII. Case Definition for Case Classification

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

Botulism, Foodborne

Clinical description

Ingestion of botulinum toxin results in an illness of variable severity. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory criteria for diagnosis

- Detection of botulinum toxin in serum, stool, or patient's food, or
- Isolation of Clostridium botulinum from stool

Case classification

Probable: a clinically compatible case with an epidemiologic link (e.g., ingestion of a home-canned food within the previous 48 hours)

Confirmed: a clinically compatible case that is laboratory confirmed or that occurs among persons who ate the same food as persons who have laboratory-confirmed botulism

Botulism, Infant

Clinical description

An illness of infants, characterized by constipation, poor feeding, and "failure to thrive" that may be followed by progressive weakness, impaired respiration, and death

Laboratory criteria for diagnosis

- Detection of botulinum toxin in stool or serum, or
- Isolation of Clostridium botulinum from stool

Case classification

Confirmed: a clinically compatible case that is laboratory-confirmed, occurring in a child aged less than 1 year

Botulism, Wound

Clinical description

An illness resulting from toxin produced by Clostridium botulinum that has infected a wound. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory criteria for diagnosis

- Detection of botulinum toxin in serum, or
- Isolation of Clostridium botulinum from wound

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed in a patient who has no suspected exposure to contaminated food and who has a history of a fresh, contaminated wound during the 2 weeks before onset of symptoms

Botulism, Other

Clinical description

See Botulism, Foodborne.

Laboratory criteria for diagnosis

- Detection of botulinum toxin in clinical specimen, or
- Isolation of Clostridium botulinum from clinical specimen

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed in a patient aged greater than or equal to 1 year who has no history of ingestion of suspect food and has no wounds

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B. Classification Table:

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

Table VII-B. Proposed table of criteria to determine whether a case is classified. Note: The following criteria are proposed for evaluation before general implementation. For purposes of current notification, the narrative description in VII-A, should be used.

	Case Definition		
Criterion	Confirmed		Probable
Historical findings			
history of a fresh, contaminated wound during the two weeks before onset of symptoms	N3		
ingestion of home-canned food within the 48 hours before onset of symptoms	A3	O1	N1
Clinical presentations			
illness of variable severity			
diplopia (double vision)	O1,O3,O4	O1	O1,O3,O4
blurred vision	O1,O3,O4	O1	O1,O3,O4
bulbar weakness	O1,O3,O4	O1	O1,O3,O4
impaired respiration	O2		O2
progressive weakness	O2		O2

progressive symmetric paralysis	O1,O3,O4	O1	O1,O3,O4
healthcare record contains a diagnosis of botulism			
death certificate lists botulism as a cause of death or a significant condition contributing to death			
Laboratory findings			
detection of botulinum toxin in serum	O		
detection of botulinum toxin in stool	O1,O2,O4		
detection of botulinum toxin in patient's food	O1,O4		
isolation of *Clostridium botulinum* from stool	O1,O2,O4		
isolation of *Clostridium botulinum* from wound	O3,O4		
Epidemiologic linkages			
ingestion of the same food as persons who have laboratory-confirmed botulism			
Special criteria			
age < 1 year	N2,A4		

N = All "N" criteria in the same column are required to classify a case. A number following an "N" indicates that this criterion is only required for a specific clinical presentation (see below).
O = At least one of these "O" criteria in each category (e.g., clinical presentation and laboratory findings) in the same column is required to classify a case. A number following an "O" indicates that this criterion is only required for a specific clinical presentation (see below).
A = This criterion must be absent (i.e., NOT present) for the case to meet the case classification.
1 = Foodborne botulism
2 = Infant botulism
3 = Wound botulism
4 = Other botulism

VIII. Period of Surveillance

Surveillance should be on-going.

IX. Data sharing/release and print criteria:

Notification to CDC of all cases prior to classification is recommended.

Expectations for sharing case data

- State and territorial health agencies will **immediately-extremely urgent** notify CDC of reports of probable or confirmed cases of botulism suspected of being intentional; foodborne (except those endemic to Alaska); and clusters or outbreaks of infantile. All other cases (e.g. wound) will be **standard** notification.
- State and territorial health agencies will submit individual reports of confirmed cases of botulism to CDC **weekly**.
- CDC will submit aggregate national counts of reports of cases of botulism to WHO **annually**.

Limitations on releasing case data

State-specific data will continue to be published in the weekly and annual MMWR, and in an annual letter to CSTE. Summary data will include the number of cases by clinical form of botulism (foodborne, wound, infant, unknown/other), toxin type, number of deaths, and comparison with numbers in preceding years. Other information will vary depending on the characteristics of specific outbreaks, novel implicated food items, and other noteworthy events but may include emergency releases through Epi-X, press releases, the CDC internet site, and/or expedited online reports through MMWR.

Restrictions on publishing case data

- State and territorial health agencies will only publish data on **confirmed** cases of botulism. Provisional data will not be used until verification procedures are complete.

X. References:

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