

Anthrax
Vaccine
Immunization
Program

Individual's Briefing

Protecting the Individual



Threat

- Anthrax: the most likely biological warfare agent:
 - Relatively easy and cheap to produce
 - Can be stored for a long time
 - Can be dispersed in a variety of ways
 - Odorless, colorless, tasteless, difficult to detect
- Anthrax can cause widespread illness and death among unvaccinated, untreated and unprotected people.
- Vaccination is critical for <u>your</u> protection.
- This vaccination program is required, except for legitimate medical exemptions.

Anthrax: Three Disease Types

Cutaneous Anthrax

- Most common form; spores enter breaks in skin
- Responds well to antibiotics
- 5% to 20% of infected people die without treatment

Gastrointestinal Anthrax

- Ingestion (e.g., eating undercooked, infected meat)
- Severe gastrointestinal symptoms
- 50% of infected people die even with treatment

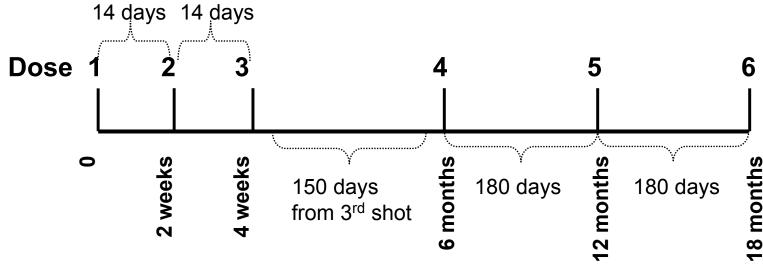
Inhalational Anthrax

- "Flu-like symptoms" early, rapid deterioration, then death
- After symptoms occur, almost 100% of unvaccinated, unprotected, and untreated people die

- About 50% die even with intensive care

Anthrax Vaccine Facts

- Manufactured by BioPort Corp., Lansing, Michigan
- FDA-licensed product since 1970; NOT an investigational new drug (IND); each lot FDA approved
- Inactivated, cell-free, made from anthrax strain that does not cause the disease
- 6 doses over 18 months; annual boosters:

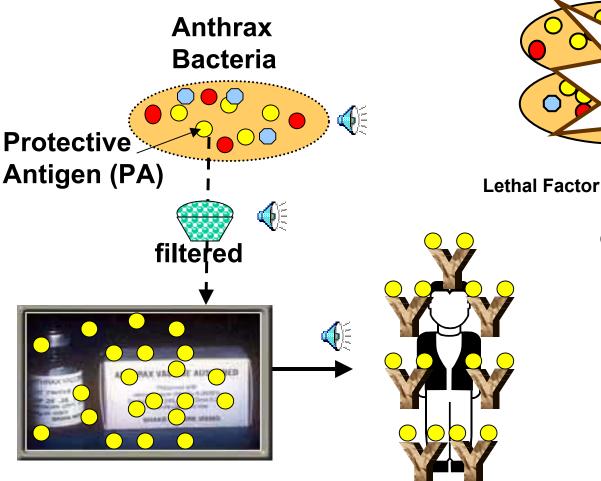


Status of AVIP

Status:

- FDA ruled anthrax vaccine is safe and effective regardless of route of anthrax exposure
- Mar 98 to Jan 04: Over 3.7 million doses to over 1 million people
- 18 human safety studies
- 7 reviews by independent panels of civilian physicians, each affirming safety and effectiveness of the vaccine
- Dec 03 injunction on AVIP has been lifted and vaccinations legally continue





Vaccine contains PA, extracted from weakened nonlethal anthrax bacteria.

Immune system develops antibodies (Y) to PA, protection from disease.

Antibodies "neutralize" PA, common part of anthrax toxins.

Exposure to Anthrax Bacteria

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Edema Factor

Disease

Death

Anthrax Vaccine Effectiveness

- Human clinical trials in the 1950's: 92.5% effective
- Multiple animal studies: 95% protective in Rhesus monkeys, and 97% in rabbits
- Protective antigen (PA) is the common diseasecausing protein in all anthrax strains
- Blocking PA blocks the disease: all strains
- National Academy of Sciences: Anthrax vaccine is "an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains"

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Exemptions

- Some people should not get anthrax vaccine.
- Temporary medical exemptions include:
 - Short term immunosuppressive therapy
 - Serious acute diseases, injuries, surgery
 - Pregnancy
 - Medical evaluation or condition pending
- Permanent exemptions include:
 - Severe reaction after previous dose of anthrax vaccine
 - HIV or other chronic immune deficiencies
 - Immunity based on previous anthrax infection

Anthrax Vaccine Safety

- More than 1 million people have received anthrax vaccine
- Injection-site reactions common:
 - 30% of men, 60% of women have injection-site reactions
 - Redness, itching, swelling, burning, soreness or pain
- Systemic symptoms (away from injection site):
 - 5% to 35% of both genders; more by women
 - Muscle/joint aches, chills, low-grade fever, headaches,
 nausea, rashes, fatigue, swelling may extend below elbow
- Acute allergic reactions after any vaccine, 1 in 100,000 doses
- Deaths have been reported rarely after any vaccine
- Consult your health care provider for adverse events

Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS):
 - FDA and CDC review 100% of adverse-event reports
 - Reviewed by independent panel of expert civilian physicians for 4 years
- DoD requires a VAERS Form submission for:
 - Loss of duty 24 hours or longer (≥ 1 duty day)
 - Hospitalization
 - Suspected vaccine vial contamination
- Other submissions are encouraged.
- Anyone can submit a VAERS Form!
- VAERS Forms may be obtained from:
 - Your clinic, 1-800-822-7967, or www.vaers.org

Reserve Component Adverse Events

- Adverse events after DoD- or USCG-directed vaccinations are line-of-duty conditions
- Someone with an adverse event in a non-duty status possibly associated to any vaccination:
 - Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
 - Must report the event to your unit commander or designated representative as soon as possible
 - Consider VAERS submission
- Commander will determine Line of Duty and/or Notice of Eligibility status, if required

Key Messages

- Your health & safety are our #1 concerns
- Anthrax vaccine is safe and effective
- The threat of anthrax is deadly and real
- Vaccination offers a layer of protection, in addition to antibiotics and other measures, needed for certain members of the Armed Forces

More Information

- Chain of Command / Supervisors
- Military Vaccine (MILVAX) Agency
 - Website: www.anthrax.mil
 - Toll-Free: 877.GET VACC
- Centers for Disease Control and Prevention (CDC):
 - Website: <u>www.bt.cdc.gov</u>
 - CDC National Immunization Hotline: 800.232.2522
- Walter Reed Vaccine Healthcare Center: 202.782.0411 (www.vhcinfo.org)
- Call your local Military Medical Treatment Facility (MTF)
- -OR- if Reserve Component seeking care at a civilian facility, contact the Military Medical Support Office (MMSO): 888-647-6676