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

Anthrax Vaccine and Antibiotics Availability Program

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.

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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

Anthrax Vaccine and Antibiotics Availability Program

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