Diphtheria anti-Toxin (DAT)

Supply Issues

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Diphtheria anti-Toxin

- Developed in 1890s
- Obtained by injecting horses with diphtheria toxoid and collecting serum.
- Widely produced and used until vaccination reduced burden.
- Few manufacturers still active.
Current Supply

- No countries have large stockpiles

- A few countries have small (hundreds) of doses approaching or past expiry date / expiry date extension

- Most countries have no stockpiles
  - In event of outbreak rely on donation from existing small stockpiles.
  - Time to access donations / shipping etc too long for emergency use
### Potential Needs: reported cases / yr by region

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- 4000-8000 courses per year?
  - 40-80,000 vials @ 8-10 vials/case?
- Do all cases have access to healthcare systems?
  - Supportive care
Options to DAT

- **Equine-DAT**
  - Technology over 100 years old
  - Risks to administration (reaction to horse serum)
  - Variability, price not a major barrier ($5-$50/vial)

- **Human anti-toxin antibody**
  - From immunized volunteers, exploratory (not currently produced)

- **Monoclonal anti-toxin antibody**
  - Under development by several biotech groups
  - Still at preclinical phase
  - Several years and significant investment before approval
  - Safer, no variability, possibly more expensive than equine
Availability of Equine Diphtheria Antitoxin

- 4 manufacturers with known production capacity
  - Horse flocks, infrastructure, process in place
    - 2 Indian, 1 Brazilian, 1 Russian
  - No stockpiles currently exist at manufacturers

- Other potential manufacturers being explored
  - Several thought to be producing but not yet confirmed

- 3-6 month lead time to produce a batch / stockpile
  - Size / price depends on order and number of horses used

- No prequalification of equine serums exists yet!
  - EUAL system being considered for anti-snake venom shortage
Proposal

- Community to confirm need for a stockpile and size
- Procurement mechanism – who and how?
- Need for prequalification or other quality validation
- Cold-chain requirements – vs operational suitability
- Stockpile locations / management