CBRN Vaccines Program
Anthrax Vaccines

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Anthrax Threat

- Category A Threat Agent
- Department of Homeland Security issued Material Threat Determination (MTD) in 2004
- Potential for massive health, economic, social, and political disruption
- Evidence of technology to enhance release and distribution of spores (weaponized anthrax)

October 2001 Amerithrax Case

- Seven letters mailed over two weeks
- 30,000 people started on PEP antibiotics
  - 11 cases of inhalational anthrax developed
  - 5 resulted in death
- Over $225 million to decontaminate seven buildings
- Lessons Learned
  - US was vulnerable and response plans were insufficient to prevent mortality
  - Antibiotics alone were not sufficient
  - 60-day antibiotic regimen led to non-compliance
  - Additional countermeasures needed

PHEMCE Anthrax Response Strategy

Anthrax Vaccine Program goal is to develop a safe and effective vaccine that can be used for post-exposure prophylaxis (PEP)

- Post-exposure Prophylaxis
- 60 day treatment course

- Treatment of symptomatic patients

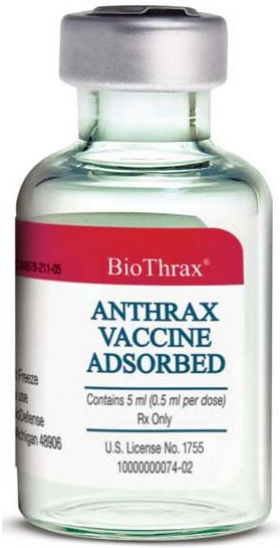
- Pre and post-exposure prophylaxis

Vaccines

Support licensure of AVA for PEP and develop a next generation vaccine that can provide equivalent protection in fewer doses

Anthrax Vaccine Adsorbed (BioThrax) 2002

- FDA licensed for general-use prophylaxis (pre-exposure) in high risk groups
- Six-dose schedule
- Local site reactogenicity – subcutaneous route
- 2-year expiry
- Limited data on post-exposure prophylaxis
- Limited manufacturing capacity



Desired Anthrax Vaccine Characteristics

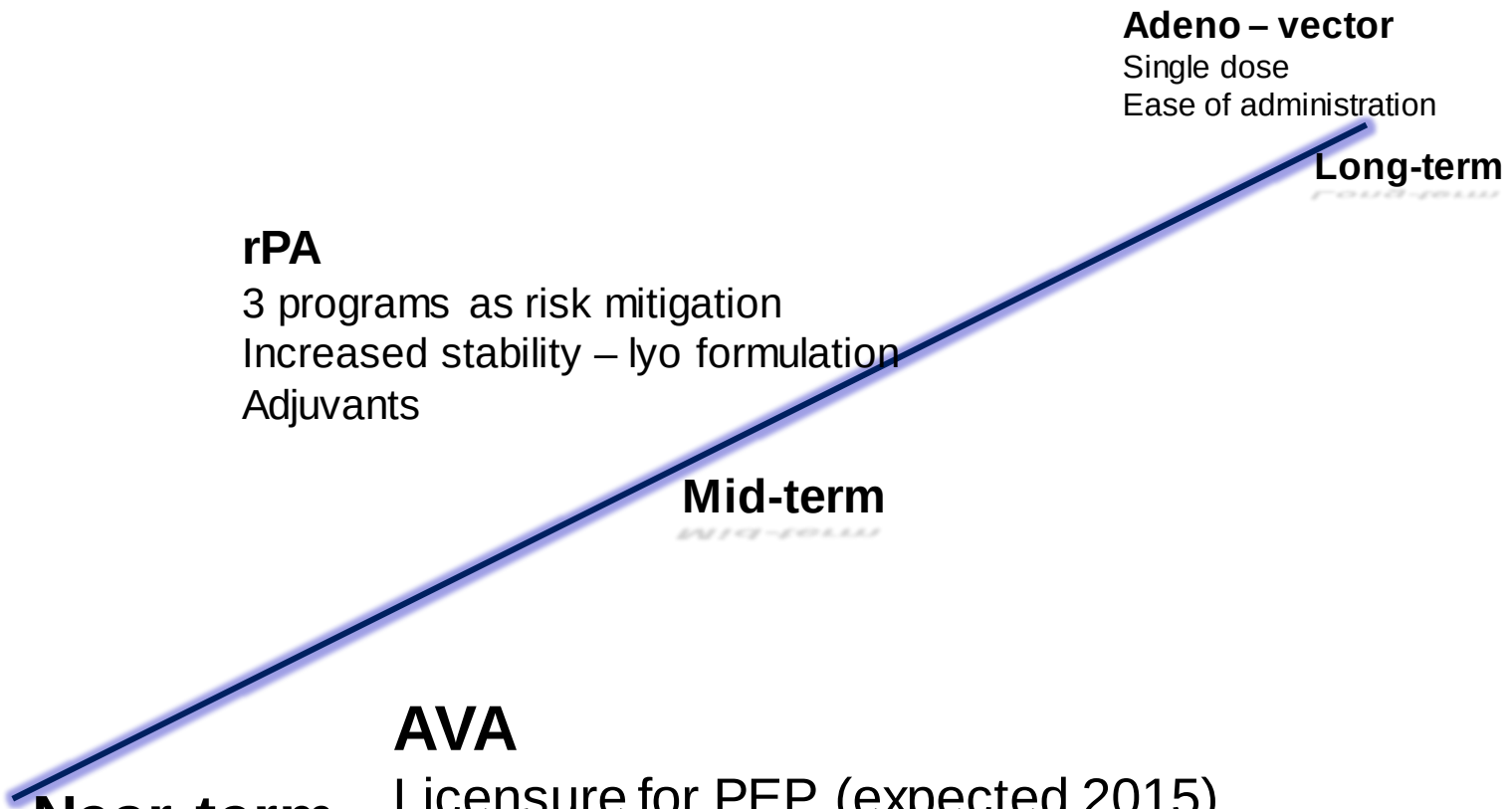
- FDA approved for both pre- and post-exposure prophylaxis
- Reduced schedule
- Acceptable reactogenicity
- Excellent safety profile
- Rapid time to protection
- Long duration of protective immunity
- Long shelf-life
- Ease of delivery
- No interference with concomitant drugs
- Large-scale manufacturing capacity and low cost

BioThrax Enhancements

- CDC AVRP "Phase IV" Program
  - Reduced the schedule to 5 doses (0, 1, 6, 12, 18 mo with yearly boosters)
  - Changed the route of administration from SQ to IM
  - Recommended AVA as component of a post-exposure prophylaxis regimen (0, 2, 4 wk) with concomitant antibiotics (60 days)
  - Recommended AVA for pregnant women exposed to anthrax
- Expiry dating extended from 2 to 4 yrs
- Room temperature stability dating up to 3 mo at 25°C

BARDA Anthrax Vaccine Strategy

Market surveillance - ongoing



Summary

- USG continues to expand the utility of BioThrax® through label expansions (PEP), manufacturing scale-up, stability studies, and dose/antigen-sparing strategies
- Development of recombinant anthrax vaccines (subunit, formulations, expression vector technologies) are still early in development and remain a challenge
- Development of vaccines that offer equivalent protection in fewer doses continue to be a long-term objective.