

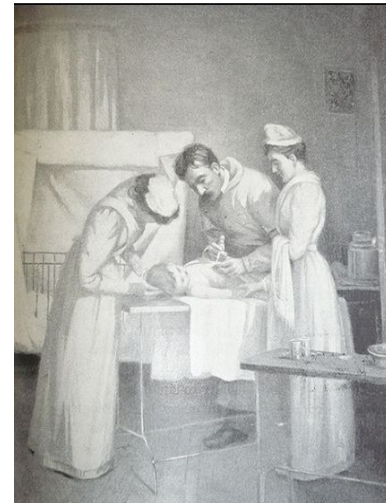
# Diphtheria anti-Toxin (DAT)

## 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

Region	2011	2012	2013	2014	2015
AFR	13	27	128	1	1654
AMR	12	2	5	10	49
EMR	352	334	392	40	43
EUR	33	32	33	35	54
SEAR	5179	3953	4080	7666	2504
WPR	37	142	42	22	226

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