10-ID-03

Committee: Infectious Disease

Title: Expanding Wound Botulism Surveillance Case Definitions

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.

Currently, the CSTE surveillance case definition for wound botulism only has a confirmed case category. However, the mouse bioassay, the laboratory gold standard for confirming wound botulism, is only up to 68% sensitive, and not all cases of wound botulism in injection drug users have an obvious contaminated wound. We propose adding a probable wound botulism case definition and expanding the confirmed case definition to improve surveillance for this disease.

II. Background and Justification:

Since 1994, wound botulism has been increasing in California and in the U.S. particularly due to drug users injecting or skin popping black tar heroin. California documented about 75% of cases of wound botulism in the US in recent years, and the main risk factors are contaminated black tar heroin and skin popping (Passaro et al, Werner et al). A recent review of cases of wound botulism in California meeting strict clinical botulism case definition found that the mouse bioassay, which is still the laboratory standard for confirming botulism, is only about 68% sensitive (Wheeler et al), and that many cases of clinical botulism among injection drug users (IDUs) can only be explained as probable wound botulism despite negative laboratory results or no laboratory testing. With the use of black tar heroin spreading across the US, wound botulism among drug users elsewhere in the US may be under-detected and under-reported, especially if relying only on laboratory confirmation. Additionally, we documented many cases of laboratory-confirmed wound botulism among IDUs who don't have an obvious infected wound at the time of clinical presentation. These cases would not have been counted if using the current Confirmed Case Definition.

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:

1. Add to the Case Classification of the CSTE Wound Botulism surveillance case definition a Probable category defined as: "***Probable: A clinically compatible case 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, or a history of injection drug use within the 2 weeks before onset of symptoms."***
2. Expand the Confirmed case definition to add the phrase "or a history of injection drug use within the 2 weeks before onset of symptoms" to the end, so that it would read:" ***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, or a history of injection drug use within the 2 weeks before onset of symptoms."***
3. Add criterion ""History of injection drug use within the two weeks before onset of symptoms" to tables VI-B and VII-B to reflect above proposed modifications of surveillance case definitions.

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 Case Identification

A. Narrative: A description of suggested criteria for case ascertainment:

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.
- A person for whom anti-toxin specific for botulism has been ordered.
- A person with *at least one* of the clinical presentations in table VI B 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 VI B AND at least one of the historical findings in table VI B.
- 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.

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**		
Historical Evidence			
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
History of injection drug use within the two weeks before onset of symptoms			O
Clinical Evidence			
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 Evidence			

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 Evidence			
Ingestion of the same food as persons who have laboratory-confirmed botulism		N	
Special criteria			
Request for anti-toxin specific for botulinum toxin	S*		

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—is required to identify a case for reporting.
* A requisition or order for any of the "S" laboratory tests is sufficient to meet the reporting criteria.

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 either a history of a fresh, contaminated wound during the 2 weeks before onset of symptoms, or a history of injection drug use within the 2 weeks before onset of symptoms.

Probable: A clinically compatible case in a patient who has no suspected exposure to contaminated food and who has either a history of a fresh, contaminated wound during the 2 weeks before onset of symptoms, or a history of injection drug use within 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

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. Table of criteria to determine whether a case is classified.

Criterion	**Case Definition**		
	Confirmed		**Probable**
Historical Evidence			
History of a fresh, contaminated wound during the two weeks before onset of symptoms	O3,A4		O3
Ingestion of home-canned food within the 48 hours before onset of symptoms	A3,A4		N1, A3
History of injection drug use within the two weeks before onset of symptoms	O3		O3
Clinical Evidence			
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
Laboratory Evidence			
Detection of botulinum toxin in serum	O1-O4	O1	
Detection of botulinum toxin in stool	O1,O2,O4	O1	
Detection of botulinum toxin in patient's food	O1,O4	O1	
Isolation of *Clostridium botulinum* from stool	O1,O2,O4	O1	
Isolation of *Clostridium botulinum* from wound	O3,O4		
Epidemiologic Evidence			
Ingestion of the same food as persons who have laboratory-confirmed botulism	A3,A4	O1	
Special criteria			
Age < 1 year	N2,A4		

N = All "N" criteria in the same column are Necessary to classify a case.
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 = 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:

1. Bleck TP, Chapter 243 – Clostridium botulinum (Botulism). In: Mandell GL, Bennett JE, Dolin R, editors. Principles and Practice of Infectious Diseases, 6th edition. Philadelphia: Churchill Livingstone; 2005.
2. Centers for Disease Control and Prevention. Botulism [Internet]. Atlanta: Centers for Disease Control and Prevention; [cited 2008 Jul 27]. Available from: http://www.bt.cdc.gov/agent/botulism/.
3. Centers for Disease Control and Prevention. Case definitions for infectious conditions under public health surveillance. MMWR 1997;46(No. RR-10):7–8.
4. Centers for Disease Control and Prevention. National notifiable diseases surveillance system: case definitions [Internet]. Atlanta: CDC. Available from: http://www.cdc.gov/ncphi/disss/nndss/casedef/index.htm. Last updated: 2008 Jan 9. Accessed 2008 Jul 27.
5. 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.
6. Council of State and Territorial Epidemiologists (CSTE). National Surveillance for Botulism. CSTE position statement 09-ID-29. Atlanta: CSTE; June 2009. Available from: http://www.cste.org.
7. Passaro DJ, Werner SB, McGee J, Mac Kenzie WR, Vugia DJ. Wound botulism associated with black tar heroin among injecting drug users. JAMA 1998;279:859-863.

8. Werner SB, Passaro D, McGee D, Schechter R, Vugia DJ. Wound Botulism in California, 1951-1998: Recent Epidemic in Heroin Injectors. Clin Infect Dis 2000;31(4):1018-1024.
9. Wheeler C, Inami G, Mohle-Boetani J, Vugia D. Sensitivity of Mouse Bioassay in Clinical Wound Botulism. Clin Infect Dis 2009;48:1669-73.

XI. Coordination:

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