Stockpiling of Botulism Antitoxin
Heptavalent (BAT)
(A, B, C, D, E, F, G) Equine

Melissa S. Willis, Ph.D.

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Botulism

• Agent
  — Botulism caused by neurotoxins secreted by Clostridium botulinum

• Botulism clinical manifestations and timelines
  — Symptoms start 6 to 36 hours after exposure (eyes, mouth)
  — Paralysis progresses to limbs, death from paralysis of respiratory system

• Incidence
  — ~145 naturally occurring cases in the U.S. per year
What is Botulism Antitoxin (BAT)?

Product Information

- Indication – for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients
- Potency – each vial contains
  - 4,500 U for serotype A antitoxin
  - 3,300 U for serotype B antitoxin
  - 3,000 U for serotype C antitoxin
  - 600 U for serotype D antitoxin
  - 5,100 U for serotype E antitoxin
  - 3,000 U for serotype F antitoxin
  - 600 U for serotype G antitoxin
BAT Stockpiling and Use


H-BAT program begins

Process, assay and control development

BARDA involvement

Human experience

Patients in CDC EAP

H-BAT only

- 22 studies
- Governmental support
  - CDC, BARDA
Clinical Use

- BAT given to 56 people in clinical trials
- In March 2010 BAT became the only drug distributed by the CDC for non-infant botulism
- 285 people treated with BAT (10 days – 85 years old) since 2008
Product Availability

• BAT is available from the SNS or can be purchased directly from the manufacturer
• BARDA added funds in 2011 to collect and store additional plasma for future use
• Shelf life: currently 4 years at -20°C with stability studies ongoing
• Licensed on March 22, 2013 under the Animal Rule
Interfacing with BARDA

• [www.phe.gov](http://www.phe.gov)  
  — Program description, information, news, announcements

• [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)  
  — Portal to BARDA  
  — Register, request a meeting  
  — Tech Watch

• [www.fedbizopps.gov](http://www.fedbizopps.gov)  
  — Official announcements and detailed information about all government contract solicitations