Anthrax Vaccine Protocol

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Anthrax Vaccine and Antibiotics Availability Program

Anthrax Vaccine, Adsorbed (AVA)

Objective:
To make vaccine and antibiotics available to people who have had a high dose exposure to *B. anthracis* spores
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Eligibility

Persons who have been exposed to high doses of anthrax spores and were directed to take 60 days of antibiotic prophylaxis
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Exclusion Criteria

• No specific exclusion criteria
Additional Options for Those Exposed to *B. anthracis* spores

- Earlier Recommendations – 60 days of antibiotics + medical monitoring
- Additional Option 1 – 40 additional days of antibiotic treatment + medical monitoring
- Additional Option 2 – 40 additional days of antibiotic treatment + 3 doses of anthrax vaccine over 4 weeks + medical monitoring
Anthrax Vaccine in this Program

• Schedule:
  – Day 0, 2-weeks, 4-weeks

• Route:
  – Subcutaneous
  – Intramuscular (<18 years age)
Risks: Antibiotics

Side effects include:

– Hypersensitivity reactions
– Photosensitivity (cipro and doxy)
– Tendonitis (cipro)
– Dental staining (doxy - prenatal to < 7 years of age)
– Fetal affects (unproven association between cipro and bone-joint formation)
Risks: Vaccine

18 safety studies

Local reactions: soreness, redness, itching, swelling
- 30% of men, 60% of women
- Lump at site occurs commonly and lasts a few weeks

Systemic reactions:
- Rashes (16%), headaches (14% to 25%), malaise (6% to 17%), muscle aches (3% to 34%), fever (1% to 5%).
- Typically resolve in a few days

Rare reactions:
- Severe allergic reactions < 1 per 100,000 doses
**Benefits**

We do not know if there is a risk of disease among people who have been exposed to anthrax spores and have taken 60 days of antibiotics.

However, if there is such a risk, then either 40 days of additional antibiotics or 40 days of additional antibiotics and the vaccine may be of benefit in reducing the risk of disease.
The anthrax vaccine used in this program is considered investigational because:

1. The vaccine is not approved for post-exposure prophylaxis;
2. The vaccine is not approved for a 3-dose regimen; and
3. The lot of vaccine to be used in this program is not approved for commercial use.
Antibiotics used in this program are investigational because:

1. No antibiotic is approved for use beyond 60 days for prophylaxis for inhalational anthrax;

2. Amoxicillin is not approved for use for any prophylaxis against inhalational anthrax
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Consent Issues

- There is no data to predict if vaccination will be a benefit after exposure
- The vaccine is not approved for this use
- Lots of vaccine to be used are not licensed by the FDA