Collecting Clinical Outcome Information Following Botulism Antitoxin Release

Seth Edmunds, MPH[1,2], Karen K. Wong, MD[2] Kevin Chatham-Stephens, MD[2]

[1] Oak Ridge Institute for Science and Education, [2] Centers for Disease Control and Prevention

Contact Information:

Seth Edmunds — wex2@cdc.gov
Karen K. Wong — vij4@cdc.gov
Kevin Chatham-Stephens — xdc4@cdc.gov

BACKGROUND

- Because of the severity and outbreak potential, each case of botulism is considered a public health emergency.
- CDC maintains a medical consultation service on all suspected botulism cases, oversees the release of heptavalent botulism antitoxin (BAT), and conducts national botulism surveillance.
- For suspected cases of botulism treated with BAT, CDC collected clinical outcome information actively during the investigational new drug (IND) period for BAT, before licensure, and passively during the BAT post-licensure period.
- To assess collection of outcome information, we investigated completeness of follow-up data during the IND period (03/21/2010-03/21/2013) and post-IND period (03/22/2013-03/22/2016) and summarize these data.

METHODS

- A suspected case of botulism is a nationally notifiable condition. Cases are most frequently reported to CDC during clinical consultations for antitoxin release.
- Using standardized questionnaires, CDC collects information on demographics and clinical features (Form 1) and outcome information (Form 2).
- Form 2 which is completed by clinicians upon patient discharge or death collects information about hospital course, final diagnosis, sequelae, and death.
- We reported final diagnosis, median admission/ICU/intubation duration, discharge location, residual disability, tracheotomy, and fatality ratio from 1994–2017.

RESULTS

Botulism consultation annual Form 2 returns:

- IND period 76%–96%
- Post-IND period 9%–44%

Suspected botulism cases

Final diagnosis (n=346)

- Botulism 65% (225)
- Guillain-Barré syndrome 18% (61)
- Myasthenia gravis 3% (12)
- Other 14% (49)

Fatality ratio (n=345)

- Botulism diagnosis 3% (11/225)
- All other diagnoses 1% (5/120)

Characteristics of cases with final diagnosis of botulism (n=225)

Admission duration, median days (range)

- 14 (1–182), [n=218]

ICU duration, median days (range)

- 7 (0–182), [n=209]

Intubation duration, median days (range)

- 15 (0–182) [n=118]

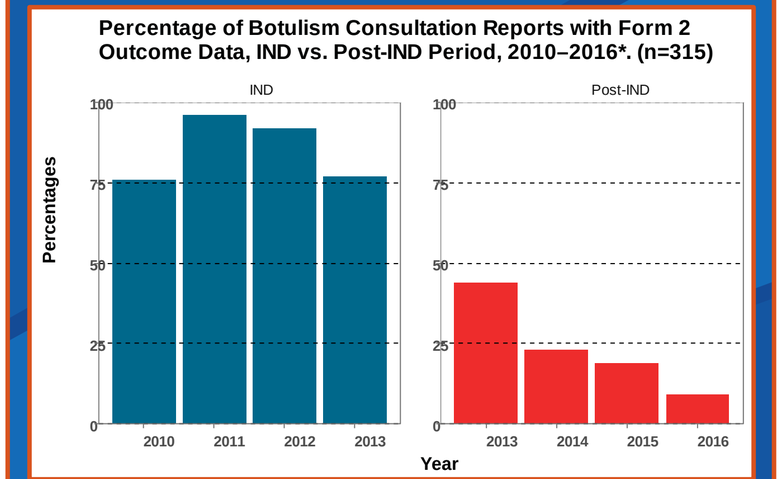
Tracheotomy performed: 43% (97)

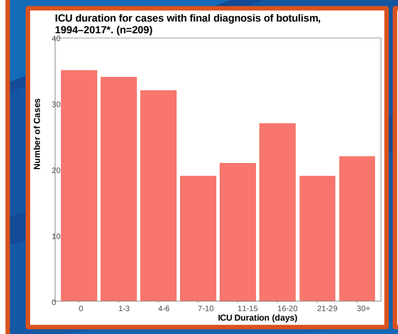
Discharge location (n=212)

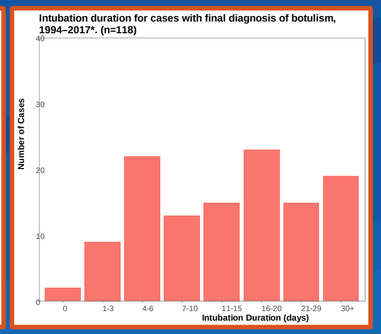
- Home 50% (105)
- Rehab Facility 24% (51)
- Other 21% (45)
- Nursing Home 5% (11)

Residual disability (n=134)

- Proximal Upper Extremity Weakness 22% (78)
- Distal Upper Extremity Weakness 18% (61)
- Proximal Lower Extremity Weakness 20% (71)
- Distal Lower Extremity Weakness 16% (55)
- Diminished Deep Tendon Reflexes 8% (27)
- Fatigue 15% (53)
- Stroke 1% (3)







DISCUSSION

- Information about the outcome of suspected botulism cases is valuable to improve consultation for both BAT release and to inform preparedness planning for large outbreaks or bioterrorism events.
- Most patients with a diagnosis of botulism required ICU admission, with a median ICU stay of 7 days. Half of patients required intubation, with a median duration of 15 days. Additionally, this data shows 50% of cases required some type of rehabilitative care after being discharged. This could put significant strain on local healthcare systems, particularly during outbreaks.
- This data is largely limited to the IND collection period with passive collection rates falling continually each following year.
- Barriers to reporting follow-up data include low awareness of Form 2, time and personnel constraints, difficulty reaching the clinician when Form 2 is not submitted, and duplicated reporting to Cangene, the manufacturer of BAT, for post-IND review.

RECOMMENDATIONS

- Improved communication and collection plans between CDC, state health departments, and treating clinicians are needed to improve follow-up data collection.
- Implementing a protocol for the CDC consultation service to follow up with clinicians could improve data collection and completeness without placing additional reporting burden on state partners.

National Center for Emerging and Zoonotic Infectious Diseases
Division of Foodborne, Waterborne, and Environmental Diseases